

NACO is committed to contain the spread of HIV in India by building an all-encompassing response reaching out to diverse populations. It endeavours to provide people with accurate, complete and consistent information about HIV and promote effective interventions and responsible behaviours. National AIDS Control Programme is built on a foundation of evidence, experience and community involvement, and is determined to formulate strategic responses to the changing HIV/AIDS situation in India.

A close watch on the HIV epidemic, its patterns of spread and vulnerabilities is critical for a successful strategic response. HIV Sentinel Surveillance system is the most important system established by NACO for monitoring the HIV epidemic among different population groups across the country. The robust system of conducting HIV surveillance annually, through a large network of personnel, health facilities, NGOs, laboratories, administrative units and institutes, symbolizes NACO's commitment to evidence-based planning and its readiness to adapt to emerging patterns of HIV epidemic.

Constant efforts are made to improve the mechanisms and methods of HIV surveillance to ensure better quality of data. This manual is an outcome of such efforts to simplify the processes and make them easily understandable. 'Operational Manual for ANC & STD Sentinel Sites' describes the eligibility criteria and sampling process to be followed for surveillance among antenatal clinic attendees and STD patients. The steps and precautions to be taken while collecting and processing the blood specimens are outlined in this manual. It gives details of data management at the sentinel sites and enlists the roles and responsibilities of the key personnel involved. The manual also highlights the important messages to be borne in mind while implementing surveillance at ANC & STD sentinel sites.

This manual is a part of HIV Sentinel Surveillance 2012-13 series with three publications. While Technical Guidelines elucidate the science of HIV Sentinel Surveillance adopted in India, the two operational manuals provide guidance to the personnel implementing it.



**National AIDS Control Organisation**

India's voice against AIDS

Department of AIDS Control

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[www.nacoonline.org](http://www.nacoonline.org)

## HIV Sentinel Surveillance 2012-13

### Operational Manual for ANC & STD Sentinel Sites

**National AIDS Control Organisation**

Department of AIDS Control

Ministry of Health and Family Welfare

Government of India

September 2012



## DOs and DON'Ts for High Quality HSS

### DOs

1. Ensure availability of all material required for documentation & blood specimen processing, well in advance.
2. Strictly follow the inclusion criteria for selection of eligible individuals at the sentinel site.
3. Ensure consecutiveness in recruiting individuals into HSS. Arrange to draw blood close to the OPD where doctor examines for eligibility.
4. Ensure that the site code and sample number are correctly written on the data form and blood specimen.
5. Fill the data forms completely, neatly and legibly.
6. Follow universal precautions and good laboratory practice for collection and processing of blood specimens.
7. Label the centrifuge tubes/vacutainer tubes and serum vials appropriately.
8. Store the sera samples at +4°C for not more than 7 days and send them to the HSS testing lab every week.
9. Send the data forms every week to Regional Institute
10. Send two copies of sample transportation sheet along with samples and two copies of data form transportation sheets along with data forms.

### DON'Ts

1. Do not selectively include or exclude an individual from HSS due to his/her HIV positivity status or whether he/she has participated in previous rounds of surveillance or whether she has been tested under PPTCT.
2. Do not include an individual who has already visited the clinic during current round of surveillance.
3. Do not mention any personal identifiers on the data form and blood specimens to maintain Unlinked Anonymous Testing.
4. Do not make any marks or notes that can link the individual to the data form or the blood specimen.
5. Do not sign blank data forms in advance.
6. Do not keep long distance between the OPD clinic and the point of blood collection.
7. Do not use same pipette/ tips for separation of different sera.
8. Do not leave sera in the refrigerator for more than a week. Do not freeze & thaw sera repeatedly.
9. Do not wait to send the data forms and samples to the testing centres till the end of the survey.
10. Do not include individuals from any other source or mobilized through any other means in order to reach the target sample size.

Other Publications from NACO in this series

Technical Guidelines for HIV Sentinel Surveillance 2012-13

HIV Sentinel Surveillance 2012-13 - Operational Manual for High Risk Group Sentinel Sites

Also available at [www.nacoonline.org](http://www.nacoonline.org)



# HIV Sentinel Surveillance 2012-13

## Operational Manual for ANC & STD Sentinel Sites



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**National AIDS Control Organisation**

**Department of AIDS Control**

Ministry of Health & Family Welfare, Government of India

**September 2012**

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## FOREWORD

HIV Sentinel Surveillance in India, since its inception in 1998, has evolved into a credible and robust system for HIV epidemic monitoring and acclaimed as one of the best in the world. Sentinel surveillance provides essential information to understand the trends and dynamics of HIV epidemic among different risk groups in the country. It aids in refinement of strategies and prioritisation of focus for prevention, care and treatment interventions under the National AIDS Control Programme (NACP). HIV estimates of prevalence, incidence and mortality developed based on findings from HIV Sentinel Surveillance enable the programme in assessing the impacts at a macro level.

Over the years, the National Institute of Health & Family Welfare (NIHFW), National Institute of Medical Statistics (NIMS) and the six designated Regional Institutes have played a vital role in the coordination, implementation and quality control of the surveillance activities. With the active support from the State AIDS Control Societies (SACS), there has been an expansion of the sentinel sites from a meagre 180 in 1998 to 1359 sentinel sites in 2010 covering all the districts of India. Involvement of experienced microbiologists from over 150 laboratories and rigorous monitoring and supervision of the activities through trained epidemiologists and public health experts from various institutes have enhanced the quality and reliability of surveillance outcomes. New technologies of blood specimen processing and web-based data management systems introduced in the recent rounds have further strengthened the surveillance activities.

During NACP-IV, HIV Sentinel Surveillance will be conducted once in two years so that adequate time is spent on in-depth analysis and modeling, epidemiological research and use of surveillance data for programmatic purposes. The 13th round of sentinel surveillance will be conducted during 2012-2013. To accomplish this endeavour, your role as a sentinel site in-charge/medical officer, counselor or Lab Technician at the sentinel site is very important. Your roles and responsibilities are described in this manual, besides guidelines for operationalising surveillance activities at the sentinel site. These may strictly be adhered to, to ensure high quality surveillance at your sentinel site.

I would like to acknowledge the contribution of NIHFW, NIMS, Regional Institutes, SACS, epidemiologists, microbiologists and experts in central and state surveillance teams, testing and reference laboratories and partner agencies for carrying out this activity of national importance.

  
(Sayan Chatterjee)

## ACRONYMS

AIDS	Acquired Immuno-Deficiency Syndrome
ANM	Auxiliary Nurse Midwife
ASHA	Accredited Social Health Activist
ANC	Antenatal Clinic
ART	Anti-Retroviral Treatment
CHC	Community Health Centre
DFTS	Data Form Transportation Sheet
DBS	Dried Blood Spot
HIV	Human Immuno-Deficiency Virus
HRG	High Risk Group
HSS	HIV Sentinel Surveillance
ICTC	Integrated Counseling and Testing Centre
NACO	National AIDS Control Organisation
NGO	Non-Governmental Organisation
OBG	Obstetrics & Gynaecology
OPD	Out-patient Department
PEP	Post-Exposure Prophylaxis
PPTCT	Prevention of Parent to Child Transmission
RI	Regional Institute
RPM	Rotations per minute
RPR	Rapid Plasma Reagin
SACS	State AIDS Control Society
SOP	Standard Operating Procedure
STD	Sexually Transmitted Disease
STI	Sexually Transmitted Infection
STS	Sample Transportation Sheet
VDRL	Venereal Disease Research Laboratory



## GLOSSARY

In order to standardize the terminology used in HIV Sentinel Surveillance (HSS) and to enable correct interpretation of different words, the key words used in this document are explained below.

**ANC Attendees:** Pregnant women visiting antenatal clinics

**Data Form:** Brief Questionnaire seeking information related to socio-demographic characteristics and vulnerabilities of the eligible individual

**HSS Testing Lab:** Laboratory where serum specimens collected under HIV Sentinel Surveillance are tested for HIV and Syphilis. This term is used to differentiate it from other laboratories or testing centres where routine tests are done in a health facility or where HIV test is done in an ICTC.

**Recruitment:** Including an eligible individual in HIV Sentinel Surveillance by filling a data form and collecting blood specimen

**Sample:** Individual/ respondent who is found to be eligible for inclusion in HIV Sentinel Surveillance as per specified criteria

**Sample Number:** Unique number given to each eligible individual recruited in HIV Sentinel Surveillance at a sentinel site. It is a three digit number starting with '001'. Sample number of an eligible individual is mentioned on the data form as well as on the blood specimen of the corresponding individual

**Sampling Method:** The approach adopted at the sentinel site for recruiting eligible individuals in HSS. Consecutive sampling is the sampling method adopted in HIV Sentinel Surveillance at ANC & STD sentinel sites

**Sentinel Site:** A designated service point or facility where a fixed number of eligible individuals from a specified population group are recruited over a fixed period of time for the purpose of monitoring the epidemic

**Sentinel Site Code:** Unique number given to each sentinel site. It is a eight digit number comprising codes for state (2 digits), district (3 digits) and site type (2 digits) followed by site number (1 digit)

**Specimen:** Blood collected from the eligible individuals or serum separated from it

STD Patients: Patients attending STD clinic or Gynaecology clinic with Sexually Transmitted Infections

Sub-site Number: Serial number given to each sub-site in a composite site, starting with 1. For a single site, the sub-site number will be '0'

Testing Strategy: The approach adopted for testing the blood specimens collected during HSS. Unlinked Anonymous Testing Strategy is adopted in HIV Sentinel Surveillance

Testing Protocol: Indicates the number of HIV tests conducted on the blood specimen collected during HSS. Two-test protocol is adopted in HIV Sentinel Surveillance (First test of high sensitivity & Second test of high specificity, if first test is positive).

