

**SAMPLE COLLECTION
MANUAL
FOR
ANTENATAL CLINICS
- SYPHILIS & HIV TESTING -
-EMTCT PROGRAMME-**



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FOR
ANTENATAL CLINICS

SYPHILIS & HIV TESTING FOR
EMTCT PROGRAMME

First Edition -2018

NATIONAL STD/AIDS CONTROL PROGRAMME
NO:29, DE SARAM PLACE, COLOMBO 10,
SRI LANKA

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Abbreviations

STI	Sexually Transmitted Infections
HIV	Human Immunodeficiency Virus
NSACP	National STD/AIDS Control Programme
AIDS	Acquired Immunodeficiency Syndrome
NRL	National Reference Laboratory
STD	Sexually Transmitted Diseases
Ag	Antigen
Ab	Antibody
ELISA	Enzyme-linked Immunosorbent Assay
VDRL	Venereal Disease Research Laboratory Test
TPPA	<i>Treponema pallidum</i> Particle Agglutination Assay
ANC	Antenatal Clinic
VOG	Visiting Obstetrician and Gynaecologist
POA	Period of Amenorrhoea
MOH	Medical Officer of Health

Preface

Elimination of mother to child transmission of HIV and Syphilis is a first and foremost target of the health system of Sri Lanka at present. Testing of pregnant mothers facilitating the detection of HIV status and Syphilis is a very important key factor in the elimination process. The pregnant mothers are provided with free testing of blood samples country wide with the technical guidance of the NSACP to achieve this target.

The reports generated in the testing centers for EMTCT should be of high quality to have reliable data on disease burden. The receipt of a good quality sample at laboratory is a prime requirement in generating an accurate, reliable report. Therefore, this manual is produced to guide all the staff in blood collecting sites for obtaining a good quality sample and how to handle the samples in storage and transport.

This booklet was produced as a supportive document for the guidance given earlier on the same subject by the EMTCT guidelines “A guide for Health care Workers 2017” for the ANC clinics.

It is common knowledge that sample collection is done either by doctors or nurses. The training they receive as students is further strengthened by this booklet as to match the special tasks or special situations, they need to handle in EMTCT. Therefore, everyone engaged in sample collection, storage and transport has to read this booklet and gather the necessary knowledge to accomplish their task with no lapses.

It is highly acknowledged the support extended from UNICEF, Global fund for HIV and PEPFAR/CDC – CMAI partnership with NSACP for printing this manual.

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The support extended by the Consultant Venereologists of NSACP and the peripheral clinics and the medical laboratory technologists of NRL/NSACP are acknowledged.

Published by:

National Reference Laboratory,

National STD/AIDS Control Programme

Ministry of Health

Colombo, Sri Lanka

Funded by UNICEF & HSS project by PEPFAR

1st Edition 2018

1. Introduction

Laboratory diagnosis of an infection is highly important for patient management. Quality of the laboratory result is dependent on the quality of specimens received at the laboratory. The quality of the specimen is achieved with proper collection of an adequate specimen from the proper site. (Right patient, Right test and Right sample). Storage and transport of specimens in the required conditions too affect the quality of specimens subjected to testing.

A proper guidance on the collection of specimens and their transportation is a must for obtaining the good quality sample for testing which leads to an accurate diagnosis. It ensures the sample integrity, prevention of sample mix up and improving the overall quality of the samples sent for testing. It is imperative that the instructions given in the manual are adhered to by all personnel involved with sample collection, storage and transport. The phlebotomy staff should use this as the guide and the lab staff too should abide by the manual when advising on sample collection and transport for EMTCT testing.

2. General information on laboratory network

The NSACP has a network of laboratories comprised of the Reference laboratory and peripheral STI laboratories. The apex body of that laboratory network is the National Reference Laboratory for STI / HIV of NSACP, located in the National STD /AIDS Control Programme, Colombo 10. Other STI Clinic laboratories are located in the peripheral STD clinics island wide. The National Reference Laboratory of NSACP offers testing and reference services on sexually transmitted infections and HIV. The other laboratories provide the screening for Syphilis and HIV & confirmation for Syphilis.

