DOC. NO.	TITLE	ISSUE NO.
AIIMS/Rajkot/Micro/ SOP/1	SOP on Sample Collection and transport of Blood for HIV Testing	1.0
Effective Date:20/06/2022		

Name	Designation	Function	Signature
Dr Mayuri Bhise	Assistant Professor	Preparation	MBhise 20/6/22
Dr Ashwini Agrawal	Prof & Head	Review and Approval	

Distribution List:
Collection Centre

REVISION SUMMARY			
Revision No.	Issue No.	Effective Date	Revision History
0	1.0	20/06/2022	NA

1.0 INTRODUCTION

All Laboratory procedures for HIV testing are carried out on blood samples. It is important to follow exact technique for collection of blood aseptically.

2.0. PURPOSE

This SOP details the procedure to be followed for collection of blood, transport and separation of serum for HIV testing.

3.0. SCOPE

This SOP is applicable to F-ICTC for collection of sera for detection of antibodies against HIV.

4.0 RESPONSIBILITY

It is the responsibility of the ICTC staff (Laboratory Technician) to read the SOP for blood collection and follow it.

5.0 REQUIREMENTS

1 Vacutainers: - Plain and EDTA.	7. Puncture proof discarding jar with 1% sodium hypochlorite (sharps)
2. Needles and Vacutainer Holders	8. Marker pens
3. Needle destroyer	9. Vacutainer rack
4. Disposable latex gloves	10 Syringe needle
5. Tourniquet	11 Tube/ vial
6. Cotton swabs and spirit	12 Red and yellow bags for disposal

6.0 PROCEDURE

6.1 Sample Collection

- Introduce yourself and identify the patient.
- Assemble all the required materials in order.
- Check the specific lab requisition form.
- Verify the identity of the patient and check for patient details Lab Id Number, age before labelling.
- Wash hands and wear gloves.
- Explain the procedure to the patient.
- Apply the tourniquet and choose the appropriate vein.
- Disinfect the phlebotomy site with spirit - soaked cotton swabs
- Insert the needle of the vacutainer device and collect 3- 5 ml of blood as required. Use syringe needle to collect blood during non-availability of vacutainer.
- Release the tourniquet after collection and withdraw the needle from the vein
- Apply pressure on the puncture site with cotton swab and request the patient to fold the arm for 5 minutes
- Destroy the needle immediately with the help of needle destroyer
- Keep the vacutainer/vial in the vacutainer rack with the requisition form, the blood is allowed to clot for 15- 30 min.
- Patient can leave the place after ensuring visible haemostasis**.**

6.2 Sample Transport from Collection Centre to Laboratory (FICTC)

- Transport the vacutainer/vial tubes with the blood samples to the laboratory
- Place these tubes in tube holder rack for transportation
- The Samples are received and verified in the laboratory

7 REFERENCES:

7.1 National guidelines for HIV testing, NACO, Ministry of health and Family welfare, Government of India, July 2015

8 APPENDICES AND FORMS:

A: -Test Requisition form (F-ICTC)

9 VALIDITY STATEMENT

This SOP is valid for one year from the date of issue.

ALL INDIA INSTITUTE OF MEDICAL SCIENCES, RAJKOT, GUJARAT
DEPARTMENT OF MICROBIOLOGY

National AIDS Control Program

NACO

FACILITY INTEGRATED COUNSELLING & TESTING CENTER

NAME OF FICTC & DISTRICT: _____

LABORATORY REPORT FROM FOR FICTO

(CONFIDENTIAL)

1. OPD Case Number: -_____ Date: - _____
2. Age: - _____ Yrs.
3. Identification Marks: - A-_____ B- _____
4. Date when sample received: -_____
5. Result of HIV Anti body test: - _____

Screening Test: _____ Non Reactive / Referred to ICTC

(Name of kit) (Please tick mark on which is applicable)

Batch No.: _____

Exp. Date: _____

6. Any Comments: _____

Signature of Doctor Signature of Lab technician

Note: (1) This report may be signed by the in charge of the HIV test Laboratory or may authorized person.

(2) To maintain strict confidentiality, the signed HIV test report must be given only to the patient.

Proprietary statement: This document contains information. It is provided to institution staff under AIIMS Rajkot only. Do not share verbally or otherwise without written consent of the Prof & Head, Department of Clinical Microbiology, AIIMS, Rajkot.

DOC. NO.	**TITLE**	**ISSUE NO.**
AIIMS/Rajkot/Micro/ SOP/2	SOP on Sample acceptance and rejection	1.0
Effective Date:20/06/2022		

Name	**Designation**	**Function**	**Signature**
Dr Mayuri Bhise	Assistant Professor	Preparation	
Dr Ashwini Agrawal	Prof & Head	Review and Approval	

Distribution List:
Collection Centre

REVISION SUMMARY			
Revision No.	Issue No.	Effective Date	Revision History
0	1.0	20/06/2022	NA

1.0 INTRODUCTION

The Samples that are collected in the Collection centre OPD campus need to be screened for acceptance/rejection and received in the Laboratory in a proper way.

2.0. PURPOSE

This SOP details the procedure to be followed for receiving, accepting and rejecting the samples at F ICTC

3.0. SCOPE

This SOP is applicable to F-ICTC laboratory for collection of Blood Samples for testing of HIV

4.0 RESPONSIBILITY

It is the responsibility of the Laboratory Technicians to read the SOP for sample acceptance and rejection for Blood sample.