### Consumables Used for Blood Specimen Collection & Processing

Aliquot: Portion of serum separated into a vial after centrifugation of blood specimen

Centrifuge tube: Plastic/ Glass tube into which the blood specimen is transferred from syringe and placed in centrifuge machine

Cryovials/ Serum Vials/ Screw capped vials with O-ring: Plastic tubes into which a portion of serum is transferred using a pipette from centrifuge tube after centrifugation

Parafilm: A flexible film, available in several different lengths and widths. It is commonly used for sealing or protecting vessels (such as flasks or cuvettes). It is stretchable, moldable, waterproof, odorless, thermoplastic, semitransparent and self-adhering. It is also used to further seal a lidded container against moisture for long term storage. Parafilm is used to seal the vials to prevent leakage during the transportation. A film should be tightly wrapped on the junction of the cap and the body of the vial

Vacutainer: Plastic/glass tube with vacuum, used with vacutainer holder for collection of venous blood from an eligible individual

## 1. Introduction

The annual national HIV Sentinel Surveillance (HSS) is one of the components of second generation HIV surveillance in India. It is one of the largest HSS systems in the world. It helps to understand the dynamics of the HIV epidemic and monitor the trends among different population groups and geographical areas and, thus, provides inputs to programme for strengthening prevention and control activities. The sentinel sites have been scaled up in a phased manner from 180 in 1998 to 1359 in 2010-11. Almost every district in the country is now covered under surveillance.

Under HSS, an antenatal clinic in government or private hospitals is designated as an ANC sentinel site where 400 pregnant women (ANC attendees) are recruited. Similarly, the STD clinic and Gynaecology (OBG) clinic in the same (or nearby) government facility are together designated as an STD sentinel site where 150 STD patients attending the STD clinic and 100 female STD patients attending the OBG clinic, are included in surveillance. Surveillance is carried out over a period of three months. Three staff-members at each facility are given the responsibility to implement the surveillance activities. They include a doctor, who is designated as the sentinel site in-charge, a nurse or counselor who assists in data collection and a laboratory technician responsible for collection of blood specimens.

This operational manual has been prepared for easy reference of the staff at sentinel sites. This manual highlights the operational and managerial issues at the sentinel site for efficient implementation of HSS. This manual details the roles and responsibilities of the staff, recruitment process, documentation including instructions to fill data form and blood specimen management. The site in-charge should be aware of the entire set of functions and responsibilities of all the designated staff involved in surveillance activities at the sentinel site. This ensures better coordination and uninterrupted implementation of surveillance activities at the sentinel site.

*Eyes see what the mind knows. The reader is strongly encouraged to refer to the technical guidelines for HIV sentinel surveillance, because a comprehensive reading of both these documents would strengthen not only operational efficiency of surveillance implementation, but would also ensure a sound understanding of the rationale for the entire process.*

## 2. Roles and Responsibilities

### *Sentinel Site In-Charge should*

1. be responsible for all the arrangements and activities for HIV surveillance at the site
2. attend trainings conducted for surveillance by the SACS
3. conduct a Pre-Surveillance on-site training of the staff participating (or expected to participate) in surveillance activities, including other medical officers, staff nurse etc.
4. correctly identify eligible respondents as per the inclusion criteria and recruit each successive eligible individual to ensure consecutive sampling
5. ensure that sample number is not linked with individual's identity thus maintaining unlinked anonymous testing strategy
6. ensure that the standard operating procedures (SOP) are complied with by the staff while collecting, processing & storing blood specimens
7. check the forms filled on a particular day for completeness, discuss issues, if any, with concerned staff, guide them and sign the filled forms. Never sign blank data forms in advance.
8. monitor progress in sample collection on a daily basis
9. arrange for transport of blood specimens under proper cold chain along with sample transportation sheet (STS) to testing laboratory every week and file the returned copy of STS at site
10. ensure that results of tests, for which blood specimen is collected, are provided to the respondent subsequently
11. contact the nodal person at SACS for any clarification/ problem regarding staff, availability of the listed consumables, user manuals, flow charts, data forms and stamps/ pre-printed stickers or any methodological issues

### *Nurse / Counselor should*

1. assist the site in-charge in identifying eligible respondents
2. fill the data form for each eligible respondent as per the instructions given
3. ensure that data form does not carry any personal identifiers
4. ensure that the completed data form and the respondent reach the laboratory technician for blood collection
5. ensure proper storage of data forms and weekly transportation of data forms to the Regional Institute (RI)
6. assist the site in-charge in the overall implementation of surveillance at the site

### *Laboratory Technician should*

1. verify completeness of the data form before taking the blood specimen; refer back to the nurse/counselor immediately if any fields are missing or illegible in the data form
2. collect blood specimen following universal safety precautions and inform respondent about details to collect the test results
3. separate sera from blood specimens, label them and store them as per SOP
4. take all the care and precautions to avoid damage to specimens (haemolysis, contamination, leakage etc.)
5. strictly follow instructions for labeling and ensure appropriate labeling of specimens for routine testing and surveillance
6. assist site in-charge in storage, packing and transportation of blood specimens every week and their documentation
7. strictly adhere to all prescribed bio-safety measures

### 3. Materials Required at ANC & STD Sentinel Site

S.No.	Materials / Consumables	ANC sites	STD sites
<b>Documents</b>			
1	Technical Guidelines	1*	2
2	Operational Manual	3*	6
3	Wall Charts/Flow Charts	1*	2
4	Data Forms	450	300
5	Data Form Transportation Sheets	20-30	20-30
6	Sample Transportation Sheets	20-30	20-30
7	Stamp / Stickers with site details	2*/500	4*/400
8	Supervisory Visit Register	1	1
<b>Consumables / Equipment</b>			
1	Apron and Tourniquet	2	4
2	Gloves & adhesive tapes	450	300
3	Spirit Swabs	450	300
4	Sterile syringes & needles/ vacutainers (5 ml)	450	300
5	Centrifuge Tube	20-30	20-30
6	Centrifuge Machine	1	1
7	Micro-pipette – Sterile disposable pipette tips OR Sterile disposable plastic dropper	1 – 450 OR 450	1 – 300 OR 300
8	Cryovials/ Serum vials/ Screw-capped vials with O Ring	450	300
9	Labels	500	400
10	Water proof marking pens for labeling	2	4
11	Test tube stands/storage racks	5	5
12	Refrigerator	1	1
13	Sample Transportation Box with lid	5	5
<b>Material for Waste Disposal</b>			
1	Needle destroyer	1*	2
2	Puncture proof containers (Jar for disposal of sharps)	1*	2
3	Hypo-chlorite solution	1*	2*
4	Color-coded waste disposal bags (Yellow, blue and black)	3* per day	6 per day
<b>Consumables for ANC/STD sites with DBS Method</b>			
1	Alcohol preps/ swabs	450	300
2	Sterile disposable rubber gloves	450	300
3	Safety lancets	450	300
4	Sterile disposable gauze pieces	450	300
5	Filter paper card/ DBS card with five circles	400	250
6	Small circular band aids	450	300
7	Drying racks	5	5
8	Drying boxes	5	5
9	Desiccant packs	4000	2500
10	Butter paper	450	300
11	Low-gas permeable zip-lock bags	400	250
12	Bigger zip lock bag (to pack 10 small zip lock bags with DBS cards)	50	30
13	Sample Transportation Boxes	50	30

\* Quantity required per site; in the case of a composite site, for every sub-site.

## 4. Eligibility Criteria

It is essential to follow uniform eligibility criteria for recruiting individuals in every round of surveillance to facilitate comparison of HSS results over time for determining trends.

### 4.1. ANC Attendees

#### Box 1. Eligibility Criteria for Inclusion of ANC Attendees in HSS

Inclusion criteria:

1. Age 15-49 years
2. Pregnant woman attending the antenatal clinic for the first time during the current round of surveillance

Note:

1. If the pregnant woman becomes eligible by the above criteria, she should be included in surveillance irrespective of:
  - date of antenatal registration
  - HIV positivity status, if known
  - participation in previous rounds of surveillance
  - whether tested under PPTCT or not
2. A pregnant woman should be recruited only once during a round of surveillance. To ensure this verify the date of her previous visit to ANC clinic. If the date of her previous visit to ANC clinic falls during the current round of surveillance, she should be excluded from the sample.
3. Women, who are already registered with the antenatal clinic but are visiting the clinic for the first time during the current round of surveillance are eligible for inclusion.

## 4.2. STD Patients

### Box 2. Eligibility Criteria for Inclusion of STD Patients in HSS

Inclusion criteria:

1. Men and women, in the age group 15-49 years
2. Diagnosed with any of the following STD syndromes during current visit:
  - a. urethral discharge in males
  - b. Cervical discharge in females (to be confirmed by per-speculum examination)
  - c. ano-genital warts
  - d. ano-genital ulcer
3. STD patients attending the STD/OBG clinic for the first time during HSS period.

Note:

1. In men, milking of urethra should be performed to determine the presence of urethral discharge, if necessary.
2. In women, visualization of the cervix by per-speculum examination is necessary to determine the presence of cervical discharge and to clearly differentiate it from vaginal discharge. The latter is not an STD. If cervical discharge is not confirmed, the woman is not eligible for HSS.
3. Cases that have been already diagnosed and prescribed treatment for their STD before the start of HSS, but are visiting the clinic the first time during the round of surveillance are eligible for inclusion.
4. Participation in a previous round of surveillance and HIV positivity status are not reasons for exclusion or inclusion from current round of HSS.



## 5. Recruitment Process

The sampling method adopted at ANC and STD sentinel sites is Consecutive Sampling. It is crucial to understand the flow of individuals at ANC & STD sentinel sites to maintain consecutive sampling. The following box explains the concept of Consecutive Sampling.

### Box 3. Consecutive Sampling Method

- After the start of surveillance, all individuals attending the sentinel site facility (ANC/STD/OBG clinic), who are eligible for inclusion in surveillance as per the defined criteria, should be recruited in the order they attend the clinic.
- This sampling method removes all chances of selection or exclusion based on individual preferences and other reasons, and hence reduces the selection bias.
- It is convenient, feasible and easy to follow.

The following general instructions on sample recruitment at ANC & STD sentinel sites may be noted:

1. From the notified date of start of the surveillance round, every individual attending the ANC/STD/OBG clinic should be assessed for eligibility for inclusion in HSS.
2. Starting with the first individual, every successive eligible individual should be recruited in HSS till the designated sample size is achieved or the designated period of three months is over, whichever is earlier.
3. The specified sample size for an ANC sentinel site is 400 and for a STD sentinel site is 250, out of which 150 are recruited at the STD clinic and 100 at OBG clinic.
4. In case of composite sites, the sample size will be specified for each sub-site and this should be obtained from SACS.
5. In clinics with large daily attendance, it is recommended that NOT MORE THAN 20 consecutive eligible attendees should be included per day to ensure quality of surveillance data collection. In such a case, the first 20 eligible attendees on a given day should be included.
6. However, there may be exceptions to the above recommendation. In such

cases, the decision about number of consecutive samples to be collected per day should be taken in consultation with RI/SACS, without compromising the overarching principles of consecutive sampling, attainment of desired sample size of 400 or 250, non-compromised patient care and high-quality surveillance.

