

# ASSESSING THE UTILITY OF PMTCT PROGRAM DATA FOR HIV SENTINEL SURVEILLANCE AMONG PREGNANT WOMEN IN SOUTH AFRICA – 2017



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# ABBREVIATIONS AND ACRONYMS

|                  |                                                              |
|------------------|--------------------------------------------------------------|
| <b>AIDS</b>      | Acquired immunodeficiency syndrome                           |
| <b>ANC</b>       | Antenatal Care                                               |
| <b>ANSUR</b>     | Antenatal HIV Sentinel surveillance                          |
| <b>ART</b>       | Triple antiretroviral therapy                                |
| <b>ARV</b>       | Antiretroviral drug                                          |
| <b>CD4</b>       | Clusters of differentiation 4 T-cell lymphocyte              |
| <b>CDC</b>       | Centers for Disease Control and Prevention                   |
| <b>CI</b>        | 95% Confidence Interval                                      |
| <b>CITC</b>      | Client-initiated Counselling and Testing                     |
| <b>DBS</b>       | Dried Blood Spots                                            |
| <b>DHIS</b>      | District Health Information System                           |
| <b>ELISA</b>     | Enzyme-linked immunosorbent assay                            |
| <b>EC</b>        | Eastern Cape                                                 |
| <b>EQA</b>       | External quality assessment                                  |
| <b>HCT</b>       | HIV Counselling and Testing                                  |
| <b>HIV</b>       | Human immunodeficiency virus                                 |
| <b>HTS</b>       | HIV Testing Services                                         |
| <b>IVDs</b>      | In vitro diagnostics                                         |
| <b>LMIC</b>      | Low- and middle-income countries                             |
| <b>M &amp; E</b> | Monitoring and Evaluation                                    |
| <b>NDOH</b>      | National Department of Health                                |
| <b>NHLS</b>      | National Health Laboratory Service                           |
| <b>NON-ANSUR</b> | Not participating in Antenatal HIV Sentinel surveillance     |
| <b>NICD</b>      | National Institute for Communicable Diseases                 |
| <b>ODK</b>       | Open Data Kit                                                |
| <b>PDA</b>       | Personal digital assistants                                  |
| <b>PEPFAR</b>    | The United States President's emergency plan for AIDS relief |

|               |                                                                 |
|---------------|-----------------------------------------------------------------|
| <b>PHC</b>    | Primary Health Care                                             |
| <b>PITC</b>   | Provider-Initiated Testing and Counselling                      |
| <b>PMTCT</b>  | Prevention of mother-to-child transmission                      |
| <b>PPS</b>    | Probability proportional to size                                |
| <b>PT</b>     | Proficiency testing                                             |
| <b>RDT</b>    | Rapid diagnostic test                                           |
| <b>RPR</b>    | Rapid Plasma Regain                                             |
| <b>QA</b>     | Quality assurance                                               |
| <b>QC</b>     | Quality control                                                 |
| <b>QI</b>     | Quality Improvement                                             |
| <b>REDCap</b> | Research Electronic Data Capture                                |
| <b>RTQII</b>  | Rapid Testing Quality Improvement Initiative                    |
| <b>SA</b>     | South African                                                   |
| <b>SAMRC</b>  | South African Medical Research Council                          |
| <b>SSA</b>    | Sub-Saharan Africa                                              |
| <b>SOP</b>    | Standard operating procedure                                    |
| <b>SPI-RT</b> | Stepwise Process for Improving the quality of HIV rapid testing |
| <b>STI</b>    | Sexually transmitted infections                                 |
| <b>UAT</b>    | Unlinked anonymous testing                                      |
| <b>UNAIDS</b> | United Nations Joint Programme on HIV & AIDS                    |
| <b>USAID</b>  | United States Agency for International Development              |
| <b>VCT</b>    | Voluntary Counselling and Testing                               |
| <b>WC</b>     | Western Cape Province                                           |
| <b>WHO</b>    | World Health Organization                                       |
| <b>ZA</b>     | South Africa                                                    |

# EXECUTIVE SUMMARY

**Introduction:** Antenatal surveys have been used over several years to monitor antenatal HIV prevalence; however, antenatal surveys are costly to implement. Furthermore, they usually use unlinked anonymous HIV testing, which poses ethical dilemmas in the current era of test and treat, as pregnant women living with HIV (PWLHIV) cannot be traced and referred into care. With increasing coverage of routine HIV testing for pregnant women it becomes prudent to investigate whether routine antenatal HIV testing can be used to monitor antenatal HIV prevalence.

**Aims and Objectives:** This survey aimed to assess the utility of routine prevention of mother-to-child transmission of HIV (PMTCT) program data for HIV sentinel surveillance amongst pregnant women. Primary objectives were:

- (i) to assess the quality of routinely collected PMTCT-related program data? Quality was assessed in two ways:
  1. documenting site procedures for PMTCT HIV testing and data recording (**PMTCT site assessment, Activity 1A**) and 2. reviewing the completeness of recorded data (**PMTCT data quality assessment, Activity 1B**), and
- (ii) to assess the quality of PMTCT HIV rapid testing procedures in selected facilities that represent a range of national scenarios: (**Activity 2**).

**Methods:** A national cross-sectional survey was conducted, between 20 February and 31 May 2017, in randomly selected public health facilities offering antenatal care (ANC) and PMTCT services. A sampling frame was developed using the list of facilities obtained from the 2014/15 South African National Department of Health (NDOH) District Health Information System (DHIS) dataset. This frame included 1570 facilities / sentinel sites included in the 2015 antenatal HIV and syphilis sero-surveillance survey (ANSUR) and 3113 facilities not included (NON-ANSUR). ANSUR sentinel sites are randomly selected using Probability Proportional to Size (PPS) sampling methods. Data for ANSUR are collected from a similar population for whom routine antenatal and PMTCT data are collected; however, ANSUR uses unlinked anonymous testing (UAT). A sample size of 360 facilities was selected for national estimates with a 5% error margin for the site assessment (Activity 1A). Given that the median number of women recruited per facility for ANSUR is 20, we

aimed to review  $20 \times 360 = 7200$  records in total for the data quality assessment (Activity 1B).

For the site assessment (**Activity 1A**) data were gathered by interviewing a facility staff member familiar with PMTCT service delivery practices. One cross sectional interview was conducted per facility, using the site assessment questionnaire which assessed how and where PMTCT services such as HIV testing are delivered to clients, processes and key obstacles, types of registers used for recording PMTCT indicators and alignment of activities with current national requirements.

For the PMTCT data quality assessment (**Activity 1B**), a retrospective review of data from facility-based registers was conducted using two different data abstraction tool formats (tick sheets and longitudinal registers). The routine data for each of the three months prior to October (the ANSUR period) i.e. July, August and September 2016, were eligible for extraction. In each facility, data collectors requested a facility-based register where antenatal and PMTCT data were recorded for first visit ANC clients. Systematic sampling involved counting the total number of women recorded under that data element for the entire month, and dividing this by the desired sample size for that month to obtain the sampling interval. For example, if 60 women were recorded for the month, and 30 record abstractions were desired, then every 2nd (60/30) record was abstracted.

For the rapid HIV testing quality assurance (**Activity 2**) a cross-sectional audit of quality assurance (QA) practices for HIV rapid testing was conducted using the adapted WHO-recommended Checklist (Tool) for the Stepwise Process for Improving the Quality of HIV Rapid Testing (SPI-RT) Version 3.0).

Data collectors used hard copies to collect data for Activities 1B and 2 (data quality assessment and rapid HIV testing quality assurance, respectively). However, site assessment data was collected electronically using hand-held personal digital assistants (PDAs) connected to web-based Mobile Researcher.

## RESULTS:

### Activity 1A: Site assessment:

Data were analysed from 348 facilities. Overall, 97.4% of participants reported that their ANC facilities offered provider-initiated HIV testing and counselling (PITC), 54.3% stated they also offered client-initiated testing and counselling (CITC) during pregnancy and 21.3% reported that HIV testing was also offered on an opt-out basis. Eight one percent and 94.5% of facilities reported not experiencing stock-outs of HIV rapid and confirmatory test kits over the past 12 months respectively. An array of registers were used to document testing and results, the tick register being the commonest. Documentation of characteristics varied between registers within facilities. For example documentation of HIV testing offered was poor ranging from 20.5% (47 of 229 facilities using the laboratory specimen register) to 61.8% (107 of 173 facilities using the integrated ANC/PMTCT longitudinal register); 7.4% (17 of 229 facilities using the laboratory specimen register) to 62.8% (59 of 74 facilities using the ANC/daily PHC/non-standardised book as a register) of facilities reported systems to document HIV test acceptance; 21.0% (48 of 229 facilities using the laboratory specimen register) to 93.6% (88 of 94 facilities using the ANC register) reported systems to document first HIV test results, and 10.0 % (23 of 229 facilities using the laboratory specimen register) to 54.3% (51 of 94 facilities using the ANC register) reported systems to document confirmatory HIV test results.

### Activity 1B: Data quality assessment:

A total of 14778 records were reviewed; of these 10943 (74.0%) were from the PHC Comprehensive Tick Sheet registers and 3835 (26.0%) were from Integrated ANC/PMTCT longitudinal registers (Table 3.11). This means that the final sample reviewed was almost double the minimum target for tick sheet registers. Tick sheet registers demonstrate that 6802 (66.1%) reviewed records indicated that an HIV test was performed during the first ANC visit of a client. Among these, the HIV 1<sup>st</sup> test result was only recorded in 59.4% of records reviewed. In longitudinal registers recording of CD4 count results was reviewed among those records with a recorded HIV-positive status during ANC or recorded known HIV status at first ANC (N=1228). Of these 1228, 22.1% had the CD4 count results recorded.

### Activity 2:

There was inadequate implementation of rapid HIV testing QA practices in facilities providing ANC. The percentage median overall score for HIV rapid testing QA was low with the majority of the facilities at either level 1 (37.0% of facilities) or level 2 (45.7% of facilities), and particularly low for specific sub-scores such as training and certification (median score was 35.0% of maximum score) and external quality assurance (EQA) (median score was 12.5% of maximum score). More than two-thirds of facilities were not enrolled in the EQA program. In 56.1% of facilities, testers reported not receiving training on HIV rapid testing; training on use of registers/logbooks was reportedly received only by 59.8% of facilities. A substantial percentage of facilities partially completed (31.5%) or did not complete (8.4%) key elements in the HIV registers/logbook.

## CONCLUSIONS:

The site assessment demonstrated that only 3% of facilities do not report offering provider-initiated HIV testing and counselling; however, up to 19% of facilities reported a stock-out of HIV rapid test kits during the past 12 months. There are large gaps in the documentation of HIV testing uptake and results. There is a lack of standardisation of antenatal and PMTCT data systems across facilities.

The data quality assessment revealed that tick sheet registers only recorded that an HIV test was performed in 66.1% of records, and amongst these, results were recorded in only 59.4% of records reviewed. In longitudinal registers CD4 cell count results were only recorded in 22.1% of records with a recorded HIV-positive status during ANC or recorded known HIV status at first ANC (N=1228). Recording of gestational age at first ANC visit and ART uptake among those with recorded HIV-positive status is impressive and routine data could potentially be used to monitor these estimates.

The assessment of HIV QA practices revealed major gaps in the training and certification and external quality assurance domains. Overall, facilities obtained the highest median percentage score for the physical facility domain. The majority of facilities inadequately implemented rapid HIV testing QA practices and only 11.0% were found to be eligible for national site certification or close to national site certification.

Routine HIV testing data at antenatal clinics data needs to be strengthened in order to monitor a) the quality of HIV testing services offered to pregnant women; and b) antenatal HIV prevalence. Documentation of PMTCT services for HIV-positive women requires improvement, specifically documentation of CD4 results, to ensure all HIV-positive pregnant women receive appropriate interventions to optimise their health and prevent MTCT. General documentation of HIV negative women tested for HIV also requires improvement, particularly for monitoring repeat testing coverage.

## RECOMMENDATIONS:

- Documentation of routine antenatal HIV testing data could be improved by using standardized training and logbooks.
- Routine antenatal HIV testing data quality needs monitoring with feedback to facilities, so that the data can be used to monitor antenatal HIV prevalence.
- The number of facilities trained and certified in HIV rapid testing and enrolled for External Quality Assurance needs to increase.



# DEFINITIONS

**Acquired immune deficiency syndrome:** A syndrome of opportunistic infections and diseases that can develop as immunosuppression deepens along the continuum of HIV infection (from acute infection to death).

**Antiretroviral therapy:** The use of combination of three or more ARV drugs to achieve viral suppression and is usually given for life.

**Antiretroviral drugs:** Medicine to treat HIV and AIDS.

**Client-initiated counselling and testing:** An HIV testing process that is initiated by an individual who wants to learn his/her HIV status (also referred to as voluntary counselling and testing [VCT]) refers to when HIV testing services (HTS) are provided within healthcare facilities for clients who present specifically for these services.

**External quality assessment (EQA) including proficiency testing (PT):** Inter-facility comparison to determine if the HIV testing service can provide the correct test status. PT involves testing of unknown samples at regular interval by the testing sites.

**Health Care Provider:** Any person providing health services in terms of any law including in terms of the Allied Health Professions Act, 1982 (Act No 63 of 1982, Health Professions Act, 1974 (Act No. 56 of 1974, Nursing Act, 2005 (Act No 33 of 2005), Pharmacy Act, 1974 (Act 53 of 1974) and Dental Technicians Act, 1978 (Act No. 19 of 1979).

**Health care personnel:** Health care providers and health care workers.

**Health Care Worker:** Any person who is involved in the provision of health services to a user, but is not a health care provider. This includes lay counsellors and community caregivers.

**HIV-exposed infant:** An infant born to a known woman living with HIV and or having a positive HIV antibody test result using BDS ELISA.

**HIV Rapid Test Device:** *In vitro* diagnostic of immunochromatographic or Immune filtration format for, in the case of HIV diagnosis, the detection of HIV-1/2 antibodies and/or HIV p24 antigen.

**HIV status:** Result from one or more HIV testing assays. It refers to reports of HIV positive, HIV-negative or HIV-inconclusive (inconclusive - status in whom the test results cannot lead to a definitive diagnosis (i.e. no clear HIV status, neither positive nor negative can be assigned).

**HIV testing services (HTS):** HIV counselling and testing (HCT) is now referred to as HIV testing services (HTS) to embrace the full range of services that should be provided together with HIV testing. These services include: counselling (pre-test information and post-test counselling); linkage to appropriate HIV prevention, treatment and care services and other clinical and support services and coordination with laboratory services to support quality assurance and the delivery of correct results.

**Mother-to -Child HIV Transmission (MTCT):** Transmission of HIV from a woman living with HIV to her infant during pregnancy, delivery or breastfeeding. The term is used because the immediate source of infection is the mother, and does not imply blame on the mother.

**Prevention of Mother-to-Child HIV Transmission (PMTCT):** Prevention of transmission of HIV from a living with HIV to her infant during pregnancy, delivery or breastfeeding.

**Proficiency Testing (PT):** Is the testing of blinded samples sent to a laboratory by an approved PT provider program. Most sets of PT samples are sent to participating laboratories on a scheduled basis. Accreditation organizations use them to routinely monitor their laboratories' performance.

**Provider-initiated Testing and Counselling (PITC):** HIV testing and counselling that is recommended by health care providers to people attending healthcare facilities as a standard component of medical care. It is offered routinely to all people attending a service (such as pregnant women attending antenatal care) and is recommended as an opt-out approach; that is, it remains voluntary and the decision not to take the test is left with the patient.

**Quality assurance (QA):** A part of quality management focused on providing confidence that quality requirements will be fulfilled.

**Quality control (QC):** A mechanism which, when used with or as part of a test system (assay), monitors the analytical performance of that test system (assay). It may monitor the entire test system (assay) or only one aspect of it.

**Quality improvement (QI):** Part of quality management focused on increasing the ability to fulfil quality requirements.

**Quality management system (QMS):** A system to direct and control an organization with regards to quality.

**Testing algorithm:** The combination and sequence of specific assays used within HIV testing strategies

**Testing strategy:** Generically describes a testing sequence for a specific objective, taking into consideration the presumed HIV prevalence in the population being tested.

# 1. INTRODUCTION

South Africa has made remarkable progress in reducing new HIV infections, including preventing mother-to-child transmission of HIV (MTCT) and improving access to triple antiretroviral therapy (ART). Between 2010 and 2015, ART coverage in South Africa increased by more than 25%; in 2016 nearly 3.4 million HIV infected people were on ART - more than any other country in the world and >95% (76% - >95%) pregnant women living with HIV were accessing ART or antiretroviral prophylaxis to prevent HIV transmission to their children.[1] Despite these improvements, South Africa still has the largest HIV epidemic in the world, housing 19% of the global number of people living with HIV, 15% of new HIV infections and 11% of AIDS related deaths.[2] Since the South African HIV epidemic is generalized and HIV transmission is predominantly heterosexual, pregnant women are the commonest sentinel population studied to determine HIV acquisition in South Africa, as they represent the sexually active adult population.[3, 4] In South Africa, over the past 25 years, annual or biennial antenatal HIV and syphilis sero-surveillance (ANSUR) has been conducted in sentinel sites during October to monitor the course of the HIV epidemic. ANSUR sentinel sites are antenatal facilities randomly selected using Probability Proportional to Size (PPS) sampling methods. PPS combines a random approach with a bias towards larger clinics, resulting in a self-weighted sample. Data for ANSUR are collected from a similar population for whom routine antenatal and PMTCT data are collected; however ANSUR uses unlinked anonymous testing (UAT).[5]

UAT-based surveillance raises ethical, methodological, and cost concerns: to prevent selection and participation bias, the UAT methodology involves the collection of anonymized blood specimens without consent; thus, the test results cannot be reported back to patients and referral into care or ensuring continuity of care, for clients living with HIV is not possible. Additionally UAT-based surveillance usually includes larger sentinel sites and duplicates HIV testing for pregnant women - one test is needed for the antenatal survey, and one test will be conducted as part of routine facility-based HIV testing.[6, 7]

The 2013 World Health Organization (WHO) guidelines recommend that countries with near universal PMTCT

coverage should use routine PMTCT-based program data to monitor HIV prevalence and trends among pregnant women. WHO guidelines further recommend that five areas need to be evaluated before a successful transition from antenatal HIV sentinel surveillance (ANSUR) to surveillance using routine antenatal HIV testing can be considered:[8]

- (1) the level of agreement between ANSUR and routine antenatal HIV test results,
- (2) the magnitude of selection bias in routine antenatal testing compared to ANSUR data,
- (3) the coverage of routine antenatal HIV testing, which should be close to 100%,
- (4) the quality of routinely collected antenatal data, and
- (5) the quality of routine HIV testing practices.

This survey evaluated the latter two areas of these guidelines.

Robust relevant data is critical for the monitoring and evaluating PMTCT program performance. Using program data has several benefits including a broader geographic representation and returning HIV test results, which can be directly used for prevention, treatment, care and support interventions. However, routine data quality and HIV testing methods may not meet the required standards; thus the WHO recommends that poor quality HIV testing, and any possible bias introduced in data sources should be assessed and addressed before a successful transition can occur from ANSUR to routine PMTCT program-based surveillance.[8]

There have been varying experiences regarding routine data: Poor quality of HIV testing services (HTS) and inaccurate recording of test results in antenatal care (ANC) have been reported, particularly in countries implementing immediate ART initiation.[9] Many countries such as Mozambique and Kenya have explored the feasibility of using routine PMTCT program data to complement or replace ANSUR.[8, 10] A comparison of HIV prevalence estimates between routine HIV rapid testing and sentinel surveillance results in Kenya found that 24 % of women who tested negative during routine testing were positive in the ANSUR test resulting in a low positive percent agreement of routine versus ANSUR HIV test results.[11] On the contrary, research in Mozambique demonstrated no significant differences in the median HIV

prevalence measured at regional level using routine PMTCT data compared with survey data.[12]

In South Africa, by 2015/16 antenatal PMTCT services were offered in more than 95% of public health facilities and antenatal HIV testing uptake in public health facilities had increased to above 95%.[13] According to current guidelines, routine ANC should offer provider-initiated HIV counselling and testing (PICT), starting with group information (outlining the benefits of HIV testing), followed by an individual information session to clarify misunderstandings and an offer to test. HIV testing is voluntary and at a minimum, verbal consent for HIV testing is obtained. This should be documented in the patient's file.[14] Women who "opt-out" are offered post-refusal counselling as well as HIV testing in every subsequent ANC visit.

### 1.1 Data collection tools used in Primary Health Care (PHC) facilities in South Africa

Routine PMTCT program data have been integrated into routine ANC and these data are aggregated into the routine District Health Management Information System (DHMIS) and TIER.net. However, at the coal-face, most public-sector primary health care facilities collect ANC and PMTCT data on multiple paper-based tools. Paper-based tools increase the margin for data errors during the collation and aggregation processes.[15] According to national policy in South Africa, all patients tested for HIV should be recorded in the HCT register (Annexure H), regardless of where the HCT is done, and those who test HIV positive have their results recorded in the pre-ART register to ensure tracking of linkage to care.[14]

### 1.2 Quality of routine data

The quality of routine PMTCT data remains poor in South Africa [15, 16], despite data quality improvement interventions.[17, 18] As recently as 2016, one study found that despite high levels of data completeness at facility and district levels, there was poor correlation between clinic-based registers and routine monthly reports.[15]

To date, South Africa has not conducted a comparison between ANSUR HIV estimates and HIV estimates from routine PMTCT-related data to assess the readiness to transition to surveillance using routine antenatal HIV testing. As a first step, a stock-take of the routine PMTCT data alone, especially routine HIV testing data, is necessary to ascertain whether it will be worthwhile to compare the two data

sources. For routine PMTCT data to give accurate estimates of antenatal HIV prevalence, uptake of HIV testing during pregnancy should be optimal. The percentage of 'opt-out' clients should be negligible. Even though more than 95% of facilities report providing PMTCT services, documented uptake of HIV testing could be sub-optimal due to factors such as off-site HTS, stock-outs of HIV test kits, use of inappropriate data collection tools and procedures, poor documentation of known pregnant women living with HIV, refusals and lack of data capturing skills among facility staff. [11,17, 19]

### 1.3 Quality of HIV Rapid testing

Rapid diagnostic tests (RDTs) to quickly diagnose HIV infection and facilitate immediate ART initiation are critical in achieving the UNAIDS 90-90-90 targets in many low- and middle-income countries (LMIC). Although HIV rapid testing facilitates early HIV diagnosis, accurate HIV testing is critical and in most resource constrained settings, ensuring quality control (QC) poses a challenge.[20] The QC/quality assurance (QA) cycle for HIV testing assesses several dimensions including personnel competency, pre-test preparation/client preparation, sample collection, record keeping, and reporting.

Surveys conducted in South Africa have demonstrated gaps in the quality of HTS. The proficiency of the tester and the performance of the test kits impact the QA of HIV testing. [21] A study conducted in 2008 demonstrated that the sensitivity and specificity of rapid HIV tests was dependent on the proficiency of the tester, with laboratory technicians scoring highest, followed by lay counsellors, and nurses scoring the lowest.[22] Similarly, one study illustrated that the quality of counselling varies between sites and does not match the South African HCT policy guidelines.[23] while another demonstrated poor adherence to HIV testing guidelines, even though 87.3% of HIV testers had received formal training in HIV testing. [9]

In 2016, the South African National DOH developed new HIV testing services policy guidelines which emphasised monitoring and evaluation and QA in accordance with defined national standards.[24] South Africa uses the serial rapid HIV testing strategy in which a non-reactive specimen is considered as true negative. These clients are offered retesting after 3 months. An HIV positive result is documented after one reactive rapid HIV screening test is followed by a second, different reactive rapid confirmation test. The National HIV Reference Laboratory located at

the National Institute for Communicable Diseases (NICD) provides guidance to the NDOH regarding the selection and approval of HIV rapid test kits included in the HIV rapid test algorithm (Annexure B).[24] Accurate recording of results in standardised facility-based registers and maternal health record is important for continuity of care. QA ensures that all the HIV testing processes follow the guidelines to prevent false positive and false negative results. Since 2014, NICD has been conducting training in "PEPFAR priority facilities" to improve HIV testing proficiency in facilities.[25]

## 1.4 Aims and Objectives

This survey aimed to assess the utility of routine PMTCT program data for HIV sentinel surveillance amongst pregnant women.

The main research question was: What is the quality of routine antenatal PMTCT - related data in South Africa and can it be used to track antenatal HIV prevalence? In this context, we defined 'quality' as the 'completeness of facility records in documenting client information for selected PMTCT indicators.

### Primary objectives:

1. To assess the quality (i.e. completeness) of routinely collected PMTCT-related program data in selected ANSUR and NON-ANSUR facilities that represent a range of national scenarios e.g. urban large, urban small, rural large, rural small etc:
  - a. To document site procedures for PMTCT HIV testing and data recording (**PMTCT site assessment, Activity 1A**)
  - b. To review completeness of recorded data (**PMTCT data quality assessment, Activity 1B**).
2. To assess the quality of PMTCT HIV rapid testing procedures in selected facilities that represent a range of national scenarios: (**Activity 2**):
  - a. To gather facility-level data on the protocols, physical space, and safety procedures available to conduct rapid HIV testing
  - b. To gather facility-level data on the pre-testing, testing, and post-testing procedures for rapid HIV testing
  - c. To gather facility-level data on external QC of rapid HIV testing.



## 2. METHODOLOGY

### 2.1 Data Collection

We aimed to conduct a national cross-sectional survey in 348 of the 360 randomly selected public health facilities offering antenatal care and PMTCT services. The same facilities were used to collect data for Activities 1A,1B and 2; however, Activity 2 was not assessed in 2 facilities due to logistical challenges.

#### 2.1.1 Sampling strategy and sample size

A sampling frame was developed from the list of facilities available in the 2014/15 South African NDOH DHIS dataset. This frame had 1570 ANSUR facilities and 3113 NON-ANSUR facilities, with antenatal care patient load data. Although the facilities were from all 9 provinces and different localities (urban/rural) in South Africa, the facilities were not allocated to ANSUR/non-ANSUR and urban/rural so that they represent the entire population of facilities in the respective province or locality. Thus, the approach to determining the sample size for the study was not designed for external validity at sub-regional level but to show how proportions of outcomes compare between rural and urban localities, ANSUR and non-ANSUR participating sites and various provinces.

For the PMTCT site assessment, the minimum feasible sample size allowing for an error margin of +/- 5% was 360 facilities. For the PMTCT data quality assessment, given that the median number of women recruited per facility for ANSUR is 20, we aimed to review 20\*360 records in total, to mirror the numbers that would be selected during the antenatal survey. Thus, we aimed to obtain a national-level target sample size of 7200 records from 360 facilities.

A stratified sampling method was used to select facilities from the above sampling frame to ensure that all provinces, ANSUR participation status, and locality (rural or urban setting) were included. Thus, thirty-six strata were initially generated from all the 9 provinces, with ANSUR or NON-ANSUR and rural or urban status within each province (i.e., 9 provinces by two ANSUR status and by rural/urban location). The proportion of facilities from the sampling frame contributed by each of the 36 strata was then calculated and was called the stratum facility contribution. Each stratum needed a facility contribution of at least 1% to

provide sufficient data, hence smaller strata were merged, resulting in 26 strata in the final sampling frame. The percentage contribution of each stratum to the total number of first ANC visits (ANC-1) observed routinely from these strata, was then used to determine the number of register records to be reviewed from each stratum, within the 7200 targeted sample size. Using the ANSUR target of 20 records per facility, the calculated total number of records needed to be reviewed per stratum was divided by 20 to obtain the number of facilities to be included in the study for each stratum. This number was then used to randomly select facilities within each stratum, proportional to size (size determined by number of ANC-1) and without replacement. Oversampling was purposively planned from larger facilities within each stratum to account for smaller facilities from which less than 20 ANC-1 clients per month were anticipated (See Annexure J (A) for final list with minimum target sample size per facility). This approach was taken to obtain a self-weighting sample within each stratum. Therefore, no weights would be required in the analyses process if the target sample sizes per stratum were obtained. Due to fewer facilities in the Northern Cape the target sample size in this province was adjusted by 10 additional clinical records per facility sampled from the register.

Data collectors were given the number of records to abstract from each facility prior to visiting facilities with sampling procedures detailed below.

### 2.2 Study Population and Inclusion/ Exclusion Criteria

**Inclusion Criteria:** A Public health facility offering ANC to pregnant women.

**Exclusion Criteria:** (i) Facilities with less than 20 1st ANC visits per month and (ii) facilities from peri-urban areas and (iii) mobile health facilities.

### 2.3 Data Collection Tools and Field Work Method

Epicentre was responsible for data collection and the SAMRC undertook supervisory visits to assure data collection quality control. Data collectors underwent 5 days training followed by supervisory-support and data validation visits conducted

by a team of experienced trainers from NICD, SAMRC, and Epicentre. Facility managers provided written informed consent for data collectors to review facility records and all interviewed participants provided informed consent before participating in the survey. Field workers used hard copies to collect data for both the Activity 1B and Activity 2 while the Activity 1A was collected electronically using hand-held personal digital assistants (PDAs) connected to web-based Mobile Researcher.

### 2.3.1 PMTCT Site Assessment (Activity 1A)

Data were gathered by interviewing a facility staff member familiar with PMTCT service delivery practices. One cross sectional interview was conducted per facility, using the site assessment questionnaire (Annexure C), which was adapted from the WHO guidance document for this work. The tool focussed on four types of information: how and where PMTCT services such as HIV testing are delivered to clients, processes and key obstacles to providing PMTCT services to clients, types of registers used for recording PMTCT indicators, and alignment of activities with current national requirements.[8]

### 2.3.2 PMTCT Data Quality Assessment (Activity 1B)

A retrospective review of data from facility-based registers was conducted using two different data abstraction tools formats (Annexure D (i) and (ii) - tick and longitudinal). These were designed to abstract data from standard primary health care (PHC) tick sheet registers and integrated ANC/PMTCT/cohort registers. The latter was included because during pilot visits to clinics, some facilities were continuing to use cohort registers despite the National Department of Health having introduced one standard tick register sheet.

The routine data for each of the three months prior to the ANSUR period i.e. July, August and September 2016, were eligible for extraction. In each facility, data collectors requested a register where antenatal and PMTCT data elements were recorded for first visit ANC clients, the data collector recorded 1 if the element was recorded and 99 if nothing was recorded. A data abstraction SOP was developed to ensure that the data abstraction process was methodologically rigorous. Systematic sampling involved counting the total number of women recorded under that data element for the entire month and dividing this by the desired sample size for that month to obtain the sampling interval. For example, if 60 women were recorded during the month of interest and if 30 record abstractions were desired then every 2nd (60/30) record was abstracted. Where the total number of clients seen were less than the

expected per month, all records for that particular month were abstracted. Abstracted data elements at first ANC visit included gestational age at booking; antenatal HIV first test; antenatal HIV first test result; CD4 test conducted, CD4 test result, ART initiated at first visit, syphilis screen test conducted, syphilis test result, TB screening conducted and TB screening result.