Service hours of the Laboratories

NRL Week days - from 8.00 am to 4.00 pm
Saturdays - from 8.00 am to 12.00 noon
Closed on public holidays.

District Laboratories

Weekdays - from 8.00 am to 4.00 pm
Saturdays - from 8.00 am to 12.00 noon
Closed on public holidays.

Contact details of NRL

National Reference Laboratory
National STD/AIDS Control Programme
No.29,
De Saram Place,
Colombo 10.

TP: 0112667163, 0112667029

3. General information on sample collection and dispatch

It is essential to follow Standard precautions at all times during specimen collection, storage, testing, transportation and disposal of bio-hazardous waste. Standard precautions are meant to reduce the risk of transmission of blood borne and other pathogens from both recognized and unrecognized sources.

- Wear appropriate personal protective equipment and follow only the recommended practices when collecting and handling specimens.
- Ensure the specimen collection kits are not expired.
- Collect adequate volume of the specimen to the correct container.
- Label each specimen container with the mother's unique identifiers, tests required, date and time of collection.
- All specimens should accompany a complete and correctly filled request form signed by the collecting officer and the medical officer in charge of the clinic.
- Once the sample is collected, it should be delivered to the laboratory in leak proof container. All measures should be taken to avoid the undue delays.
- All the information pertaining to sample collection and dispatch has to be recorded in a register.
- Disposal of collecting devices and contaminated material should be done according to the waste management procedures of the institution.

4. Specimen collection for HIV and Syphilis testing

4.1 Materials required for collection of blood

It is recommended to use sterile vacutainer plastic/glass tubes for collecting blood.

- vacutainer needle holder, needles or syringes and needles
- Vacutainer tubes (plain)
- Well-fitting, latex, non-sterile gloves
- A tourniquet
- 70% alcohol
- Alcohol hand rub
- Gauze or cotton-wool
- Laboratory specimen labels
- Writing pen
- Request form
- Leak-proof transportation containers
- Ice packs
- Sharps bin and waste bins.

Collect all the materials needed for the procedure and place it within safe and easy reach on a tray or trolley, ensuring that all the items are clearly visible.

4.2 Instructions for blood collection

Blood collection should always be done under aseptic conditions.

- Identify the mother by checking the mother's identification details.
- Label the tube with mother's identification and other relevant details.
- Make the mother sit comfortably for venepuncture
- Select the site.
 - Inspect the antecubital fossa or forearm on the extended arm.
 - Select a vein of a good size that is visible, straight and clear (The vein should preferably be visible without applying the tourniquet).
- Apply the tourniquet about 4–5 finger widths above the venepuncture site and re-examine.
- Clean the entry site with 70% alcohol in a circular manner from inside to out.
- If vacutainer is used insert the needle and the holder. Then fix the tube to the holder and draw blood. Blood can be collected to number of tubes in this manner without using a syringe.
- When the bleeding is over, remove the needle and discard it into the sharp bin.
- If the vacutainer holder is contaminated put it in to the sharp bin.
- If the syringe is used, use a syringe with appropriate volume and after collecting discard both syringe and the needle together into the sharp bin. **Do not recap the needle.**