7. Sample collection should be stopped once the target of 400 has been achieved or at the end of three month period, even if the target of 400 or 250 is not achieved.
8. In order to reach the target, sentinel sites SHOULD NOT recruit pregnant women/ STD patients admitted in the hospital/labour ward or through special campaigns to increase OPD attendance or by holding special camps or by any other means. Data from sentinel sites are much more useful and reliable when the strategy of consecutive sampling is strictly adhered to.

## 5.1. ANC Site

Following the expansion of the ICTC programme, PPTCT services are available in many hospitals. So, some ANC sentinel sites may also have an ICTC in the same facility providing PPTCT services, while some may not have PPTCT services. In these two scenarios, procedure for recruitment of pregnant women differs as outlined below (Flow Chart No. 1) and it is important to adhere to the steps outlined, in order to avoid selection bias.

### Scenario-1: ANC sites with PPTCT services

1. The pregnant women coming to the clinic for ANC check up will go to the doctor. Following antenatal check up, the doctor will assess her eligibility for inclusion in HSS and refer her to counselor/nurse for the purpose of PPTCT and /or HSS.
2. The counselor/nurse will enquire whether the pregnant woman is already enrolled and tested for HIV under PPTCT or not.
3. If not, after providing pre-test counseling, the counselor will enquire whether the pregnant woman is agreeable to undergo HIV testing under PPTCT.
4. If the woman agrees to undergo HIV testing under PPTCT, the counselor will reassess her eligibility for inclusion in HSS. If found eligible, the counselor will fill the data form for HSS and refer the pregnant woman to the Laboratory

Technician to collect blood specimen for HIV testing under PPTCT and for routine testing (VDRL/RPR).

5. If the woman is not eligible for HSS, she is not recruited in HSS and data form is not filled. However, she is referred to Laboratory Technician for blood specimen collection for PPTCT and routine testing.
6. If the woman has already been tested under PPTCT OR has not agreed to undergo HIV testing under PPTCT, Counselor will reassess her eligibility for inclusion in HSS. If found eligible, Counselor will fill up the data form for HSS and refer her to Laboratory Technician to collect blood specimen for routine testing (VDRL/RPR).
7. If the woman is not eligible for inclusion in HSS, she is not recruited in HSS and data form is not filled. However, she is referred to laboratory technician for blood collection for routine testing, if prescribed.
8. In all cases where blood specimen is collected from the pregnant woman, she should be informed by the laboratory technician about the time and other details to collect the test results (VDRL/RPR under routine testing & HIV under PPTCT if applicable).
9. Test results should be provided to the pregnant woman subsequently.

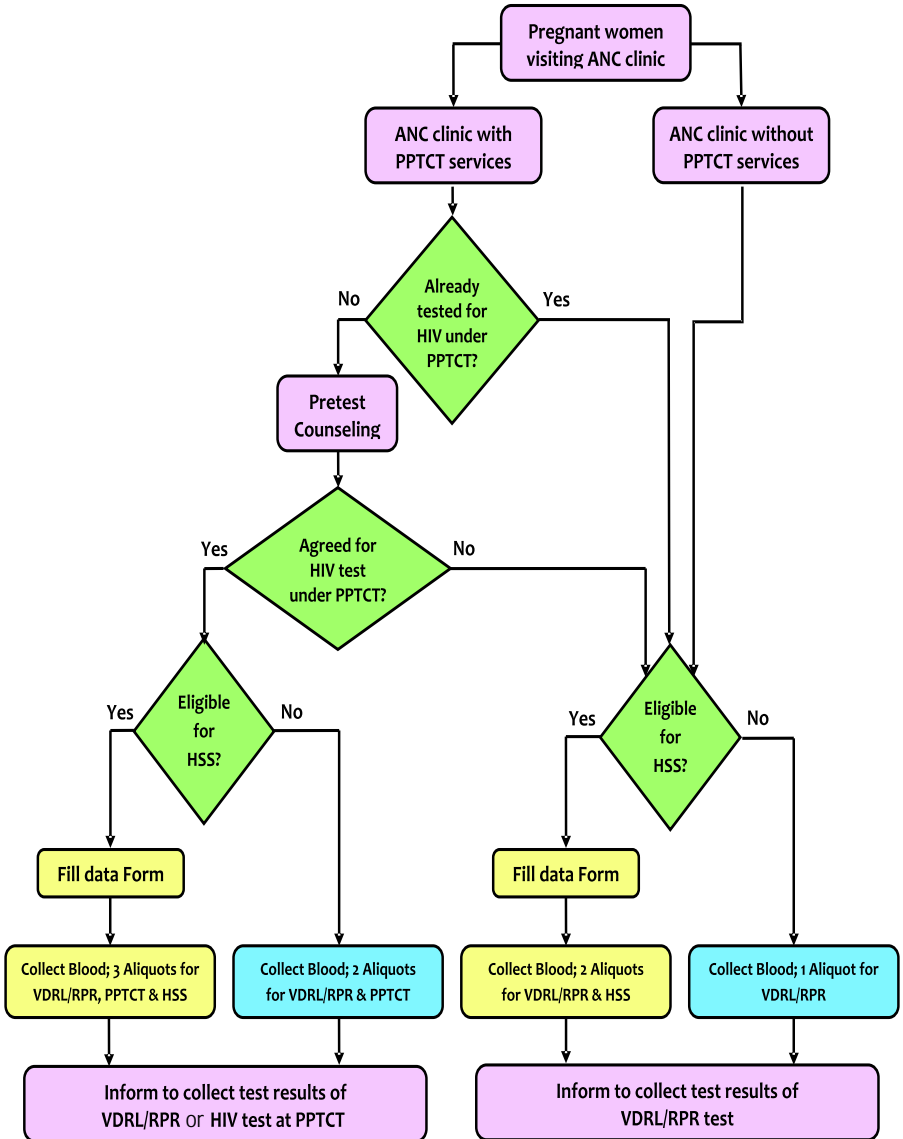
### Scenario-2: ANC sites without PPTCT services

1. Following the antenatal check up of the pregnant woman visiting the hospital/ clinic, the doctor will assess her eligibility for recruitment in HSS and refer her to the nurse, if found eligible.
2. The nurse will reassess the eligibility, fill the data form and refer her to the laboratory technician for blood collection for routine testing (VDRL/RPR).
3. If the woman is not eligible for inclusion in HSS, she is not recruited in HSS and the data form is not filled. However, she is referred to laboratory technician for blood collection for routine testing, if prescribed.
4. In all cases where blood specimen is collected from the pregnant woman for routine testing, she should be informed about the time and other details to collect the test results.
5. Results of the routine tests should be provided to the pregnant woman subsequently.

With respect to the recruitment process at ANC sites, the following points may be noted:

1. The OPD where the medical officer conducts antenatal check up and assesses eligibility for HSS, the place where nurse/counselor fills the data form and the place of blood specimen collection should be arranged as close to one another as possible, so that all steps of recruitment are completed and there is no loss of eligible individuals between one step and the next.
2. If these are situated at a distance, someone at the facility (nurse/hospital attendant) should accompany the eligible individual. If no one accompanies, there is a chance that she does not go to the nurse or laboratory technician and consecutive sampling may get affected.
3. Similarly in some hospitals where the ICTC is situated at a distance from the antenatal clinic, it may be appropriate to arrange for filling of data forms and blood specimen collection at the antenatal clinic itself and then send the pregnant woman to the counselor in the ICTC. In such cases, if the woman needs to be tested at the ICTC, arrangements should be made to ensure that the blood specimen collected earlier is used and a second specimen is not collected at the ICTC. Three serum aliquots should be prepared and one should be used for HIV testing at ICTC.

## Flow Chart 1. Recruitment Process at ANC Sentinel Site



## Flow Chart 2. Blood Specimen Management for an Eligible Individual at ANC Sentinel Sites



## 5.2. STD Site

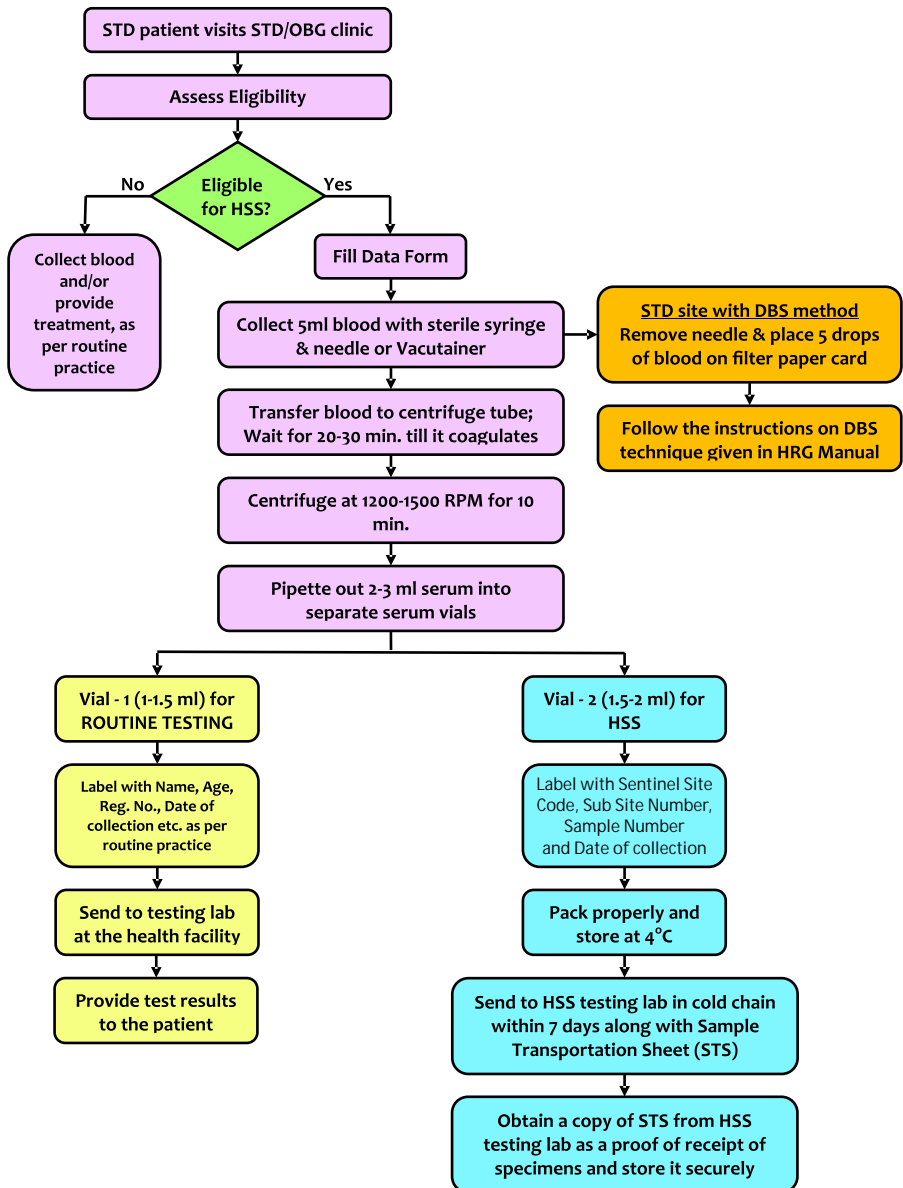
The following steps describe the recruitment process at STD sentinel site. (Flow Chart No.3)