No client names were abstracted; each client was allocated a confidential code, which was recorded. Data collectors signed confidentiality agreements.

### 2.3.3 PMTCT HIV rapid testing quality assurance (QA) assessment (Activity 2)

A cross-sectional audit of quality assurance (QA) practices for HIV rapid testing was conducted using the adapted WHO-recommended Checklist (Tool) for the Stepwise Process for Improving the Quality of HIV Rapid Testing (SPI-RT) Version 3.0) (SPI-RT Tool (Annexure E). [8, 26]

## 2.4 Data Entry, Analysis and Outcomes

### 2.4.1 PMTCT Site Assessment (Activity 1A)

#### **Number of facilities practising various PMTCT service delivery approaches**

Data were captured into Mobile Researcher.[27] SAMRC and Epicentre cleaned data and the SAMRC conducted the analysis. Descriptive statistics were used to describe the distribution of services by province and facility characteristic.

Outcomes included documenting: how HIV testing is conducted, including off-site testing; availability of viable HIV testing kits or challenges with sample transportation; types of registers used and the process of collecting information and health indicators.

### 2.4.2 PMTCT Data Quality Assessment (Activity 1B)

Data collection was conducted over a period of three months (i.e. it was extended beyond one months) in each facility in order to achieve the minimum required sample sizes from the smaller facilities.

However, this resulted in oversampling from some sites leading to realization of more than twice of the total target sample size, i.e., 14778 records were reviewed compared to the 7200 targeted. Although there was oversampling overall, under-sampling was still observed for some strata (see Annexure J (B) for sample realization per stratum). To adjust for over- and under-sampling, the realized sample

percentages per stratum were calculated and the inverse of each one used as sample weights to adjust the estimates to maintain the ANC-1 patient load proportionality across strata, and to report the results by ANSUR status, locality type and province as initially designed. The realized sample for one of the four strata in the Western Cape province was so low that a provincial average sample weight had to be used for all strata within this province.

All proportions and results in Activity 1B pertaining to review of completeness of register records have been weighted accordingly. Weights were applied to all reported proportions and estimates to adjust for under- and over-sampling at stratum level (see Annexure J-B for the final sample realization by strata) and the strata specified to adjust for intra-strata correlation. Similarly adjusted confidence intervals, at the 95% default level, were calculated using the logit method.

We measured data quality as the completeness and availability of the recorded data elements of interest. For each ANC data element recorded in the routine register, a value was considered complete if it was present and legible in the record field. If the data field was blank or illegible, the value was considered incomplete. If a data element was not contained in any register under examination, the value was also considered incomplete. High quality was defined as data element for which 90% of site records were complete and valid.[11] Table 2.1 summarises the numerators and denominators applied to this part of the analysis.

Descriptive statistics were used to describe prevalence of recorded data elements in facility-based registers. The logit method was used to calculate 95% confidence intervals for all estimates, using the 'proportion' function in STATA. We used non-overlapping confidence intervals to imply that true differences are likely to exist between two estimates.

Table 2.1: Numerators and denominators assessing data availability and completeness

| Indicator                                | Numerator<br>Number of records with:                                                                                                              | Denominator                                                                                                                                |
|------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Gestational age at ANC-1 visit</b>    | Gestational age at ANC-1 recorded                                                                                                                 | All reviewed ANC records                                                                                                                   |
| <b>*ANC client HIV first test result</b> | HIV first test result recorded IF HIV first test at ANC-1 visit recorded                                                                          | Number of records with recorded HIV first test done at ANC-1 visit                                                                         |
| <b>ANC client CD4 count result</b>       | CD4 count results recorded IF CD4 count test done at ANC recorded OR HIV-positive result recorded or known HIV-positive before first ANC recorded | Number of records with recorded CD4 count test done at ANC OR HIV-positive result recorded or known HIV-positive before first ANC recorded |
| <b>~ART uptake or regimen status</b>     | ART uptake or regimen status recorded IF ANC HIV-positive status recorded                                                                         | Number of records with ANC client HIV-positive status recorded                                                                             |
| <b>*ANC client syphilis test</b>         | ANC syphilis test done recorded                                                                                                                   | All reviewed ANC records                                                                                                                   |
| <b>*ANC client syphilis results</b>      | ANC syphilis test results recorded IF syphilis screening done at ANC recorded                                                                     | Number of records with recorded syphilis screening done at ANC                                                                             |
| <b>ANC client TB screening</b>           | ANC TB screening status recorded                                                                                                                  | All reviewed ANC records                                                                                                                   |
| <b>ANC client TB symptoms</b>            | ANC TB symptoms status recorded IF recorded TB screening done at ANC                                                                              | Number of records with recorded TB screening DONE at ANC                                                                                   |

\*Analysed from PHC Comprehensive Tick register sheets only; ~analysed from Integrated ANC/PMTCT longitudinal registers only. ANC- antenatal care, ANC-1 antenatal care first visit. ART - lifelong antiretroviral therapy

### 2.4.3 PMTCT HIV rapid testing QA assessment (Activity 2)

The adapted SPI-RT Tool was used to audit sites, after adapting it to the local context. The NICD team assisted with tool adaptation due to their experience in supporting the NDOH in the HIV Rapid testing quality improvement initiative (RTQII). As part of this assessment, data collectors observed HIV testers performing a simulated HIV rapid test. One ANC /PMTCT testing point was audited per facility.

#### 2.4.3.1 Data entry and analysis

Hard copies from the field were entered on Open Data Kit (ODK), a web-based data collection and capturing system[28], and the NICD team conducted the analysis for the adapted SPI-RT Tool data. Descriptive statistics were used to describe the distribution of facilities by province and sample size realization. The median and interquartile ranges (IQR) of the total scores and the percentage scores were determined for the overall dataset, by domain, province, geographical type (rural vs urban), PEPFAR support (being in a PEPFAR-supported district vs being in a NON-PEPFAR-supported districts), and participation in ANSUR (ANSUR sentinel facilities in 2015 vs NON-ANSUR facilities). The number and proportion of facilities at the different levels of implementation were determined by province. Rank sum tests and logistic regression were used to assess statistically significant differences in scores and implementation levels between rural and urban areas, facilities in PEPFAR-supported districts vs. non-PEPFAR-supported facilities, and ANSUR sentinel facilities (2015) vs NON-ANSUR facilities. Key gaps identified during the assessment which contributed to facilities obtaining low scores, were tabulated.

#### 2.4.3.2 Scoring Criteria

The adapted SPI-RT Tool Version 3.0 10/1/2015 was used to score facilities. This comprises seven domains, namely (i) training and certification, (ii) physical facility, (iii) safety, (iv) pre-testing phase, (v) testing phase, (vi) post-testing phase, and (vii) external quality assessment (EQA), that align to standard requirements (Table 3.21). For each of the seven domains data collectors assessed and ticked responses and observations under “yes”, when all elements were satisfactorily present and there was evidence of compliance; “partial”, when some testing elements were present but there was no evidence of consistent implementation or if there was non-adherence and “no”, when an element required a written procedure but it was not available at the testing point or when documentation was unsatisfactory. In addition, field workers provided comments to explain “partial” or “no” responses. Items marked “yes” were scored 1 point, “partial”-0.5 points and “no”- 0 point each. At the end of each domain total points scored were recorded . For

this study the overall total points for all sections were 64. We excluded some sections which were “not applicable”; namely, in South Africa, the EQA program does not include retesting of serum or dried blood spots (DBS) (User’s guide for Site Audit for the adapted SPI-RT Tool Version 3.0 10/1/2015).[29]

This activity measured the following outcomes:

- total scores on the adapted SPI-RT Tool, determined as a total of the seven domain scores and expressed as raw totals and also as percentages of the total possible scores.
- domain or area specific scores.
- differences in median scores between rural and urban areas, facilities in PEPFAR-supported district vs. facilities not in PEPFAR-supported districts, and ANSUR sentinel facilities (2015) vs NON-ANSUR facilities.
- HIV Rapid Testing (RT) QA implementation level, which represented levels of HIV rapid test quality assurance program implementation in readiness for national certification. The HIV RT QA implementation level total percentage scores were categorised into levels 0 to 4 (Table 2.2).

Table 2.2 Implementation levels

| Levels | Total percentage scores | Interpretation                                           |
|--------|-------------------------|----------------------------------------------------------|
| 0      | <40%                    | needs improvement in all areas and immediate remediation |
| 1      | 40- 59%                 | needs improvement in specific areas                      |
| 2      | 60- 79%                 | facility partially ready for national site certification |
| 3      | 80- 89%                 | facility close to national site certification            |
| 4      | >=90%                   | eligible for national site certification                 |

Source: WHO SPI-RT Tool Version 3.0

## 2.5 Ethical Considerations

Ethical clearance was obtained from the South African Medical Research Council (SAMRC) Ethics Committee, (EC029-9/2015), United States Centers for Disease Control and Prevention, CDC, Atlanta (IRB approval) and from Provincial Ethics Committees. The study obtained permission and support from the South African National Department of Health and from provincial and district management. Written informed consent was obtained from participants before data collection.

## 3. RESULTS

Data were gathered between 20 February 2017 and 31 May 2017. Data collection was conducted in 348 out of 360 targeted facilities for Activities 1A and 1B: 12 facilities were not visited because they were referral facilities of because of logistical challenges. Additionally, of 348 facilities visited, field workers could not collect data for Activity 2 in two facilities due to logistical challenges.

### 3.1 Activity 1A - PMTCT Site Assessment

#### Distribution of facilities by province, ANSUR site and locality:

Just over half of facilities assessed were from rural sites (52.6%). NON-ANSUR sites constituted 37.6% of the sample (Table 3.1).

Table 3.1: Distribution of facilities according to province, sentinel site and locality type in South Africa

|                 | Number of facilities | %    |
|-----------------|----------------------|------|
| <b>Province</b> |                      |      |
| Eastern Cape    | 43                   | 12.4 |
| Free State      | 17                   | 4.9  |
| Gauteng         | 81                   | 23.3 |

|                      | Number of facilities | %          |
|----------------------|----------------------|------------|
| KwaZulu-Natal        | 77                   | 22.1       |
| Limpopo              | 43                   | 12.4       |
| Mpumalanga           | 29                   | 8.3        |
| North West           | 20                   | 5.7        |
| Northern Cape        | 8                    | 2.3        |
| Western Cape         | 30                   | 8.6        |
| <b>Sentinel site</b> |                      |            |
| ANSUR                | 217                  | 62.4       |
| NON-ANSUR            | 131                  | 37.6       |
| <b>Locality type</b> |                      |            |
| Rural                | 183                  | 52.6       |
| Urban                | 165                  | 47.4       |
| <b>Total</b>         | <b>348</b>           | <b>100</b> |

#### Types of registers used to record data in the facilities:

Data collectors observed five types of registers to validate interviewee responses on where certain data elements for antenatal clients were captured. The commonest register type was the tick sheet register, followed by the laboratory specimen register/ book (Table 3.2).

Table 3.2: Facility registers used to record selected data:

| Registers used to record variables in selected facilities |            |     |      |     |      |
|-----------------------------------------------------------|------------|-----|------|-----|------|
| Register type                                             | Total<br>n | Yes |      | No  |      |
|                                                           |            | n   | %    | n   | %    |
| PHC Comprehensive Tick Register                           | 348        | 295 | 84.8 | 53  | 15.2 |
| Laboratory Specimen Register/                             | 348        | 229 | 65.8 | 119 | 34.2 |
| Integrated ANC/ PMTCT longitudinal Register               | 348        | 173 | 49.7 | 175 | 50.3 |
| ANC Register//Daily PHC register/non-standardized books   | 348        | 94  | 27.0 | 254 | 73.0 |
| HCT Register                                              | 348        | 45  | 12.9 | 303 | 87.1 |

PHC- primary health care facilities, ANC - antenatal care, PMTCT-prevention of mother-to-child transmission of HIV, HCT - HIV testing and counselling



### Key data elements recorded in each register:

An array of registers were used to document testing and results, the tick register being the commonest. Documentation of characteristics varied between registers within facilities. Table 3.3 summarises the data elements recorded in each type of site register and the prevalence of recorded data elements per register during the antenatal care visit. The date of the client visit was recorded (>68% of the time) in at least one of the five different registers, age of the client (>40% of the time) in four different registers, but this was infrequently recorded in the PHC Tick register. Education level and occupation were recorded poorly in all registers. Documentation of HIV testing offered was poor ranging from 20.5% (47 of 229 facilities using the laboratory specimen register) to 61.8% (107 of 173 facilities using the integrated ANC/PMTCT longitudinal register); 7.4% (17 of 229 facilities using the laboratory specimen register) to 62.8% (59 of 74 facilities using the ANC/daily PHC/non-standardised book as a register) of facilities reported

systems to document HIV test acceptance; 21.0 (48 of 229 facilities using the laboratory specimen register) to 93.6% (88 of 94 facilities using the ANC register) reported systems to document first HIV test results, and 10.0 (23 of 229 facilities using the laboratory specimen register) to 54.3% (51 of 94 facilities using the ANC register) reported systems to document confirmatory HIV test results. When all HIV testing activities were pooled together, it was clear that the ANC, longitudinal and the tick registers were the most commonly used for documenting activities related to HIV testing. About 90% of the facilities recorded HIV testing activities in at least one register. Another data element recorded by most facilities was the date of visit (95.1%). Over 60% of facilities also actively recorded the client's age. Less than half of the facilities recorded client demographic details such as parity and residence, in at least one register. It was also disappointing that only a quarter of the facilities recorded information on syphilis screening in any of their registers.

Table 3.3 Data elements recorded in each register reviewed

| Characteristic recorded         | ANC register /Daily PHC register/non-standardized books |      | HCT Register |      | Integrated ANC/PMTCT longitudinal register |      | Laboratory Specimen Register |      | PHC Comprehensive tick register |      | Facilities recording in at least one register type |      |
|---------------------------------|---------------------------------------------------------|------|--------------|------|--------------------------------------------|------|------------------------------|------|---------------------------------|------|----------------------------------------------------|------|
|                                 | N=94                                                    |      | N=45         |      | N=173                                      |      | N=229                        |      | N=295                           |      | N=348                                              |      |
|                                 | n                                                       | %    | n            | %    | n                                          | %    | n                            | %    | n                               | %    | n                                                  | %    |
| Age                             | 68                                                      | 72.3 | 26           | 57.8 | 83                                         | 48.0 | 99                           | 43.2 | 45                              | 15.3 | 217                                                | 62.3 |
| Gravidity                       | 56                                                      | 59.6 | 6            | 13.3 | 9                                          | 5.2  | 3                            | 1.3  | 4                               | 1.4  | 65                                                 | 18.7 |
| Parity                          | 55                                                      | 58.5 | 6            | 13.3 | 10                                         | 5.8  | 4                            | 1.7  | 4                               | 1.4  | 67                                                 | 19.3 |
| Residence                       | 40                                                      | 42.6 | 3            | 6.7  | 8                                          | 4.6  | 81                           | 35.4 | 3                               | 1.0  | 120                                                | 34.5 |
| Date of visit                   | 87                                                      | 92.6 | 31           | 68.9 | 161                                        | 93.1 | 209                          | 91.3 | 277                             | 93.9 | 331                                                | 95.1 |
| Education level                 | 3                                                       | 3.2  | 1            | 2.2  | 0                                          | -    | 0                            | -    | 1                               | 0.3  | 5                                                  | 1.4  |
| Occupation                      | 0                                                       | -    | 1            | 2.2  | 0                                          | -    | 5                            | 2.2  | 2                               | 0.7  | 10                                                 | 2.9  |
| HIV Test offered                | 56                                                      | 59.6 | 20           | 44.4 | 107                                        | 61.8 | 47                           | 20.5 | 127                             | 43.1 | 183                                                | 52.6 |
| HIV Test accepted/done          | 59                                                      | 62.8 | 21           | 46.7 | 78                                         | 45.1 | 17                           | 7.4  | 80                              | 27.1 | 143                                                | 41.1 |
| HIV 1 <sup>st</sup> test result | 88                                                      | 93.6 | 31           | 68.9 | 144                                        | 83.2 | 48                           | 21.0 | 248                             | 84.1 | 310                                                | 89.1 |
| Confirmatory HIV test results   | 51                                                      | 54.3 | 24           | 53.3 | 87                                         | 50.3 | 23                           | 10.0 | 68                              | 23.1 | 144                                                | 41.4 |
| Any HIV test                    | 90                                                      | 95.7 | 33           | 73.3 | 157                                        | 90.8 | 76                           | 33.2 | 273                             | 92.5 | 325                                                | 93.4 |
| Syphilis screening test         | 42                                                      | 44.7 | 3            | 6.7  | 27                                         | 15.6 | 25                           | 10.9 | 11                              | 3.7  | 88                                                 | 25.3 |

### Number of First Antenatal visits per month:

The number of pregnant women enrolling in ANC for a new pregnancy each month ranged between 10 and 39 at provincial level. Gauteng province reported the highest median while Eastern Cape had the lowest (Table 3.4).

Table 3.4: Median number of pregnant women enrolling in ANC service for a new pregnancy each month at facilities

| Province      | Median | Interquartile Range |
|---------------|--------|---------------------|
| Eastern Cape  | 10     | [5-23]              |
| Free State    | 13     | [7-18]              |
| Gauteng       | 39     | [24-58]             |
| KwaZulu-Natal | 31     | [10-78]             |
| Limpopo       | 13     | [9-27]              |
| Mpumalanga)   | 17     | [8-31]              |
| North West    | 13     | [7-20.5]            |

Table 3.5: Proportion of facilities performing off-site/on site HIV rapid testing

|                      | Total      | On- site    |                  | Off-site   |                |
|----------------------|------------|-------------|------------------|------------|----------------|
|                      | N          | %           | 95% CI           | %          | 95% CI         |
| <b>Locality</b>      |            |             |                  |            |                |
| Rural                | 183        | 94.5        | 90.1-97.0        | 5.5        | 3.0-9.9        |
| Urban                | 164        | 97.6        | 93.6-99.1        | 2.4        | 0.9-6.4        |
| <b>Sentinel site</b> |            |             |                  |            |                |
| ANSUR                | 216        | 95.8        | 92.2-97.8        | 4.2        | 2.2-7.8        |
| NON-ANSUR            | 131        | 96.2        | 91.1-98.4        | 3.8        | 1.6-8.9        |
| Total*               | <b>348</b> | <b>96.0</b> | <b>93.3-97.6</b> | <b>4.0</b> | <b>2.4-6.7</b> |

CI-Confidence Interval. \*locality and ANSUR status information missing for one facility hence the total add up to 347 but the calculated proportions are for N=348.

### HIV testing approach:

Overall, 97.4% of participants indicated that their ANC facilities offered PICT, 54.3% stated they also offered client-initiated counselling and testing (CICT) approach to HIV testing during pregnancy and 21.3% reported that HIV testing was also offered on an opt-out basis.

### Number of stock outs of HIV rapid test kits in the past 12 months:

Overall, the majority of facilities did not experience

| Province      | Median | Interquartile Range |
|---------------|--------|---------------------|
| Northern Cape | 12     | [7.5-26.5]          |
| Western Cape  | 26     | [15-61]             |

Interquartile range = Q1 and Q3

### On and Off-site rapid HIV testing:

Data collectors interviewed staff on HIV testing processes from 96.7% (n=348) of sampled facilities. In this context, "on-site"/ "at this site" referred to the building or compound of buildings that contains ANC services and "Off-site" referred to locations outside the building or compound of buildings that contains ANC services.

Overall, a high proportion of facilities (96.0%) conducted onsite antenatal HIV testing. Four percent of facilities reported conducting off-site HIV testing and all off-site testing was done at VCT clinics within the same facilities (Table 3.5).

stock-outs of HIV rapid test kits, HIV Screening, and HIV confirmatory assays in the last 12 months (81.0%, 81.9%, and 94.5%, respectively). Prevalence of no stock outs of HIV rapid test kits and screening tests was higher in urban than rural facilities (87.3% versus 75.4% and 89.1% versus 75.4%, respectively). There were no stock-outs of HIV confirmatory test kits in Mpumalanga and Western Cape provinces (100.0% respectively). Northern Cape and Limpopo provinces both had stock-out of HIV screening test kits of 50.0% and 58.1%, respectively) (Table 3.6).

Table 3.6: Prevalence of NO stock-outs of different HIV testing kits in the past twelve months by locality, sentinel site status, and province

|                      | HIV rapid test kits |             |                  | HIV Screening assay |             |                  | HIV Confirmatory assay |             |                  |
|----------------------|---------------------|-------------|------------------|---------------------|-------------|------------------|------------------------|-------------|------------------|
|                      | n                   | %           | 95% CI           |                     | %           | 95% CI           |                        | %           | 95% CI           |
| <b>Locality</b>      |                     |             |                  |                     |             |                  |                        |             |                  |
| Rural                | 183                 | 75.4        | 68.7-81.1        | 183                 | 75.4        | 68.8-81.0        | 183                    | 94.5        | 90.0-97.1        |
| Urban                | 165                 | 87.3        | 81.1-91.6        | 165                 | 89.1        | 83.2-93.1        | 165                    | 94.5        | 89.8-97.2        |
| <b>Sentinel site</b> |                     |             |                  |                     |             |                  |                        |             |                  |
| NON-ANSUR            | 131                 | 83.2        | 75.8-88.7        | 131                 | 83.2        | 75.6-88.8        | 131                    | 93.9        | 88.1-97.0        |
| ANSUR                | 217                 | 79.7        | 74.0-84.5        | 217                 | 81.1        | 75.7-85.6        | 217                    | 94.9        | 91.0-97.2        |
| <b>Province</b>      |                     |             |                  |                     |             |                  |                        |             |                  |
| Eastern Cape         | 43                  | 76.7        | 61.7-87.1        | 43                  | 83.7        | 69.6-92.0        | 43                     | 88.4        | 74.4-95.2        |
| Free State           | 17                  | 82.4        | 54.0-94.9        | 17                  | 88.2        | 60.8-97.3        | 17                     | 88.2        | 60.8-97.3        |
| Gauteng              | 81                  | 86.4        | 77.0-92.4        | 81                  | 86.4        | 76.9-92.4        | 81                     | 93.8        | 85.8-97.4        |
| KwaZulu-Natal        | 77                  | 85.7        | 75.7-92.0        | 77                  | 84.4        | 74.2-91.1        | 77                     | 97.4        | 90.3-99.3        |
| Limpopo              | 43                  | 58.1        | 42.8-72.0        | 43                  | 58.1        | 43.1-71.8        | 43                     | 95.3        | 82.7-98.9        |
| Mpumalanga           | 29                  | 82.8        | 63.9-92.9        | 29                  | 86.2        | 67.8-94.9        | 29                     | 100         | -                |
| North West           | 20                  | 85.0        | 62.4-95.1        | 20                  | 80.0        | 57.6-92.2        | 20                     | 95.0        | 70.5-99.3        |
| Northern Cape        | 8                   | 50.0        | 17.4-82.6        | 8                   | 50.0        | 17.4-82.6        | 8                      | 75.0        | 31.9-95.0        |
| Western Cape         | 30                  | 96.7        | 79.1-99.6        | 30                  | 96.7        | 79.1-99.6        | 30                     | 100.0       | -                |
| <b>Total</b>         | <b>348</b>          | <b>81.0</b> | <b>76.6-84.8</b> | <b>348</b>          | <b>81.9</b> | <b>77.6-85.5</b> | <b>348</b>             | <b>94.5</b> | <b>91.5-96.5</b> |

CI-Confidence Interval

#### Expired HIV rapid test kits:

Overall, 10.9% of facilities reported expired HIV test kits in the last 12 months. There did not appear to be a wide variation in expired HIV test kits prevalence by locality or ANSUR status. Eastern Cape, Northern Cape and Free State provinces reported a high prevalence of expired HIV test kits (27.9%, 25.0% and 23.5%), respectively while Western Cape reported the lowest prevalence (3.3%) (Table 3.7).

Table 3.7: Prevalence of expired HIV test kits in the last 12 months by locality, sentinel site status and province

| Facilities with expired test kits in the past 12 months |       |     |      |           |      |           |
|---------------------------------------------------------|-------|-----|------|-----------|------|-----------|
|                                                         | Total | Yes |      | No        |      |           |
|                                                         |       | n   | %    | 95% CI    | %    | 95% CI    |
| <b>Locality</b>                                         |       |     |      |           |      |           |
| Rural                                                   | 183   |     | 9.8  | 6.4-14.8  | 90.2 | 85.2-93.6 |
| Urban                                                   | 165   |     | 12.1 | 8.0-18.0  | 87.9 | 82.0-92.0 |
| <b>Sentinel site</b>                                    |       |     |      |           |      |           |
| ANSUR                                                   | 131   |     | 13.7 | 8.9-20.7  | 86.3 | 79.3-91.1 |
| NON-ANSUR                                               | 217   |     | 9.2  | 6.1-13.7  | 90.8 | 86.3-93.9 |
| <b>Province</b>                                         |       |     |      |           |      |           |
| Eastern Cape                                            | 43    |     | 27.9 | 16.5-43.1 | 72.1 | 56.9-83.5 |
| Free State                                              | 17    |     | 23.5 | 9.3-48.0  | 76.5 | 52.0-90.7 |

| Facilities with expired test kits in the past 12 months |            |             |                 |             |                  |
|---------------------------------------------------------|------------|-------------|-----------------|-------------|------------------|
|                                                         | Total      | Yes         |                 | No          |                  |
|                                                         | n          | %           | 95% CI          | %           | 95% CI           |
| Gauteng                                                 | 81         | 6.2         | 2.6-14.1        | 93.8        | 85.9-97.4        |
| KwaZulu-Natal                                           | 77         | 3.9         | 1.2-11.5        | 96.1        | 88.5-98.8        |
| Limpopo                                                 | 43         | 14.0        | 6.3-28.1        | 86.0        | 71.9-93.7        |
| Mpumalanga                                              | 29         | 6.9         | 1.6-24.8        | 93.1        | 75.2-98.4        |
| North West                                              | 20         | 15.0        | 4.8-38.0        | 85.0        | 62.0-95.2        |
| Northern Cape                                           | 8          | 25.0        | 5.0-68.1        | 75.0        | 31.9-95.0        |
| Western Cape                                            | 30         | 3.3         | 0.4-20.9        | 96.7        | 79.1-99.6        |
| <b>Total</b>                                            | <b>348</b> | <b>10.9</b> | <b>8.1-14.6</b> | <b>89.1</b> | <b>85.4-91.9</b> |

CI-Confidence Interval

### Facilities offering HIV re-test to known positive pregnant women:

Almost half (n=166, 47.7%) of facilities offer HIV re-test to ANC clients known to be living with HIV at first ANC visit. The confidence intervals around the estimates did not differ by locality or ANSUR status. The high prevalence of offering re-testing to women known to be living with HIV was in Gauteng Province (66.7%) and Free State (64.7%). (Table 3.8).

Table 3.8 Prevalence of facilities offering HIV re-test to known positive pregnant women by locality, sentinel site status, and province

| Facilities offering HIV re-test to known positive pregnant women |            |             |                  |             |                  |
|------------------------------------------------------------------|------------|-------------|------------------|-------------|------------------|
|                                                                  | Total      | Yes         |                  | No          |                  |
|                                                                  | n          | %           | 95% CI           | %           | 95% CI           |
| <b>Locality</b>                                                  |            |             |                  |             |                  |
| Rural                                                            | 183        | 40.4        | 33.8-47.4        | 59.6        | 52.6-66.2        |
| Urban                                                            | 165        | 55.8        | 48.1-63.1        | 44.2        | 36.9-51.9        |
| <b>Sentinel site</b>                                             |            |             |                  |             |                  |
| ANSUR                                                            | 217        | 49.3        | 43.1-55.5        | 50.7        | 44.5-56.9        |
| NON-ANSUR                                                        | 131        | 45.0        | 36.9-53.4        | 55.0        | 46.6-63.1        |
| <b>Province</b>                                                  |            |             |                  |             |                  |
| Eastern Cape                                                     | 43         | 32.6        | 19.8-48.6        | 67.4        | 51.4-80.2        |
| Free State                                                       | 17         | 64.7        | 39.4-83.8        | 35.3        | 16.2-60.6        |
| Gauteng                                                          | 81         | 66.7        | 55.7-76.0        | 33.3        | 24.0-44.3        |
| KwaZulu-Natal                                                    | 77         | 58.4        | 47.0-69.1        | 41.6        | 30.9-53.0        |
| Limpopo                                                          | 43         | 7.0         | 2.2-19.9         | 93.0        | 80.1-97.8        |
| Mpumalanga                                                       | 29         | 37.9        | 21.5-57.7        | 62.1        | 42.3-78.5        |
| North West                                                       | 20         | 55.0        | 32.5-75.6        | 45.0        | 24.4-67.5        |
| Northern Cape                                                    | 8          | 62.5        | 24.1-89.8        | 37.5        | 10.2-75.9        |
| Western Cape                                                     | 30         | 40.0        | 24.0-58.4        | 60.0        | 41.6-76.0        |
| <b>Total</b>                                                     | <b>348</b> | <b>47.7</b> | <b>42.8-52.7</b> | <b>52.3</b> | <b>47.3-57.2</b> |

CI-Confidence Interval

### Information recorded in registers indicating known positive status for pregnant women not re-tested:

Over half, 182 (52.3%) of facilities do not offer HIV re-testing to known women living with HIV. For these women, "Known positive" was mostly documented in the HIV testing registers (89.0%); 1.6% facilities did not record anything on the register fields (Table 3.9).