Figure 1: Steps in drawing Blood

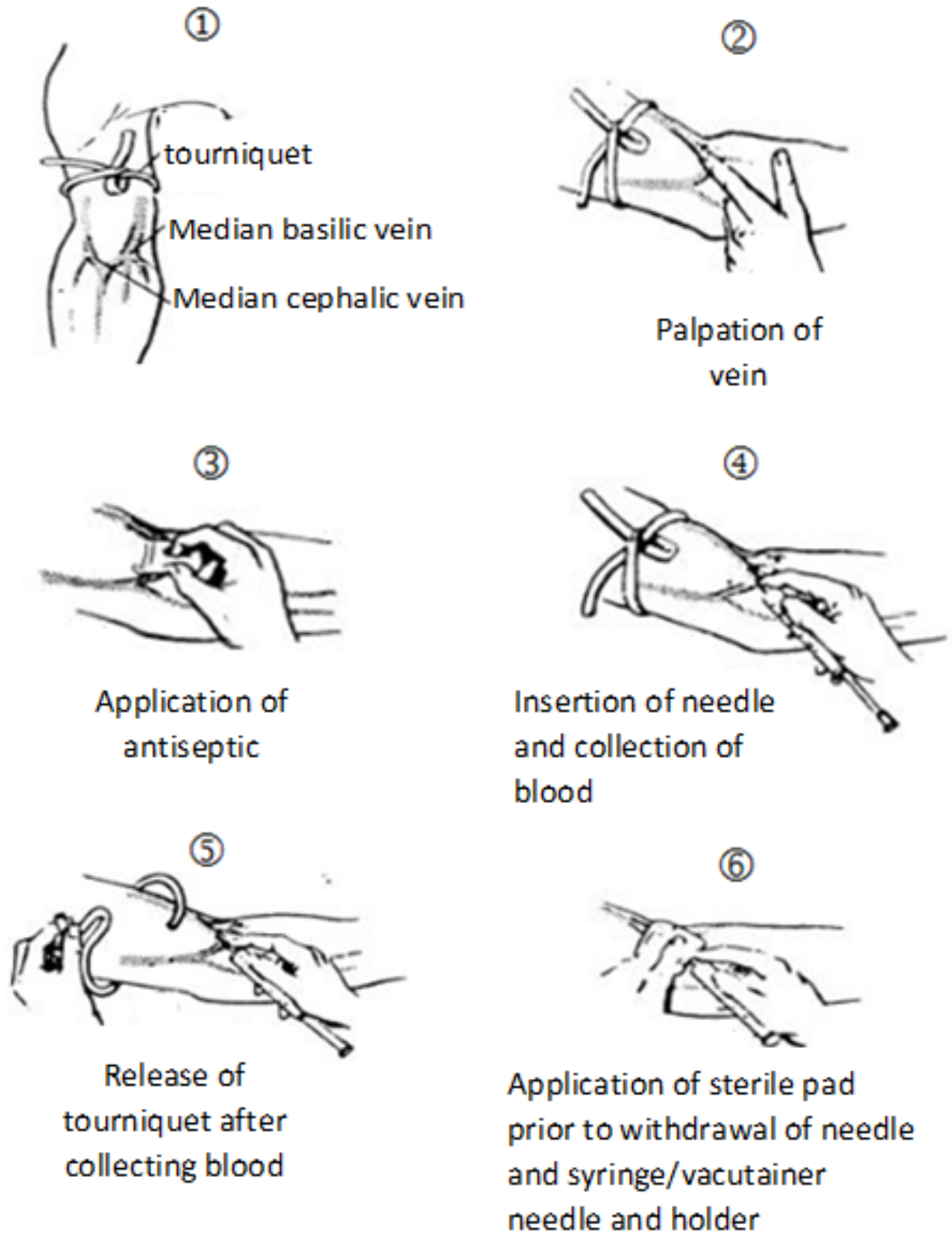






Table 1: General instructions for sample collection

Investigation	Sample acceptance time		Container with colour of the stopper	Volume	Specimen	Request form *	Form number *
	Week days	Saturdays					
HIV + Syphilis (Both tests together)	8am-3.30pm	8am-11.30am	 Plain tube Size 10 cc	5cc	Blood/Serum	Request form for Syphilis/HIV in Antenatal Mother	NSACP/10/ANC/2
	8am-3.30pm	8am-11.30am	 Plain tube Size 10 cc	3cc	Blood/Serum		
Syphilis VDRL	8am-3.30pm	8am-11.30am	 Plain tube Size 10 cc	3cc	Blood/Serum		
	8am-3.30pm	8am-11.30am	 Plain tube Size 10 cc	3cc	Blood/Serum		

* Refer the annexure

All the mothers are expected to be bled for Syphilis and HIV together

Figure 2: Plain tube for blood collection



Plain tube
for HIV and Syphilis
screening tests

4.3 Sample collection

- Collect correct amount of blood in to a dry, sterile plain tube. The mothers are expected to be bled for Syphilis and HIV together.
- Allow blood to clot at room temperature for a minimum of 20-25 minutes in vertical position.