1. Patients visiting the STD/OBG clinic will go to the doctor for check-up. After clinical examination, the doctor will assess the eligibility for inclusion of the STD patient in HSS. If found eligible, the patient will be referred to the nurse.
2. The nurse will fill the data form and refer the patient to laboratory technician for blood collection for routine testing.
3. If the patient is not eligible for inclusion in HSS, the patient is not recruited and data form is not filled. However, he/she will be referred to laboratory technician for blood collection for routine testing, if prescribed.
4. In all cases where blood specimen is collected from the patient for routine testing, he/she should be informed about the time and other details to collect the test results.
5. Results of the routine tests should be provided to the patient subsequently.

With respect to the recruitment process at STD sentinel sites, the following points may be noted.

1. Since the STD clinic and the OBG clinic of the STD sentinel site may not be located close to each other, separate arrangements should be made for filling data forms and blood specimen collection at each of the clinics.
2. If the place of blood collection is situated at a distance, someone at the facility (nurse/hospital attendant) should accompany the eligible individual. If no one accompanies him/her, there is a chance that he/she does not go to the lab technician and consecutive sampling may get affected.
3. Since eligibility of STD patients for inclusion in HSS can be ascertained only through clinical examination by doctor, once the syndrome is diagnosed, the doctor should communicate it to the nurse either by mentioning it clearly over the OPD case sheet or any other means, so that nurse can mark the appropriate option while filling the HSS data form.

## Flow Chart 3. Recruitment Process & Blood Specimen Management at STD Sentinel Site





## 6. Documentation

### 6.1. General Instructions

1. Documentation to be maintained at ANC & STD sentinel sites and norms for submission are provided in Table 1 below.
2. Only designated and trained personnel should maintain the documentation at the sentinel site.
3. Site in-charge should ensure that all the documentation at the sentinel site is properly maintained and complete.
4. All the documents should be stored securely at the site.
5. At the end of HSS, except for one copy of the STS and DFTS, NONE OF THE OTHER DOCUMENTS should be retained or photocopied for retention at the site. All documents should be dispatched from the site as per the instructions given below.
6. Unlinked Anonymous Testing strategy (UAT) should be strictly adopted at the sentinel site in all its documentation. The concept of UAT is described in Box 4.

Table 1. Documentation to be maintained at ANC & STD sentinel sites and norms for submission

S.No.	Document	Managed by	Verified by	Norms for Submission
1.	Data Forms	Nurse/ Counselor	Site In-charge	Send to Regional Institute EVERY WEEK along with Data Form Transportation Sheet
2.	Data Form Transportation Sheet (DTS)	Nurse/ Counselor	Site In-charge	Send to Regional Institute EVERY WEEK along with data forms
3.	Sample Transportation Sheet (STS)	Lab Technician	Site In-charge	Send to HSS Testing Lab EVERY WEEK along with serum specimens
4.	Supervisory Visit Register	Nurse/ Counselor	Site In-charge	Send to SACS at the end of HSS

### 6.2. Data Forms

#### 6.2.1. General Instructions for Handling Data Forms

1. The Data form is a brief questionnaire seeking information related to socio-demographic characteristics and vulnerabilities of the eligible individual.
2. The Nurse/ Counselor should fill the data form for each individual respondent.

### Box 4. Unlinked Anonymous Testing Strategy

- Testing for HIV is done on a portion of blood specimen collected for routine diagnostic purposes (such as Syphilis, Hb) after removing all personal identifiers.
  - Neither the information collected in the data form nor the HIV test result from the blood specimen should EVER be linked to the individual from whom the information/specimen is collected.
  - Neither the personnel collecting the blood specimen nor the personnel testing the blood specimen should be able to track the results back to the individual.
  - Hence, personal identifiers such as name, address, OPD registration number etc. SHOULD NOT be mentioned anywhere on the data form, blood specimen, data form transportation sheet or sample transportation sheet.
  - Similarly, the HSS sample number or any mark indicating inclusion in HSS SHOULD NOT be mentioned in the ANC register or ANC Patient/OPD Card
  - Part of the blood specimen with identifiers will be used for reporting the results of the test for which it has been collected. Part of the blood specimen without identifiers will be sent for HIV testing under HSS.
  - Report of the prescribed routine diagnostic test (e.g. syphilis test) SHOULD BE communicated to the participant.
3. Only designated & trained personnel should complete the data form.
  4. Only one data form should be completed per individual.
  5. Data forms should be filled only after confirmation of the eligibility of the attendee by the medical officer/sentinel site in-charge.
  6. Data Forms should be completed before blood specimen collection.
  7. Stamps/stickers with site details including state, district, site name, sub-site number and site code should be obtained from SACS. They should be stamped or pasted in the space provided on each data form before starting to fill the data form.
  8. The sample number should be manually written in the appropriate boxes. The same sample number should be mentioned by the lab technician on the blood specimen sent to the HSS testing lab.
  9. To ensure Unlinked Anonymous Testing, any personal identifiers such as name, address, OPD/ANC registration number etc., which could link the data form to an individual, should not be mentioned anywhere on the data form.
  10. Data forms should be filled neatly and legibly, without any overwriting and strike marks. In case of an error while filling the form, use a fresh data form.

11. The person completing the form is advised to use a hard ball point pen to complete the data form. Ink pens may cause seepage and may make the entries illegible.
12. Except for two questions (Age & Duration of stay at current residence) where the appropriate number of years/months should be written, for all the other questions, responses should be recorded by CIRCLING the appropriate option.
13. Only one appropriate option should be circled. Circling more than one option will be considered invalid. The only exception to this rule is the syndromic diagnosis question in the STD data form where multiple options are allowed.
14. Each and every question on the form should be completed.
15. Besides the specified information, nothing else should be written on the data forms.
16. Data forms should not be handed over to the participants.
17. The person completing the data forms should check for completeness, write his/her name, sign and date.
18. The Laboratory Technician must check that all questions in the data form are completed or not, before collecting blood specimen. If response is not recorded for any question, it should be sent back to the nurse/counselor so that information may be collected when the individual is still in the facility.
19. Completed data forms should be kept securely at the sentinel site.
20. The Site in-charge should verify the completed data forms every day and then sign and date. Blank data forms should NEVER be signed in advance.
21. If there are any issues or mistakes in filling the data forms, the site in-charge should discuss with the concerned staff and guide them.
22. Completed data forms should be sent to the respective RI every week.
23. In case of composite sites and STD sentinel sites, the data forms from all sub-sites/STD & OBG clinic should be compiled at the main site and sent together to the RI.

### 6.2.2. Instructions to Fill Data Forms

The following sections present the instructions to fill data forms. Instructions for questions that are common between ANC & STD data forms are presented first. Instructions for questions that are specific to ANC data form (Order of Pregnancy) & STD data form (Sex, Marital Status & Syndromic Diagnosis) are presented subsequently.

**Box 5. Sub-site Number & Sample Number**

Sub-site Number:

In case of composite sites, write the sub-site number allotted by SACS from 1-5, incase of a single site, write '0'. In case of STD sentinel sites, the STD clinic may be given the sub-site no.1 & the OBG clinic may be given the sub-site no.2.

Sample Number:

The sample number at each site and sub-site should begin from '001'. If some of the samples are found to be invalid at the testing lab and the site is asked to collect additional samples, these additional samples should be given fresh sample numbers after 400/250/x (where x is the sample size allotted to a sub-site). The sample number of the invalid sample SHOULD NOT be given to these additional samples. The following example illustrates these points:

Eg 1. At a sub-site with the allotted number '2' with an allotted sample size of 050, the sub-site number should be mentioned as '2' and sample numbers should be given from 001 to 050, successively. Sample numbers 020, 034 & 042 are found to be invalid at HSS testing lab. The three additional samples that will be collected at the sub-site no.2 should be given the sample numbers 051, 052 & 053.

Eg 2. At an ANC single site, the sub-site number should be mentioned as '0' and sample numbers should be from 001 to 400, successively. If four samples were found to be invalid, the additional four samples should be given sample numbers 401, 402, 403 & 404.

Sample Code = Sentinel Site Code + Sub-site number + Sample number  
 (12 digits)                      (8 digits)                      (1 digit)                      (3 digits)

**Instructions for questions common to ANC & STD data forms**

Question/Field	Description / Instructions
Box with site and sample details	Stamp or place the sticker in the empty box on the right with details of state, District, site name, site code and sub site number.  Write the following 2 items manually. 1. Sample number    2. Date of sample collection  If stamp/stickers are not provided by SACS, manually enter all these details in the box on the left.