Table 3.9 What information is recorded in registers for known positive pregnant women who are not re-tested

|                      | N          |            | Positive       |             | Known positive   |            | Nothing recorded |            | Other          |  |
|----------------------|------------|------------|----------------|-------------|------------------|------------|------------------|------------|----------------|--|
|                      | n          | %          | 95% CI         | %           | 95% CI           | %          | 95% CI           | %          | 95% CI         |  |
| <b>Locality</b>      |            |            |                |             |                  |            |                  |            |                |  |
| Rural                | 109        | 0.9        | 0.9-0.9        | 90.8        | 90.8-90.8        | 0.0        | -                | 8.3        | 8.3-8.3        |  |
| Urban                | 73         | 1.4        | 1.4-1.4        | 86.3        | 86.3-86.3        | 4.1        | 4.1-4.1          | 8.2        | 8.2-8.2        |  |
| <b>Sentinel site</b> |            |            |                |             |                  |            |                  |            |                |  |
| ANSUR                | 110        | 0.9        | 0.9-0.9        | 89.1        | 89.1-89.1        | 2.7        | 2.7-2.7          | 7.3        | 7.3-7.3        |  |
| NON-ANSUR            | 72         | 1.4        | 1.4-1.4        | 88.9        | 88.9-88.9        | 0.0        |                  | 9.7        | 9.7-9.7        |  |
| <b>Total</b>         | <b>182</b> | <b>1.1</b> | <b>1.1-1.1</b> | <b>89.0</b> | <b>89.0-89.0</b> | <b>1.6</b> | <b>1.6-1.6</b>   | <b>8.2</b> | <b>8.2-8.2</b> |  |

CI-Confidence Interval

### Interventions for HIV known positive already on ART at first ANC visit:

Over half (58.0%) of facilities perform viral load testing for women living with HIV already on ART at first ANC and 27.9% implement adherence counselling for women living with HIV already on ART at first ANC visit. Performing a viral load did not show huge differences by locality or ANSUR status. Fourteen percent of facilities reported doing either a combination of viral load testing and adherence counselling (Table 3.10).

Table 3.10 Interventions recorded on registers to indicate what is done for known HIV-positive women already on ART at first visit

|                      | Total      | Viral Load test |                  | Adherence improvement interventions |                  | Other       |                  |
|----------------------|------------|-----------------|------------------|-------------------------------------|------------------|-------------|------------------|
|                      |            | n               | %                | 95% CI                              | %                | 95% CI      | %                |
| <b>Locality</b>      |            |                 |                  |                                     |                  |             |                  |
| Rural                | 183        | 52.5            | 45.2-59.6        | 33.9                                | 27.4-41.1        | 13.7        | 9.4-19.5         |
| Urban                | 165        | 64.0            | 56.4-71.0        | 21.3                                | 15.7-28.3        | 14.5        | 10.0-21.0        |
| <b>Sentinel site</b> |            |                 |                  |                                     |                  |             |                  |
| ANSUR                | 217        | 60.6            | 53.9-67.0        | 27.3                                | 21.8-33.7        | 12.0        | 8.4-17.1         |
| NON-ANSUR            | 131        | 53.4            | 44.8-61.9        | 29.0                                | 21.8-37.4        | 17.6        | 11.9-25.1        |
| <b>Total</b>         | <b>348</b> | <b>58.0</b>     | <b>52.8-63.1</b> | <b>27.9</b>                         | <b>23.4-32.8</b> | <b>14.1</b> | <b>10.8-18.2</b> |

CI-Confidence Interval

## 3.2 Activity 1B - PMTCT Data Quality Assessment

The sampling target was 7200 records from 360 facilities. A total of 14778 records were reviewed; of these 10943 (74.0%) were from the PHC Comprehensive Tick Sheet registers (Annexure F) and 3835 (26.0%) from Integrated ANC/PMTCT longitudinal registers (Annexure G) (Table 3.11).



Table 3.11 Total number of records reviewed in facilities across South Africa

|                 | Total number of records | PHC Comprehensive Tick register |              | Integrated ANC/PMTCT Longitudinal register |              |
|-----------------|-------------------------|---------------------------------|--------------|--------------------------------------------|--------------|
|                 | N                       | n                               | %            | n                                          | %            |
| <b>Locality</b> |                         |                                 |              |                                            |              |
| Urban           | 9430                    | 6937                            | 63.4         | 2493                                       | 65.0         |
| Rural           | 5348                    | 4006                            | 36.6         | 1342                                       | 35.0         |
| <b>Province</b> |                         |                                 |              |                                            |              |
| Eastern Cape    | 800                     | 642                             | 5.9          | 158                                        | 4.1          |
| Free State      | 1429                    | 436                             | 4.0          | 993                                        | 25.9         |
| Gauteng         | 7016                    | 5121                            | 46.8         | 1895                                       | 49.4         |
| KwaZulu-Natal   | 1745                    | 1745                            | 15.9         | 0.0                                        | 0.0          |
| Limpopo         | 1202                    | 914                             | 8.4          | 288                                        | 7.5          |
| Mpumalanga      | 921                     | 591                             | 5.4          | 330                                        | 8.6          |
| North West      | 568                     | 406                             | 3.7          | 162                                        | 4.2          |
| Northern Cape   | 368                     | 359                             | 3.3          | 9.0                                        | 0.2          |
| Western Cape    | 729                     | 729                             | 6.7          | 0.0                                        | 0.0          |
| <b>Total</b>    | <b>14778</b>            | <b>10943</b>                    | <b>100.0</b> | <b>3835</b>                                | <b>100.0</b> |

**Indicators analysed for completeness of recording in the PHC Tick sheet and Integrated ANC/PMTCT Longitudinal registers:**

Data collectors reviewed the completeness of recording numerators and denominators of key indicators for activities known to be performed during the first ANC visit of a client. These indicators are described in Table 3.12 below. The analysis of completeness of each indicator is then presented separately for tick and longitudinal register reviews.

Table 3.12: List of indicators analysed for completeness of recording

| Indicator                                | Denominator                                                                                                                      | Numerator                                                                                                                                               |
|------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Gestational age at ANC-1 visit</b>    | All reviewed ANC records                                                                                                         | Records with gestational age at ANC-1 recorded                                                                                                          |
| <b>*ANC client HIV first test result</b> | Records with recorded HIV first test done at ANC-1 visit                                                                         | HIV first test result recorded IF HIV first test at ANC-1 visit recorded                                                                                |
| <b>ANC client CD4 count result</b>       | Records with recorded CD4 count test done at ANC OR HIV-positive result recorded or known HIV-positive before first ANC recorded | ANC CD4 count results recorded IF (CD4 count test done at ANC recorded OR HIV-positive result recorded or known HIV-positive before first ANC recorded) |
| <b>~ART uptake or regimen status</b>     | Records with ANC client HIV-positive status recorded                                                                             | ART uptake or regimen status recorded IF ANC HIV-positive status recorded                                                                               |
| <b>*ANC client syphilis test</b>         | All reviewed ANC records                                                                                                         | Records with recorded syphilis test done at ANC                                                                                                         |
| <b>*ANC client syphilis results</b>      | Records with recorded syphilis screening done at ANC                                                                             | ANC Syphilis test results recorded IF syphilis screening done at ANC recorded                                                                           |
| <b>ANC client TB screening</b>           | All reviewed ANC records                                                                                                         | Records with recorded ANC TB screening status                                                                                                           |
| <b>ANC client TB symptoms</b>            | Records with recorded TB screening DONE at ANC                                                                                   | ANC TB symptoms status recorded IF recorded TB screening done at ANC                                                                                    |

\*Analysed from PHC Comprehensive Tick sheet registers only; ~analysed from Integrated ANC/PMTCT longitudinal registers only. ANC- antenatal care, ANC-1 antenatal care first visit. ART - lifelong antiretroviral therapy

### 3.2.1 Cross-sectional (PHC Comprehensive Tick sheet) registers

The completeness of key data elements of interest in the PHC Comprehensive Tick registers is shown in the following tables:

#### *Gestational age at first ANC visit*

Nearly all facilities recorded the client's gestational age at the first ANC visit 98.8%. This high level of completeness in recording this data element appeared to be similar across locality, ANSUR groups and provinces (Table 3.13).

*Table 3.13: Recording of gestational age at first ANC visit*

|                  | Gestational age at first ANC visit |              |                   |
|------------------|------------------------------------|--------------|-------------------|
|                  | Total                              | Yes recorded |                   |
|                  | N                                  | %            | 95% CI            |
| <b>Locality</b>  |                                    |              |                   |
| Urban            | 6937                               | 98.3         | 97.5- 98.9        |
| Rural            | 4006                               | 99.4         | 98.9- 99.7        |
| <b>Site type</b> |                                    |              |                   |
| NON-ANSUR        | 2710                               | 99.2         | 98.4- 99.6        |
| ANSUR            | 8233                               | 98.6         | 98.0- 99.1        |
| <b>Province</b>  |                                    |              |                   |
| Eastern Cape     | 642                                | 98.8         | 97.2- 99.1        |
| Free State       | 436                                | 100.0        | -                 |
| Gauteng          | 5121                               | 99.0         | 98.7- 99.2        |
| KwaZulu-Natal    | 1745                               | 99.6         | 99.3- 99.8        |
| Limpopo          | 914                                | 99.6         | 98.9- 99.9        |
| Mpumalanga       | 591                                | 98.5         | 96.6- 99.3        |
| North West       | 406                                | 100.0        | -                 |
| Northern Cape    | 359                                | 100.0        | -                 |
| Western Cape     | 729                                | 97.9         | 96.6- 98.8        |
| <b>Total</b>     | <b>10943</b>                       | <b>98.8</b>  | <b>98.3- 99.1</b> |

*CI-Confidence Interval*

#### *Antenatal client HIV 1st test result*

Table 3.14 shows the distribution of the prevalence of recording of antenatal client HIV first test result by locality, ANSUR group and province. Overall, 6802 (66.1%) reviewed records indicated that an HIV test was performed during the first ANC visit of a client. Among these, the HIV 1<sup>st</sup> test result was only recorded in 59.4% of the records. Urban sites had a high proportion of HIV test results recorded compared to rural sites (68.0%, versus 42.3%). ANSUR sites had more than twice the number of HIV 1<sup>st</sup> test results recorded compared with NON-ANSUR sites (68.0% versus 29.4%). Western Cape and Eastern Cape provinces had 98.9% and 82.2% of records with antenatal HIV 1<sup>st</sup> test result recorded, respectively while North West, Limpopo and Free State provinces had 7.8%, 7.6% and 3.4%, respectively. Nationally- approved PHC Comprehensive Tick registers only record an HIV 1<sup>st</sup> test positive therefore "Missing /not recorded" also includes HIV negative results.

Based on these recorded first ANC HIV-positive results, plus those who were recorded to be known HIV-positive before first ANC visit (437 not yet on ART with 61 retested at ANC and 1107 already on ART with 44 retested at ANC), the estimated weighted sample HIV positivity of the first ANC visit is 52.4% (95% CI: 50.9 - 54.0) according to the Tick register records. This estimate is only internally valid to this sample and has no external validity to any geographic level, because the sample denominator is not representative of specific geographic populations. Therefore, this HIV positive proportion should not be

referenced. The high estimate could reflect the biased recording of HIV positive results and/or data collection performance bias introduced by data collectors by selecting those records which appeared more complete.

Table 3.14: Prevalence of recording of antenatal client HIV first test result

| Antenatal client HIV 1st test result |             |             |            |                      |                   |
|--------------------------------------|-------------|-------------|------------|----------------------|-------------------|
|                                      | Total       | Recorded    |            | Missing/not recorded |                   |
|                                      | N           | %           | 95% CI     | %                    | 95% CI            |
| <b>Locality</b>                      |             |             |            |                      |                   |
| Urban                                | 4692        | 68.0        | 66.1- 69.9 | 32.0                 | 30.1- 33.9        |
| Rural                                | 2110        | 42.3        | 39.1- 45.7 | 57.7                 | 54.3- 60.9        |
| <b>Site type</b>                     |             |             |            |                      |                   |
| NON-ANSUR                            | 1629        | 29.4        | 26.0- 32.9 | 70.6                 | 67.1- 74.0        |
| ANSUR                                | 5173        | 68.0        | 66.2- 69.7 | 32.0                 | 30.3- 33.8        |
| <b>Province</b>                      |             |             |            |                      |                   |
| Eastern Cape                         | 463         | 82.2        | 77.5- 86.1 | 17.8                 | 14.0- 22.5        |
| Free State                           | 316         | 3.4         | 1.9- 5.9   | 96.6                 | 94.1- 98.1        |
| Gauteng                              | 3561        | 16.6        | 15.4- 17.8 | 83.4                 | 82.2- 84.6        |
| KwaZulu-Natal                        | 806         | 25.1        | 22.0- 28.5 | 74.5                 | 71.5- 78.0        |
| Limpopo                              | 475         | 7.6         | 5.5- 10.5  | 92.4                 | 89.5- 94.5        |
| Mpumalanga                           | 283         | 19.9        | 15.4- 25.3 | 80.1                 | 74.7- 84.6        |
| North West                           | 204         | 7.8         | 5.1- 11.8  | 92.2                 | 88.2- 94.9        |
| Northern Cape                        | 128         | 21.5        | 15.5- 28.9 | 78.5                 | 71.2- 84.5        |
| Western Cape                         | 566         | 98.9        | 97.7- 99.5 | 1.1                  | 0.5-2.3           |
| <b>Total</b>                         | <b>6802</b> | <b>59.4</b> | 57.6- 61.1 | <b>40.6</b>          | <b>38.9- 42.4</b> |

Nationally- approved PHC Comprehensive Tick registers only record a HIV 1<sup>st</sup> test positive therefore "Missing /not recorded" also includes HIV negative results. CI-Confidence Interval

#### ANC client CD4 count result

A total of 123 records (out of 1963 recorded as HIV-positive) were observed with a recording of CD4 count test done during ANC. Half of these (49.9%) had the CD4 cell count result recorded. There was a higher prevalence of recorded CD4 cell count results in urban and NON-ANSUR sites (59.6% and 61.6%, respectively). Western Cape had the highest recorded CD4 cell results (83.3%), while Limpopo, Mpumalanga and North West provinces had no record of CD4 cell count result (Table 3.15). There were no data for Free State and Northern Cape provinces. Overall, confidence intervals are two wide due to the small denominators.

Table 3.15: Prevalence of recording of antenatal client CD4 count result

| ANC client CD4 count result |       |          |            |
|-----------------------------|-------|----------|------------|
|                             | Total | Recorded |            |
|                             | N     | %        | 95% CI     |
| <b>Locality</b>             |       |          |            |
| Urban                       | 96    | 59.6     | 44.1- 73.3 |
| Rural                       | 27    | 22.1     | 8.3- 47.4  |
| <b>Site type</b>            |       |          |            |

| ANC client CD4 count result |            |             |                   |
|-----------------------------|------------|-------------|-------------------|
|                             | Total      | Recorded    |                   |
|                             | N          | %           | 95% CI            |
| NON-ANSUR                   | 20         | 61.6        | 37.1- 81.4        |
| ANSUR                       | 103        | 46.7        | 31.1- 63.0        |
| <b>Province</b>             |            |             |                   |
| Eastern Cape                | 58         | 32.9        | 20.5- 48.3        |
| Free State*                 | -          | -           | -                 |
| Gauteng                     | 38         | 7.7         | 2.5- 21.6         |
| KwaZulu-Natal               | 5          | 35.0        | 7.9- 77.2         |
| Limpopo                     | 1          | 0.0         | -                 |
| Mpumalanga                  | 6          | 0.0         | -                 |
| North West                  | 3          | 0.0         | -                 |
| Northern Cape*              | -          | -           | -                 |
| Western Cape                | 12         | 83.3        | 51.7- 95.9        |
| <b>Total</b>                | <b>123</b> | <b>49.9</b> | <b>36.7- 63.2</b> |

NB-Only the 'Recorded' proportions are reported because of the small denominator sample sizes. \*Both denominator and numerator not available. CI-Confidence Interval

#### ANC client syphilis testing and syphilis results

Only 6 of the 10943 reviewed records indicated that clients were screened for syphilis. All the six were from urban facilities, two were ANSUR, five from Eastern Cape province and 1 from Gauteng province. The syphilis screening results were only recorded in 3 of the six facilities which were all from Eastern Cape province and Non-ANSUR.

#### ANC client TB screening

Of all the records reviewed 62.9% had documented that TB screening was performed. Table 3.16 shows how recording of TB screening was distributed. Urban sites had a highest proportion of recorded TB screening compared to rural sites (72.6% and 48.2% respectively). ANSUR sites also had better recording of TB screening compared to non-ANSUR (69.4% versus 44.1%). Western Cape province had the highest proportion of records indicating clients TB screened (95.7%) and North West province had the lowest (1.7%).

Table 3.16: Prevalence of recording of antenatal client TB screening

| ANC client TB screening |       |          |            |                       |            |
|-------------------------|-------|----------|------------|-----------------------|------------|
|                         | Total | Recorded |            | Missing/ not recorded |            |
|                         | N     | %        | 95% CI     | %                     | 95% CI     |
| <b>Locality</b>         |       |          |            |                       |            |
| Urban                   | 6937  | 72.5     | 71.1- 74.0 | 27.4                  | 26.0- 28.9 |
| Rural                   | 4006  | 48.2     | 46.0- 50.4 | 51.8                  | 49.6- 54.0 |
| <b>Site type</b>        |       |          |            |                       |            |
| NON-ANSUR               | 2710  | 44.1     | 41.8- 46.5 | 55.9                  | 53.5- 58.2 |
| ANSUR                   | 8233  | 69.4     | 68.0- 70.8 | 30.6                  | 29.2- 32.0 |
| <b>Province</b>         |       |          |            |                       |            |
| Eastern Cape            | 642   | 69.7     | 65.4- 73.8 | 30.3                  | 26.2- 34.6 |

| ANC client TB screening |              |             |                   |                       |                   |
|-------------------------|--------------|-------------|-------------------|-----------------------|-------------------|
|                         | Total        | Recorded    |                   | Missing/ not recorded |                   |
|                         | N            | %           | 95% CI            | %                     | 95% CI            |
| Free State              | 436          | 10.4        | 7.9- 13.6         | 89.6                  | 86.4- 92.1        |
| Gauteng                 | 5121         | 40.8        | 39.4- 42.2        | 59.2                  | 57.8- 60.6        |
| KwaZulu-Natal           | 1745         | 74.4        | 71.9- 76.8        | 25.6                  | 23.2- 28.1        |
| Limpopo                 | 914          | 20.1        | 17.6- 22.9        | 79.9                  | 77.1- 82.4        |
| Mpumalanga              | 591          | 27.2        | 23.5- 31.2        | 72.8                  | 68.8- 76.5        |
| North West              | 406          | 1.7         | 0.9- 3.2          | 98.3                  | 96.8- 99.1        |
| Northern Cape           | 359          | 46.3        | 40.6- 52.1        | 53.7                  | 47.9- 59.4        |
| Western Cape            | 729          | 95.7        | 94.0- 97.0        | 4.3                   | 3.0- 6.0          |
| <b>Total</b>            | <b>10943</b> | <b>62.9</b> | <b>61.6- 64.3</b> | <b>37.1</b>           | <b>35.7- 38.4</b> |

CI-Confidence Interval

#### ANC client TB symptoms

Out of all the 62.9% (n=5106) records with TB screening documented, only 4.2% had TB symptoms recorded. The highest prevalence of recording of TB symptoms was in rural sites (8.3%) compared to urban sites (2.4%). Eastern Cape province had the highest prevalence of recording (12.4%) while Gauteng, Mpumalanga, Limpopo and North West provinces had no TB symptoms recorded in their registers.

Table 3.17: Prevalence of recording of antenatal client TB symptoms

| ANC client TB symptoms |             |            |                 |                       |                   |
|------------------------|-------------|------------|-----------------|-----------------------|-------------------|
|                        | Total       | Recorded   |                 | Missing/ not recorded |                   |
|                        | N           | %          | 95% CI          | %                     | 95% CI            |
| <b>Locality</b>        |             |            |                 |                       |                   |
| Urban                  | 3510        | 2.4        | 1.7- 3.3        | 97.6                  | 96.7-98.3         |
| Rural                  | 1596        | 8.3        | 6.3- 10.8       | 91.7                  | 89.2- 93.7        |
| <b>Site type</b>       |             |            |                 |                       |                   |
| NON-ANSUR              | 1247        | 2.6        | 1.6- 4.0        | 97.4                  | 96.0- 98.4        |
| ANSUR                  | 3859        | 4.6        | 3.6-5.7         | 95.4                  | 94.3- 96.4        |
| <b>Province</b>        |             |            |                 |                       |                   |
| Eastern Cape           | 480         | 12.4       | 9.7- 15.7       | 87.6                  | 84.3- 90.3        |
| Free State             | 51          | 11.2       | 3.8- 28.7       | 88.8                  | 71.3- 96.2        |
| Gauteng                | 2024        | 0.0        | -               | 100                   | -                 |
| KwaZulu-Natal          | 1367        | 6.5        | 5.3- 8.0        | 93.5                  | 92.0- 94.7        |
| Limpopo                | 180         | 0.0        | -               | 100                   | -                 |
| Mpumalanga             | 149         | 0.0        | -               | 100                   | -                 |
| North West             | 9           | 0.0        | -               | 100                   | -                 |
| Northern Cape          | 148         | 0.5        | 0.1- 3.4        | 99.5                  | 96.6- 99.9        |
| Western Cape           | 698         | 3.6        | 2.4- 5.2        | 96.4                  | 94.8- 97.6        |
| <b>Total</b>           | <b>5106</b> | <b>3.7</b> | <b>3.2- 4.2</b> | <b>96.3</b>           | <b>95.8- 96.8</b> |

CI-Confidence Interval



### 3.2.2 Records from Integrated ANC/PMTCT longitudinal registers

A total of 3835 ANC records were reviewed from longitudinal registers. There were no longitudinal registers reviewed in the Free State and Western Cape provinces and only 8 reviewed in Northern Cape. Indicators which could be analysed and presented in the tables below include Gestational age at ANC-1 visit, ANC CD4 count results, ANC ART uptake, ANC TB screening and ANC TB symptoms.

#### Gestational age at ANC-1 visit

Overall, 92.1% of ANC records had complete recording of timing of first ANC visit, recorded as either before 20 weeks pregnancy or after. Completeness in recording was more than 86.0% across all area localities, ANSUR groups, and provinces (Table 3.18).

Table 3.18: Recording of gestational age at first ANC visit

|                  | Gestational age at first ANC visit |              |            |
|------------------|------------------------------------|--------------|------------|
|                  | Total                              | Yes recorded |            |
|                  | N                                  | %            | 95% CI     |
| <b>Locality</b>  |                                    |              |            |
| Urban            | 2493                               | 90.1         | 89.5- 91.5 |
| Rural            | 1342                               | 93.8         | 92.2- 95.1 |
| <b>Site type</b> |                                    |              |            |
| NON-ANSUR        | 783                                | 90.6         | 88.2-92.5  |
| ANSUR            | 3052                               | 93.0         | 91.9-93.9  |
| <b>Province</b>  |                                    |              |            |
| Eastern Cape     | 137                                | 90.8         | 85.7-94.2  |
| Free State*      | -                                  | -            | -          |
| Gauteng          | 860                                | 86.0         | 83.6-88.1  |
| KwaZulu-Natal    | 1798                               | 94.9         | 93.6-96.0  |

Table 3.19: Prevalence of recording of antenatal client CD4 count result

|                  | ANC client CD4 count result |          |            |                      |            |
|------------------|-----------------------------|----------|------------|----------------------|------------|
|                  | Total                       | Recorded |            | Not recorded/missing |            |
|                  | N                           | %        | 95% CI     | %                    | 95% CI     |
| <b>Locality</b>  |                             |          |            |                      |            |
| Urban            | 844                         | 24.5     | 19.3- 26.0 | 77.5                 | 74.0- 80.7 |
| Rural            | 384                         | 21.6     | 17.6- 26.3 | 78.4                 | 73.7- 82.4 |
| <b>Site type</b> |                             |          |            |                      |            |
| NON-ANSUR        | 231                         | 20.5     | 15.5- 26.6 | 79.5                 | 73.4- 84.5 |
| ANSUR            | 997                         | 23.0     | 20.3- 26.0 | 77.0                 | 74.0-79.7  |

|               | Gestational age at first ANC visit |              |                  |
|---------------|------------------------------------|--------------|------------------|
|               | Total                              | Yes recorded |                  |
|               | N                                  | %            | 95% CI           |
| Limpopo       | 279                                | 97.0         | 94.3-98.4        |
| Mpumalanga    | 293                                | 87.8         | 83.5-91.1        |
| North West    | 152                                | 88.6         | 79.1-94.2        |
| Northern Cape | 8                                  | 88.9         | 50.0-98.5        |
| Western Cape* | -                                  | -            | -                |
| <b>Total</b>  | <b>3835</b>                        | <b>92.1</b>  | <b>90.9-93.0</b> |

CI-Confidence Interval. \*no longitudinal registers in the province

#### HIV positivity

The weighted ANC sample HIV positivity of the first ANC records was 31.8% (95% CI: 30.1-33.6) according to the longitudinal registers. This estimate should not be referenced as it's denominator was not designed to be representative of any geographical population with respect to estimating HIV prevalence.

#### ANC client CD4 count result

Recording of CD4 count results was reviewed among those records with a recorded HIV-positive status or recorded as 'known HIV-positive before first ANC' (N=1228). Of these, 22.1% had the CD4 count results recorded (Table 3.19). This analysis is placed on an assumption that all confirmed HIV-positive ANC clients are expected to have a CD4 count test. The recording of CD4 count results did not appear to differ much by ANSUR status or type of area locality. The two provinces with the highest prevalence of recorded CD4 results were Mpumalanga and KwaZulu-Natal provinces (35.7%, 23.7%), respectively, although even these were sub-optimal.

| ANC client CD4 count result |             |             |                   |                      |                   |
|-----------------------------|-------------|-------------|-------------------|----------------------|-------------------|
|                             | Total       | Recorded    |                   | Not recorded/missing |                   |
|                             | N           | %           | 95% CI            | %                    | 95% CI            |
| <b>Province</b>             |             |             |                   |                      |                   |
| Eastern Cape                | 57          | 8.8         | 3.3- 21.3         | 91.2                 | 78.7- 96.6        |
| Free State*                 | -           | -           | -                 | -                    | -                 |
| Gauteng                     | 253         | 17.9        | 13.8- 22.9        | 82.1                 | 77.1-86.2         |
| KwaZulu-Natal               | 711         | 23.7        | 20.1- 27.7        | 76.3                 | 72.3- 80.0        |
| Limpopo                     | 47          | 14.0        | 6.8- 26.7         | 86.0                 | 73.3- 93.2        |
| Mpumalanga                  | 116         | 35.7        | 27.2- 45.2        | 64.3                 | 54.7- 72.8        |
| North West                  | 41          | 19.0        | 10.0- 33.1        | 81.0                 | 61.4- 90.2        |
| Northern Cape               | 3           | 0.0         | -                 | 100                  | -                 |
| Western Cape*               | -           | -           | -                 | -                    | -                 |
| <b>Total</b>                | <b>1228</b> | <b>22.1</b> | <b>19.4- 24.9</b> | <b>77.9</b>          | <b>75.1- 80.6</b> |

CI-Confidence Interval. \*no longitudinal registers in the province

#### ART uptake or regimen status

Of the 1228 records with HIV-positive status recorded, 84.1% had complete recording of either 'whether or not the ANC client was on lifelong ART' or the 'specific ART regimen' they were on. Similar proportions (ranging between 83.5% and 84.5%) were observed within both locality types and within each ANSUR status. All the seven provinces which used the longitudinal registers also had high recording of ART status (ranging between 72.9% in Gauteng and 100% in Northern Cape provinces).

#### ANC client TB screening

Of all the records reviewed, 99.0% had the status of TB screening recorded as either 'screened' (73.5%) or 'not screened' (25.5%). Disaggregated analysis is not presented due to the very high coverage of recording in all sites.

#### ANC client TB symptoms

Of those with status of TB screening recorded as 'screened' (n= 2891) only 1 entry did not record the status of TB symptoms whether client had symptoms or no symptoms. Disaggregated analysis is not presented due to the very high coverage of recording.

for HIV rapid testing QA assessment. The majority (71.1%) of facilities assessed were in PEPFAR-supported districts and 63.9% were not antenatal sentinel sites (NON-ANSUR).

Table 3.20: Distribution of facilities visited by province and sample size realization

| Province      | Planned sample size Number (%)* | Number (%) ** assessed |
|---------------|---------------------------------|------------------------|
| Eastern Cape  | 43 (11.9)                       | 43 (100.0)             |
| Free State    | 17 (4.7)                        | 17 (100.0)             |
| Gauteng       | 86 (23.9)                       | 80 (93.0)              |
| KwaZulu-Natal | 78 (21.7)                       | 77 (98.7)              |
| Limpopo       | 45 (12.5)                       | 43 (95.6)              |
| Mpumalanga    | 30 (8.3)                        | 29 (96.7)              |
| North West    | 20 (5.6)                        | 20 (100.0)             |
| Northern Cape | 8 (2.2)                         | 8 (100.0)              |
| Western Cape  | 33 (9.2)                        | 29 (87.9)              |
| <b>Total</b>  | <b>360 (100.0)</b>              | <b>346 (96.1)</b>      |

\*as proportion of total number of facilities in the province

\*\* As proportion of planned sample size

## 3.3 Activity 2 - HIV Rapid Testing QA

### 3.3.1 Sample size realization:

Table 3.20 shows the distribution of facilities by province, planned sample size and sample size realization for HIV rapid testing QA. In two of 348 facilities visited, HIV rapid testing QA could not be assessed due to logistical reasons. Seven provinces achieved above 95.0% of the planned sample size

### 3.3.2 Overall score distribution by province and domains assessed:

#### Overall scores

Facilities obtained a median overall score of 39.8 (IQR 32.5 - 46.0) out of a highest possible score of 64 (see methods for detailed explanation) which corresponded to a median overall percentage score of 62.1% (IQR 50.8 - 71.9%), Table 3.21.

Table 3.21: Distribution of median score and median percentage score by service area (domain) assessed

| Domain                                  | Median score (IQR)*     | Median score* (IQR) as percentage of highest possible score |
|-----------------------------------------|-------------------------|-------------------------------------------------------------|
| 1. Personnel Training and certification | 3.5 (1.0 -5.0)          | 35.0% (10.0-50.0%)                                          |
| 2. Physical Facility                    | 4.5 (4.0-5.0)           | 90.0% (80.0-100.0%)                                         |
| 3. Safety                               | 8.5 (7.0-10.0)          | 77.3% (63.6 - 90.9%)                                        |
| 4. Pre-testing phase                    | 10 (9.0-11.0)           | 83.3% (75.0 -91.7%)                                         |
| 5. Testing phase                        | 5.5 (3.0-7.0)           | 61.1% (33.3 -77.8%)                                         |
| 6. Post-testing phase                   | 7 (5.5 -8.0)            | 77.8% (61.1 -88.9%)                                         |
| 7. External quality assessment (EQA)    | 1 (0.0-4.0)             | 12.5% (0.0-50.0%)                                           |
| <b>Overall score</b>                    | <b>39.8 (32.5-46.0)</b> | <b>62.1% (50.8 - 71.9%)</b>                                 |

\* Note: the highest possible score for each domain are as follows: personnel Training and certification = 10; Physical Facility = 5; Safety=11; pre-testing phase=12; testing phase=9; post-testing phase=9; and EQA= 8.