4.4 Storage and transportation

- Samples should be transported to the laboratory immediately in all possible instances.
- If the samples cannot be dispatched immediately, keep the blood tubes in a rack and store in a refrigerator with 4-8°C.
- Refrigerated samples should be sent to the laboratory within 72 hours.
- If further delay in transport is expected, centrifuge the sample at 2500 rpm for 10-15 minutes to separate the serum. Pipette the supernatant serum into another sterile plain tube and label it. Separated serum should reach the laboratory within 5 days.

Factors influencing a good outcome of laboratory results during collection and transport include,

- Carrying out phlebotomy by properly trained staff.
- Not allowing the alcohol used for cleaning the site to remain in the puncture site as it may cause haemolysis.
- Use of the correct gauge of hypodermic needle (preferably 21G) to prevent haemolysis.
- Drawing blood slowly and steadily.
- Avoiding vigorous suction on the tube which causes haemolysis.
- Injecting the blood sample extremely slowly into the tube minimizing the pressure and velocity to prevent haemolysis.
- Labelling immediately all specimen tubes by the collector and ensure they are accurately labelled.
- Keeping the samples in room temperature and allowing to clot before refrigerating.
- Transporting samples to the laboratory as soon as possible. (The longer you keep samples in the refrigerator, the chance of haemolysis and decomposition will increase)

5. Guide lines for transport of specimens

5.1 General instructions

Transport of specimens should always ensure the safety of all individuals handling the specimen and should meet the specific criteria involved in receiving a good sample to perform the test. Therefore, packaging and transportation of specimens should be done appropriately to obtain accurate results.

5.2 Packing of specimens

For blood and blood products the International standard of packing identified is the “Three-layer packing”.

The three layers involve

1. Primary receptacle
2. Secondary receptacle
3. Outer package

Primary receptacle

- This is a watertight, leak-proof receptacle which is labelled and contains the specimen.
- The receptacle is sufficiently wrapped in absorbent material to absorb all fluid at instances of breakage.

Secondary receptacle

- The primary receptacle(s) should be placed in a second durable, watertight, leak-proof receptacle to enclose and protect the primary receptacle(s).
- Several wrapped primary receptacles may be placed in one secondary receptacle.
- Sufficient absorbent material must be used to cushion multiple primary receptacles in the secondary container.
- Specimen data forms, letters and other types of information that identify or describe the specimen and also identify the sender and receiver should be taped to the outside of the secondary receptacle, preferably in a zip pouch.
Ice or dry ice required to maintain temperature should be placed in the secondary receptacle.

When there are many samples to be transported a rack of tubes can be located in a plastic container (secondary receptacle) in a fixed manner with no allowance for spillage)

Outer package

- The secondary receptacle should be placed in an outer package which protects contents from outside influences such as physical damage and water while in transport.
- This container must bear the label which identifies the sender and receiver along with biohazard sign.
- Ziploc plastic bags may also be used as leak-proof containers if suitable boxes are not available. Packed specimens should be sent to the referral laboratory for testing.