1. Age	Write the age of the participant in completed years.
2. Literacy status	<p>Circle the appropriate educational category using the explanation given below:</p> <ol style="list-style-type: none"> <li>1. Illiterate: Without any formal or non-formal education</li> <li>2. Literate and till 5th standard: Those with non-formal education or those who joined school but not studied beyond 5th standard</li> <li>3. 6th to 10th standard: Those who studied beyond 5th standard but not beyond 10th standard</li> <li>4. 11th to Graduation: Those who studied beyond 10th standard but not beyond graduation. Includes those with technical education/diplomas.</li> <li>5. Post Graduation: Those who studied beyond graduation</li> </ol>
4. Source of Referral	Enquire about who referred the woman for ANC visit. Government health care providers include ANM, ASHA, doctors / nurses at PHC, CHC, etc. Circle the appropriate option.
5. Current Place of residence	<p>Enquire if the current place of residence of the respondent (the place she is living with her husband) falls under Municipal Corporation or Municipal Council or Cantonment Area.</p> <ul style="list-style-type: none"> <li>- If yes, circle the first option (Urban).</li> <li>- If no, circle the second option (Rural).</li> </ul> <p>Don't write the name of the place.</p>
6. Duration of Stay	<p>Enquire the duration of stay at the current place of residence (the place she is living with her husband) and write the response in years and months.</p> <ul style="list-style-type: none"> <li>- If the duration is less than one year, write '0' years and the number of months as reported by the respondent.</li> <li>- If the duration is less than one month, write '0' years, '1' month.</li> </ul>
7. Occupation of Respondent	Circle the appropriate current occupation of the respondent using the explanations given below. Only the categories which need some elaboration are explained below.

	<ol style="list-style-type: none"> <li>1. Non-Agricultural Labourer: includes workers at construction sites, quarries, stone crushers, road or canal works, brick-kilns, etc.</li> <li>2. Skilled/ Semi-skilled worker: includes workers in small-scale or cottage industries; industrial/ factory workers; technicians such as electricians, masons, plumbers, carpenters, goldsmiths, iron-smiths, those involved in automobile repair works etc.; artisans such as weavers, potters, painters, cobblers, shoe-makers, tailors etc.</li> <li>3. Petty business/small shop: Includes vendors selling vegetables, fruits, pan shop, milk, newspapers, etc.</li> <li>4. Large business/ self-employed: Includes professionals and businessmen</li> <li>5. Service: Those working on salary basis in government, private or institutional sector excluding drivers, hotel staff.</li> </ol>
8. Occupation of Spouse	Same as occupation of the respondent (Question no. 7). If the person in question was never married / widow/ widower, circle option '99' (not applicable)
9. Migration Status	This question is asked to understand migration status of the spouse. If the spouse usually happens to live away from the wife for longer than 6 months in a year, then circle 'Yes', otherwise, circle 'No'. If the woman is widowed or never married/ divorced/separated, circle the third option 'Not Applicable'.

### Instructions for questions specific to ANC data form

Question/Field	Description / Instructions
3. Order of Pregnancy	The order of pregnancy denotes the number of times a woman has become pregnant. It includes the number of live births, still births and abortions. Enquire about each of the above and add them to arrive at the order of pregnancy. Circle the appropriate number.

## Instructions for questions specific to STD data form

Question/Field	Description / Instructions
2. Sex	This would be important only at STD clinic where both males and females could be recruited. In OBG clinic, obviously, all participants are females.
3. Marital status	Encircle appropriate option depending on whether the participant was never married, or currently married, or divorced/separated/widowed.
10. Syndromic Diagnosis	Circle the appropriate option/s for the Syndromic diagnosis of STD, as diagnosed by the physician. It is possible that the same person may have more than one syndromic diagnosis, in which case, all the corresponding options should be encircled. This is the only question where multiple answers are allowed.

### 6.3. Data Form Transportation Sheet

- As mentioned earlier, the responsibility of sending the data forms along with the data form transportation sheet is primarily that of the nurse/Counselor.
- A properly filled data form transportation sheet (Annex 3), in duplicate, should accompany each set of data forms. One more copy should be retained at the sentinel site.
- Clearly write the name and complete address of the sentinel site/sub-site, including district and state.
- Mention the type of sentinel site (ANC/STD), write the site code and sub-site number.
- The period of sample collection i.e the period for which data forms are being sent, should be written in dd/mm/yy format.
- Write the total number of data forms and the number of envelopes (containing the data forms) being sent.
- In the table, write the date of collection and sample number of each sample, whose data forms are being sent.
- If the space provided in the table is not sufficient, please attach another sheet.

9. The sender should write legibly his / her name and telephone number and sign at the designated place before sending the data forms.
10. Also write the date of dispatch of the data forms.
11. The name, signature of the person receiving the data forms and date of receiving the data forms at the RI will be written by the recipient and one of the two sheets will be returned to sentinel site.
12. The signed copy of data form transportation sheet received from the RI should be securely stored for any future reference.

#### 6.4. Sample Transportation Sheet

1. The responsibility of sending the blood specimens and the sample transportation sheet is primarily that of the laboratory technician.
2. A properly filled sample transportation sheet (Annex 4), in duplicate, should accompany each set of blood specimens sent to the HSS testing lab. One more copy should be retained at sentinel site.
3. Clearly write the name and complete address of the sentinel site, including the district and state.
4. Mention the type of sentinel site (ANC/STD) and write the site code as well as sub-site number.
5. The period of sample collection i.e the period for which the current batch of blood specimens are being sent, should be written in dd/mm/yy format.
6. Write the total number of blood specimens and the number of sample transportation boxes (containing the blood specimens) being sent.
7. In the table, write the date of collection and sample number of each blood specimen being sent.
8. If space provided in the table is not sufficient, please attach another sheet.
9. The sender should write legibly his / her name and telephone number and sign at the designated place before sending the blood specimens.
10. Also write the date of dispatch of the blood specimens.



11. The name, signature of the person receiving the blood specimens and date of receiving the blood specimens at HSS testing laboratory will be written on the sample transport sheet by the recipient at the lab by the recipient and one of the two sheets will be returned to sentinel site.
12. The signed copy of STS received from the HSS testing lab should be securely stored for any future reference.

### 6.5. Supervisory Visit Register

1. Every site & sub-site should maintain one register where supervisors who visit the site/sub-site can record their observations and recommendations.
2. The site/sub-site personnel should take corrective action as recommended in the register.
3. This will also enable supervisors, who visit the site/sub-site subsequently, to know previous observations and verify if action has been taken or not.
4. Please refer to Annex-5 for the implementation structure of HIV Sentinel Surveillance.

## 6.6.Examples of wrong practices of filling Data Form of ANC and Sample Transportation Sheet

**HSS 2010: Data Form for Antenatal Clinic Attendees (ANC)**  
*(Please fill the site details in the box below OR Paste the sticker with site details/ Stamp the site details in the empty box.)*

State: \_\_\_\_\_ District: \_\_\_\_\_  
 Site Name: \_\_\_\_\_  
 Site Code: (Sub-site No.) Sample No. Date: DD/MM/YY

1. Age (in completed years) \_\_\_\_\_

2. Literacy Status  
 1. Illiterate  2. Literate and till 5th standard  3. 6th to 10th standard  4. 11th to Graduation  5. Post Graduation

3. Order of Current Pregnancy \_\_\_\_\_

Fig 1: The age field should not be left blank in the data form

**HSS 2010: DATA FORM FOR PATIENTS ATTENDING STD/ GYN CLINICS (STD)**  
*(Please fill the site details in the box below OR Paste the sticker with site details/ Stamp the site details in the empty box.)*

State: \_\_\_\_\_ District: \_\_\_\_\_  
 Site Name: \_\_\_\_\_  
 Site Code: (Sub-site No.) Sample No. Date: DD/MM/YY

1. Age (in completed years): 50

2. Sex of the participant:  1. Male  2. Female

3. Marital status:  1. Never married  2. Married  3. Divorced/separated/widowed

4. Literacy Status  
 1. Illiterate  2. Literate and till 5th standard  3. 6th to 10th standard  4. 11th to Graduation  5. Post Graduation

Fig 2: The age mentioned in this form does not fall within the inclusion criteria of HSS i.e. 15-49 years

**HSS 2010: Data Form for Antenatal Clinic Attendees (ANC)**  
*(Please fill the site details in the box below OR Paste the sticker with site details/ Stamp the site details in the empty box.)*

State: \_\_\_\_\_ District: \_\_\_\_\_  
 Site Name: \_\_\_\_\_  
 Site Code: (Sub-site No.) Sample No. Date: DD/MM/YY

1. Age (in completed years) 25

2. Literacy Status  
 1. Illiterate  2. Literate and till 5th standard  3. 6th to 10th standard  4. 11th to Graduation  5. Post Graduation

Fig 3: It is mandatory to fill the Site code, Sub-site No, Sample No and the Date in DD/MM/YY format in the data form

9. Does spouse reside alone in another place/ town away from wife for work for longer than 6 months?

1. Yes  2. No  99. Not Applicable (For widows /unmarried women)

Signature \_\_\_\_\_ Signature \_\_\_\_\_

Name \_\_\_\_\_ Name \_\_\_\_\_  
(Person filling the form) (In charge of the Surveillance Site)

Fig 4: The data form should be duly signed by the In-charge of the Surveillance Site. Otherwise it is considered as an incomplete form.

PHS 2018: Data Form for Antenatal Clinic Attendance (ANC)

1. Age (in completed years) \_\_\_\_\_

2. Education \_\_\_\_\_

3. Highest level of education \_\_\_\_\_

4. Highest level of completed education \_\_\_\_\_

5. Number of children in the ANC clinic \_\_\_\_\_

6. Current place of residence \_\_\_\_\_

Fig 5: Data form should be filled without over writing & strike mark. In case of an error while filling the form, use a fresh data form

Ministry of Health, Government of Karnataka  
Department of Health Services  
Directorate of Family and Community Health Services, Government of Karnataka  
PHS 2018: TRANSPORTATION SHEET FOR SAMPLE COLLECTION FROM ANC/SENTINEL SITES

1. Name of the Site \_\_\_\_\_

2. No. of Forms of S/N \_\_\_\_\_

3. Name of the Site \_\_\_\_\_

4. No. of Forms of S/N \_\_\_\_\_

5. Name of the Site \_\_\_\_\_

6. No. of Forms of S/N \_\_\_\_\_

S/N	Date of Collection	Name of Client	Age	Sex	Religion	Education	Occupation	Address
1	20/10/2018	...	...	...	...	...	...	...
2	20/10/2018	...	...	...	...	...	...	...
3	20/10/2018	...	...	...	...	...	...	...
4	20/10/2018	...	...	...	...	...	...	...
5	20/10/2018	...	...	...	...	...	...	...
6	20/10/2018	...	...	...	...	...	...	...
7	20/10/2018	...	...	...	...	...	...	...
8	20/10/2018	...	...	...	...	...	...	...
9	20/10/2018	...	...	...	...	...	...	...
10	20/10/2018	...	...	...	...	...	...	...