IQR=Interquartile Range

#### Distribution of scores by province

Table 3.22 shows that Limpopo and Mpumalanga provinces obtained highest median overall scores (71.1% (IQR 67.2-78.1%) and 70.3 % (IQR 63.3-78.1%), respectively). Free State and Northern Cape provinces obtained median percentage scores of 46.9% (IQR 43.0- 59.4%) and 43.4% (IQR 37.5-48.0%), respectively).

Table 3.22: Distribution of median overall and median overall percentage scores by province

| Province      | Number of facilities | Median overall scores* (IQR) | Median overall score* (IQR) as percentage of highest possible score |
|---------------|----------------------|------------------------------|---------------------------------------------------------------------|
| Eastern Cape  | 43                   | 37.0 (31.0 - 45.0)           | 57.8% (48.4-70.3%)                                                  |
| Free State    | 17                   | 30.0 (27.5-38.0)             | 46.9% (43.0 -59.4%)                                                 |
| Gauteng       | 80                   | 42.5 (36.3 -47.3)            | 66.4% (56.6 -73.8%)                                                 |
| KwaZulu-Natal | 77                   | 38.0 (33.0-42.5)             | 59.4% (51.6 -66.4%)                                                 |
| Limpopo       | 43                   | 45.5 (43.0 -50.0)            | 71.1% (67.2 -78.1%)                                                 |
| Mpumalanga    | 29                   | 45.0 (40.5 -50.0)            | 70.3% (63.3 - 78.1%)                                                |
| North West    | 20                   | 39.3 (34.8 -52.3)            | 61.3% (54.3 -81.6%)                                                 |
| Northern Cape | 8                    | 27.8 (24.0 -30.75)           | 43.4% (37.5- 48.0%)                                                 |
| Western Cape  | 29                   | 33.0 (29.5 -37.5)            | 51.6% (46.1 - 58.6%)                                                |
| <b>Total</b>  | <b>346 (96.1)**</b>  | <b>39.8 (32.5-46.0)</b>      | <b>62.1% (50.8 - 71.9%)</b>                                         |

\*includes all seven domains

IQR=Interquartile Range

#### Stratified analysis of overall scores by geographical type, PEPFAR support, and participation in 2015 antenatal survey

Facilities in PEPFAR-supported districts had significantly higher median scores and percentage scores (p- value from rank sum test: <0.001). Rural areas and NON-ANSUR facilities had slightly higher scores compared to urban and ANSUR facilities; however, this difference was not statistically significant) (Table 3.23).

Table 3.23: Stratified analysis of overall scores by geographical type, PEPFAR support, and participation in 2015 antenatal survey

|                                          | Number (%) of facilities visited | Median score (IQR)*     | Median score (IQR) as percentage Score of highest possible score* | P- Value ** |
|------------------------------------------|----------------------------------|-------------------------|-------------------------------------------------------------------|-------------|
| <b>Locality</b>                          |                                  |                         |                                                                   |             |
| Urban                                    | 163 (47.1)                       | 39.5 (32.5-45.0)        | 61.7% (50.8-70.3%)                                                | 0.3         |
| Rural                                    | 183 (52.9)                       | 40.0 (33.0 -47.0)       | 62.5% (51.6-73.4%)                                                |             |
| <b>Site type</b>                         |                                  |                         |                                                                   |             |
| ANSUR facilities                         | 125 (36.1)                       | 39.5 (32.0-46.0)        | 61.7% (50-71.1%)                                                  | 0.5         |
| NON-ANSUR facilities                     | 221 (63.9)                       | 40.5 (33.0-46.5)        | 63.3% (51.6-72.7%)                                                |             |
| <b>PEPFAR</b>                            |                                  |                         |                                                                   |             |
| Facilities in PEPFAR-supported districts | 246 (71.1)                       | 42.0 (35.0-47.5)        | 65.6% (53.9 -74.2%)                                               | <0.001      |
| Non-PEPFAR facilities                    | 100 (28.9)                       | 36.3 (30.5 -42.3)       | 56.6% (47.7-66.0%)                                                |             |
| <b>Total</b>                             | <b>346 (100)</b>                 | <b>39.8 (32.5-46.0)</b> | <b>62.1% (50.8 - 71.9%)</b>                                       |             |

\*includes all seven domains \*\* Wilcoxon rank sum test; IQR=Interquartile Range

#### Distribution of median percentage score by domain assessed in PEPFAR supported and NON-PEPFAR facilities

The domains that had substantial difference in median percentage scores between PEPFAR and non-PEPFAR facilities were EQA (median percentage score of 25% for PEPFAR facilities vs median percentage score of 0 in non-PEPFAR facilities), testing (61.1% for PEPFAR facilities vs 44.4% for non-PEPFAR facilities), post-testing (66.7% % for PEPFAR facilities vs 77.8% for non-PEPFAR facilities), and pre-testing (87.5% for PEPFAR facilities vs 79.2% non-PEPFAR facilities). The scores for safety, physical facility, and training and certification were not substantially different between PEPFAR and non-PEPFAR facilities. (Table 3.24)

Table 3.24 Distribution of median percentage score by domain assessed in PEPFAR supported and NON-PEPFAR facilities

| Domain                                  | PEPFAR                                                           | NON-PEPFAR                                                       |
|-----------------------------------------|------------------------------------------------------------------|------------------------------------------------------------------|
|                                         | Median score (IQR) as percentage Score of highest possible score | Median score (IQR) as percentage Score of highest possible score |
| 1. Personnel Training and certification | 35.0% (15.0-50.0%)                                               | 38.0% (10.0-50.0%)                                               |
| 2. Physical Facility                    | 90.0% (80.0-100.0%)                                              | 90.0% (80.0-100.0%)                                              |
| 3. Safety                               | 81.8% (68.2 - 90.9%)                                             | 77.3% (59.1 - 86.4%)                                             |
| 4. Pre-testing phase                    | 87.5% (79.2 -91.7%)                                              | 79.2% (70.8 -87.5%)                                              |
| 5. Testing phase                        | 61.1% (33.3 -77.8%)                                              | 44.4% (22.2 -69.4%)                                              |
| 6. Post-testing phase                   | 66.7% (55.6 -77.8%)                                              | 77.8% (66.7 -88.9%)                                              |
| 7. External quality assessment (EQA)    | 25.0% (0.0 -62.5%)                                               | 0% (0.0-25.0%)                                                   |
| <b>Overall score</b>                    | <b>65.6% (53.9 - 74.2%)</b>                                      | <b>56.6% (47.7 - 66.1%)</b>                                      |

IQR=Interquartile Range

### 3.3.3 Distribution of implementation levels by province

Table 3.25 shows the number of facilities classified under each implementation level. Forty-three percent (150) of facilities were at level 1 or below (with 22 facilities requiring improvement in all areas and immediate remediation); 9.8% (34) close to national certification and only 1.2% (4) eligible for national site certification. Facilities found eligible for national site certification were in Gauteng, Eastern Cape and KwaZulu-Natal. Five provinces (Western Cape, Free State, Northern Cape, KwaZulu-Natal & Eastern Cape) had the highest proportion of facilities classified under level 1 compared to other provinces and provinces with the highest number of facilities in level 0 were KwaZulu-Natal and Western Cape (5 and 4, respectively).

Table 3.25: Distribution of implementation levels by province

| Provinces      | Number of facilities | Level 0 (<40%)<br>Number (%) | Level 1 (40-59%)<br>Number (%) | Level 2 (60-79%)<br>Number (%) | Level 3 (80- 89%)<br>Number (%) | Level 4 (>=90%)<br>Number (%) |
|----------------|----------------------|------------------------------|--------------------------------|--------------------------------|---------------------------------|-------------------------------|
| Eastern Cape   | 43                   | 3 (7.0%)                     | 19 (44.2%)                     | 15 (34.9%)                     | 5 (11.6%)                       | 1 (2.3%)                      |
| Free State     | 17                   | 3 (17.7%)                    | 11 (64.7%)                     | 3 (17.7%)                      | 0 (0%)                          | 0 (0%)                        |
| Gauteng        | 80                   | 3 (3.8%)                     | 23 (28.8%)                     | 43 (53.8%)                     | 9 (11.3%)                       | 2 (2.5%)                      |
| KwaZulu- Natal | 77                   | 5 (6.5%)                     | 34 (44.2%)                     | 36 (46.8%)                     | 1 (1.3%)                        | 1 (1.3%)                      |
| Limpopo        | 43                   | 0 (0%)                       | 2 (4.7%)                       | 33 (76.7%)                     | 8 (18.6%)                       | 0 (0%)                        |
| Mpumalanga     | 29                   | 0 (0%)                       | 7 (24.1%)                      | 16 (55.2%)                     | 6 (20.7%)                       | 0 (0%)                        |
| North West     | 20                   | 1 (5%)                       | 8 (40.0%)                      | 6 (30.0%)                      | 5 (25.0%)                       | 0 (0%)                        |
| Northern Cape  | 8                    | 3 (37.5%)                    | 5 (62.5%)                      | 0 (0%)                         | 0 (0%)                          | 0 (0%)                        |
| Western Cape   | 29                   | 4 (13.8%)                    | 19 (65.5%)                     | 6 (20.7%)                      | 0 (0%)                          | 0 (0%)                        |
| <b>All</b>     | <b>346</b>           | <b>22 (6.4%)</b>             | <b>128 (37.0%)</b>             | <b>158 (45.7%)</b>             | <b>34 (9.8%)</b>                | <b>4 (1.2%)</b>               |

- Level 0 site; a score of less than 40%, needs improvement in all areas and immediate remediation
- Level 1 site; a score between 40% - 59%, needs improvement in specific areas
- Level 2 site; a score between 60% - 79%, is partially ready for national site certification
- Level 3 site; a score between 80% - 89%, is close to national site certification
- Level 4 site; a score of 90% or higher, is eligible for national site certification

Stratified analysis of implementation levels by geographical type, PEPFAR support, and participation in 2015 antenatal survey

A higher proportion (14.2%, 35) of facilities in PEPFAR districts were at level 3 and 4 compared to only 3.0 % (3) of non-PEPFAR facilities. In a univariate logistic regression, facilities in PEPFAR-supported districts had 5.4 times higher odds of being at level 3 and 4 compared to non-PEPFAR facilities (Table 3.26).

A higher proportion of rural facilities (11.5%) and NON-ANSUR facilities (12.7%) compared to urban (10.4%) and ANSUR facilities (8.0%) were at level 3 and 4, however these differences were not statistically significant (Table 3.26).

Table 3.26: Stratified analysis of implementation levels by geographical type, PEPFAR support, and participation in 2015 antenatal survey

| Province        | Number of facilities | Level 0<br>Number (%) | Level 1<br>Number (%) | Level 2<br>Number (%) | Level 3<br>Number (%) | Level 4<br>Number (%) | Odds ratio<br>(95% CI) * |
|-----------------|----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|--------------------------|
| <b>Locality</b> |                      |                       |                       |                       |                       |                       |                          |
| Urban           | 163                  | 13 (8.0%)             | 58 (35.6%)            | 75 (46.0%)            | 15 (9.2%)             | 2 (1.2%)              |                          |
| Rural           | 183                  | 9 (4.9%)              | 70 (38.3%)            | 83 (45.4%)            | 19 (10.4%)            | 2 (1.1%)              | 1.1 (0.6 -2.2)           |
| <b>Site</b>     |                      |                       |                       |                       |                       |                       |                          |
| ANSUR           | 125                  | 7 (5.6%)              | 50 (40.0%)            | 58 (46.4%)            | 8 (6.4%)              | 2 (1.6%)              |                          |
| NON-ANSUR       | 221                  | 15 (6.8%)             | 78 (35.3%)            | 100 (45.2%)           | 26 (11.8%)            | 2 (0.9%)              | 0.6 (0.3 -1.3)           |
| PEPFAR          | 246                  | 14 (5.7%)             | 75 (30.5%)            | 122 (49.6%)           | 32 (13.0%)            | 3 (1.2%)              |                          |
| Non-PEPFAR      | 100                  | 8 (8.0%)              | 53 (53.0%)            | 36 (36.0%)            | 2 (2.0%)              | 1 (1.0%)              | 5.4 (1.6-17.9)           |
| <b>All</b>      | <b>346</b>           | <b>22 (6.4%)</b>      | <b>128 (37.0%)</b>    | <b>158 (45.7%)</b>    | <b>34 (9.8%)</b>      | <b>4 (1.1%)</b>       |                          |

\*univariate logistic regression assessed the odds of being at levels 3 and above (vs being at levels < 3) for facilities in PEPFAR districts, ANSUR facilities and rural facilities.

CI-Confidence Interval

### 3.3.4 Assessment results for specific questions within domains and challenges documented

The following section below provides a detailed analysis of performance by assessment questions for the seven domains assessed.

Overall median scores varied substantially by domains assessed. Two domains that scored overall median scores below 50% were external quality assessment (EQA) at 12.5% (IQR 0.0-50.0%) and training and certification at 35.0% (IQR 10.0-50.0%) (Table 3.21).

#### 3.3.4.1 Personnel training and Certification:

Table 3.26 shows that the majority of facilities did not meet 70.0% of the elements assessed in this domain. The proportion of facilities with evidence of tester-training on use of standardised HIV testing registers and QC process were 59.8% and 52.9% respectively. Common challenges identified in this domain are listed in Table 3.27.

Only a third (35.8%) of interviewees reported that all the testers had received comprehensive training on HIV rapid testing using the nationally approved curriculum, and only 20.8% had received refresher training. Documentation indicating all testers showed competency prior to client HIV testing was found only in 11.9% of facilities. The majority of facilities (84.4%) had testers that were not certified through a national certification programme, as there is no national certification process in place. The remaining 15.6% who reported being certified might have misunderstood the requirement because although trainees receive certificates of completion, this does not fulfil the requirement of a national certification program. Further analysis of challenges documented under these two domains (sub-section 3.3.4.6 below) indicated that majority (62.7.0%) of facilities were not enrolled in PT/EQA program which affected most of the assessment results/scores for both EQA and training and certification.

*Table 3.27: Personnel training and Certification: performance by assessment questions and most common challenges documented during assessment*

| Assessment questions                                                        | Yes Number (%) | Partial Number (%) | No Number (%) | Most common challenges                                                                                     |
|-----------------------------------------------------------------------------|----------------|--------------------|---------------|------------------------------------------------------------------------------------------------------------|
| All testers received comprehensive training on HIV rapid testing            | 124 (35.8%)    | 28 (8.1%)          | 194 (56.1%)   | Testers were either not trained; or if trained, there was no record/ documentation                         |
| Testers trained on the use of standardised HIV testing registers/logbooks   | 207 (59.8%)    | 27 (7.8%)          | 112 (32.4%)   | Either not trained/no standardised register/log books on testing points                                    |
| Testers trained on EQA and PT process                                       | 124 (35.8%)    | 16 (4.6%)          | 206 (59.5%)   | Facility not enrolled, and PT not done at the facility                                                     |
| Testers trained on QC process                                               | 183 (52.9%)    | 9 (2.6%)           | 154 (44.5%)   | Not trained /Trained but no record; Trained but QC logs not properly recorded; QC not done at the facility |
| All testers received refresher training in the last two years               | 72 (20.8%)     | 7 (2.0%)           | 267 (77.2%)   | Refresher training received a long time ago<br>No evidence / documentation                                 |
| Record indicating all testers showed competency prior to client HIV testing | 41 (11.9%)     | 4 (1.2%)           | 301 (87.0%)   | Done but no recorded;<br>Not done and no record                                                            |
| All testers have been certified through a national certification program    | 54 (15.6%)     | 0.0 (0%)           | 292 (84.4%)   | No national certification process in place                                                                 |



### 3.3.4.2. Physical Facility

Facilities scored the highest median percentage score (90.0%) for this domain compared to other domains (Table 3.28). The highest proportion of facilities had clean and organized testing areas (80.9%), sufficient lighting (93.4%) and secure storage space for test kits and other consumables (87.3%). Facilities scored lowest on keeping test kits in a temperature controlled environment (61.9%) and having a designated area for testing (75.1%).

*Table 3.28. Physical Facility: performance by assessment questions and most common challenges documented during assessment*

| Assessment questions                                     | Yes Number (%) | Partial Number (%) | No Number (%) | Most common challenges                                                              |
|----------------------------------------------------------|----------------|--------------------|---------------|-------------------------------------------------------------------------------------|
| Have designated area for HIV testing                     | 260 (75.1%)    | 59 (17.1%)         | 27 (7.8%)     | Room used for multiple purpose                                                      |
| Clean and organized testing areas                        | 280 (80.9%)    | 44 (12.7%)         | 22 (6.4%)     | Not enough space                                                                    |
| Sufficient lighting                                      | 323 (93.4%)    | 8 (2.3%)           | 15 (4.3%)     | Light not working                                                                   |
| Kits kept in a temperature controlled environment        | 214 (61.8%)    | 63 (18.2%)         | 69 (19.9%)    | No temperature gauge<br>No temperature chart<br>Test kits directly getting sunlight |
| Secure storage space for test kits and other consumables | 302 (87.3%)    | 24 (6.9%)          | 20 (5.8%)     | Not enough space<br>Storage cupboard not locked                                     |

### 3.3.4.3 Safety

The overall median percentage score for safety domain was 77.3%. The two areas with lowest scores within this domain were the availability of SOPs/job aids for managing spill of blood (49.7%) and use of PPE during testing (54.3%), Table 3.29.

*Table 3.29. Safety: performance by assessment questions and most common challenges documented during assessment*

| Assessment questions                                     | Yes Number (%) | Partial Number (%) | No Number (%) | Most common challenges                                                        |
|----------------------------------------------------------|----------------|--------------------|---------------|-------------------------------------------------------------------------------|
| SOPs and/or job aides in place to manage spills of blood | 172 (49.7%)    | 53 (15.3%)         | 121 (35.0%)   | No job aids no SOP; job aid/ SOP available but in the clinic managers' office |
| PPE properly used by all testers during testing          | 188 (54.3%)    | 130 (37.6%)        | 28 (8.1%)     | Run out of apron/glove, incorrect size glove                                  |

### 3.3.4.4 Pretesting Phase

Overall, most facilities performed relatively well in the pretesting phase domain, Table 3.30. The overall median score for this domain was 10 (IQR: 9-11) out of a maximum score of 12. This was the second highest score among the domains assessed. All elements in this domain, except one, were met by the majority of facilities. In 62.4% of facilities, HIV test kits were not labelled with initials and dates.

**Table 3.30: Pretesting phase: performance by assessment questions and most common challenges documented during assessment**

| Assessment questions                                      | Yes Number (%) | Partial Number (%) | No Number (%) | Most common challenges                                                                                             |
|-----------------------------------------------------------|----------------|--------------------|---------------|--------------------------------------------------------------------------------------------------------------------|
| National testing guidelines available                     | 240 (69.4%)    | 18 (5.2%)          | 88 (25.4%)    | Guidelines not available/available but kept in the manager's office/ shared between testing points; old guidelines |
| SOPs and job aids in place for each HIV rapid testing     | 253 (73.1%)    | 27 (7.8%)          | 66 (19.1%)    | Job aids available but not placed in the testing room                                                              |
| Test kits labelled with date received and initials        | 116 (33.5%)    | 14 (4.1%)          | 216 (62.4%)   | In most facilities, test kits were not labelled with initials and dates                                            |
| Process in place for stock management                     | 241 (69.7%)    | 47 (13.6%)         | 58 (16.8%)    |                                                                                                                    |
| Job aids on client sample collection available and posted | 223 (64.5%)    | 30 (8.7%)          | 93 (26.9%)    | No job aids; Job aids available but not posted;                                                                    |

### 3.3.4.5 Testing phase

The majority (66.8%) of facilities followed the correct testing procedures and (81.5%) used sample devices accurately (Table 3.31). The most common errors in sample collection were the use of inaccurate drops. Internal QC using samples provided by the NICD, was done by 50.0% facilities. Performing internal QC depends on a number of factors including: 1) samples reaching the sites 2) sites knowing how to perform IQC, or 3) individuals at sites with knowledge on how to perform IQC but these individuals do not perform it routinely.

**Table 3.31: Testing phase: performance by assessment questions and most common challenges documented during assessment**

| Assessment questions                                                  | Yes Number (%) | Partial Number (%) | No Number (%) | Most common challenges                                                                                                                     |
|-----------------------------------------------------------------------|----------------|--------------------|---------------|--------------------------------------------------------------------------------------------------------------------------------------------|
| SOPs/ Job aids on HIV testing procedures                              | 231 (66.8%)    | 55 (15.9%)         | 60 (17.3%)    | Job aids available but not referred<br>No SOPs and No job aids                                                                             |
| Timers available, functional and used correctly for HIV rapid testing | 164 (47.4%)    | 44 (12.7%)         | 138 (39.9%)   | Available but not working/no battery; using personal watch/cell phone;                                                                     |
| Sample collection devices used accurately                             | 282 (81.5%)    | 34 (9.8%)          | 30 (8.7%)     | Number of drops inaccurate;                                                                                                                |
| Test procedures adequately followed                                   | 234 (67.6%)    | 63 (18.2%)         | 49 (14.2%)    | Procedures wrong for advanced quality                                                                                                      |
| Negative and positive QC specimens routinely used                     | 170 (49.1%)    | 26 (7.5%)          | 150 (43.4%)   | QC not done;/ Facility not enrolled for QC/no PT done at facility/ Not trained;/ Don't have sample;                                        |
| QC results properly recorded                                          | 174 (50.3%)    | 13 (3.8%)          | 159 (46.0%)   | QC not done; Facility not enrolled for QC/no PT done at facility; Not trained;<br>Don't have sample; Done but no documentation to prove it |

| Assessment questions                                                     | Yes Number (%) | Partial Number (%) | No Number (%) | Most common challenges                                                         |
|--------------------------------------------------------------------------|----------------|--------------------|---------------|--------------------------------------------------------------------------------|
| Incorrect/invalid QC results properly recorded                           | 97 (28.0%)     | 5 (1.5%)           | 244 (70.5%)   | QC not done; Facility not enrolled for QC/no PT done at facility;              |
| Appropriate steps taken and documented when QC results invalid/incorrect | 96 (27.8%)     | 7 (2.0%)           | 243 (70.2%)   | Not trained; Not sure what to do with invalid result; never had invalid result |
| QC results reviewed by a person in charge routinely                      | 161 (46.5%)    | 10 (2.9%)          | 175 (50.6%)   | Not routinely reviewed; not reviewed at all                                    |

### 3.3.4.6. Post-testing phase

In this domain, lowest scores were obtained due to poor recording of invalid test results, Table 3.32. Standardised registers were available in 80.1% of the facilities assessed; however, key elements were partially completed and not completed by 31.5% and 8.4% of facilities, respectively. Commonly completed elements were client names and HIV test results. Quality control (QC) elements such as assay test lot number, and expiry date were either not captured or incompletely recorded.

The majority (64.5%) of facilities correctly completed the total summaries on registers, and (49.1%) did not record the invalid repeat tests.

*Table 3.32: Post-Testing phase: performance by assessment questions and most common challenges documented during assessment*

| Assessment                                                    | Yes Number (%) | Partial Number (%) | No Number (%) | Most common challenges                                                                                                        |
|---------------------------------------------------------------|----------------|--------------------|---------------|-------------------------------------------------------------------------------------------------------------------------------|
| HIV rapid testing register/log book include all key elements  | 277 (80.1%)    | 56 (16.2%)         | 13 (3.8%)     | Doesn't have all key elements                                                                                                 |
| All key elements in the register/log book recorded correctly  | 208 (60.1%)    | 109 (31.5%)        | 29 (8.4%)     | Usually client names and HIV test results only completed; Mostly QC elements (lot number, expiry date) not captured correctly |
| Total summary at the end of each register compiled accurately | 223 (64.5%)    | 54 (15.6%)         | 69 (19.9%)    | No summary; or there is summary but inconsistent; Summary incomplete                                                          |
| Invalid test results recorded in the register/logbook         | 144 (41.6%)    | 9 (2.6%)           | 193 (55.8%)   | Not recorded; Never had invalid result; Record on comment space; Document in a separate QC book                               |
| Invalid tests repeated and recorded                           | 163 (47.1%)    | 13 (3.8%)          | 170 (49.1%)   | Don't know what to do; Repeat test but not record; Report to supervisor; Never had invalid result                             |
| Registers /logbooks properly labelled and archived when full  | 196 (56.7%)    | 66 (19.1%)         | 84 (24.3%)    | No archives                                                                                                                   |

### 3.3.4.7. External quality audit (EQA) (PT, supervision and retesting)

The overall median score for EQA was 1 (0.0-4.0) out of 8. Majority of facilities (62.7%) were not enrolled in EQA/PT program, and (32.1%) did report that the test the EQA and PT samples. More than three quarters (86.1%) of the testing points did not implement corrective action in case of unsatisfactory result (Table 3.33).

*Table 3.33: External Quality Audit (EQA): performance by assessment questions and most common challenges documented during assessment*

| Assessment                                                                  | Yes Number (%) | Partial Number (%) | No Number (%) | Most common challenges                                                   |
|-----------------------------------------------------------------------------|----------------|--------------------|---------------|--------------------------------------------------------------------------|
| Testing point enrolled in EQA/ PT program                                   | 125 (36.1%)    | 4 (1.2%)           | 217 (62.7%)   | Not enrolled                                                             |
|                                                                             | 111 (32.1%)    | 8 (2.3%)           | 227 (65.6%)   | Not done;                                                                |
| Person in charge review the PT results before submission                    | 99 (28.6%)     | 5 (1.5%)           | 242 (69.9%)   | No documentation;<br>No training; Don't have results yet                 |
| EQA/PT report received from NRL                                             | 80 (23.1%)     | 4 (1.2%)           | 262 (75.7%)   | No report yet                                                            |
| Testing point implement corrective action in case of unsatisfactory results | 43 (12.4%)     | 5 (1.5%)           | 298 (86.1%)   | No corrective action; Never had unsatisfactory result; No documentation; |
| Testing point receive periodic supervisory visits                           | 135 (39.0%)    | 3 (0.9%)           | 208 (60.1%)   | No documentation;<br>No supervisory visits                               |
| Feedback provided and documented during supervisory visits                  | 92 (26.6%)     | 4 (1.2%)           | 250 (72.3%)   | They give feedback verbally no documentation                             |
| Testers (if needed) retrained during supervisory visits                     | 67 (19.4%)     | 1 (0.3%)           | 278 (80.4%)   | No visit; no retraining; Visited but given feedback; not retrained;      |

## 4. DISCUSSION

The use of RDTs to accurately diagnose HIV in pregnant women and routine data quality is critical as South Africa has adopted the 'test and treat' approach to achieve the first 90 of the UNAIDS 90-90-90 Fast-track targets.

### ACTIVITY 1 A

Our study found major gaps in the site processes for PMTCT implementation for first ANC visits. The prevalence of stock-outs of HIV screening and confirmatory assays was around 20.0% and 0.5% respectively. Our study found that overall around 19% of facilities reported to have experienced HIV test kits stock-outs in the past 12 months. These findings are concerning given adoption of UNAIDS 90-90-90 Fast-track Targets by South Africa.

We found no uniformity in how facilities implement ART guidelines across facilities. About half of facilities reported they offer a HIV re-test to known pregnant women living with HIV. Discussions with health facility staff suggested that this was done in instances where the HIV positive status could not be verified. Although this practice is in line with the WHO recommendation: "...retesting to verify an HIV-positive diagnosis before enrolling in care and/or starting antiretroviral therapy (ART)... to assure accurate diagnosis" [30, 31], where and how this get recorded in registers can affect data quality. However, "retesting people on ART is not recommended, as there are potential risks of incorrect diagnosis, particularly for in vitro diagnostics (IVDs) that use oral fluid specimens"[30]. We also found that less than 58.0% of Known clients living with HIV already on ART have VL testing done at 1st ANC visit.

The WHO guideline recommends that 'high quality' refers to a data element for which 90% of site records are complete and valid (WHO 2013). Despite an attempt made by the SA NDOH to rationalize PHC registers by introducing one standard PHC Comprehensive Tick Register in 2015, facilities continue to use multiple non-standard registers to capture ANC client data. We found that in one facility, up to five registers were used to capture the same data element. Although 84.8% of records used PHC tick registers to record HIV 1<sup>st</sup> test result, this data element was also recorded in three other non-standard facility-based registers. This could

have contributed to poor completeness and quality of records.

Our study found that overall, urban sites and ANSUR sites had better site-testing procedures and processes compared to rural and NON-ANSUR sites. We report a high prevalence of stock-outs of HIV test screening assays, off-site HIV testing and low VL monitoring for known clients living with HIV already on ART at 1<sup>st</sup> visit among rural sites compared to urban sites. NON-ANSUR sites reported low VL monitoring for known clients living with HIV already on ART at 1<sup>st</sup> visit compared to ANSUR sites. In contrast, we found a high prevalence of expired HIV test kits in urban and ANSUR sites. It is possible that clients moving between different facilities could have contributed to expired test kits in urban facilities, which is unlikely in rural areas because of fewer facilities. We also observed stark variations in site processes between different provinces with Western Cape performing better in most instances compared to other provinces.

Our results show a few encouraging findings:

- i) more than 95.0% of antenatal facilities conduct HIV testing on site (i.e. within the same building where ANC services are provided) and this provides an opportunity for accurate and timely documentation of HIV results and ART initiation for clients living with HIV.
- ii) Almost all (97.4%) facilities provide PICT and
- iii) a high proportion of facilities (84.7%) use the approved standardised PHC tick registers to document HIV 1<sup>st</sup> test results. The presence of stock-out and of expired HIV test kits makes a strong case for promoting self-testing and home testing and making these test kits commercially available and affordable, to avoid delays in HIV diagnosis.

### ACTIVITY 1B

Our findings from data reviewed from facility-based registers for 1<sup>st</sup> ANC visit clients show that facility-based registers are incomplete and many data elements for 1<sup>st</sup> visit clients are not accurately captured. Our findings of poor PMTCT data quality support previous findings of surveys conducted in South Africa [15, 16, 18] and elsewhere. (12, 29, 30). We found that although most of data were

abstracted from records in approved PHC Tick registers, more than 3835 records were abstracted from Integrated ANC/PMTCT longitudinal registers, no longer approved by the Department of Health. It is possible that data quality could be impacted negatively in facilities that used both tick and longitudinal registers

Overall, out of a total of 14778 records reviewed, most of data elements were incompletely recorded in both tick and longitudinal registers. We found that that 6802 out of 10943 records (66.1%) recorded 1<sup>st</sup> HIV test done in PHC Tick registers with urban and ANSUR sites performing better compared to rural and NON-ANSUR sites. HIV 1<sup>st</sup> test result was recorded in 59.4% of PHC Tick registers and this varied widely at provincial level from a low of 3.4% recording in one province to a high of 98.9% recording in another province Overall, seven of the nine provinces had recording coverage of less than 26% while the Free State and Western Cape had over 80% and over 95% coverage respectively. Since PHC Tick registers are designed to record only HIV Positive results, it is likely that missing data is over-estimated since it also includes HIV negative results. The older longitudinal registers captured both HIV negative and HIV positive statuses.