Figure 3: Three-layer packing for transport of specimens

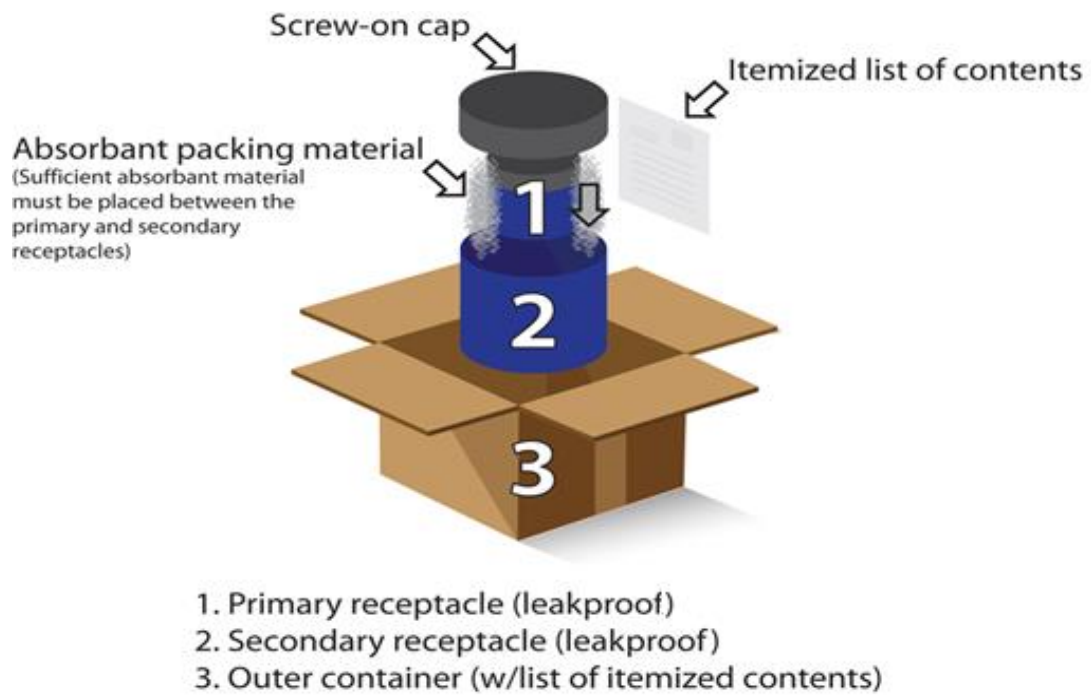


Figure 4: Biohazard sign



Figure 5: A cool box to transport specimens



6. Sample reception

All the samples are collected at a sample reception counter of NRL or the district clinic laboratories. A medical laboratory technologist (MLT) and a lab orderly are available at all times in the sample reception counter.

6.1 Sample reception procedure

- The specimens should correctly be paired with the appropriate request forms.
- Check the suitability of the sample for testing.
- Check following information on the label.
 - a. Mother's number
 - b. Clinic/Institution/Hospital
 - c. Investigation/s
 - d. Date and time of collection

- Specimen is registered in the sample reception register.

Note:

- For HIV and VDRL screening tests, blood sample should come with NSACP/10/ANC/2 request form (Annexure). Incomplete request forms should be brought to the notice of the Medical officers of the laboratory immediately.

6.2 Sample rejection

Any specimen not meeting the required conditions are to be rejected.

Reasons for potential specimen rejection may include the following:

- Samples without labels/ Inadequately written labels.
- Samples without accompanying request forms.
- Incomplete request forms - Request forms are incomplete without the following information.
 - Clinic number or mother's identity
 - Clinic/ ward
 - Tests requested
 - Date & Time of sample collection
 - Any relevant detail which specifically requested in request form
- If the details on the label of the sample and the request form are not identical.
- Specimens showing gross evidence of decomposition.
- Haemolyzed samples.
- Inadequate volume of the specimen for the tests requested.
- Samples in inappropriate containers.
- Specimens which were not transported properly and were not stored properly.
- Specimens that have leaked or have specimen material on the outside of the container.
- Delay in receipt of sample.

What happens to rejected samples:

The requests of rejected specimens are given to medical officers of laboratory without a delay.

If samples are rejected it will be informed to the originating location/collector for re-collect the specimen and re-order the test.

All the rejected samples are entered in a special register. (sample rejection register)

7. Reporting of results

Specimens are processed upon receipt. Reporting times vary depending on the nature of the test and the analytical time required for the procedure. All the laboratories have a turn around time for their tests.

7.1 Collection of reports from STD clinic laboratory

- Reports are made available in the laboratory as soon as the testing is performed and according to the turnaround time of the test.
- The reports should be collected by the MOH clinic staff regularly.
- If there is a delay in receiving the reports contact the medical officer of the STD clinic.
- All negative screening test reports for HIV and syphilis will be issued to the ANC clinic.
- HIV and Syphilis positive screening test results will be informed to the relevant authorities (MOH/VOG) keeping confidentiality.