Fig 6: In the Data Form Transportation Sheet, the total number of forms should tally with the details of the Sample Numbers whose data forms are being sent. Sample number should not be repeated at the site

## 7. Standard Operating Procedures for Processing Blood Specimens

### 7.1. Consumables Required for Blood Collection

1. Cotton with spirit
2. Vacutainer tube & tube holder or Needle & Syringe
3. Centrifuge tube
4. Latex hand gloves
5. Tourniquet
6. Adhesive bandage
7. Test tube stand
8. Needle destroyer
9. Puncture proof sharps disposal container
10. Pipette/Micro pipette with tips
11. Plastic serum vials
12. Labels
13. 1% Sodium hypochlorite solution

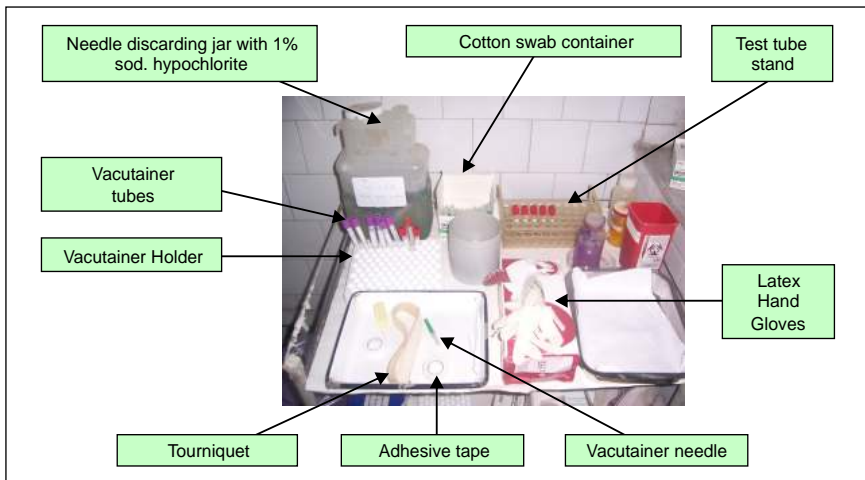


Fig 7 : Consumables required for blood collection

### 7.2. Blood Specimen Collection

Step 1 :

- Observe all universal precautions at all times by wearing gloves, lab coat & safety glasses.
- Collect 5 ml blood by venipuncture in pre-labeled vacutainer/centrifuge tubes
- Prepare and label the tube for blood collection with name, reg. no. etc. as per routine practice, only one tube at a time.
- Keep this single labeled tube in test tube rack to avoid picking up the wrong tube for specimen collection.



Fig 8 : Red Top vacutainer tube

Step 2 :

- Remove the rear protective cover (white) of the needle.
- Fix the rear end of the needle to the holder.
- Remove the forward / front protective cover of the needle (green).
- If blood is collected using needle & syringe, take a sterile disposable syringe & needle.



Fig 9 : Assembling the vacutainer system

Step 3 :

- The respondent made to sit on the chair and asked to Incline the arm in a downward position.
- Ask the respondent to clench and unclench the fist.
- Lightly tap the vein.
- Apply tourniquet.



Fig 10 : suggested position of the arm for blood specimen collection

Step 4 :

- Disinfect the puncture site carefully and thoroughly.
- Wipe the skin surface with a cotton swab containing spirit or alcohol solution.
- Wipe in an outward moving circular motion. When dry, collect blood specimen.



Fig 11 : Disinfecting the puncture site for blood specimen collection

Step 5 :

- Slowly insert the needle with the holder/syringe into the lumen of the vein.
- Hold the puncture device/syringe firmly to avoid any jerking movement with the needle in place to avoid unnecessary pain for the patient.



Fig 12 : Inserting needle into the vein

Step 6 :

- Hold the needle holder firmly and gently insert the vacutainer tube into the holder.
- Press the tube gently into the rear end of the needle in the holder so that the rear end of the needle penetrates the rubber top of the tube.
- Now the blood will flow into the tube.



Fig 13 : Inserting vacutainer tube into needle holder

- Holding the puncture device firmly gently remove the tube from the holder.
- If needle & syringe are used, gently pull the piston of the syringe to draw 5 ml blood into the syringe barrel.
- Placing cotton on the punctured site, gently remove the needle from the vein.
- Holding the puncture device/syringe in one hand, release the tourniquet completely.



Fig 14 : Removing vacutainer tube from needle holder

Step 7 :

- Place the vacutainer tube with blood specimen in the test tubercrack .
- If needle & syringe are used, remove the needle and transfer the blood into the pre-labeled centrifuge tube from the syringe. Place the centrifuge tube with blood specimen in the test tubercrack .



Fig 15 : Place vacutainer/centrifuge tube with blood specimen in the rack

Step 8 :

- Cover the puncture site with a sterile adhesive bandage. (Fig 16)
- Destroy the needle using the needle-cutter and discard it into the puncture proof discarding jar/sharps disposal container having 1% sodium hypochlorite solution. (Fig17)
- Discard the gloves, cotton swab and guaze piece into the waste bucket with the yellow bag. (Fig 18)



Fig 16 : Apply adhesive tape over puncture site



Fig 17 : Discard needle in puncture proof container



Fig 18 : Use appropriate waste basket

## 7.3. Sample Processing

### Step1:

- The blood specimen is allowed to stand for at least 20-30 minutes until the formation of clot before centrifugation.
- The blood specimen is centrifuged to separate the serum. Care must be taken to balance the vacutainer/ centrifuge tubes in the centrifuge, in order to prevent agitation and there by hemolysis.



Fig 19 : Blood specimen is allowed to stand before centrifugation

### Step2:

- The specimen should be centrifuged at 1,200 to 1,500 RPM for 10 minutes.
- Meanwhile, label the cryovials/serum vials into which serum will be transferred after centrifugation and keep them ready.
- Do not use glass tubes for storing specimens. Use only plastic vials.
- Determine the number of aliquots to be prepared from each blood specimen and prepare the labels accordingly. (Refer to Box 6 below)



Fig 20 : Centrifugation of blood specimens



Fig 21 : Blood specimen after centrifugation

### Box 6. Determining the Number of Aliquots to be Prepared (Refer Flow Charts 1 & 3)

- At an ANC sentinel site with PPTCT services, if the woman is not registered for PPTCT/not tested for HIV under PPTCT earlier and if she agrees to get tested for HIV under PPTCT now, and
  - If HSS data form has been filled for the woman, then prepare 3 aliquots - one for routine testing (VDRL/RPR), second for HIV test under PPTCT and the third for HSS.
  - If HSS data form has NOT been filled for the woman, then prepare 2 aliquots - one for routine testing (VDRL/RPR) and the second for HIV test under PPTCT.
- (i) At an ANC sentinel site with PPTCT services, if the woman had already been tested for HIV under PPTCT, (ii) at an ANC sentinel site with PPTCT services, if the woman does not agree for HIV test under PPTCT now, (iii) at an ANC sentinel site without PPTCT services and (iv) at an STD sentinel site,
  - If HSS data form has been filled for the respondent, then prepare 2 aliquots - one for routine testing (VDRL/RPR) and the second for HSS.
  - If HSS data form has not been filled for the respondent, then prepare 1 aliquot for routine testing (VDRL/RPR).



Step 3 : (Refer Flow Charts 2 & 3)

- Aliquot for routine testing (VDRL/RPR) and aliquot for HIV test under PPTCT should be labelled with personal identifiers (Name, Reg.No., Age, Sex, Date etc.) as per the routine practice.
- ALIQUOT FOR HSS SHOULD BE LABELED WITH HSS SITE CODE, SAMPLE NUMBER, SUB-SITE NUMBER AND DATE OF COLLECTION. No personal identifiers should be mentioned on HSS specimen, to ensure Unlinked Anonymous Testing.
- Make sure that the label is placed on the side of the tube, not on the cap.
- Only water resistant markers or lead pencil only should be used for labeling. Avoid use of ink or gel pens.
- Ensure that the HSS sample number is written only on the designated vial and the data collection form. It should not be recorded in the logbook or in any other place where it could be traced back to the patient.

Step 4 :

- After the specimen is centrifuged, transfer 0.5 ml of serum to the required number of sterile labeled serum vials (plastic, not glass) or cryovial (2.0 ml with screw cap) using a clean pipette (disposable plastic pipettes or micropipette with disposable tips).
- DO NOT POUR the serum from one tube to another. USE a pipette.
- Use separate pipette tips for each specimen.
- Make sure that the screw cap is tightly closed on the labeled cryovial or serum vial.
- After serum separation, the centrifuge tube with the clot should be decontaminated by autoclaving. Subsequently, tubes can be washed, cleaned & re-used.



Fig 22 & 23 : Aliquoting the serum

Step 5 :

- Send the vial for routine testing to the concerned testing lab at the facility and return test results to the respondent subsequently.
- Send the vial for PPTCT to ICTC laboratory and return the test result subsequently.
- Store the vial for HSS at 4°C in the refrigerator UPTO A MAXIMUM OF SEVEN DAYS.
- Do not freeze. Do not de-frost the refrigerator when specimens are stored.



Fig 24 : Storage of HSS serum specimens



## 7.4. Packaging and Transportation of Specimens

### Step 1 :

- Check that each vial is tightly closed and sealed.
- Seal each vial with 'parafilm', just before transportation.
- The surface should be dried to ensure proper sticking of the film.
- Tightly wrap the parafilm on the junction of the cap & vial.



Fig 25 & 26 : Securing serum vials

### Step 2 :

- Sealed vials are packed in a proper sample transportation box with a numbered lid so that the serum specimens remain upright during transportation.
- Do not transport any other material in this box.
- This container should be placed in a double plastic bag and sealed well.