The design of the currently preferred Tick register, allowing only the HIV-positive status to be recorded, challenges the use of routine data for estimating ANC HIV prevalence. This is because, it is likely to introduce a bias of better recording of HIV-positive clients ANC activities data in general and less focus on recording of HIV-negative clients' ANC activities. The HIV-positivity results calculated from the collected data between the two types of registers mirrors this potential challenge. That is, the ANC HIV-positivity estimate seen here from the longitudinal registers is 31.8% which is within the national antenatal HIV prevalence recorded between 2010 and 2014 in South Africa [5]. On the other hand, the HIV-positivity estimate from the tick register is a very high 52.4% and is likely to reflect several potential sources of bias. The first is already mentioned that the requirement to only record an HIV-positive results could introduce favourable recording of ANC client data by HIV status. The second follows the effect of the first, in that the data collectors might have been drawn towards selecting those records which appeared more complete when 'randomly' selecting the required number of records per facility. The third is that the denominator was unclear, and under-estimated, and lastly that there could have been double counting of individuals who are documented as being HIV positive. Thus, these potential biases will need to be considered carefully when

routine data is used for calculating ANC HIV prevalence for any geographic population in South Africa.

Although recording of TB screening status was higher than 70% in the longitudinal register, it was somewhat disappointing in the currently preferred tick registers, with only three provinces with a recording coverage above 50%. Even though one province recorded as low as only <2%, the feasibility of excellent recording of this indicator is undeniable, as seen by a recording coverage of >95% in Western Cape. One possible way forward would be for provinces to learn from one another, share and adopt practices which improve healthcare information systems and performance.

We also found that syphilis screening was poorly recorded in PHC tick registers. Given that adverse pregnancy outcomes such as abortions, stillbirths, congenital syphilis and prematurity are strongly associated with women with syphilis,[34] WHO guidance on global processes and criteria for validation of EMTCT and syphilis recommend that more than 95% of pregnant women should be screened for syphilis and 95% of those with syphilis should receive treatment.[35] Interventions are therefore needed to re-emphasize the necessity of recording of this outcome, considering that the country's performance against the WHO recommendation cannot be assessed with the current recording status.

The poor recording of CD4 count results is expected due to the prioritization of viral load as the main indicator for monitoring HIV health.

The following could be attributed to poor data quality in facility-based records:

- Decision not to use PHC Tick registers for recording data elements which have already been captured by lay counsellors in the HCT registers, to avoid double counting when monthly statistics are compiled such as HIV 1<sup>st</sup> test done and results, STI and TB screening),
- Non-standard use of registers by different provinces and facilities; some facilities added columns in PHC tick registers such as age which they felt were important,
- Tick register stock-outs, resulting in loose photocopies of tick sheets being used,
- Issuing IPT is delayed and not always issued at ART initiation for eligible clients to prevent side effects. (Discussions with facility managers during field worker supervisory support visits).



Good coverage of data recording was also observed for some ANC healthcare indicators: coverage of gestational age at first ANC visit recording was more than 85%, antiretroviral uptake recording was above 70%. Although this study did not aim to gather the actual timing of the first ANC visit and the actual ART regimen uptake, the good recording system of these indicators is likely make it possible to report national and sub-regional estimates around these healthcare factors.

## ACTIVITY 2

Overall, the study demonstrated inadequate implementation of rapid HIV testing QA practices in facilities providing ANC. The percentage median overall score for HIV rapid testing QA was low with the majority of the facilities at either level 1 (37% of facilities) or level 2 (46% of facilities), and particularly low for specific sub-scores such as training and certification (35.0%) and EQA (12.5%). It is important for testers to follow the testing process (i.e. pre-analytic, analytic and post analytic phases. Testers may not be certified, but if competency to conduct a test is assessed and verified, coupled with on-going supervision, this may be sufficient (HTS policy). More than two-thirds of facilities were not enrolled in EQA/PT program. In 56% of facilities, testers did not receive training on HIV rapid testing; and training on use of registers/logbooks was received only by 60% of facilities.

In assessment of the completion of HIV registers/logbooks, substantial number of facilities partially completed (32%) or did not complete (8%) key elements in the record/logbook. The assessment result indicated usually client name and HIV tests result fields were complete. However, the total summary captured for each page was partially accurate or not accurate in 34% of facilities. Hence, although the completeness rate /documentation of HIV test results are high, inaccurate tallying of records could result in inaccurate estimation of HIV prevalence.

In terms of quality of rapid testing, a substantial number of facilities (33%) did not follow or partially followed correct testing procedures. Many facilities were reading the result before waiting for the stipulated time or they used inaccurate number of drops. The use of IQC specimens (routine negative and positive specimen prior to routine testing) would contribute to monitoring of accuracy of testing.

Facilities in PEPFAR-supported districts performed better which may be reflective of the effect of the additional

support provided by PEPFAR to promote QA practices in these districts.

Compared to previous assessments done targeting VCT service points, this assessment shows that antenatal service points are at slightly lower (implementation) levels of HIV testing compared to previous work conducted in VCT service points. An assessment conducted in 2015/16 in 694 VCT service points nationally, demonstrated that 64.7% of facilities were on level 2 and above compared to 56% of facilities that are in level 2 and above in this assessment. [36]

## STUDY STRENGTHS:

We used three different tools in this study to assess if routine ANC/PMTCT data on HIV testing can currently be used to monitor antenatal HIV prevalence in South Africa. We assessed PMTCT site processes, data quality, and HIV Rapid Testing QA. Field workers also used registers to validate information collected during the interview. The NICD team who are experts on RTQII and support the Department of Health were involved through all stages of the survey.

## STUDY LIMITATIONS:

### Activity 1A

Qualitative data on the entire ANC/PMTCT site processes, patient and information flow was not documented. This could have highlighted aspects which quantitative data collection may have missed.

### Activity 1B:

Our analysis on data abstraction included both the nationally approved PHC tick register and the Integrated ANC/PMTCT/longitudinal register, no longer approved by the DOH. Our record review was retrospective and the latter was included in order to accommodate facilities that may have not started to use the PHC Tick. It is possible that our findings underestimate the quality of data; data completeness may have improved with the revised versions of the PHC tick registers and the number of facilities using these may have increased over time. The actual prevalence of ANC HIV could not be estimated accurately because the study sample size was not planned to provide a valid denominator which could accurately represent an external population.

### Activity 2:

The testing process was simulated and thus nuances of observing actual testing may have been missed.

# 5. CONCLUSION AND RECOMMENDATIONS

## CONCLUSIONS:

- There are significant gaps in the quality of a) HIV testing services offered to pregnant women attending antenatal clinics, and b) documentation of these HIV testing services
- Gaps were also seen in documentation of PMTCT services provided to positive pregnant women, specifically CD4 testing, but this could be attributed to preferential use of viral load for HIV health monitoring.
- Although systems exist for recording antenatal and PMTCT-related information, these are not standardised across facilities.
- Gestational age at first ANC visit and ART uptake are well-recorded and thus routine data could possibly be used to report national estimates on these
- Estimating ANC HIV prevalence using the Tick register should be done with caution due to biased recording of information by HIV status, other sources could be required to accurately estimate the denominator
- Facility-level data are mostly incomplete and of poor quality.
- Many gaps exist with regards to QA of antenatal HIV testing.

## RECOMMENDATIONS:

- Resources should be directed towards improving the quality of HIV testing services offered to pregnant women at antenatal clinics, in order to ensure that all ANC attendees know their true HIV status and that HIV-positive pregnant women receive appropriate ART to prevent MTCT.
- Monitoring routine HIV testing data at antenatal clinics need to be strengthened with feedback to facilities to

monitor a) the quality of HIV testing services offered to pregnant women; and b) antenatal HIV prevalence.

- Documentation of PMTCT services for HIV-positive women requires improvement, specifically documentation of CD4 results, to ensure all HIV-positive pregnant women receive appropriate interventions to optimise their health and prevent MTCT.
- Registers need to be standardised across all provinces.
- National efforts should prioritise investing in data-driven quality improvement interventions and scale-up electronic data collection systems (tier.net) to properly monitor the 90-90-90 treatment targets.
- Efforts to improve HIV testing procedures and data quality should be intensified. This includes proper documentation of training and refresher trainings, providing adequate resources and consistent monitoring and follow-up (supervision) activities need to be strengthened. In this regard, the rollout of the national PT program needs to be strengthened and given higher priority.
- Quality management implementation of HIV rapid testing including training, assessing competency of testers, enrolment in PT, supervision and monitoring activities should be prioritized in facilities assessed as having level 0 or 1 implementation; these facilities require immediate remedial action or improvement in specific areas.
- Best practices should be shared between provinces.
- Focused attention should be given to rural and NON-ANSUR sites.
- We recommend that this evaluation be repeated in future (after 3yrs) and should include the qualitative assessment of site processes to evaluate progress.

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# 7. ANNEXURES

## ANNEXURE A

The National DOH rationalized registers to minimize the number of registers used to capture data elements for different programmes in PHC facilities. One standard PHC Comprehensive Tick Register Sheet was introduced to capture key data elements for different programmes (including antenatal clients). However, during our survey, we found the following list of registers/ books being in different PHC facilities.

### Different records used to document data elements for first visit antenatal clients

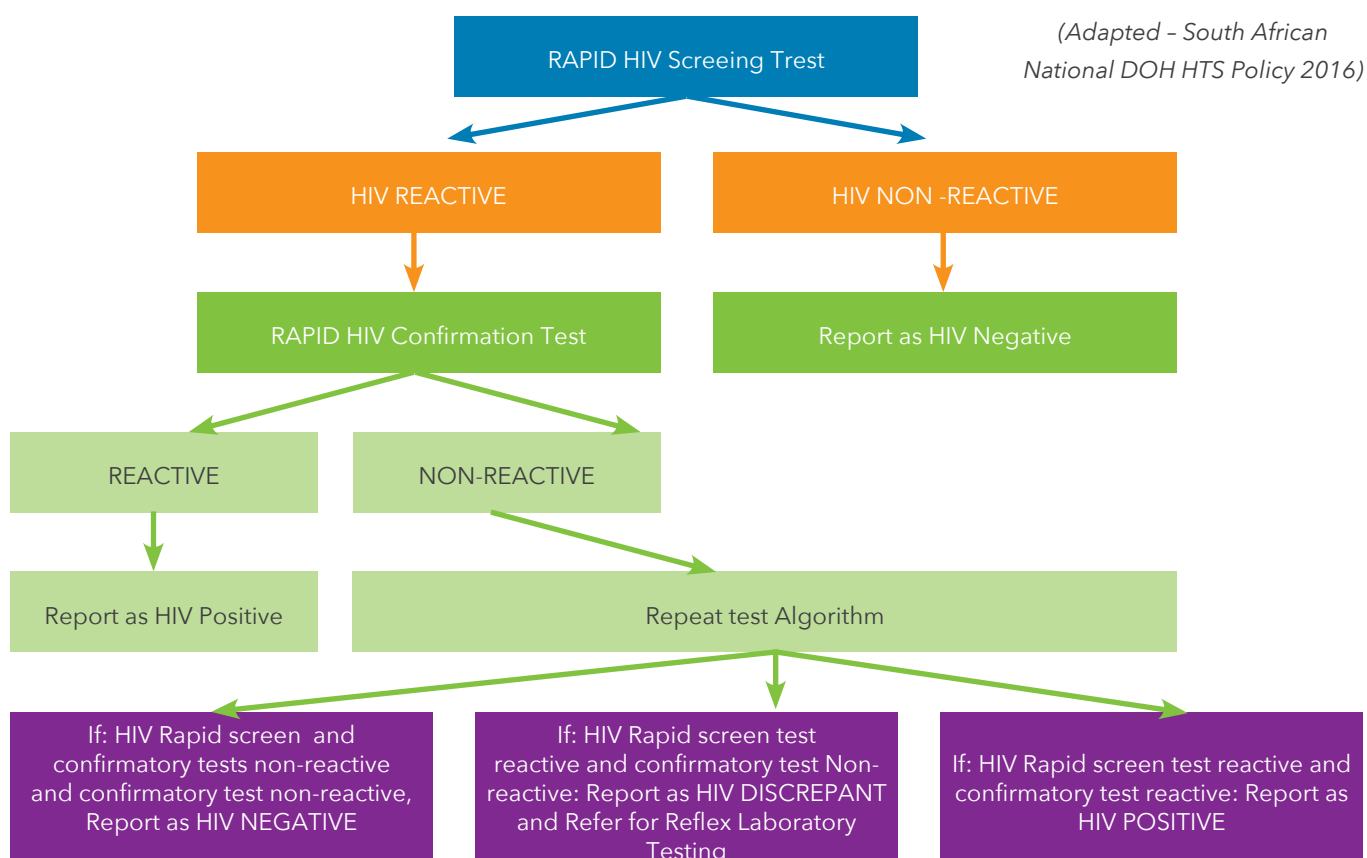
- i) Head count register-all clients visiting the PHC facilities are recorded.
- ii) One standard PHC Comprehensive Tick Register sheet for recording all clients attending different programmes

(including antenatal clients) in PHC facilities (in some instances due to stock-outs, photocopies of tick sheets were stapled together).

- iii) Weekly summary tally sheets - to summarize from Tick registers and to compile monthly PHC statistics for the DHIS. Prior to PHC tick registers, Integrated ANC / PMTCT cohort/longitudinal registers were used.
- iv) Standard HCT registers (sometimes referred to as (PMTCT/VCT Testing Registers) used for HIV testing services.
- v) Facilities or District Implementing partners design these as laboratory specimen books or for VL monitoring or use 2 quire notebooks to collect additional data elements).
- vi) Maternity-Case records - clinical records kept by clients during ANC but remain in facilities after delivery.
- i) Adult Female Patient Health Record- - these are retained by facilities and completed at subsequent ANC visits.

## ANNEXURE B

### National HIV testing algorithm



## ANNEXURE C



### Annexure C: PMTCT DATA QUALITY ASSESSMENT: SITE ASSESSMENT FORM

*INSTRUCTIONS: Please complete this form with one designated staff member, designated by the Facility manager, who provides PMTCT HIV testing services at the ANSUR site. Provide the following information to the interviewee:*

**"Today we would like to ask you some questions about this clinic, how PMTCT HIV testing services are delivered and data are recorded. We are not here to assess the clinics or your performance, but rather to learn about the process of collecting information in PMTCT programmes. This process will take approximately 40 minutes to complete."**

#### A. Site Information

*INSTRUCTIONS: This section collects basic information about the interview and the site.*

|                                                                                                                                                                                      |                                                                                                   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------|
| <b>1. Today's date</b>                                                                                                                                                               | __ / __ / ____ (dd / mm / y)                                                                      |
| <b>2. Interviewer's name</b>                                                                                                                                                         |                                                                                                   |
| <b>3. Interviewee's name and position</b>                                                                                                                                            |                                                                                                   |
| <b>4. Site name</b>                                                                                                                                                                  |                                                                                                   |
| <b>5. District</b>                                                                                                                                                                   |                                                                                                   |
| <b>6. Province/Region</b>                                                                                                                                                            |                                                                                                   |
| <b>7. Setting: Would you say this clinic setting is:</b><br><i>(as defined by the clinic manager)</i>                                                                                | <input type="checkbox"/> Urban <input type="checkbox"/> Rural <input type="checkbox"/> Peri-urban |
| <b>8. Average number of pregnant women enrolling in ANC services for a new pregnancy each month</b> <i>(check for the last three months from registers (not from staff reports))</i> | ___ pregnant women                                                                                |

#### B. PMTCT Programme Information

*INSTRUCTIONS: The second section collects information about PMTCT HIV testing and syphilis testing services provided at this site and off-site.*

|                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                            |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>9. What is the ANC HIV testing approach</b><br><i>(Read all and tick all that apply)</i>                                                                                                                                                                                                         | <input type="checkbox"/> Opt-out<br><input type="checkbox"/> Client-initiated counselling and testing (CICT)<br><input type="checkbox"/> Provider-initiated counselling and testing (PICT) |
| <b>10. Is ANC HIV testing done at this site</b><br><br><i>(Explain to the interviewee that "at this site" refers to the building or compound of buildings that contains ANC services. "Off-site" refers to locations outside the building or compound of buildings that contains ANC services).</i> | <input type="checkbox"/> At this site <b>if Yes, skip to Question 15</b><br><input type="checkbox"/> Off-site <input type="checkbox"/> If No, go to next question                          |

|                                                                                                                                    |                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>11. Where is off-site ANC HIV testing done?</b>                                                                                 | <input type="checkbox"/> Off-site laboratory<br><input type="checkbox"/> VCT site                                                                                                                                                                                          | <input type="checkbox"/> Care and treatment center<br><input type="checkbox"/> Other (specify) _____                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>12. If a pregnant woman is referred to an off-site location for ANC HIV testing, when does she do her off-site HIV testing?</b> | <input type="checkbox"/> Always the same day she is referred for testing<br><input type="checkbox"/> Sometimes the same day she is referred for testing<br><input type="checkbox"/> Rarely the same day she is referred for testing                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>13. How are off-site ANC HIV test results physically returned to this facility?</b>                                             | <input type="checkbox"/> Returned by the testing site (lab, VCT site, etc.)<br><input type="checkbox"/> Returned by the pregnant woman<br><input type="checkbox"/> Other (Specify) _____                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>14. When are off-site ANC HIV test results physically returned to this facility?</b>                                            | <input type="checkbox"/> Always the same day a pregnant woman is referred for testing<br><input type="checkbox"/> Sometimes the same day a pregnant woman is referred for testing<br><input type="checkbox"/> Rarely the same day a pregnant woman is referred for testing | Skip to <b>Question Section C</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>15. Please explain the ANC HIV testing algorithm for on-site rapid testing.</b><br><i>Write all that apply</i>                  | <b>15a.</b> Name of the Screening assay:<br><b>15b.</b> Name of the Confirmatory assay:<br><b>15c.</b> Name of the assay for indeterminate results:                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>16. In the last 12 months, was there ever a time when HIV test kits were unavailable due to stock outs?</b>                     | <input type="checkbox"/> No<br><input type="checkbox"/> Yes ⇨                                                                                                                                                                                                              | <b>16a.</b> If Yes, how many distinct instances of stock out were there in the last 12 months?<br><input type="checkbox"/> 1<br><input type="checkbox"/> 2<br><input type="checkbox"/> 3 or more                                                                                                                                                                                                                                                                                      |
| <b>16.1 In the last 12 months, was there ever a time when the screening assay was unavailable due to stock outs?</b>               | <input type="checkbox"/> No<br><input type="checkbox"/> Yes ⇨                                                                                                                                                                                                              | <b>16.1a</b> If Yes, how many distinct instances of screening assay not available in the last 12 months?<br><input type="checkbox"/> 1<br><input type="checkbox"/> 2<br><input type="checkbox"/> 3 or more<br><br><b>16.1b</b> What did you do?<br><input type="checkbox"/> Used <b>Confirmatory assay used</b><br><input type="checkbox"/> <b>Used ELISA assay</b><br><input type="checkbox"/> <b>Stopped HCT</b><br><input type="checkbox"/> <b>Other</b> .....<br>(Please explain) |
| <b>16.2 In the last 12 months, was there ever a time when confirmatory assay was unavailable due to stock outs?</b>                | <input type="checkbox"/> No<br><input type="checkbox"/> Yes ⇨                                                                                                                                                                                                              | <b>16.2a</b> If Yes, how many distinct instances of confirmatory assay not available in the last 12 months?<br><input type="checkbox"/> 1<br><input type="checkbox"/> 2<br><input type="checkbox"/> 3 or more<br><br><b>16.2b</b> What did you do?<br><input type="checkbox"/> <b>Used ELISA assay</b><br><input type="checkbox"/> <b>Stopped HCT</b><br><input type="checkbox"/> <b>Other</b> .....<br>(Please explain)                                                              |



|                                                                                                                                                                                                                  |                                                               |                                                                                                                                                                                                                |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p><b>16.3 In the last 12 months, was there ever a time when the supplies and transport systems to take blood to the laboratory for the ELISA assay was unavailable due to stock outs/ transport issues?</b></p> | <input type="checkbox"/> No<br><input type="checkbox"/> Yes ⇨ | <p><b>16.3a</b> If Yes, how many distinct instances were experienced in the last 12 months?</p> <input type="checkbox"/> 1<br><input type="checkbox"/> 2<br><input type="checkbox"/> 3 or more                 |
| <p><b>16.4 In the past 12 months, was there ever a time when the HIV test kits had expired?</b></p>                                                                                                              |                                                               | <p><b>16.3b</b> What did you do?</p> <input type="checkbox"/> <b>Stopped HCT</b><br><input type="checkbox"/> <b>Other</b> .....<br>(Please explain)                                                            |
| <p><b>16.4</b> In the past 12 months, was there ever a time when the HIV test kits had expired?</p>                                                                                                              | <input type="checkbox"/> No<br><input type="checkbox"/> Yes ⇨ | <p><b>16.4a</b> If Yes, how many distinct instances of the HIV test kits had expired in the last 12 months?</p> <input type="checkbox"/> 1<br><input type="checkbox"/> 2<br><input type="checkbox"/> 3 or more |
|                                                                                                                                                                                                                  |                                                               | <p><b>16.4b</b> What did you do?</p> <input type="checkbox"/> <b>Stopped HCT</b><br><input type="checkbox"/> <b>Other</b> .....<br>(Please explain)                                                            |

### C. Patient Data Recording in the Site Registers

**INSTRUCTIONS:** This section asks about site registers, what data elements are routinely recorded in each register and when HIV test results are routinely recorded. This section asks whether each data element is recorded in: a separate ANC register,

a separate PMTCT HIV testing register (for all women who attend ANC services, not only those who are HIV-positive), a combined ANC/PMTCT register (ANC and PMTCT HIV testing records both contained in one physical register), a laboratory register, (or other)

or if the data element is not recorded.

(These questions are only interested in site registers, not patient files or patient records retained by the pregnant woman.

**Please ask to see the registers to verify that all the data elements are recorded as described).**

**Please show me which registers are used for ANC clients in this facility? Tick which apply**

| Variable | A. Separate ANC register / any book designed<br><input type="checkbox"/> | B. Separate PMTCT HIV testing register/HCT (for all women who attend ANC services, not only HIV-positive women)<br><input type="checkbox"/> | C. Integrated ANC/PMTCT longitudinal register (ANC and PMTCT HIV testing records both contained in one register)<br><input type="checkbox"/> | D. Laboratory/specimen Register OR Specimen book used to record bloods taken<br><input type="checkbox"/> | E. PHC Comprehensive Tick register<br><input type="checkbox"/> | F. Other.<br><input type="checkbox"/> |
|----------|--------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------|----------------------------------------------------------------|---------------------------------------|
|----------|--------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------|----------------------------------------------------------------|---------------------------------------|

**In what site registers are the following data elements recorded (check all that apply)?**

|                                                                        |                          |                          |                          |                          |                          |                          |
|------------------------------------------------------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| 17. Age                                                                | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 18. Gravidity                                                          | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 19. Parity                                                             | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 20. Residence                                                          | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 21. Date of visit                                                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 22. Educational level                                                  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 23. Occupation                                                         | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 24. HIV test offered                                                   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 25. HIV test accepted                                                  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 26.1 1 <sup>st</sup> HIV test result                                   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 26.2 confirmatory HIV test results following the first positive result | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 27. Syphilis test result                                               | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Note: Ask only which applies to the registers used in the facility (Q29-31):

**28. On which ANC visit is a woman's PMTCT HIV test results recorded in the separate ANC register?**

- Always 1<sup>st</sup> visit       Usually 2<sup>nd</sup> or 3<sup>rd</sup> visit  
 Usually 1<sup>st</sup> visit       Not recorded in this register

**29. On which ANC visit is a woman's PMTCT HIV test results recorded in the separate PMTCT HIV testing/HCT register?**

- Always 1<sup>st</sup> visit       Usually 2<sup>nd</sup> or 3<sup>rd</sup> visit  
 Usually 1<sup>st</sup> visit       Not recorded in this register

**30. On which ANC visit is a woman's PMTCT HIV test results recorded in the Integrated ANC/PMTCT longitudinal register?**

- Always 1<sup>st</sup> visit       Usually 2<sup>nd</sup> or 3<sup>rd</sup> visit  
 Usually 1<sup>st</sup> visit       Not recorded in this register

**31. On which ANC visit is a woman's PMTCT HIV test results recorded in the laboratory/specimen register?**

- Always 1<sup>st</sup> visit       Usually 2<sup>nd</sup> or 3<sup>rd</sup> visit  
 Usually 1<sup>st</sup> visit       Not recorded in this register

**Register Formats**

|                                                                                                                                                                   |                                                                                                                                     |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|
| <i>INSTRUCTIONS: This section asks about the format of site registers. Please ask to see the current registers to confirm the format of the registers in use.</i> |                                                                                                                                     |
| <b>32. Is the site using the current national standard ANC register?</b>                                                                                          | <input type="checkbox"/> No <input type="checkbox"/> Not applicable<br><input type="checkbox"/> Yes<br>If No specify/comment.....   |
| <b>33. Is the site using the current national standard PMTCT HIV testing register?</b>                                                                            | <input type="checkbox"/> No <input type="checkbox"/> Not applicable<br><input type="checkbox"/> Yes<br>If no, specify /comment..... |
| <b>34. Is the site using the current national standard combined ANC/PMTCT HIV testing register?</b>                                                               | <input type="checkbox"/> No <input type="checkbox"/> Not applicable<br><input type="checkbox"/> Yes<br>If no specify /comment.....  |
| <b>35. Is the site using the current national standard laboratory testing register?</b>                                                                           | <input type="checkbox"/> No <input type="checkbox"/> Not applicable<br><input type="checkbox"/> Yes<br>If no specify /comment.....  |
| <b>Is the site using the current national standard laboratory testing register?</b>                                                                               | <input type="checkbox"/> No <input type="checkbox"/> Not applicable<br><input type="checkbox"/> Yes<br>If no specify /comment.....  |

**E. Previously Known Positive Pregnant Women**

*INSTRUCTIONS: This section collects information about pregnant women who already know they are HIV-positive upon presenting at their first ANC visit, what kind of PMTCT HIV testing services they receive, and how their information is recorded.*

|                                                                                                                                                                                                   |                                                                                |                                                                                                                                                                                                                                                                                         |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>36. If a pregnant woman already knows she is HIV-positive upon presenting at her first ANC visit, is she still offered an HIV test for PMTCT?</b>                                              | <input type="checkbox"/> No ⇒<br><input type="checkbox"/> Yes                  | <b>36a.</b> If No, what is recorded in the pregnant woman's "HIV test result" field in the relevant register?<br><input type="checkbox"/> "Positive"<br><input type="checkbox"/> "Known positive"<br><input type="checkbox"/> Nothing recorded<br><input type="checkbox"/> Other _____  |
| <b>36.1 what is done if a pregnant woman already knows she is HIV-positive and already on ARVs upon presenting at her ANC visit?</b>                                                              | Please explain:<br><input type="checkbox"/> No<br><input type="checkbox"/> Yes |                                                                                                                                                                                                                                                                                         |
| <b>36b. is this information recorded in site registers to indicate what is done (if a pregnant woman already knows she is HIV-positive and already on ARVs upon presenting at her ANC visit?)</b> | <i>Please check</i>                                                            |                                                                                                                                                                                                                                                                                         |
| <b>36c. what information is recorded</b>                                                                                                                                                          |                                                                                |                                                                                                                                                                                                                                                                                         |
| <b>37. Is any information recorded in site registers to indicate that a pregnant woman already knows she is HIV-positive upon presenting at her first ANC visit?</b>                              | <input type="checkbox"/> No<br><input type="checkbox"/> Yes⇒                   | <b>37a.</b> If Yes, in which column in the relevant register is this information recorded?<br><input type="checkbox"/> HIV test accepted / HIV test done<br><input type="checkbox"/> HIV test result<br><input type="checkbox"/> Notes/comments<br><input type="checkbox"/> Other _____ |

## F. Women who opt-out of PMTCT HIV testing

**38. If a pregnant woman (who does NOT already know she is HIV-positive) opts out of PMTCT HIV testing, where is this opt-out recorded?**

- Opt-out recorded in a "HIV test acceptance" or "HIV test done" column
- Opt-out recorded in the "HIV test results" column
- Nothing recorded
- Other specify \_\_\_\_\_

Instructions: *The goal of this section is to understand in more depth the flow of a pregnant woman through the clinic and the collection of her data. This will be done by PHYSICALLY walking through the entire process while each step is explained and recorded below. You may use information collected in sections 1-4 to probe or clarify responses. You may also use this section to further describe non-standard practices not adequately captured before now. Each time the interviewee indicates that a piece of information (e.g. age) is recorded in a certain place (e.g. ANC register), ask to look and visually verify that the information is recorded there. Make sure that the walkthrough covers each step in PMTCT HIV testing and what information is collected (e.g., age, parity, etc.), where it is recorded (e.g., registers, etc.), when it is recorded, and how it is recorded.*

**39.** *Please walk me through the entire process by which a pregnant woman moves through the clinic during her first ANC visit, from the time she enters to her departure. At every step of the way, please describe in detail PMTCT HIV testing procedures, when patient information is collected, where it is recorded, and who is responsible for recording it.*

*Please record your findings in this space*

NOTE: QUESTIONS 40-43 ARE ADDITIONAL QUESTIONS:

*Instructions: The following additional questions should be asked **ONLY** if this information was not described (or not described in sufficient detail) in Question 42 above.*

**40. Is PMTCT HIV testing done at this site or off-site?**

(PROBE: If off-site, at what point of a pregnant woman's first visit does she go to the off-site location? When and how are HIV test results returned to the clinic to be recorded in the register?)

**41. Please describe the clinical flow and how information is recorded for pregnant women who already know that they are HIV-positive upon presenting at their first ANC visit.**

(PROBE: Is information indicating that a pregnant woman already knows she is positive recorded anywhere? Are these pregnant women still tested for HIV?)

**42. If a pregnant woman opts out of PMTCT HIV testing, what are the procedures?**

(PROBE: Is opt-out recorded? If yes, where is this recorded? Are reasons for opting out of HIV testing documented?)


**43. Where are PMTCT HIV test results recorded?**

(PROBE: Are HIV test results recorded in one or multiple data tools? Where is this information recorded for the first time?)

**44. Please document any additional notes about missing data**

INSTRUCTIONS: Thank the interviewee for his or her time and assistance.

# Annexure D

| ANNEXURE D(i)                                                                     |  | Data Collector name _____                                                          |   |   |                 |   |   |                         |   |   |                       |                                                 |    |    |    |    |    |    |    |    |    |  |  |  |
|-----------------------------------------------------------------------------------|--|------------------------------------------------------------------------------------|---|---|-----------------|---|---|-------------------------|---|---|-----------------------|-------------------------------------------------|----|----|----|----|----|----|----|----|----|--|--|--|
|  |  | Province: _____                                                                    |   |   | District: _____ |   |   | Name of facility: _____ |   |   | Data collector: _____ |                                                 |    |    |    |    |    |    |    |    |    |  |  |  |
|                                                                                   |  | Register type/s used to abstract data: _____ specify: i)..... ii) ..... iii) ..... |   |   |                 |   |   |                         |   |   |                       | Number of registers used to abstract data:...   |    |    |    |    |    |    |    |    |    |  |  |  |
|                                                                                   |  | Month of abstraction: _____                                                        |   |   |                 |   |   |                         |   |   |                       | Total number of 1st ANC visit this month: _____ |    |    |    |    |    |    |    |    |    |  |  |  |
| Record Number                                                                     |  | 1                                                                                  | 2 | 3 | 4               | 5 | 6 | 7                       | 8 | 9 | 10                    | 11                                              | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 |  |  |  |
| PREGNANT                                                                          |  |                                                                                    |   |   |                 |   |   |                         |   |   |                       |                                                 |    |    |    |    |    |    |    |    |    |  |  |  |
| Participant ID/MRC Code                                                           |  |                                                                                    |   |   |                 |   |   |                         |   |   |                       |                                                 |    |    |    |    |    |    |    |    |    |  |  |  |
| Register page Register Row                                                        |  |                                                                                    |   |   |                 |   |   |                         |   |   |                       |                                                 |    |    |    |    |    |    |    |    |    |  |  |  |
| Date of client visit                                                              |  |                                                                                    |   |   |                 |   |   |                         |   |   |                       |                                                 |    |    |    |    |    |    |    |    |    |  |  |  |
| 1st ANC visit (Enter Gestational Age)                                             |  | ≤ 13 weeks                                                                         |   |   |                 |   |   |                         |   |   |                       |                                                 |    |    |    |    |    |    |    |    |    |  |  |  |
|                                                                                   |  | 14-19 weeks                                                                        |   |   |                 |   |   |                         |   |   |                       |                                                 |    |    |    |    |    |    |    |    |    |  |  |  |
|                                                                                   |  | ≥20 weeks                                                                          |   |   |                 |   |   |                         |   |   |                       |                                                 |    |    |    |    |    |    |    |    |    |  |  |  |
| LNMP (dd/mm/yy)                                                                   |  |                                                                                    |   |   |                 |   |   |                         |   |   |                       |                                                 |    |    |    |    |    |    |    |    |    |  |  |  |
| EDD (dd/mm/yy)                                                                    |  |                                                                                    |   |   |                 |   |   |                         |   |   |                       |                                                 |    |    |    |    |    |    |    |    |    |  |  |  |
| Gravidity                                                                         |  |                                                                                    |   |   |                 |   |   |                         |   |   |                       |                                                 |    |    |    |    |    |    |    |    |    |  |  |  |
| Parity                                                                            |  |                                                                                    |   |   |                 |   |   |                         |   |   |                       |                                                 |    |    |    |    |    |    |    |    |    |  |  |  |
| RPR                                                                               |  | Result(Neg/Pos)                                                                    |   |   |                 |   |   |                         |   |   |                       |                                                 |    |    |    |    |    |    |    |    |    |  |  |  |
|                                                                                   |  | Date of B.Pen (Dose1)                                                              |   |   |                 |   |   |                         |   |   |                       |                                                 |    |    |    |    |    |    |    |    |    |  |  |  |
|                                                                                   |  | Date of B.Pen (Dose2)                                                              |   |   |                 |   |   |                         |   |   |                       |                                                 |    |    |    |    |    |    |    |    |    |  |  |  |
| Hb                                                                                |  | Date of B.Pen (Dose1)                                                              |   |   |                 |   |   |                         |   |   |                       |                                                 |    |    |    |    |    |    |    |    |    |  |  |  |
|                                                                                   |  |                                                                                    |   |   |                 |   |   |                         |   |   |                       |                                                 |    |    |    |    |    |    |    |    |    |  |  |  |
| Known HIV pos at 1st ANC (Y/N)                                                    |  |                                                                                    |   |   |                 |   |   |                         |   |   |                       |                                                 |    |    |    |    |    |    |    |    |    |  |  |  |
| On life-long ART                                                                  |  |                                                                                    |   |   |                 |   |   |                         |   |   |                       |                                                 |    |    |    |    |    |    |    |    |    |  |  |  |
| e counselled and tested                                                           |  | Pre                                                                                |   |   |                 |   |   |                         |   |   |                       |                                                 |    |    |    |    |    |    |    |    |    |  |  |  |
|                                                                                   |  | Post                                                                               |   |   |                 |   |   |                         |   |   |                       |                                                 |    |    |    |    |    |    |    |    |    |  |  |  |
|                                                                                   |  | Positive                                                                           |   |   |                 |   |   |                         |   |   |                       |                                                 |    |    |    |    |    |    |    |    |    |  |  |  |
| V test result (Tick on)                                                           |  | Negative                                                                           |   |   |                 |   |   |                         |   |   |                       |                                                 |    |    |    |    |    |    |    |    |    |  |  |  |
|                                                                                   |  | Declined                                                                           |   |   |                 |   |   |                         |   |   |                       |                                                 |    |    |    |    |    |    |    |    |    |  |  |  |
|                                                                                   |  |                                                                                    |   |   |                 |   |   |                         |   |   |                       |                                                 |    |    |    |    |    |    |    |    |    |  |  |  |
| HIV-positive patients's assessment                                                |  | WHO stage (i)                                                                      |   |   |                 |   |   |                         |   |   |                       |                                                 |    |    |    |    |    |    |    |    |    |  |  |  |
|                                                                                   |  | Date CTX                                                                           |   |   |                 |   |   |                         |   |   |                       |                                                 |    |    |    |    |    |    |    |    |    |  |  |  |
|                                                                                   |  | CD4 count                                                                          |   |   |                 |   |   |                         |   |   |                       |                                                 |    |    |    |    |    |    |    |    |    |  |  |  |
| Life-long ART                                                                     |  | Date CD4 result given to patient                                                   |   |   |                 |   |   |                         |   |   |                       |                                                 |    |    |    |    |    |    |    |    |    |  |  |  |
|                                                                                   |  | Date referred                                                                      |   |   |                 |   |   |                         |   |   |                       |                                                 |    |    |    |    |    |    |    |    |    |  |  |  |
| TB screening and treatment                                                        |  | Date Initiated                                                                     |   |   |                 |   |   |                         |   |   |                       |                                                 |    |    |    |    |    |    |    |    |    |  |  |  |
|                                                                                   |  | Regime                                                                             |   |   |                 |   |   |                         |   |   |                       |                                                 |    |    |    |    |    |    |    |    |    |  |  |  |
|                                                                                   |  | TB symptoms screened(Y/N)                                                          |   |   |                 |   |   |                         |   |   |                       |                                                 |    |    |    |    |    |    |    |    |    |  |  |  |
|                                                                                   |  | B symptoms (Y/N)                                                                   |   |   |                 |   |   |                         |   |   |                       |                                                 |    |    |    |    |    |    |    |    |    |  |  |  |
|                                                                                   |  | TB                                                                                 |   |   |                 |   |   |                         |   |   |                       |                                                 |    |    |    |    |    |    |    |    |    |  |  |  |
|                                                                                   |  | TB Diagnosis                                                                       |   |   |                 |   |   |                         |   |   |                       |                                                 |    |    |    |    |    |    |    |    |    |  |  |  |
|                                                                                   |  | TB treatment                                                                       |   |   |                 |   |   |                         |   |   |                       |                                                 |    |    |    |    |    |    |    |    |    |  |  |  |
|                                                                                   |  | Date IPT                                                                           |   |   |                 |   |   |                         |   |   |                       |                                                 |    |    |    |    |    |    |    |    |    |  |  |  |



## Annexure E

### Annexure E: PMTCT HIV RAPID TESTING QUALITY ASSURANCE ASSESSMENT CHECKLIST

(Checklist for Stepwise Process for improving the quality of rapid testing Version 3.0)

#### SPI-RT Checklist

#### PART A: CHARACTERISTICS OF THE FACILITY OR TESTING POINT AUDITED

Before completing the checklist, it is important to characterize the testing point to be audited. Please provide relevant information in the summary table below.

|                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                 |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Date of Audit</b> (dd/mm/yyyy):                                                                                                                                                                                                                                                                                                                                                              | <b>MRC ANC EVALUATION</b>                                                                                                                                                                                                                                                                       |
| <b>Testing Facility Name:</b>                                                                                                                                                                                                                                                                                                                                                                   | <b>Testing Facility ID</b> (if applicable)                                                                                                                                                                                                                                                      |
| <b>Location/Address:</b>                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                 |
| <b>Level</b> (Circle One and specify name)<br><input type="checkbox"/> <b>Region/Province/Zone:</b><br><input type="checkbox"/> <b>District:</b><br><input type="checkbox"/> <b>Referral center:</b><br><input type="checkbox"/> <b>Health center:</b><br><input type="checkbox"/> <b>Dispensary:</b><br><input type="checkbox"/> <b>Health Post:</b><br><input type="checkbox"/> <b>Other:</b> | <b>Affiliation</b> (Circle One)<br><input type="checkbox"/> <b>Government</b><br><input type="checkbox"/> <b>Private</b><br><input type="checkbox"/> <b>Faith-based Organization</b><br><input type="checkbox"/> <b>Non-governmental organization</b><br><input type="checkbox"/> <b>Other:</b> |
| <b>Number of Testers:</b>                                                                                                                                                                                                                                                                                                                                                                       | <b>Average tested per month:</b>                                                                                                                                                                                                                                                                |
| <b>Name of the Auditor 1:</b>                                                                                                                                                                                                                                                                                                                                                                   | <b>Name of the Auditor 2:</b>                                                                                                                                                                                                                                                                   |

#### PART B. SPI- RT Checklist

For each of the sections listed below, please check **Yes, Partial or No**, where applicable. Indicate **"Yes"** only when all elements are satisfactorily present. Provide comments for each **"Partial"** or **"No"** response. State N/A in the comments section if "not applicable" where appropriate (\*).

|          | SECTION                                                                                                                                                                                                                                                                                                                              | YES | PARTIAL | NO | COMMENTS | SCORE     |
|----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----|---------|----|----------|-----------|
| <b>1</b> | <b>PERSONNEL TRAINING AND CERTIFICATION</b>                                                                                                                                                                                                                                                                                          |     |         |    |          | <b>10</b> |
| 1.1      | Have all testers received a comprehensive training on HIV rapid testing using the nationally approved curriculum?<br><br><i>*Note- Nationally Approved- NIMAART and PHC do not qualify. RTQII (left disk with Cherie). Need to determine if the testers have been trained appropriately in rapid testing. QA- quality assurance.</i> |     |         |    |          |           |
| 1.2      | Are the testers trained on the use of standardized HIV testing registers/logbooks?<br><br><i>*Note- Difficult to count RN's as testers. If they haven't received training it will be a no.</i>                                                                                                                                       |     |         |    |          |           |



|     | SECTION                                                                                                                                                                                                                                                                                                                                                                                                | YES | PARTIAL | NO | COMMENTS | SCORE |
|-----|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----|---------|----|----------|-------|
| 1.3 | <p>Are the testers trained on external quality assessment (EQA) or proficiency testing (PT) process?</p> <p><i>*Note- PT is done once a week. PT is external. Most people do not know about EQA.</i></p> <p><b>If two testers have done the tests- Yes</b><br/> <b>If neither tester have done the test- No</b><br/> <b>If one has done it and one has not- Partial (if 1 in a group of 4= ¼).</b></p> |     |         |    |          |       |
| 1.4 | <p>Are the testers trained on quality control (QC) process?</p> <p><i>*Note- Facilities may not understand QC but may understand QCTO this is linked back to 1.1.</i></p> <p><i>*Do they want the 2016 algorithm (new algorithm has challenges).</i></p>                                                                                                                                               |     |         |    |          |       |
| 1.5 | <p>Are the testers trained on safety and waste management procedures and practices?</p> <p><i>*Note- Challenges around waste management and safety- the documents may be on other areas. General practices should fall under this. Documentation is important- if it is not there it doesn't exist!</i></p>                                                                                            |     |         |    |          |       |
| 1.6 | <p>Have all testers received a refresher training within the last two years?</p> <p><i>*Note- Some people, after receiving their first training, they never do training again. There must always be recorded evidence of training, we do not take word of mouth.</i></p> <p><b>Without documentation no.</b></p>                                                                                       |     |         |    |          |       |
| 1.7 | <p>Are there records indicating all testers have demonstrated competency in HIV rapid testing prior to client testing?</p> <p><i>*Note- <b>Without documentation no.</b></i></p>                                                                                                                                                                                                                       |     |         |    |          |       |
| 1.8 | <p>Have all testers been certified through a national certification program?</p> <p><i>*Note- (No national certification program)- scratched out because we know <b>the answer is no. For no answers you need comments.</b></i></p>                                                                                                                                                                    |     |         |    |          |       |

|          | SECTION                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | YES | PARTIAL | NO | COMMENTS | SCORE    |
|----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----|---------|----|----------|----------|
| 1.9      | Are only certified testers allowed to perform HIV testing?<br><br><i>*Note- scratched out because we know the answer is no. For no answers you need comments.</i>                                                                                                                                                                                                                                                                                                                                                                                              |     |         |    |          |          |
| 1.10     | Are all testers required to be re-certified periodically (e.g., every two years)?<br><br><i>*Note- scratched out because we know the answer is no. For no answers you need comments.</i>                                                                                                                                                                                                                                                                                                                                                                       |     |         |    |          |          |
| <b>1</b> | <b>PERSONNEL TRAINING AND CERTIFICATION SCORE</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |     |         |    |          |          |
| <b>2</b> | <b>PHYSICAL FACILITY</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |     |         |    |          | <b>5</b> |
| 2.1      | Is there a designated area for HIV testing?<br><br><i>*Note- Referring to ANC. Yes, or no. Partial if the area is used for other things as well.</i>                                                                                                                                                                                                                                                                                                                                                                                                           |     |         |    |          |          |
| 2.2      | Is the testing area clean and organized for HIV rapid testing?<br><br><i>*Note- Organised-is everything need for the testing there, accessible and available. Clean- is everything sterile and disinfected not just things thrown away.</i>                                                                                                                                                                                                                                                                                                                    |     |         |    |          |          |
| 2.3      | Is sufficient lighting available in the designated testing area?<br><br><i>*Note- Observe and record, do not ask this question.</i>                                                                                                                                                                                                                                                                                                                                                                                                                            |     |         |    |          |          |
| 2.4      | Are the test kits kept in a temperature controlled environment based on the manufacturers' instructions?<br><br><i>*Note- Observe and record- do not ask this question. Is there a temperature gage? Are they kept out in the sun? There must be records for the temperature- look at a month or more to see if it is regulated (one or two days will not show you that). You need to understand the conditions the kits must be kept in. Environment conditions + temperature= Yes. Partial if only one is met-explain in comments. No if neither is met.</i> |     |         |    |          |          |

|          | SECTION                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | YES | PARTIAL | NO | COMMENTS | SCORE     |
|----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----|---------|----|----------|-----------|
| 2.5      | <p>Is there sufficient and secure storage space for test kits and other consumables?</p> <p><i>*Note- Secured, meaning not only the room being locked but also the cabinets- must be out of reach. Sufficient- It does not need to be over stocked, extra stock must be in storage and not in the testing room (basically for one or two days- shouldn't be more).</i></p> <p><b>Both conditions met= Yes</b><br/> <b>Some/one condition(s) met= Partial</b><br/> <b>Neither conditions met= No</b></p> |     |         |    |          |           |
| <b>2</b> | <b>PHYSICAL FACILITY SCORE</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |     |         |    |          |           |
| <b>3</b> | <b>SAFETY</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |     |         |    |          | <b>11</b> |
| 3.1      | <p>Are there SOPs and/or job aides in place to implement safety practices?</p> <p><i>*Note- Things often change when we are on site. This is a double question.</i></p> <p><b>Both conditions met= Yes</b><br/> <b>Some/one condition(s) met= Partial</b><br/> <b>Neither conditions met= No</b></p>                                                                                                                                                                                                    |     |         |    |          |           |
| 3.2      | <p>Are there SOPs and/or job aides in place on how to dispose of infectious and non-infectious waste?</p> <p><i>*Note- This is a double question.</i></p> <p><b>Both conditions met= Yes</b><br/> <b>Some/one condition(s) met= Partial</b><br/> <b>Neither conditions met= No</b></p>                                                                                                                                                                                                                  |     |         |    |          |           |
| 3.3      | <p>Are there SOPs and/or job aides in place to manage spills of blood and other body fluids?</p> <p><i>*Note- Generally in job aid and this must be in the testing room, as well as the SOPs.</i></p>                                                                                                                                                                                                                                                                                                   |     |         |    |          |           |
| 3.4      | <p>Are there SOPs and/or job aides in place to address accidental exposure to potentially infectious body fluids through a needle stick injury, splash or other sharps injury?</p> <p><i>*Note- Important to have SOPs specific to these three aspect. One qualifies as a partial.</i></p>                                                                                                                                                                                                              |     |         |    |          |           |

|      | SECTION                                                                                                                                                                                                                                                                                                                                                                  | YES | PARTIAL | NO | COMMENTS | SCORE |
|------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----|---------|----|----------|-------|
| 3.5  | <p>Is personal protective equipment (PPE) always available to testers?</p> <p><i>*Note- This is more of an observation than a question.</i></p> <p><b>If 3.5 is partial 3.6 and 3.7 should be partial too.</b></p>                                                                                                                                                       |     |         |    |          |       |
| 3.6  | <p>Is PPE consistently used by all testers?</p> <p><i>*Note- This is not always easy to see as you are only there once and people may be acting differently when you are observing things. They should not skip steps. The issue here is trying to look for consistency. <b>If they ask for consistency its either yes or no.</b></i></p>                                |     |         |    |          |       |
| 3.7  | <p>Is PPE properly used by all testers through the testing process?</p> <p><i>*Note- Properly is the operative term- using/ removing the equipment correctly. They do not use equipment when doing other things (infecting them). They have the correct size. Do not use soiled/torn/broken equipment.</i></p> <p><b>Always explain if you give a partial or no.</b></p> |     |         |    |          |       |
| 3.8  | <p>Is there clean water and soap available for hand washing?</p> <p><i>*Note- Check what type of soap it is - solid or liquid (solid is not recommended but we will not penalize for that). It must be accessible. NICD argues that without clean water it will be a partial.</i></p>                                                                                    |     |         |    |          |       |
| 3.9  | <p>Is there an appropriate disinfectant to clean the work area available?</p>                                                                                                                                                                                                                                                                                            |     |         |    |          |       |
| 3.10 | <p>Are sharps, infectious, and non-infectious waste handled properly?</p> <p><i>*Note- Wastes must be properly discarded.</i></p>                                                                                                                                                                                                                                        |     |         |    |          |       |

|          | SECTION                                                                                                                                                                                                                                                                                                                                                                                                                                                             | YES | PARTIAL | NO | COMMENTS | SCORE     |
|----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----|---------|----|----------|-----------|
| 3.11     | <p>Are infectious and non-infectious waste containers emptied regularly per the SOP and/or job aides?</p> <p><i>*Note- Two aspects- waste containers being emptied regularly [at least daily] and according to SOP regulations. This also depends on who is emptying the bin and do they know the SOP regulations (this is very hard to determine). <b>Ask how often do they get emptied and who does it and are they trained to empty waste correctly?</b></i></p> |     |         |    |          |           |
| <b>3</b> | <b>SAFETY SCORE</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                 |     |         |    |          |           |
| <b>4</b> | <b>PRE-TESTING PHASE</b>                                                                                                                                                                                                                                                                                                                                                                                                                                            |     |         |    |          | <b>12</b> |
| 4.1      | <p>Are there national testing guidelines specific to the program (e.g. HTS, PMTCT, TB, etc.) available at the testing point?</p> <p><i>*Note- Physically observe this. <b>This will either be yes no.</b></i></p>                                                                                                                                                                                                                                                   |     |         |    |          |           |
| 4.2      | <p>Is the national HIV testing algorithm being used?</p> <p><i>*Note- Check to see which year is being used but 2015 is fine for now. Observe the procedure.</i></p>                                                                                                                                                                                                                                                                                                |     |         |    |          |           |
| 4.3      | <p>Is there a process in place for an alternative HIV testing algorithm in case of expired or shortage of test kit(s)?</p> <p><i>*Note- Say yes if there isn't one in South Africa because we do not have the alternative in this country. <b>Don't ask the question just tick yes.</b></i></p>                                                                                                                                                                     |     |         |    |          |           |
| 4.4      | <p>Are there SOPs and/or job aides in place for each HIV rapid test used in the testing algorithm?</p> <p><i>*Note- Job aids must be displayed. If not there must be an SOP in the testing area.</i></p>                                                                                                                                                                                                                                                            |     |         |    |          |           |
| 4.5      | <p>Are only nationally approved HIV rapid kits available for use currently?</p> <p><i>*Note- This changes among the provinces. Nationally approved means screen with advanced, and confirm with Abon.</i></p>                                                                                                                                                                                                                                                       |     |         |    |          |           |

|          | SECTION                                                                                                                                                                                                                                                                            | YES | PARTIAL | NO | COMMENTS | SCORE    |
|----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----|---------|----|----------|----------|
| 4.6      | Are all the test kits currently in use within the expiration date?<br><br><i>*Note- Just check on the expiry dates. <b>Partial applies to two different batches open at the same time.</b></i>                                                                                     |     |         |    |          |          |
| 4.7      | Are test kits labelled with date received and initials?<br><br><i>*Note- <b>Mark as yes-</b> this is not achievable in a South African context.</i>                                                                                                                                |     |         |    |          |          |
| 4.8      | Is there a process in place for stock management?<br><br><i>*Note- Looking at bin cards in particular. No minimum or maximum stock established for stock- must be stock records as well.</i>                                                                                       |     |         |    |          |          |
| 4.9      | Are job aides on client sample collection available and posted at the testing point?<br><br><i>*Note- Possible that they are available but not posted.<br/><b>Both conditions met= Yes</b><br/><b>Some/one condition(s) met= Partial</b><br/><b>Neither conditions met= No</b></i> |     |         |    |          |          |
| 4.10     | Are there sufficient supplies available for client sample collection?<br><br><i>*Note- Need enough stock in the testing room for that day.</i>                                                                                                                                     |     |         |    |          |          |
| 4.11     | Are there national guidelines describing how client identification should be recorded in the HIV testing register?<br><br><i>*Note- The register is a guideline.</i>                                                                                                               |     |         |    |          |          |
| 4.12     | Are client identifiers recorded in the HIV testing register per national guidelines and on test devices?<br><br><i>*Note- They use names here. Check register, do not need to ask. <b>Specify if the device is not labelled.</b></i>                                               |     |         |    |          |          |
| <b>4</b> | <b>PRE-TESTING PHASE SCORE</b>                                                                                                                                                                                                                                                     |     |         |    |          |          |
| <b>5</b> | <b>TESTING PHASE</b>                                                                                                                                                                                                                                                               |     |         |    |          | <b>9</b> |

|          | SECTION                                                                                                                                                                                                                                                                | YES | PARTIAL | NO | COMMENTS | SCORE    |
|----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----|---------|----|----------|----------|
| 5.1      | Are SOPs and/or job aides on HIV testing procedures available and posted at the testing point?<br><br><i>*Note- Job aids- posted. SOPs- available. Tester must refer to the SOPs if the job aid is not available.</i>                                                  |     |         |    |          |          |
| 5.2      | Are timers available and used routinely for HIV rapid testing?<br><br><i>*Note- Two aspects, timers are available and are they routinely used. <b>Both conditions met= Yes</b><br/><b>Some/one condition(s) met= Partial</b><br/><b>Neither conditions met= No</b></i> |     |         |    |          |          |
| 5.3      | Are sample collection devices (e.g., capillary tube, loop, disposable pipettes, etc.) used accurately?<br><br><i>*Note- <b>Both conditions met= Yes</b><br/><b>Some/one condition(s) met= Partial</b><br/><b>Neither conditions met= No</b></i>                        |     |         |    |          |          |
| 5.4      | Are testing procedures adequately followed?<br><br><i>*Note- Physical and in simulation- ensure they stick to procedures. Observe the drops of blood and drops of buffer (enough and in the right areas/holes). Don't switch equipment accidentally.</i>               |     |         |    |          |          |
| 5.5      | Are positive and negative quality control (QC) specimens routinely used (e.g., daily or weekly) according to country guidelines?<br><br><i>*Note- South Africa context- it is done weekly and mostly on a Monday.</i>                                                  |     |         |    |          |          |
| 5.6      | Are QC results properly recorded?                                                                                                                                                                                                                                      |     |         |    |          |          |
| 5.7      | Are incorrect/invalid QC results properly recorded?                                                                                                                                                                                                                    |     |         |    |          |          |
| 5.8      | Are appropriate steps taken and documented when QC results are incorrect and/or invalid?                                                                                                                                                                               |     |         |    |          |          |
| 5.9      | Are QC records reviewed by the person in charge routinely?                                                                                                                                                                                                             |     |         |    |          |          |
| <b>5</b> | <b>TESTING PHASE SCORE</b>                                                                                                                                                                                                                                             |     |         |    |          |          |
| <b>6</b> | <b>POST TESTING PHASE - DOCUMENTS AND RECORDS</b>                                                                                                                                                                                                                      |     |         |    |          | <b>9</b> |



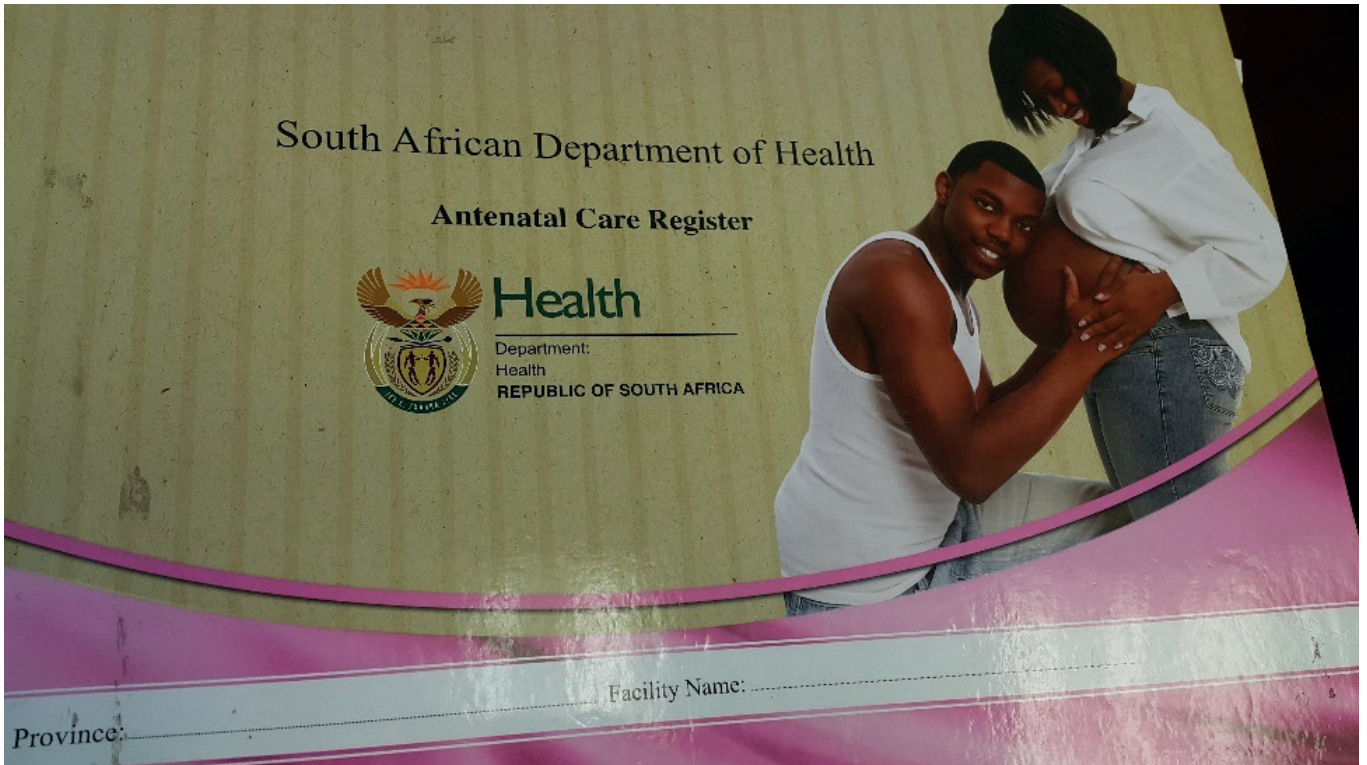
|          | SECTION                                                                                                                                                                                                                                                                                                             | YES | PARTIAL | NO | COMMENTS | SCORE |
|----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----|---------|----|----------|-------|
| 6.1      | Is there a national standardized HIV rapid testing register/logbook available and in use?<br><br><i>*Note- If yes, need to physically check and view it. Generally, the PMTCT register or the ANC register.</i>                                                                                                     |     |         |    |          |       |
| 6.2      | Does the HIV testing register/logbook include all of the key quality elements?<br><br><i>*Note- PMTCT and ANC register do.</i>                                                                                                                                                                                      |     |         |    |          |       |
| 6.3      | Are all the elements in the register/ logbook recorded/captured correctly? (e.g., client demographics, kit names, lot numbers, expiration dates, tester name, individual and final HIV results, etc.)?<br><br><i>*Note- No kit name and lot number - but check if they try make something similar or improvise.</i> |     |         |    |          |       |
| 6.4      | Is the total summary at the end of each page of the register/logbooks compiled accurately.                                                                                                                                                                                                                          |     |         |    |          |       |
| 6.5      | Are invalid test results recorded in the register/ logbook?<br><br><i>*Note- NICD recommends asking if they ever have negative results and if they ever record it?</i>                                                                                                                                              |     |         |    |          |       |
| 6.6      | Are invalid tests repeated and results properly recorded in the register/logbook?<br><br><i>*Note- some registers don't have space for recording repeated tests.</i>                                                                                                                                                |     |         |    |          |       |
| 6.7      | Are all client documents and records securely kept throughout all phases of the testing process?<br><br><i>*Note- Mainly through observation.</i>                                                                                                                                                                   |     |         |    |          |       |
| 6.8      | Are all registers/logbooks and other documents kept in a secure location when not in use?<br><br><i>*Note- Ask where they keep current and old registers.</i>                                                                                                                                                       |     |         |    |          |       |
| 6.9      | Are registers/logbooks properly labelled and archived when full?<br><br><i>*Note- Observe this.</i>                                                                                                                                                                                                                 |     |         |    |          |       |
| <b>6</b> | <b>POST TESTING PHASE - DOCUMENTS AND RECORDS SCORE</b>                                                                                                                                                                                                                                                             |     |         |    |          |       |

|          | SECTION                                                                                                                                                                                            | YES | PARTIAL | NO | COMMENTS | SCORE       |
|----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----|---------|----|----------|-------------|
| <b>7</b> | <b>EXTERNAL QUALITY AUDITY (PT, SUPERVISION AND RETESTING)</b>                                                                                                                                     |     |         |    |          | <b>8/14</b> |
| 7.1      | Is the testing point enrolled in an EQA/PT program?<br><br><i>*Note- <b>Yes or no.</b></i>                                                                                                         |     |         |    |          |             |
| 7.2      | Do all testers at the testing point test the EQA/PT samples?<br><br><i>*Note- Testing should at least be done twice a year. <b>If two or more people have done it then you can give a yes.</b></i> |     |         |    |          |             |
| 7.3      | Does the person in charge at the testing point review the /PT results before submission to NRL or designee?<br><br><i>*Note- <b>Yes or no.</b></i>                                                 |     |         |    |          |             |
| 7.4      | Is an EQA/PT report received from NRL and reviewed by testers and/or the person in charge at the testing point?                                                                                    |     |         |    |          |             |
| 7.5      | Does the testing point implement corrective action in case of unsatisfactory results?<br><br><i>*Note- If they say they do, check the documentation.</i>                                           |     |         |    |          |             |
| 7.6      | Does the testing point receive periodic supervisory visits?<br><br><i>*Note- External QC or audit.</i>                                                                                             |     |         |    |          |             |
| 7.7      | Is feedback provided during supervisory visit and documented?<br><br><i>*Note- Check the documents.</i>                                                                                            |     |         |    |          |             |
| 7.8      | If testers need to be retrained, are they being retrained during the supervisory visit?<br><br><i>*Note- Check the documents- you can get documents from the OM.</i>                               |     |         |    |          |             |