Fig 27 : Proper Sample Transportation Box

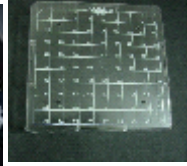


Fig 28 : Numbered Lid of Sample Transportation Box



Fig 29 & 30 : Proper way of transporting serum specimens



### Step 3 :

- Place the sample transportation box in a vaccine carrier/ice box containing adequate number of pre-chilled cold packs to produce an ambient temperature of 4°C within the box for the duration of the journey.



Fig 31 : Placing sample containers in bigger box

### Step 4 :

- The serum specimens are transported to the testing laboratory on a weekly basis.
- Ensure that the specimens are delivered to the testing laboratory during working hours only (Ensure that its not a holiday before you leave).
- The samples should be accompanied by a duly completed and signed sample transportation sheet in duplicate.
- Once packed, the samples should reach the testing laboratory directly and there should be no deviation en route.
- The samples should remain in the fridge until the last moment and should not be taken home or elsewhere.

Step 5 :

- On reaching the HSS testing lab, the specimens along with the STS should be handed over to the testing lab in-charge or lab technician.
- Please wait while the samples are verified.
- Take back with you a signed copy of sample transport sheet and verification checklist.
- This should be handed over to the sentinel site in-charge on return and kept in a file for future reference.

## 7.5. Instructions for ANC/STD Sites where Dried Blood Spot (DBS) Technique is Implemented

1. At remotely located ANC/STD sites where sample transportation and cold chain maintenance have consistently been a problem, the venous blood specimens will be used to prepare Dried Blood Spots.
2. Collect 2-3 ml blood from the eligible respondent using syringe & needle as described earlier in this section. Do not use vacutainer for drawing blood.
3. After collecting the blood specimen, remove the needle from the syringe and discard it as per the instructions.
4. IMMEDIATELY, transfer the blood specimen into a centrifuge tube and gently place 50µl of blood over the center of each circle on the filter paper card using a pipette/micro-pipette.
5. This should be done immediately after the collection of the blood specimen, as Dried Blood Spots should be made with fresh, whole blood.
6. For all other instructions on handling filter paper cards & other consumables, preparing the DBS specimens, labelling, drying, packing, storage and transport, please refer to Section 7 of the Operational Manual for HRG Sentinel Sites.

## 7.6. Examples of wrong practices of specimen processing



Fig 32 : Wrong practice of recapping the needle; Wrong practice of allowing blood to clot in the syringe itself. After collection, blood should immediately be transferred to the centrifuge tube and the tube should be allowed to stand for 20-30 minutes for clot formation, before centrifugation.



Fig 33 : Serum vials used in different states; Screw capped vials with O-ring should be used for holding serum.



Fig 34 : Varying Quality of Sera at the Sentinel Site



Fig 35 : Wrong practice of packing serum vials using rubber bands leads to chances of cross-contamination



Fig 36 : Sample Transportation Box or Tiffin Box for School Kids? Use appropriate sample transportation box with numbered lid to avoid leakage of specimens during transport



Fig 37 : Sharps Disposal container not used for discarding needles.

## 8. Bio-Waste Management

It is essential to follow universal safety precautions at all points in the specimen collection, storage, testing, transportation and disposal of bio-hazardous wastes. The Laboratory Technician should take the responsibility of implementing safe bio-waste management procedures at the sentinel site under active supervision of the sentinel site in-charge. Colour-coded waste-bags should be used as per standard specification for disposal of waste materials and contaminated sharps.

- Used needles and syringes should be disposed off by using a needle cutter. After crushing the hub of the needles, they should be put in a puncture proof container containing freshly prepared 1% sodium hypochlorite solution. At the end of each day's work, the contents of the container should be put in a bio-waste bag (Blue-Bag) and disposed off as per the standard procedure at the site.
- Alcohol swabs, gloves and guaze pieces should be discarded into the Biohazard Waste Bag. (Yellow Bag)
- General waste such as the wrapper of gloves, papers etc. Should be discarded in the bio-waste bag (black bag).
- The biohazard waste bags should be sent for final disposal as per the standard procedures at the site.
- Any spillage of potentially dangerous material should be properly cleaned and decontaminated following standard procedures

Table 2. Preparation of 1% Sodium Hypochlorite Solution (10g/L- 10,000 ppm)

Parts of stock solution: parts of water			
4% stock Solution	5% stock Solution	10% stock Solution	15% stock Solution
1:4*	1:5*	1:10*	1:15*

## 9. Management of Needle Stick Injury

- Needle stick, puncture wounds, cuts, open skin contaminated by spills or splashes should be washed thoroughly with soap and water.
- Report the injury to the laboratory in-charge or site in-charge as the case may be; the person should be assessed for Post Exposure Prophylaxis (PEP)
- PEP, preferably should be started within 2 hours and no later than 72 hours of the accidental exposure for maximum benefit
- Appropriate medical evaluation, treatment and counseling should be provided
- For details on PEP, please refer to Guidelines for Post Exposure Prophylaxis nested within the document: "Antiretroviral Therapy Guidelines for HIV infected Adults and Adolescents including Post-exposure"; downloadable at [http://www.nacoonline.org/Quick\\_Links/Publication/Treatment\\_Care\\_Support/](http://www.nacoonline.org/Quick_Links/Publication/Treatment_Care_Support/)



<b>6. Duration of Stay at Current Place of Residence / वर्तमान निवास स्थान में ठहरने की अवधि</b>	<input type="text"/>	years / वर्ष	<input type="text"/>	months / महीने
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<b>7. Current Occupation of the Respondent / प्रतिवादी का वर्तमान व्यवसाय</b>	<ol style="list-style-type: none"> <li>1. Agricultural Labourer / कृषि श्रमिक</li> <li>2. Non-Agricultural Labourer / गैर कृषि श्रमिक</li> <li>3. Domestic Servant / घरेलू नौकर</li> <li>4. Skilled / Semiskilled worker / कुशल / अर्धकुशल श्रमिक</li> <li>5. Petty business / small shop / लघु उद्योग / छोटी दुकान</li> <li>6. Large Business/Self employed/वित्तृत उद्योग / स्वरोजगार</li> <li>7. Service (Govt./Pvt.) / कर्मचारी (सरकारी / निजी)</li> <li>8. Student / विद्यार्थी</li> <li>9. Truck Driver/helper / ट्रक चालक / सहायक</li> <li>10. Local transport worker (auto/ taxi driver, handcart pullers, rickshaw pullers etc./ स्थानीय परिवहन कर्मचारी (ऑटो/ टैक्सी ड्राइवर, ठेलेवाले, रिक्शेवाले)</li> <li>11. Hotel Staff / होटल कर्मचारी</li> <li>12. Agricultural cultivator / landholder / कृषक / जमींदार</li> <li>14. Housewife / गृहणी</li> </ol>
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<b>8. Current Occupation of the Spouse / प्रतिवादी के पति का वर्तमान व्यवसाय</b>	<ol style="list-style-type: none"> <li>1. Agricultural Labourer / कृषि श्रमिक</li> <li>2. Non-Agricultural Labourer / गैर कृषि श्रमिक</li> <li>3. Domestic Servant / घरेलू नौकर</li> <li>4. Skilled / Semiskilled worker / कुशल / अर्धकुशल श्रमिक</li> <li>5. Petty business / small shop / लघु उद्योग / छोटी दुकान</li> <li>6. Large Business/Self employed/वित्तृत उद्योग / स्वरोजगार</li> <li>7. Service (Govt./Pvt.) / कर्मचारी (सरकारी / निजी)</li> <li>8. Student / विद्यार्थी</li> <li>9. Truck Driver/helper / ट्रक चालक / सहायक</li> <li>10. Local transport worker (auto/ taxi/ personal driver, handcart pullers, rickshaw pullers etc./स्थानीय परिवहन कर्मचारी (ऑटो/ टैक्सी/ व्यक्तिगत ड्राइवर, ठेलेवाले रिक्शेवाले)</li> <li>11. Hotel Staff / होटल कर्मचारी</li> <li>12. Agricultural cultivator / landholder / कृषक / जमींदार</li> <li>13. Unemployed / बेरोजगार</li> <li>99. Not Applicable (For Never married/Widowed/Divorced/Separated) / लागू नहीं होता (अविवाहिता/ विधवा / तलाकशुदा/ अलग महिलाओं के लिए)</li> </ol>
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<b>9. Does spouse reside alone in another place/ town away from wife for longer than 6 months? / क्या प्रतिवादी के पति उनसे दूर काम के लिए 6 महीनों से ज्यादा किसी दूसरे स्थान पर रहते हैं?</b>	<ol style="list-style-type: none"> <li>1. Yes / हाँ</li> <li>2. No / नहीं</li> <li>99. Not Applicable (For Never married/Widows/Divorced/Separated) / लागू नहीं होता (अविवाहिता/ विधवा / तलाकशुदा/ अलग महिलाओं के लिए)</li> </ol>
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**Signature / हस्ताक्षर :** \_\_\_\_\_

**Name / नाम :** \_\_\_\_\_

(Person who filled the form/  
 व्यक्ति जिसके द्वारा फार्म भरा गया)

Signature / हस्ताक्षर : \_\_\_\_\_  
 Name / नाम : \_\_\_\_\_  
 (Sentinel site in-charge/  
 सेन्टिनल साइट के प्रभारी)