Annexure G- Combined ANC/PMTCT Register



**ANC REGISTER**

Year: \_\_\_\_\_ Month: \_\_\_\_\_ Facility: \_\_\_\_\_

| No.   | Date of Visit (dd/mm/yy) | ANC Clinic No. | AI entry                              |           |           |                | Client Demographics |           |                             |                           | Exam at 1st ANC Visit |                |             |     |                                  |                                     | ATT                     |  | HIV Status |  |
|-------|--------------------------|----------------|---------------------------------------|-----------|-----------|----------------|---------------------|-----------|-----------------------------|---------------------------|-----------------------|----------------|-------------|-----|----------------------------------|-------------------------------------|-------------------------|--|------------|--|
|       |                          |                | 1st ANC Visit (Enter Gestational Age) | 2nd Visit | 3rd Visit | Transfer (FOI) | Name and Surname    | ID Number | Address and Contact Details | Age (Enter Age) < 18 x 18 | LNMP (dd/mm/yy)       | EDD (dd/mm/yy) | Grav. Para. | RPR | Cervical Cancer (Screening Done) | Date Counsell'd & Test'd (dd/mm/yy) | HIV Test Results (Tick) |  |            |  |
| 1     |                          |                |                                       |           |           |                |                     |           |                             |                           |                       |                |             |     |                                  |                                     |                         |  |            |  |
| 2     |                          |                |                                       |           |           |                |                     |           |                             |                           |                       |                |             |     |                                  |                                     |                         |  |            |  |
| 3     |                          |                |                                       |           |           |                |                     |           |                             |                           |                       |                |             |     |                                  |                                     |                         |  |            |  |
| 4     |                          |                |                                       |           |           |                |                     |           |                             |                           |                       |                |             |     |                                  |                                     |                         |  |            |  |
| 5     |                          |                |                                       |           |           |                |                     |           |                             |                           |                       |                |             |     |                                  |                                     |                         |  |            |  |
| 6     |                          |                |                                       |           |           |                |                     |           |                             |                           |                       |                |             |     |                                  |                                     |                         |  |            |  |
| 7     |                          |                |                                       |           |           |                |                     |           |                             |                           |                       |                |             |     |                                  |                                     |                         |  |            |  |
| 8     |                          |                |                                       |           |           |                |                     |           |                             |                           |                       |                |             |     |                                  |                                     |                         |  |            |  |
| 9     |                          |                |                                       |           |           |                |                     |           |                             |                           |                       |                |             |     |                                  |                                     |                         |  |            |  |
| 10    |                          |                |                                       |           |           |                |                     |           |                             |                           |                       |                |             |     |                                  |                                     |                         |  |            |  |
| 11    |                          |                |                                       |           |           |                |                     |           |                             |                           |                       |                |             |     |                                  |                                     |                         |  |            |  |
| 12    |                          |                |                                       |           |           |                |                     |           |                             |                           |                       |                |             |     |                                  |                                     |                         |  |            |  |
| 13    |                          |                |                                       |           |           |                |                     |           |                             |                           |                       |                |             |     |                                  |                                     |                         |  |            |  |
| 14    |                          |                |                                       |           |           |                |                     |           |                             |                           |                       |                |             |     |                                  |                                     |                         |  |            |  |
| 15    |                          |                |                                       |           |           |                |                     |           |                             |                           |                       |                |             |     |                                  |                                     |                         |  |            |  |
| 16    |                          |                |                                       |           |           |                |                     |           |                             |                           |                       |                |             |     |                                  |                                     |                         |  |            |  |
| 17    |                          |                |                                       |           |           |                |                     |           |                             |                           |                       |                |             |     |                                  |                                     |                         |  |            |  |
| 18    |                          |                |                                       |           |           |                |                     |           |                             |                           |                       |                |             |     |                                  |                                     |                         |  |            |  |
| 19    |                          |                |                                       |           |           |                |                     |           |                             |                           |                       |                |             |     |                                  |                                     |                         |  |            |  |
| 20    |                          |                |                                       |           |           |                |                     |           |                             |                           |                       |                |             |     |                                  |                                     |                         |  |            |  |
| 21    |                          |                |                                       |           |           |                |                     |           |                             |                           |                       |                |             |     |                                  |                                     |                         |  |            |  |
| 22    |                          |                |                                       |           |           |                |                     |           |                             |                           |                       |                |             |     |                                  |                                     |                         |  |            |  |
| 23    |                          |                |                                       |           |           |                |                     |           |                             |                           |                       |                |             |     |                                  |                                     |                         |  |            |  |
| 24    |                          |                |                                       |           |           |                |                     |           |                             |                           |                       |                |             |     |                                  |                                     |                         |  |            |  |
| 25    |                          |                |                                       |           |           |                |                     |           |                             |                           |                       |                |             |     |                                  |                                     |                         |  |            |  |
| TOTAL |                          |                |                                       |           |           |                |                     |           |                             |                           |                       |                |             |     |                                  |                                     |                         |  |            |  |

Neg = \_\_\_\_\_ Pos = \_\_\_\_\_





## Annexure J

### A: List of Facilities sampled and minimum target sample

| Province     | District         | Facility             | ANSUR status | Locality | Stratum | Minimum target number of records |
|--------------|------------------|----------------------|--------------|----------|---------|----------------------------------|
| Eastern Cape | A Nzo DM         | Mt Hargreaves        | NON-ANSUR    | RURAL    | 3       | 4                                |
| Eastern Cape | A Nzo DM         | St Patrick's Gateway | ANSUR        | URBAN    | 2       | 15                               |
| Eastern Cape | Amathole DM      | Nkanya               | NON-ANSUR    | RURAL    | 3       | 4                                |
| Eastern Cape | Amathole DM      | Nqabara              | ANSUR        | RURAL    | 1       | 7                                |
| Eastern Cape | Amathole DM      | Stutterheim Clinic   | ANSUR        | URBAN    | 2       | 15                               |
| Eastern Cape | Buffalo City MM  | Breidbach            | ANSUR        | URBAN    | 2       | 15                               |
| Eastern Cape | Buffalo City MM  | EL Central           | ANSUR        | URBAN    | 2       | 15                               |
| Eastern Cape | Buffalo City MM  | Frere Hosp           | NON-ANSUR    | URBAN    | 4       | 7                                |
| Eastern Cape | Buffalo City MM  | Masakhane (Zwe)      | ANSUR        | URBAN    | 2       | 15                               |
| Eastern Cape | Buffalo City MM  | Philani NU 1         | ANSUR        | URBAN    | 2       | 15                               |
| Eastern Cape | Buffalo City MM  | Zanempilo (EL)       | NON-ANSUR    | URBAN    | 4       | 7                                |
| Eastern Cape | Buffalo City MM  | Zwelitsha Zone 5     | NON-ANSUR    | URBAN    | 4       | 7                                |
| Eastern Cape | C Hani DM        | Kuyasa CHC           | ANSUR        | RURAL    | 1       | 7                                |
| Eastern Cape | C Hani DM        | Sifonondile          | NON-ANSUR    | RURAL    | 3       | 4                                |
| Eastern Cape | C Hani DM        | Tembelihle           | ANSUR        | RURAL    | 1       | 7                                |
| Eastern Cape | Joe Gqabi DM     | Bluegums             | NON-ANSUR    | RURAL    | 3       | 4                                |
| Eastern Cape | Joe Gqabi DM     | Herschel             | ANSUR        | RURAL    | 1       | 7                                |
| Eastern Cape | Joe Gqabi DM     | Hlankomo             | NON-ANSUR    | RURAL    | 3       | 4                                |
| Eastern Cape | Joe Gqabi DM     | Jamestown Clinic     | NON-ANSUR    | URBAN    | 4       | 7                                |
| Eastern Cape | Joe Gqabi DM     | Maclear Clinic       | ANSUR        | URBAN    | 2       | 15                               |
| Eastern Cape | Joe Gqabi DM     | Mzamomhle            | NON-ANSUR    | RURAL    | 3       | 4                                |
| Eastern Cape | Joe Gqabi DM     | Ncembu               | NON-ANSUR    | RURAL    | 3       | 4                                |
| Eastern Cape | Joe Gqabi DM     | Pelandaba            | ANSUR        | RURAL    | 1       | 7                                |
| Eastern Cape | Joe Gqabi DM     | St Michael's         | NON-ANSUR    | RURAL    | 3       | 4                                |
| Eastern Cape | Joe Gqabi DM     | Umnga Flats          | ANSUR        | RURAL    | 1       | 7                                |
| Eastern Cape | N Mandela Bay MM | Algoa Park Clinic    | NON-ANSUR    | URBAN    | 4       | 7                                |
| Eastern Cape | N Mandela Bay MM | Nomangesi Jayiya     | NON-ANSUR    | URBAN    | 4       | 8                                |
| Eastern Cape | O Tambo DM       | Civic Centre         | ANSUR        | URBAN    | 2       | 15                               |
| Eastern Cape | O Tambo DM       | Cwele                | ANSUR        | RURAL    | 1       | 7                                |
| Eastern Cape | O Tambo DM       | Lutshaya             | NON-ANSUR    | RURAL    | 3       | 5                                |
| Eastern Cape | O Tambo DM       | Mahlungulu (KSD)     | NON-ANSUR    | URBAN    | 4       | 7                                |
| Eastern Cape | O Tambo DM       | Mhlakulo CHC         | ANSUR        | RURAL    | 1       | 7                                |
| Eastern Cape | O Tambo DM       | Mqanduli CHC         | ANSUR        | URBAN    | 2       | 15                               |

| Province     | District          | Facility                  | ANSUR status | Locality | Stratum | Minimum target number of records |
|--------------|-------------------|---------------------------|--------------|----------|---------|----------------------------------|
| Eastern Cape | O Tambo DM        | Mqhekezweni               | NON-ANSUR    | RURAL    | 3       | 4                                |
| Eastern Cape | O Tambo DM        | Mthatha Gateway           | ANSUR        | URBAN    | 2       | 16                               |
| Eastern Cape | Sarah Baartman DM | B Ngwentle                | NON-ANSUR    | URBAN    | 4       | 7                                |
| Eastern Cape | Sarah Baartman DM | Loerie Clinic             | NON-ANSUR    | RURAL    | 3       | 4                                |
| Eastern Cape | Sarah Baartman DM | Louterwater               | NON-ANSUR    | RURAL    | 3       | 4                                |
| Eastern Cape | Sarah Baartman DM | Masakhane (Aberdeen)      | ANSUR        | URBAN    | 2       | 15                               |
| Eastern Cape | Sarah Baartman DM | Nolukhanyo                | NON-ANSUR    | RURAL    | 3       | 4                                |
| Eastern Cape | Sarah Baartman DM | Settlers Day Hosp         | ANSUR        | URBAN    | 2       | 15                               |
| Eastern Cape | Sarah Baartman DM | St Francis Bay            | NON-ANSUR    | RURAL    | 3       | 4                                |
| Eastern Cape | Sarah Baartman DM | Twee Riviere Clinic       | ANSUR        | RURAL    | 1       | 7                                |
| Free State   | Fezile Dabi DM    | Heilbron Clinic           | NON-ANSUR    | URBAN    | 7       | 8                                |
| Free State   | Fezile Dabi DM    | Rammulotsi Clinic         | ANSUR        | URBAN    | 5       | 12                               |
| Free State   | Fezile Dabi DM    | Relebohile (Vrdef) Clinic | ANSUR        | URBAN    | 5       | 12                               |
| Free State   | Fezile Dabi DM    | Thusanang (Sasol) Clinic  | NON-ANSUR    | URBAN    | 7       | 8                                |
| Free State   | Fezile Dabi DM    | Tshepong (Kroon) Clinic   | ANSUR        | URBAN    | 5       | 12                               |
| Free State   | Lejweleputswa DM  | Phomolong (Henn) Clinic   | ANSUR        | RURAL    | 5       | 12                               |
| Free State   | Lejweleputswa DM  | Welkom Clinic             | ANSUR        | URBAN    | 5       | 12                               |
| Free State   | Mangaung MM       | Fichardtpark Clinic       | ANSUR        | URBAN    | 5       | 12                               |
| Free State   | Mangaung MM       | Kgalala Clinic            | NON-ANSUR    | RURAL    | 6       | 4                                |
| Free State   | Mangaung MM       | Mokwena Clinic            | ANSUR        | RURAL    | 5       | 12                               |
| Free State   | T Mofutsanyane DM | Eva Mota Clinic           | NON-ANSUR    | RURAL    | 6       | 4                                |
| Free State   | T Mofutsanyane DM | Makoane Clinic            | ANSUR        | RURAL    | 5       | 12                               |
| Free State   | T Mofutsanyane DM | Mphohadi Clinic           | ANSUR        | URBAN    | 5       | 12                               |
| Free State   | T Mofutsanyane DM | Tshiame B Clinic          | ANSUR        | URBAN    | 5       | 12                               |



| Province   | District      | Facility               | ANSUR status | Locality | Stratum | Minimum target number of records |
|------------|---------------|------------------------|--------------|----------|---------|----------------------------------|
| Free State | Xhariep DM    | Diamond (Diamant) Hosp | NON-ANSUR    | RURAL    | 6       | 4                                |
| Free State | Xhariep DM    | Fauresmith Clinic      | ANSUR        | RURAL    | 5       | 13                               |
| Free State | Xhariep DM    | Lephoi Clinic          | ANSUR        | RURAL    | 5       | 12                               |
| Gauteng    | Ekurhuleni MM | Barcelona Clinic       | ANSUR        | URBAN    | 8       | 33                               |
| Gauteng    | Ekurhuleni MM | Birchleigh Clinic      | ANSUR        | URBAN    | 8       | 33                               |
| Gauteng    | Ekurhuleni MM | Bonaero Park Clinic    | NON-ANSUR    | URBAN    | 9       | 20                               |
| Gauteng    | Ekurhuleni MM | Brackenhurst Clinic    | NON-ANSUR    | URBAN    | 9       | 20                               |
| Gauteng    | Ekurhuleni MM | Calcot Dhlephu Clinic  | ANSUR        | URBAN    | 8       | 33                               |
| Gauteng    | Ekurhuleni MM | Chief A Luthuli Clinic | NON-ANSUR    | URBAN    | 9       | 20                               |
| Gauteng    | Ekurhuleni MM | Dan Kubheka Clinic     | ANSUR        | URBAN    | 8       | 33                               |
| Gauteng    | Ekurhuleni MM | Daveyton East Clinic   | NON-ANSUR    | URBAN    | 9       | 20                               |
| Gauteng    | Ekurhuleni MM | Duduza Clinic          | ANSUR        | URBAN    | 8       | 33                               |
| Gauteng    | Ekurhuleni MM | Eden Park Clinic       | ANSUR        | URBAN    | 8       | 33                               |
| Gauteng    | Ekurhuleni MM | Emaphupheni Clinic     | ANSUR        | URBAN    | 8       | 33                               |
| Gauteng    | Ekurhuleni MM | Ethafeni Clinic        | ANSUR        | URBAN    | 8       | 33                               |
| Gauteng    | Ekurhuleni MM | First Avenue Clinic    | ANSUR        | URBAN    | 8       | 33                               |
| Gauteng    | Ekurhuleni MM | Germiston Clinic       | NON-ANSUR    | URBAN    | 9       | 20                               |
| Gauteng    | Ekurhuleni MM | J Dumane CHC           | ANSUR        | URBAN    | 8       | 33                               |
| Gauteng    | Ekurhuleni MM | Joy Clinic             | NON-ANSUR    | URBAN    | 9       | 20                               |
| Gauteng    | Ekurhuleni MM | Khumalo Clinic         | ANSUR        | URBAN    | 8       | 33                               |
| Gauteng    | Ekurhuleni MM | Kingsway Clinic        | ANSUR        | URBAN    | 8       | 33                               |
| Gauteng    | Ekurhuleni MM | Kwa-Thema CHC          | ANSUR        | URBAN    | 8       | 33                               |
| Gauteng    | Ekurhuleni MM | M Moodley Mem CDC      | ANSUR        | URBAN    | 8       | 33                               |
| Gauteng    | Ekurhuleni MM | Magagula Clinic        | NON-ANSUR    | URBAN    | 9       | 20                               |
| Gauteng    | Ekurhuleni MM | Payneville Clinic      | ANSUR        | URBAN    | 8       | 34                               |
| Gauteng    | Ekurhuleni MM | Phola Park CHC         | ANSUR        | URBAN    | 8       | 33                               |
| Gauteng    | Ekurhuleni MM | Simunye (Brak) Clinic  | ANSUR        | URBAN    | 8       | 33                               |
| Gauteng    | Ekurhuleni MM | Spartan Clinic         | ANSUR        | URBAN    | 8       | 34                               |
| Gauteng    | Ekurhuleni MM | Tembisa Health Clinic  | NON-ANSUR    | URBAN    | 9       | 20                               |
| Gauteng    | Ekurhuleni MM | Thembelisha Clinic     | ANSUR        | URBAN    | 8       | 33                               |
| Gauteng    | Ekurhuleni MM | Tswelopele Clinic      | NON-ANSUR    | URBAN    | 9       | 20                               |

| Province | District        | Facility                  | ANSUR status | Locality | Stratum | Minimum target number of records |
|----------|-----------------|---------------------------|--------------|----------|---------|----------------------------------|
| Gauteng  | Ekurhuleni MM   | Winnie Mandela Clinic     | ANSUR        | RURAL    | 8       | 34                               |
| Gauteng  | Johannesburg MM | Alexandra CHC             | ANSUR        | URBAN    | 8       | 33                               |
| Gauteng  | Johannesburg MM | B Molokoane Clinic        | NON-ANSUR    | URBAN    | 9       | 20                               |
| Gauteng  | Johannesburg MM | Bezvalley Clinic          | NON-ANSUR    | URBAN    | 9       | 20                               |
| Gauteng  | Johannesburg MM | Bosmont Clinic            | NON-ANSUR    | URBAN    | 9       | 20                               |
| Gauteng  | Johannesburg MM | Chris Hani Hosp           | NON-ANSUR    | URBAN    | 9       | 20                               |
| Gauteng  | Johannesburg MM | Diepkloof Prov Clinic     | ANSUR        | RURAL    | 8       | 33                               |
| Gauteng  | Johannesburg MM | Eikenhof Prov Clinic      | NON-ANSUR    | URBAN    | 9       | 20                               |
| Gauteng  | Johannesburg MM | Elias Motsoaledi Clinic   | NON-ANSUR    | RURAL    | 9       | 20                               |
| Gauteng  | Johannesburg MM | Florida Clinic            | NON-ANSUR    | URBAN    | 9       | 20                               |
| Gauteng  | Johannesburg MM | Helderkruin Clinic        | NON-ANSUR    | URBAN    | 9       | 20                               |
| Gauteng  | Johannesburg MM | Hikhensile Clinic         | ANSUR        | URBAN    | 8       | 34                               |
| Gauteng  | Johannesburg MM | Jabavu (Vusabantu) Clinic | NON-ANSUR    | URBAN    | 9       | 20                               |
| Gauteng  | Johannesburg MM | Lawley 2 Clinic           | NON-ANSUR    | URBAN    | 9       | 20                               |
| Gauteng  | Johannesburg MM | Lawley Clinic             | NON-ANSUR    | URBAN    | 9       | 20                               |
| Gauteng  | Johannesburg MM | M Maponya Prov Clinic     | ANSUR        | URBAN    | 8       | 33                               |
| Gauteng  | Johannesburg MM | Mofolo South Clinic       | NON-ANSUR    | URBAN    | 9       | 20                               |
| Gauteng  | Johannesburg MM | OR Tambo Clinic           | ANSUR        | URBAN    | 8       | 33                               |
| Gauteng  | Johannesburg MM | Orchards Clinic           | ANSUR        | URBAN    | 8       | 34                               |
| Gauteng  | Johannesburg MM | Orlando Prov Clinic       | ANSUR        | URBAN    | 8       | 33                               |
| Gauteng  | Johannesburg MM | Protea Glen Clinic        | ANSUR        | URBAN    | 8       | 33                               |

| Province | District        | Facility                | ANSUR status | Locality | Stratum | Minimum target number of records |
|----------|-----------------|-------------------------|--------------|----------|---------|----------------------------------|
| Gauteng  | Johannesburg MM | Rabie Ridge Clinic      | ANSUR        | URBAN    | 8       | 33                               |
| Gauteng  | Johannesburg MM | Sandown Clinic          | NON-ANSUR    | URBAN    | 9       | 20                               |
| Gauteng  | Johannesburg MM | Sophiatown Clinic       | NON-ANSUR    | URBAN    | 9       | 20                               |
| Gauteng  | Johannesburg MM | South Hills Clinic      | NON-ANSUR    | RURAL    | 9       | 20                               |
| Gauteng  | Johannesburg MM | Weilers Farm Clinic     | NON-ANSUR    | URBAN    | 9       | 20                               |
| Gauteng  | Johannesburg MM | Weltevreden Clinic      | ANSUR        | URBAN    | 8       | 33                               |
| Gauteng  | Johannesburg MM | Wildebessies Clinic     | NON-ANSUR    | URBAN    | 9       | 20                               |
| Gauteng  | Johannesburg MM | Windsor Clinic          | ANSUR        | URBAN    | 8       | 33                               |
| Gauteng  | Johannesburg MM | Yeoville Clinic         | ANSUR        | URBAN    | 8       | 33                               |
| Gauteng  | Sedibeng DM     | A Sisulu Clinic         | ANSUR        | URBAN    | 8       | 33                               |
| Gauteng  | Sedibeng DM     | Beverly Hills Clinic    | ANSUR        | URBAN    | 8       | 33                               |
| Gauteng  | Sedibeng DM     | J Heyns CHC             | ANSUR        | URBAN    | 8       | 33                               |
| Gauteng  | Sedibeng DM     | Kookrus Clinic          | NON-ANSUR    | URBAN    | 9       | 20                               |
| Gauteng  | Sedibeng DM     | Ratanda Ext 7 Clinic    | ANSUR        | URBAN    | 8       | 33                               |
| Gauteng  | Sedibeng DM     | Rensburg Clinic         | ANSUR        | URBAN    | 8       | 33                               |
| Gauteng  | Sedibeng DM     | Sebei Motsoeneng Clinic | NON-ANSUR    | URBAN    | 9       | 20                               |
| Gauteng  | Sedibeng DM     | Sebokeng Hosp           | NON-ANSUR    | URBAN    | 9       | 20                               |
| Gauteng  | Tshwane MM      | Dr G Mukhari Hosp       | NON-ANSUR    | URBAN    | 9       | 20                               |
| Gauteng  | Tshwane MM      | East Lynne Clinic       | ANSUR        | URBAN    | 8       | 33                               |
| Gauteng  | Tshwane MM      | Eldoraigne Clinic       | NON-ANSUR    | URBAN    | 9       | 20                               |
| Gauteng  | Tshwane MM      | Lotus Gardens Clinic    | NON-ANSUR    | URBAN    | 9       | 20                               |
| Gauteng  | Tshwane MM      | Lyttelton Clinic        | ANSUR        | URBAN    | 8       | 33                               |
| Gauteng  | Tshwane MM      | M Shiceka Clinic        | NON-ANSUR    | URBAN    | 9       | 20                               |
| Gauteng  | Tshwane MM      | Nellmapius Clinic       | ANSUR        | URBAN    | 8       | 33                               |
| Gauteng  | Tshwane MM      | Skinner Street Clinic   | ANSUR        | RURAL    | 8       | 33                               |
| Gauteng  | Tshwane MM      | Tlamelong Clinic        | NON-ANSUR    | URBAN    | 9       | 20                               |
| Gauteng  | Tshwane MM      | Ubuntu Clinic           | NON-ANSUR    | URBAN    | 9       | 20                               |
| Gauteng  | West Rand DM    | Badirile Clinic         | ANSUR        | RURAL    | 8       | 33                               |

| Province      | District     | Facility                 | ANSUR status | Locality | Stratum | Minimum target number of records |
|---------------|--------------|--------------------------|--------------|----------|---------|----------------------------------|
| Gauteng       | West Rand DM | Bekkersdal East Clinic   | ANSUR        | URBAN    | 8       | 33                               |
| Gauteng       | West Rand DM | Eric Ndeleni Clinic      | ANSUR        | URBAN    | 8       | 33                               |
| Gauteng       | West Rand DM | Fanyana Nhlapo Clinic    | ANSUR        | RURAL    | 8       | 33                               |
| Gauteng       | West Rand DM | Luipaardsvlei Satellite  | NON-ANSUR    | RURAL    | 9       | 20                               |
| Gauteng       | West Rand DM | ML Pessen Clinic         | ANSUR        | URBAN    | 8       | 33                               |
| Gauteng       | West Rand DM | Muldersdrift Clinic      | ANSUR        | RURAL    | 8       | 33                               |
| Gauteng       | West Rand DM | PJ Maree Clinic          | ANSUR        | URBAN    | 8       | 33                               |
| Gauteng       | West Rand DM | Simunye (West) Clinic    | ANSUR        | URBAN    | 8       | 33                               |
| Gauteng       | West Rand DM | Ya Rona Clinic           | ANSUR        | URBAN    | 8       | 33                               |
| KwaZulu-Natal | Amajuba DM   | Madadeni 5 Clinic        | ANSUR        | URBAN    | 11      | 29                               |
| KwaZulu-Natal | Amajuba DM   | Madadeni 7 Clinic        | ANSUR        | URBAN    | 11      | 29                               |
| KwaZulu-Natal | Amajuba DM   | Naas Farm Clinic         | ANSUR        | RURAL    | 10      | 19                               |
| KwaZulu-Natal | eThekwini MM | Athlone Park Hall Clinic | NON-ANSUR    | URBAN    | 13      | 10                               |
| KwaZulu-Natal | eThekwini MM | Austerville Clinic       | ANSUR        | URBAN    | 11      | 29                               |
| KwaZulu-Natal | eThekwini MM | Bluff Clinic             | ANSUR        | URBAN    | 11      | 29                               |
| KwaZulu-Natal | eThekwini MM | Chatsworth Centre Clinic | ANSUR        | URBAN    | 11      | 29                               |
| KwaZulu-Natal | eThekwini MM | Chesterville Clinic      | ANSUR        | URBAN    | 11      | 29                               |
| KwaZulu-Natal | eThekwini MM | Glen Earle Clinic        | ANSUR        | URBAN    | 11      | 29                               |
| KwaZulu-Natal | eThekwini MM | Grove End Clinic         | NON-ANSUR    | URBAN    | 13      | 10                               |
| KwaZulu-Natal | eThekwini MM | Inanda Seminary Clinic   | ANSUR        | URBAN    | 11      | 29                               |
| KwaZulu-Natal | eThekwini MM | King Edward VIII Hosp    | NON-ANSUR    | URBAN    | 13      | 10                               |
| KwaZulu-Natal | eThekwini MM | KwaMashu B Clinic        | ANSUR        | URBAN    | 11      | 29                               |
| KwaZulu-Natal | eThekwini MM | Lamontville Clinic       | ANSUR        | URBAN    | 11      | 29                               |
| KwaZulu-Natal | eThekwini MM | Mariannridge Clinic      | ANSUR        | URBAN    | 11      | 30                               |
| KwaZulu-Natal | eThekwini MM | Mpola Clinic             | ANSUR        | URBAN    | 11      | 29                               |
| KwaZulu-Natal | eThekwini MM | Newlands East Clinic     | NON-ANSUR    | URBAN    | 13      | 10                               |
| KwaZulu-Natal | eThekwini MM | Ntshongweni Clinic       | ANSUR        | URBAN    | 11      | 29                               |
| KwaZulu-Natal | eThekwini MM | Oakford Clinic           | NON-ANSUR    | URBAN    | 13      | 10                               |
| KwaZulu-Natal | eThekwini MM | Osizweni (Uml Q) Clinic  | ANSUR        | URBAN    | 11      | 29                               |
| KwaZulu-Natal | eThekwini MM | Phoenix CHC              | ANSUR        | URBAN    | 11      | 29                               |