<b>7. Duration of Stay at Current Place of Residence / वर्तमान निवास स्थान में ठहरने की अवधि</b>	<input type="text"/>	years / वर्ष	<input type="text"/>	months / महीने
<b>8. Current Occupation of the Respondent / प्रतिवादी का वर्तमान व्यवसाय</b>				
1. Agricultural Labourer / कृषि श्रमिक 2. Non-Agricultural Labourer / गैर कृषि श्रमिक 3. Domestic Servant / घरेलू नौकर 4. Skilled / Semiskilled worker / कुशल / अर्धकुशल श्रमिक 5. Petty business/small shop / लघु उद्योग / छोटी दुकान 6. Large Business/Self employed / विस्तृत उद्योग / स्वरोजगार 7. Service (Govt./Pvt.) / कर्मचारी (सरकारी / निजी) 8. Student / विद्यार्थी 9. Truck Driver/helper / ट्रक चालक / सहायक 10. Local transport worker (auto/ taxi/ personal driver, handcart pullers, rickshaw pullers etc./स्थानीय परिवहन कर्मचारी (ऑटो/ टैक्सी/ व्यक्तिगत ड्राइवर, देलेवाले रिक्शेवाले) 11. Hotel Staff / होटल कर्मचारी 12. Agricultural cultivator/landholder / कृषक / जमींदार 13. Unemployed / बेरोजगार 14. Housewife / गृहणी				
<b>9. Current Occupation of the Spouse / प्रतिवादी के पति / पत्नी का वर्तमान व्यवसाय</b>				
1. Agricultural Labourer / कृषि श्रमिक 2. Non-Agricultural Labourer / गैर कृषि श्रमिक 3. Domestic Servant / घरेलू नौकर 4. Skilled / Semiskilled worker / कुशल / अर्धकुशल श्रमिक 5. Petty business / small shop / लघु उद्योग / छोटी दुकान 6. Large Business/Self employed/विस्तृत उद्योग / स्वरोजगार 7. Service (Govt./Pvt.) / कर्मचारी (सरकारी / निजी) 8. Student / विद्यार्थी 9. Truck Driver/helper / ट्रक चालक / सहायक 10. Local transport worker (auto/ taxi/ personal driver, handcart pullers, rickshaw pullers etc./स्थानीय परिवहन कर्मचारी (ऑटो/ टैक्सी/ व्यक्तिगत ड्राइवर, देलेवाले रिक्शेवाले) 11. Hotel Staff / होटल कर्मचारी 12. Agricultural cultivator /landholder / कृषक / जमींदार 13. Unemployed / बेरोजगार 14. Housewife / गृहणी 99. Not Applicable (For Never married/Widows/Divorced/Separated) / लागू नहीं होता (अविवाहित/विधवा/विधुर/ तलाकशुदा/अलग के लिये)				
<b>10. Syndromic Diagnosis of STD (Multiple options are allowed) / यौन संचारित रोगों का सिंड्रोमिक निदान (एक से अधिक विकल्प चुनने की अनुमति है)</b>				
1. Ano-genital Ulcer / यौन अंगों/गुदा द्वार में घाव 2. Urethral discharge/Cervical discharge / यौन अंगों से स्राव 3. Genital Ulcer & Urethral Discharge/ Cervical discharge / यौन अंगों/ गुदा द्वार में घाव और स्राव 4. Ano-genital/Warts / यौन अंगों/ गुदा द्वार में मससे				
(The following question has to be asked ONLY FOR FEMALE RESPONDENTS. For Male Respondents, circle 99. निम्नलिखित प्रश्न केवल महिलाओं से पूछें। पुरुषों के लिए 99 गोल करें)				
<b>11. Does husband reside alone in another place/town away from wife for longer than 6 months? / क्या प्रतिवादी के पति उनसे दूर काम के लिए 6 महीनों से ज्यादा किसी दूसरे स्थान पर रहते हैं?</b>				
1. Yes / हाँ 2. No / नहीं 99. Not Applicable (For Never married/Widows/Divorced/Separated/ Male Respondent) / लागू नहीं होता (अविवाहित/विधवा महिलाओं/तलाकशुदा/अलग/पुरुषों के लिये)				
<b>Signature / हस्ताक्षर :</b> _____				
<b>Name / नाम :</b> _____ (Person who filled the form/ व्यक्ति जिसके द्वारा फार्म भरा गया)				
<b>Signature / हस्ताक्षर :</b> _____ (Sentinel site in-charge/ सेंटिनल साइट के प्रभारी)				

## DATA FORM TRANSPORTATION SHEET

(To be sent in duplicate along with Data Forms)

1. Name and Complete Address of the Sentinel Site/Sub-site (Tick whichever is applicable) \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_ District: \_\_\_\_\_ State: \_\_\_\_\_
2. A) Type of Site: \_\_\_\_\_ B) Site Code:         C) Sub-site No.
3. Period of Sample Collection: \_\_\_\_\_ (dd/mm/yy) to \_\_\_\_\_ (dd/mm/yy)
4. Total No. of Data Forms: \_\_\_\_\_
5. Total Number of Envelopes: \_\_\_\_\_
6. Details of Sample Numbers whose data forms are being sent:

S. No	Date of Collection	Sample No.	S. No	Date of Collection	Sample No.	S. No	Date of Collection	Sample No.	S. No	Date of Collection	Sample No.
1			26			51			76		
2			27			52			77		
3			28			53			78		
4			29			54			79		
5			30			55			80		
6			31			56			81		
7			32			57			82		
8			33			58			83		
9			34			59			84		
10			35			60			85		
11			36			61			86		
12			37			62			87		
13			38			63			88		
14			39			64			89		
15			40			65			90		
16			41			66			91		
17			42			67			92		
18			43			68			93		
19			44			69			94		
20			45			70			95		
21			46			71			96		
22			47			72			97		
23			48			73			98		
24			49			74			99		
25			50			75			100		

If space provided above is not sufficient, please attach another sheet.

Data Forms Sent by: \_\_\_\_\_ (Name) \_\_\_\_\_ (Signature) \_\_\_\_\_ (Tel/ Mobile No.)

Date of Sending Data Forms: \_\_\_\_\_

Data Forms Received by: \_\_\_\_\_ (Name) \_\_\_\_\_ (Signature)

Date of Receipt of Data Forms: \_\_\_\_\_

Annex-4

**SAMPLE TRANSPORTATION SHEET**

*(To be sent in duplicate along with the serum specimens)*

1. Name and Complete Address of the Sentinel Site/Sub-site (Tick whichever is applicable) \_\_\_\_\_  
 \_\_\_\_\_ District: \_\_\_\_\_ State: \_\_\_\_\_
2. A) Type of Site: \_\_\_\_\_ B) Site Code:  C) Sub-site No.
3. Period of Sample Collection: \_\_\_\_\_(dd/mm/yy) to \_\_\_\_\_(dd/mm/yy)
4. Total Number of Samples: \_\_\_\_\_
5. Total Number of Boxes: \_\_\_\_\_
6. Details of Sample Numbers:

S. No	Date of Collection	Sample No.	S. No	Date of Collection	Sample No.	S. No	Date of Collection	Sample No.	S. No	Date of Collection	Sample No.
1			26			51			76		
2			27			52			77		
3			28			53			78		
4			29			54			79		
5			30			55			80		
6			31			56			81		
7			32			57			82		
8			33			58			83		
9			34			59			84		
10			35			60			85		
11			36			61			86		
12			37			62			87		
13			38			63			88		
14			39			64			89		
15			40			65			90		
16			41			66			91		
17			42			67			92		
18			43			68			93		
19			44			69			94		
20			45			70			95		
21			46			71			96		
22			47			72			97		
23			48			73			98		
24			49			74			99		
25			50			75			100		

If space provided above is not sufficient, please attach another sheet.

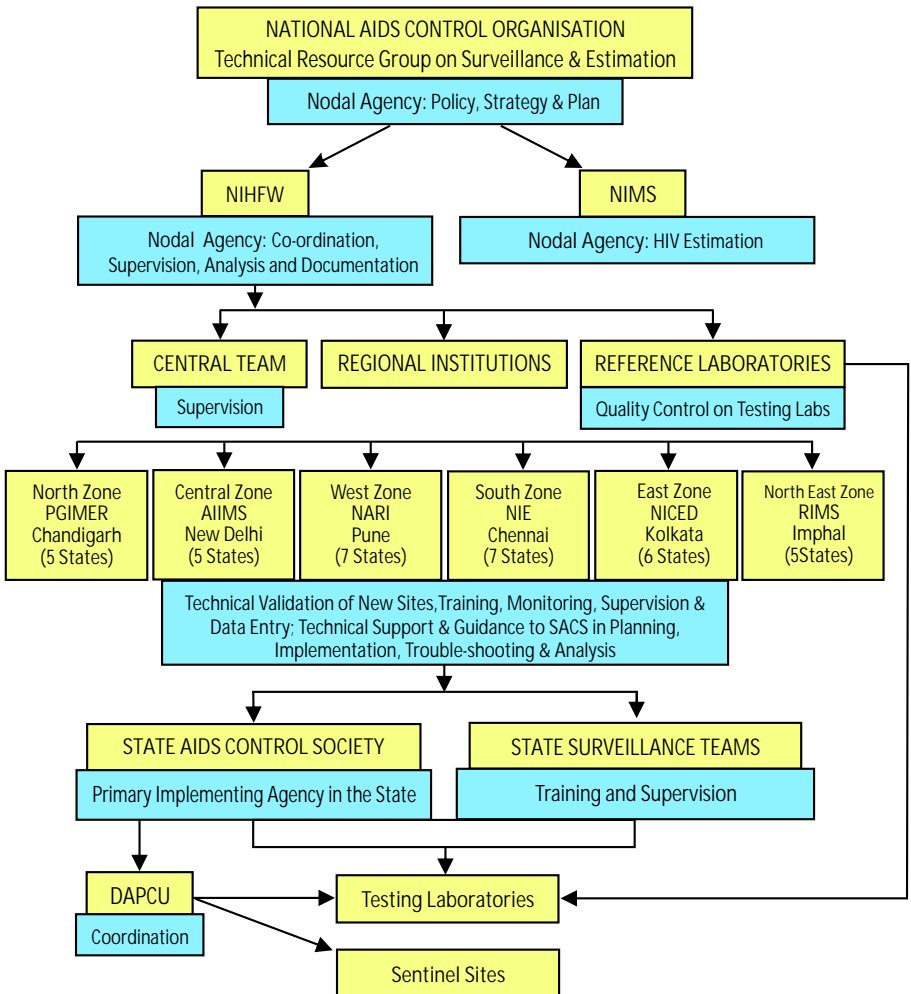
Samples Sent by: \_\_\_\_\_ (Name) \_\_\_\_\_ (Signature) \_\_\_\_\_ (Tel/ Mobile No.)

Date of Sending Samples: \_\_\_\_\_

Samples Received by: \_\_\_\_\_ (Name) \_\_\_\_\_ (Signature)

Date of Receipt of Samples: \_\_\_\_\_

## Implementation Structure of HIV Sentinel Surveillance



## Notes

## Notes