| Province      | District         | Facility                 | ANSUR status | Locality | Stratum | Minimum target number of records |
|---------------|------------------|--------------------------|--------------|----------|---------|----------------------------------|
| KwaZulu-Natal | eThekweni MM     | Qadi Clinic              | ANSUR        | URBAN    | 11      | 29                               |
| KwaZulu-Natal | eThekweni MM     | Redcliffe Clinic         | NON-ANSUR    | URBAN    | 13      | 11                               |
| KwaZulu-Natal | eThekweni MM     | Redhill Clinic           | ANSUR        | URBAN    | 11      | 29                               |
| KwaZulu-Natal | eThekweni MM     | Starwood Clinic          | NON-ANSUR    | URBAN    | 13      | 10                               |
| KwaZulu-Natal | eThekweni MM     | Umlazi G Clinic          | ANSUR        | URBAN    | 11      | 29                               |
| KwaZulu-Natal | eThekweni MM     | Umzomuhle (Uml H) Clinic | ANSUR        | URBAN    | 11      | 29                               |
| KwaZulu-Natal | eThekweni MM     | Westville Clinic         | ANSUR        | URBAN    | 11      | 29                               |
| KwaZulu-Natal | eThekweni MM     | Wyebank Clinic           | ANSUR        | URBAN    | 11      | 29                               |
| KwaZulu-Natal | Harry Gwala DM   | Nokweja Clinic           | NON-ANSUR    | RURAL    | 12      | 7                                |
| KwaZulu-Natal | Harry Gwala DM   | Siphamandla Clinic       | ANSUR        | RURAL    | 10      | 19                               |
| KwaZulu-Natal | Harry Gwala DM   | St Margaret's Clinic     | ANSUR        | RURAL    | 10      | 19                               |
| KwaZulu-Natal | iLembe DM        | Mbekaphansi Clinic       | ANSUR        | RURAL    | 10      | 19                               |
| KwaZulu-Natal | iLembe DM        | Molokohlo Clinic         | ANSUR        | RURAL    | 10      | 19                               |
| KwaZulu-Natal | iLembe DM        | Mthandeni Clinic         | ANSUR        | RURAL    | 10      | 19                               |
| KwaZulu-Natal | iLembe DM        | Ndwedwe CHC              | ANSUR        | RURAL    | 10      | 19                               |
| KwaZulu-Natal | iLembe DM        | Umphumulo Gateway        | ANSUR        | RURAL    | 10      | 19                               |
| KwaZulu-Natal | Ugu DM           | Dlangezwa Clinic         | NON-ANSUR    | RURAL    | 12      | 7                                |
| KwaZulu-Natal | Ugu DM           | Gqayinyanga Clinic       | NON-ANSUR    | RURAL    | 12      | 8                                |
| KwaZulu-Natal | Ugu DM           | Turton CHC               | ANSUR        | RURAL    | 10      | 19                               |
| KwaZulu-Natal | uMgungundlovu DM | Appelsbosch Gateway      | NON-ANSUR    | RURAL    | 12      | 7                                |
| KwaZulu-Natal | uMgungundlovu DM | Bambanani Clinic         | NON-ANSUR    | RURAL    | 12      | 7                                |
| KwaZulu-Natal | uMgungundlovu DM | Bruntville CHC           | ANSUR        | RURAL    | 10      | 19                               |
| KwaZulu-Natal | uMgungundlovu DM | Esigodini Clinic         | NON-ANSUR    | URBAN    | 13      | 10                               |
| KwaZulu-Natal | uMgungundlovu DM | Imbalenhle CHC           | ANSUR        | URBAN    | 11      | 29                               |
| KwaZulu-Natal | uMgungundlovu DM | Mafakathini Clinic       | ANSUR        | URBAN    | 11      | 29                               |
| KwaZulu-Natal | Umkhanyakude DM  | KwaMsane Clinic          | ANSUR        | RURAL    | 10      | 19                               |
| KwaZulu-Natal | Umkhanyakude DM  | Manyiseni Clinic         | ANSUR        | RURAL    | 10      | 19                               |
| KwaZulu-Natal | Umkhanyakude DM  | Mshudu Clinic            | NON-ANSUR    | RURAL    | 12      | 7                                |
| KwaZulu-Natal | Umkhanyakude DM  | Oqondweni Clinic         | ANSUR        | RURAL    | 10      | 19                               |

| Province      | District      | Facility                | ANSUR status | Locality | Stratum | Minimum target number of records |
|---------------|---------------|-------------------------|--------------|----------|---------|----------------------------------|
| KwaZulu-Natal | Umzinyathi DM | Eshane Clinic           | NON-ANSUR    | RURAL    | 12      | 7                                |
| KwaZulu-Natal | Umzinyathi DM | Hlathi Dam Clinic       | ANSUR        | RURAL    | 10      | 19                               |
| KwaZulu-Natal | Umzinyathi DM | Kranskop Clinic         | NON-ANSUR    | RURAL    | 12      | 7                                |
| KwaZulu-Natal | Umzinyathi DM | KwaSenge Clinic         | NON-ANSUR    | RURAL    | 12      | 7                                |
| KwaZulu-Natal | Uthukela DM   | Cornfields Clinic       | NON-ANSUR    | RURAL    | 12      | 7                                |
| KwaZulu-Natal | Uthukela DM   | KwaMteyi Clinic         | NON-ANSUR    | RURAL    | 12      | 7                                |
| KwaZulu-Natal | Uthukela DM   | Ntabamhlope Clinic      | ANSUR        | RURAL    | 10      | 19                               |
| KwaZulu-Natal | Uthungulu DM  | Empangeni Clinic        | ANSUR        | URBAN    | 11      | 29                               |
| KwaZulu-Natal | Uthungulu DM  | KwaMagwaza Hosp         | ANSUR        | RURAL    | 10      | 19                               |
| KwaZulu-Natal | Uthungulu DM  | KwaYanguye Clinic       | NON-ANSUR    | RURAL    | 12      | 7                                |
| KwaZulu-Natal | Uthungulu DM  | L Umfolozi War Mem Hosp | NON-ANSUR    | URBAN    | 13      | 11                               |
| KwaZulu-Natal | Uthungulu DM  | Mabhuqweni Clinic       | NON-ANSUR    | RURAL    | 12      | 7                                |
| KwaZulu-Natal | Uthungulu DM  | Malunga Clinic          | NON-ANSUR    | RURAL    | 12      | 7                                |
| KwaZulu-Natal | Uthungulu DM  | Mpandleni Clinic        | ANSUR        | RURAL    | 10      | 19                               |
| KwaZulu-Natal | Uthungulu DM  | Nogajuka Clinic         | NON-ANSUR    | RURAL    | 12      | 8                                |
| KwaZulu-Natal | Uthungulu DM  | Nseleni CHC             | ANSUR        | RURAL    | 10      | 19                               |
| KwaZulu-Natal | Uthungulu DM  | Phaphamani Clinic       | ANSUR        | RURAL    | 10      | 19                               |
| KwaZulu-Natal | Uthungulu DM  | Richards Bay Clinic     | ANSUR        | URBAN    | 11      | 29                               |
| KwaZulu-Natal | Uthungulu DM  | Samungu Clinic          | NON-ANSUR    | RURAL    | 12      | 7                                |
| KwaZulu-Natal | Uthungulu DM  | Thokozani Clinic        | ANSUR        | RURAL    | 10      | 19                               |
| KwaZulu-Natal | Zululand DM   | Lomo Clinic             | NON-ANSUR    | RURAL    | 12      | 7                                |
| KwaZulu-Natal | Zululand DM   | Luneburg Clinic         | ANSUR        | RURAL    | 10      | 19                               |
| KwaZulu-Natal | Zululand DM   | Makhwela Clinic         | NON-ANSUR    | RURAL    | 12      | 7                                |
| KwaZulu-Natal | Zululand DM   | Mason Str Clinic        | ANSUR        | RURAL    | 10      | 19                               |
| KwaZulu-Natal | Zululand DM   | Nhlopheni Clinic        | NON-ANSUR    | URBAN    | 13      | 10                               |
| KwaZulu-Natal | Zululand DM   | Okhukho Clinic          | NON-ANSUR    | RURAL    | 12      | 7                                |
| KwaZulu-Natal | Zululand DM   | Queen Nolonolo Clinic   | ANSUR        | RURAL    | 10      | 19                               |
| KwaZulu-Natal | Zululand DM   | Ulundi A Clinic         | ANSUR        | RURAL    | 10      | 19                               |
| Limpopo       | Capricorn DM  | Chuene Clinic           | ANSUR        | RURAL    | 14      | 15                               |
| Limpopo       | Capricorn DM  | Dithabaneng Clinic      | ANSUR        | RURAL    | 14      | 15                               |
| Limpopo       | Capricorn DM  | Mamotshwa Clinic        | ANSUR        | RURAL    | 14      | 15                               |
| Limpopo       | Capricorn DM  | Moletlane Clinic        | ANSUR        | RURAL    | 14      | 15                               |
| Limpopo       | Capricorn DM  | Nthabiseng Clinic       | ANSUR        | RURAL    | 14      | 15                               |
| Limpopo       | Capricorn DM  | Sehlale Clinic          | NON-ANSUR    | RURAL    | 15      | 8                                |
| Limpopo       | Capricorn DM  | Seshego IV Clinic       | NON-ANSUR    | RURAL    | 15      | 8                                |
| Limpopo       | Mopani DM     | Bolobedu Clinic         | NON-ANSUR    | RURAL    | 15      | 8                                |

| Province | District      | Facility                  | ANSUR status | Locality | Stratum | Minimum target number of records |
|----------|---------------|---------------------------|--------------|----------|---------|----------------------------------|
| Limpopo  | Mopani DM     | Duiwelskloof CHC          | NON-ANSUR    | RURAL    | 15      | 8                                |
| Limpopo  | Mopani DM     | Duiwelskloof Clinic       | NON-ANSUR    | RURAL    | 15      | 8                                |
| Limpopo  | Mopani DM     | Hlaneki Clinic            | ANSUR        | RURAL    | 14      | 15                               |
| Limpopo  | Mopani DM     | Julesburg                 | ANSUR        | RURAL    | 14      | 15                               |
| Limpopo  | Mopani DM     | Makhushane Clinic         | ANSUR        | RURAL    | 14      | 15                               |
| Limpopo  | Mopani DM     | Mamaila Clinic            | NON-ANSUR    | RURAL    | 15      | 8                                |
| Limpopo  | Mopani DM     | Mashishimale Clinic       | NON-ANSUR    | RURAL    | 15      | 8                                |
| Limpopo  | Mopani DM     | Mhlava Willem Clinic      | ANSUR        | RURAL    | 14      | 15                               |
| Limpopo  | Mopani DM     | Modjadji 5 Clinic         | NON-ANSUR    | RURAL    | 15      | 8                                |
| Limpopo  | Mopani DM     | Namakgale A Clinic        | ANSUR        | URBAN    | 14      | 15                               |
| Limpopo  | Mopani DM     | Nkhensani Gateway         | NON-ANSUR    | RURAL    | 15      | 8                                |
| Limpopo  | Mopani DM     | Ooghoek Clinic            | ANSUR        | RURAL    | 14      | 16                               |
| Limpopo  | Mopani DM     | Relela Clinic             | NON-ANSUR    | URBAN    | 15      | 8                                |
| Limpopo  | Mopani DM     | Shitlakati Clinic         | NON-ANSUR    | RURAL    | 15      | 8                                |
| Limpopo  | Mopani DM     | Shivulani Clinic          | ANSUR        | RURAL    | 14      | 15                               |
| Limpopo  | Mopani DM     | Tzaneen LA Clinic         | NON-ANSUR    | RURAL    | 15      | 8                                |
| Limpopo  | Sekhukhune DM | Eerstegeluk Clinic        | ANSUR        | RURAL    | 14      | 15                               |
| Limpopo  | Sekhukhune DM | Mankotsane Clinic         | NON-ANSUR    | RURAL    | 15      | 8                                |
| Limpopo  | Sekhukhune DM | Naboomkoppies Clinic      | NON-ANSUR    | RURAL    | 15      | 8                                |
| Limpopo  | Sekhukhune DM | Phokoane Clinic           | NON-ANSUR    | RURAL    | 15      | 8                                |
| Limpopo  | Sekhukhune DM | Probeerin Clinic          | ANSUR        | RURAL    | 14      | 15                               |
| Limpopo  | Sekhukhune DM | Schoonoord Clinic         | ANSUR        | RURAL    | 14      | 16                               |
| Limpopo  | Sekhukhune DM | St Rita's Gateway         | ANSUR        | RURAL    | 14      | 15                               |
| Limpopo  | Sekhukhune DM | Swaranang Clinic          | ANSUR        | RURAL    | 14      | 15                               |
| Limpopo  | Sekhukhune DM | Tshehlwaneng Clinic       | ANSUR        | RURAL    | 14      | 15                               |
| Limpopo  | Vhembe DM     | Kuruleni Clinic           | ANSUR        | RURAL    | 14      | 15                               |
| Limpopo  | Vhembe DM     | Makahlule Clinic          | NON-ANSUR    | RURAL    | 15      | 8                                |
| Limpopo  | Vhembe DM     | Malamulele Clinic         | ANSUR        | RURAL    | 14      | 15                               |
| Limpopo  | Vhembe DM     | Matsa Clinic              | ANSUR        | RURAL    | 14      | 15                               |
| Limpopo  | Vhembe DM     | Ntlhaveni D Clinic        | NON-ANSUR    | RURAL    | 15      | 8                                |
| Limpopo  | Vhembe DM     | Olifantshoek Clinic       | NON-ANSUR    | RURAL    | 15      | 8                                |
| Limpopo  | Vhembe DM     | Shingwedzi Clinic         | NON-ANSUR    | RURAL    | 15      | 8                                |
| Limpopo  | Vhembe DM     | Vhufuli Tshitereke Clinic | ANSUR        | RURAL    | 14      | 15                               |
| Limpopo  | Vhembe DM     | William Eddie CHC         | ANSUR        | RURAL    | 14      | 15                               |
| Limpopo  | Waterberg DM  | Ellisras Clinic           | ANSUR        | RURAL    | 14      | 15                               |



| Province   | District     | Facility                  | ANSUR status | Locality | Stratum | Minimum target number of records |
|------------|--------------|---------------------------|--------------|----------|---------|----------------------------------|
| Limpopo    | Waterberg DM | Mamaselela Clinic         | NON-ANSUR    | RURAL    | 15      | 8                                |
| Limpopo    | Waterberg DM | Roedtan Clinic            | NON-ANSUR    | RURAL    | 15      | 8                                |
| Mpumalanga | Ehlanzeni DM | Barberton Gateway         | NON-ANSUR    | URBAN    | 18      | 13                               |
| Mpumalanga | Ehlanzeni DM | Dludluma Clinic           | NON-ANSUR    | RURAL    | 17      | 8                                |
| Mpumalanga | Ehlanzeni DM | Gutshwa Clinic            | ANSUR        | RURAL    | 16      | 17                               |
| Mpumalanga | Ehlanzeni DM | Kaapschehoop Clinic       | NON-ANSUR    | RURAL    | 17      | 8                                |
| Mpumalanga | Ehlanzeni DM | Mananga Clinic            | NON-ANSUR    | RURAL    | 17      | 8                                |
| Mpumalanga | Ehlanzeni DM | Mbonisweni Clinic         | ANSUR        | RURAL    | 16      | 17                               |
| Mpumalanga | Ehlanzeni DM | Mgobodi CHC               | ANSUR        | RURAL    | 16      | 17                               |
| Mpumalanga | Ehlanzeni DM | Mpakeni Clinic            | NON-ANSUR    | URBAN    | 18      | 13                               |
| Mpumalanga | Ehlanzeni DM | Ndindindi Clinic          | NON-ANSUR    | RURAL    | 17      | 8                                |
| Mpumalanga | Ehlanzeni DM | Nelsville Clinic          | NON-ANSUR    | URBAN    | 18      | 13                               |
| Mpumalanga | Ehlanzeni DM | Rolle Clinic              | NON-ANSUR    | RURAL    | 17      | 8                                |
| Mpumalanga | Ehlanzeni DM | Tonga Block C Clinic      | ANSUR        | RURAL    | 16      | 17                               |
| Mpumalanga | Ehlanzeni DM | Xanthia Clinic            | ANSUR        | RURAL    | 16      | 17                               |
| Mpumalanga | G Sibande DM | Breyten Clinic            | NON-ANSUR    | RURAL    | 17      | 8                                |
| Mpumalanga | G Sibande DM | Derby (Rustplaas) Clinic  | NON-ANSUR    | RURAL    | 17      | 8                                |
| Mpumalanga | G Sibande DM | Driefontein CHC           | ANSUR        | RURAL    | 16      | 17                               |
| Mpumalanga | G Sibande DM | Eerstehoek Clinic         | ANSUR        | RURAL    | 16      | 17                               |
| Mpumalanga | G Sibande DM | Hartebeeskop Clinic       | NON-ANSUR    | RURAL    | 17      | 8                                |
| Mpumalanga | G Sibande DM | Iswepe CHC                | ANSUR        | RURAL    | 16      | 17                               |
| Mpumalanga | G Sibande DM | Kinross/Thistle Grov      | NON-ANSUR    | RURAL    | 17      | 8                                |
| Mpumalanga | G Sibande DM | Langverwacht Ext14 Clinic | ANSUR        | URBAN    | 16      | 17                               |
| Mpumalanga | G Sibande DM | Mayflower CHC             | ANSUR        | RURAL    | 16      | 17                               |
| Mpumalanga | G Sibande DM | Sheepmoor CHC             | NON-ANSUR    | RURAL    | 17      | 8                                |
| Mpumalanga | G Sibande DM | Tjakastad Clinic          | ANSUR        | RURAL    | 16      | 17                               |
| Mpumalanga | Nkangala DM  | Beatty Clinic             | ANSUR        | URBAN    | 16      | 17                               |
| Mpumalanga | Nkangala DM  | Bloedfontein Clinic       | ANSUR        | RURAL    | 16      | 17                               |
| Mpumalanga | Nkangala DM  | Empumelweni CHC           | ANSUR        | RURAL    | 16      | 17                               |
| Mpumalanga | Nkangala DM  | Gemsbokspruit Clinic      | ANSUR        | RURAL    | 16      | 17                               |
| Mpumalanga | Nkangala DM  | Hendrina Clinic           | ANSUR        | RURAL    | 16      | 17                               |
| Mpumalanga | Nkangala DM  | Vlaklaagte 2 CHC          | ANSUR        | RURAL    | 16      | 17                               |

| Province      | District                  | Facility                  | ANSUR status | Locality | Stratum | Minimum target number of records |
|---------------|---------------------------|---------------------------|--------------|----------|---------|----------------------------------|
| North West    | Bojanala Platinum DM      | Anna Legoale Clinic       | ANSUR        | RURAL    | 19      | 14                               |
| North West    | Bojanala Platinum DM      | Brits Hosp                | NON-ANSUR    | URBAN    | 20      | 4                                |
| North West    | Bojanala Platinum DM      | Cyferkuil Clinic          | ANSUR        | RURAL    | 19      | 14                               |
| North West    | Bojanala Platinum DM      | Hartebeesfontein Clinic   | ANSUR        | RURAL    | 19      | 14                               |
| North West    | Bojanala Platinum DM      | Lebotloane Clinic         | ANSUR        | RURAL    | 19      | 14                               |
| North West    | Bojanala Platinum DM      | Modderkuil Clinic         | ANSUR        | RURAL    | 19      | 14                               |
| North West    | Bojanala Platinum DM      | Rietfontein Clinic        | NON-ANSUR    | RURAL    | 20      | 4                                |
| North West    | Bojanala Platinum DM      | Sandfontein Clinic        | ANSUR        | RURAL    | 19      | 14                               |
| North West    | Bojanala Platinum DM      | Swarddam Clinic           | ANSUR        | RURAL    | 19      | 14                               |
| North West    | Dr K Kaunda DM            | Botshabelo CHC            | ANSUR        | URBAN    | 19      | 14                               |
| North West    | Dr K Kaunda DM            | Park Street Clinic        | ANSUR        | URBAN    | 19      | 14                               |
| North West    | Dr K Kaunda DM            | Stilfontein Clinic        | ANSUR        | URBAN    | 19      | 14                               |
| North West    | Ngaka Modiri Molema DM    | Boikhutso Clinic          | ANSUR        | RURAL    | 19      | 14                               |
| North West    | Ngaka Modiri Molema DM    | Carlisonia HP             | NON-ANSUR    | RURAL    | 20      | 4                                |
| North West    | Ngaka Modiri Molema DM    | Matshepe Clinic           | NON-ANSUR    | RURAL    | 20      | 4                                |
| North West    | Ngaka Modiri Molema DM    | Mofufutso Clinic          | NON-ANSUR    | RURAL    | 20      | 4                                |
| North West    | Ruth Segomotsi Mompoti DM | Buxton Clinic             | ANSUR        | RURAL    | 19      | 14                               |
| North West    | Ruth Segomotsi Mompoti DM | Christiana Town Clinic    | ANSUR        | RURAL    | 19      | 14                               |
| North West    | Ruth Segomotsi Mompoti DM | Dryharts Clinic           | NON-ANSUR    | RURAL    | 20      | 4                                |
| North West    | Ruth Segomotsi Mompoti DM | Upper Majeakgoro Clinic   | ANSUR        | RURAL    | 19      | 14                               |
| Northern Cape | Frances Baard DM          | Florianville Clinic       | ANSUR        | RURAL    | 21      | 30                               |
| Northern Cape | J T Gaetsewe DM           | Kagiso CHC                | ANSUR        | RURAL    | 21      | 30                               |
| Northern Cape | Namakwa DM                | Bergsig (M Shapiro) Clini | ANSUR        | RURAL    | 21      | 30                               |

| Province      | District          | Facility                | ANSUR status | Locality | Stratum | Minimum target number of records |
|---------------|-------------------|-------------------------|--------------|----------|---------|----------------------------------|
| Northern Cape | Pixley ka Seme DM | Britstown Clinic        | NON-ANSUR    | RURAL    | 22      | 12                               |
| Northern Cape | Pixley ka Seme DM | Ethembeni               | NON-ANSUR    | RURAL    | 22      | 12                               |
| Northern Cape | ZF Mgcawu DM      | Kakamas Clinic          | ANSUR        | RURAL    | 21      | 30                               |
| Northern Cape | ZF Mgcawu DM      | Leerkrans Sat           | NON-ANSUR    | RURAL    | 22      | 12                               |
| Northern Cape | ZF Mgcawu DM      | Postdene Clinic         | ANSUR        | RURAL    | 21      | 30                               |
| Western Cape  | Cape Town MM      | Bellville S CDC         | ANSUR        | URBAN    | 24      | 20                               |
| Western Cape  | Cape Town MM      | Blue Downs Clinic       | ANSUR        | URBAN    | 24      | 20                               |
| Western Cape  | Cape Town MM      | Bothasig Clinic         | ANSUR        | URBAN    | 24      | 20                               |
| Western Cape  | Cape Town MM      | Crossroads CDC          | ANSUR        | URBAN    | 24      | 20                               |
| Western Cape  | Cape Town MM      | E River CHC             | ANSUR        | URBAN    | 24      | 20                               |
| Western Cape  | Cape Town MM      | Fagan Street Clinic     | ANSUR        | URBAN    | 24      | 20                               |
| Western Cape  | Cape Town MM      | False Bay Hosp          | ANSUR        | URBAN    | 24      | 20                               |
| Western Cape  | Cape Town MM      | Fisantekraal Clinic     | ANSUR        | URBAN    | 24      | 20                               |
| Western Cape  | Cape Town MM      | Gustrouw CDC            | ANSUR        | URBAN    | 24      | 20                               |
| Western Cape  | Cape Town MM      | Kuyasa CDC              | ANSUR        | URBAN    | 24      | 20                               |
| Western Cape  | Cape Town MM      | Mamre CDC               | ANSUR        | URBAN    | 24      | 21                               |
| Western Cape  | Cape Town MM      | Matthew Goniwe CDC      | ANSUR        | URBAN    | 24      | 20                               |
| Western Cape  | Cape Town MM      | Michael M CDC           | ANSUR        | URBAN    | 24      | 20                               |
| Western Cape  | Cape Town MM      | Nolungile CDC           | ANSUR        | URBAN    | 24      | 20                               |
| Western Cape  | Cape Town MM      | Parkwood Clinic         | NON-ANSUR    | URBAN    | 26      | 5                                |
| Western Cape  | Cape Town MM      | Parow Clinic            | ANSUR        | URBAN    | 24      | 20                               |
| Western Cape  | Cape Town MM      | Silvertown Clinic       | ANSUR        | URBAN    | 24      | 20                               |
| Western Cape  | Cape Town MM      | Sir Lowry's Pass Clinic | ANSUR        | URBAN    | 24      | 20                               |
| Western Cape  | Cape Town MM      | Site B CHC              | NON-ANSUR    | URBAN    | 26      | 5                                |
| Western Cape  | Cape Town MM      | Site C Youth Clinic     | ANSUR        | URBAN    | 24      | 21                               |
| Western Cape  | Cape Town MM      | Vuyani Clinic           | ANSUR        | URBAN    | 24      | 20                               |
| Western Cape  | Cape Winelands DM | Cogmanskloof Clinic     | ANSUR        | RURAL    | 23      | 8                                |
| Western Cape  | Cape Winelands DM | Touws River Clinic      | ANSUR        | RURAL    | 23      | 8                                |
| Western Cape  | Eden DM           | Bridgeton CDC           | ANSUR        | RURAL    | 23      | 8                                |
| Western Cape  | Eden DM           | Conville CDC            | ANSUR        | RURAL    | 23      | 8                                |
| Western Cape  | Eden DM           | Heidelberg Clinic       | ANSUR        | URBAN    | 24      | 20                               |
| Western Cape  | Eden DM           | Lawaikamp Clinic        | ANSUR        | RURAL    | 23      | 8                                |
| Western Cape  | Eden DM           | New Horizon Clinic      | ANSUR        | RURAL    | 23      | 8                                |
| Western Cape  | Eden DM           | Oudtshoort Clinic       | NON-ANSUR    | RURAL    | 25      | 2                                |

| Province                                               | District    | Facility                | ANSUR status | Locality | Stratum | Minimum target number of records |
|--------------------------------------------------------|-------------|-------------------------|--------------|----------|---------|----------------------------------|
| Western Cape                                           | Eden DM     | Riversdale Clinic       | ANSUR        | RURAL    | 23      | 8                                |
| Western Cape                                           | Eden DM     | Shuda GP                | NON-ANSUR    | URBAN    | 26      | 5                                |
| Western Cape                                           | Eden DM     | Themba lethu CDC        | ANSUR        | RURAL    | 23      | 8                                |
| Western Cape                                           | Overberg DM | Buffeljagsrivier Clinic | NON-ANSUR    | RURAL    | 25      | 2                                |
| Total minimum target (to sample +2-3 records per site) |             |                         |              |          |         | 6170                             |

## B: Actual targeted and realised sample size by sampling strata

| Strata | Province      | ANSUR status | TARGET SAMPLE SIZES  |                   |                                   | REALISED SAMPLE             |                    |
|--------|---------------|--------------|----------------------|-------------------|-----------------------------------|-----------------------------|--------------------|
|        |               |              | Number of facilities | Number of records | Contribution to total sample size | Number of extracted records | Sample realization |
| 1      | Eastern Cape  | ANSUR        | 10                   | 202               | 3%                                | 144                         | 71%                |
| 2      | Eastern Cape  | ANSUR        | 11                   | 223               | 3%                                | 386                         | 173%               |
| 3      | Eastern Cape  | NON          | 14                   | 280               | 4%                                | 133                         | 47%                |
| 4      | Eastern Cape  | NON          | 8                    | 154               | 2%                                | 137                         | 89%                |
| 5      | Free State    | ANSUR        | 12                   | 245               | 3%                                | 368                         | 150%               |
| 6      | Free State    | NON          | 3                    | 54                | 1%                                | 33                          | 61%                |
| 7      | Free State    | NON          | 2                    | 47                | 1%                                | 35                          | 75%                |
| 8      | Gauteng       | ANSUR        | 53                   | 1060              | 15%                               | 4342                        | 410%               |
| 9      | Gauteng       | NON          | 33                   | 669               | 9%                                | 1772                        | 265%               |
| 10     | KwaZulu-Natal | ANSUR        | 24                   | 476               | 7%                                | 1079                        | 227%               |
| 11     | KwaZulu-Natal | ANSUR        | 26                   | 518               | 7%                                | 2011                        | 388%               |
| 12     | KwaZulu-Natal | NON          | 19                   | 377               | 5%                                | 345                         | 92%                |
| 13     | KwaZulu-Natal | NON          | 9                    | 181               | 3%                                | 205                         | 113%               |
| 14     | Limpopo       | ANSUR        | 25                   | 506               | 7%                                | 776                         | 153%               |
| 15     | Limpopo       | NON          | 20                   | 393               | 5%                                | 426                         | 108%               |
| 16     | Mpumalanga    | ANSUR        | 17                   | 340               | 5%                                | 662                         | 195%               |
| 17     | Mpumalanga    | NON          | 10                   | 193               | 3%                                | 210                         | 109%               |
| 18     | Mpumalanga    | NON          | 3                    | 58                | 1%                                | 49                          | 84%                |
| 19     | North West    | ANSUR        | 14                   | 281               | 4%                                | 499                         | 177%               |
| 20     | North West    | NON          | 6                    | 129               | 2%                                | 69                          | 54%                |

| Strata       | Province      | ANSUR status | TARGET SAMPLE SIZES  |                   |                                   | REALISED SAMPLE             |                    |
|--------------|---------------|--------------|----------------------|-------------------|-----------------------------------|-----------------------------|--------------------|
|              |               |              | Number of facilities | Number of records | Contribution to total sample size | Number of extracted records | Sample realization |
| 21           | Northern Cape | ANSUR        | 5                    | 107               | 1%                                | 312                         | 290%               |
| 22           | Northern Cape | NON          | 3                    | 53                | 1%                                | 56                          | 105%               |
| 23           | Western Cape  | ANSUR        | 10                   | 192               | 3%                                | 120                         | 62%                |
| 24           | Western Cape  | ANSUR        | 18                   | 364               | 5%                                | 586                         | 161%               |
| 25           | Western Cape  | NON          | 2                    | 33                | 0%                                | 18                          | 54%                |
| 26           | Western Cape  | NON          | 3                    | 63                | 1%                                | 5                           | 8%                 |
| <b>Total</b> |               |              | <b>360</b>           | <b>7200</b>       | <b>100%</b>                       | <b>14778</b>                |                    |