5.0 PROCEDURE

5.1 Sample Acceptance:

- Check and verify the details mentioned on the sample container & on the Test Requisition form are same.
- Check that the samples are brought to the laboratory as early as possible without delay
- Check the sample containers are intact and there is no leakage

5.2 Sample Rejection Criteria:

The sample is rejected if any of the following is observed.

- Sample is haemolyzed
- Sample container is leaked
- Sample volume insufficient
- Unlabelled/mislabelled samples
- Sample without requisition form

6 REFERENCES:

6.1 National guidelines for HIV testing, NACO, Ministry of health and Family welfare, Government of India, July 2015

7 APPENDICES AND FORMS:

NA

8 VALIDITY STATEMENT

This SOP is valid for one year from the date of issue.

DOC. NO.	TITLE	ISSUE NO.
AIIMS/Rajkot/Micro/ SOP/3	SOP on Sample Testing by Meri screen test for HIV	1.0
Effective Date:20/06/2022		

Name	Designation	Function	Signature
Dr Mayuri Bhise	Assistant Professor	Preparation	
Dr Ashwini Agrawal	Prof & Head	Review and Approval	

Distribution List:
Laboratory

REVISION SUMMARY			
Revision No.	Issue No.	Effective Date	Revision History
0	1.0	20/06/2022	NA

1 PURPOSE:

This SOP is details of the procedure Lab technician has to follow while doing the MERISCREEN HIV 1-2 WB rapid test.

2 PRINCIPLE AND METHOD:

2.1 Principle

MERISCREEN HIV 1-2 WB rapid test kit contains a membrane strip, which is precoated with HIV -1 & HIV -2 antigens on test region '1' and test region '2' respectively. Recombinant antigen gold conjugate will form a colored band in the test region '1' and test region '2' of result window. As the test sample flows through the membrane after addition of assay buffer, the antigen gold conjugate complexes with anti-HIV antibodies. The complex moves further on the membrane towards the test region, where HIV antigens are coated and leads to formation of reddish-purple band(s) at test region(s). Absence of test bands indicates a negative test result.

The control band is used for procedural control and should always appear if the test procedure is performed correctly.

2.2 Method

MERISCREEN HIV 1-2 WB test is an immunochromatographic (rapid), qualitative, screening, in-vitro diagnostic test for detection of antibodies of all classes specific to HIV 1 and HIV 2 in human serum, plasma and whole blood.

2.3 Performance Characteristics

Sensitivity: 100%

Specificity: 100%

2.4 TYPE OF SAMPLE:

Serum or plasma or whole blood.

2.5 PATIENT PREPARATION:

It is a responsibility of Laboratory Technician is to prepare the patient i.e.to ensure that the patient is counselled and aware of collection and testing of blood. It is a responsibility of Laboratory Technician is to collect blood for testing.

2.6 TYPE OF CONTAINER AND ADDITIVES:

Container: 5-6 ml red-topped vacutainer for serum collection (plastic tube preferable)

Additives: No additives are required

2.7 REQUIRED EQUIPMENT AND REAGENT:

Equipment: Centrifuge, Micropipettes, Refrigerator, Timer

Reagents

The kit contains the following items:

- Test device individually sealed in a foil pouch with one desiccant
- Assay buffer
- Positive control
- Negative control
- Disposable sample dropper
- KIT inserts

Other Requirements:

- Apron
- Blotting paper
- Discarding beaker containing 1% Sodium Hypochlorite
- Gloves
- Micropipettes (Capacity - 10-20ul)
- Tissue Paper
- Tips
- Disposable gloves

Note: Test devices are sensitive to humidity hence use the test device immediately once pouch is opened.

3 ENVIRONMENTAL AND SAFETY CONTROLS:

Room and refrigerator temperature log, Room cleaning log, Refrigerator and centrifuge cleaning log.

4 CALIBRATION PROCEDURES:

Calibration of Centrifuge, Micropipettes and digital Thermometer

5 PROCEDURAL STEPS:

Note: Bring all reagents to room temperature before use (20-30^0 c). Return all reagents and controls to 2-8°C immediately after use.

Do not use kit components beyond the expiry date, which is printed on the kit.

Procedure of the Test:

1. Open the pouch at the notch and remove the test device; place it on flat, dry and clean surface.
2. Add 10 µl of serum or plasma specimen or 20 µl whole blood to the sample well (S) using disposable dropper. Dispose of used dropper as a bio-hazard waste. OR Using a micropipette add 10 µl of serum or plasma specimen or 20 µl whole blood into the sample well(s). Dispose of used microtip as a bio-hazard waste.
3. Add 3 drops of assay buffer into the sample well (S).
4. Interpret test result at the end of 20 minutes.

6 QUALITY CONTROL PROCEDURES:

Positive and negative control: Run a positive and negative control every fortnight of testing.

Inbuilt control: The inbuilt control should be positive for each of the sample to accept the result.

7 INTERFERENCES AND CROSS REACTIONS:

Sample rejection criteria:

Samples are rejected if any of the following occurs

- Inadequate sample information
- Insufficient quantity

- Improper sample transportation: Leakage of sample, cold chain is not maintained.
- Use of heat inactivated, icteric hyperglycemic and hemolyzed samples should be avoided as may give erroneous results.

8 LABORATORY CLINICAL INTERPRETATION:

- A colored band will appear in the right section of the result window to show that the test is working properly. This band is control line(C).

Negative result:

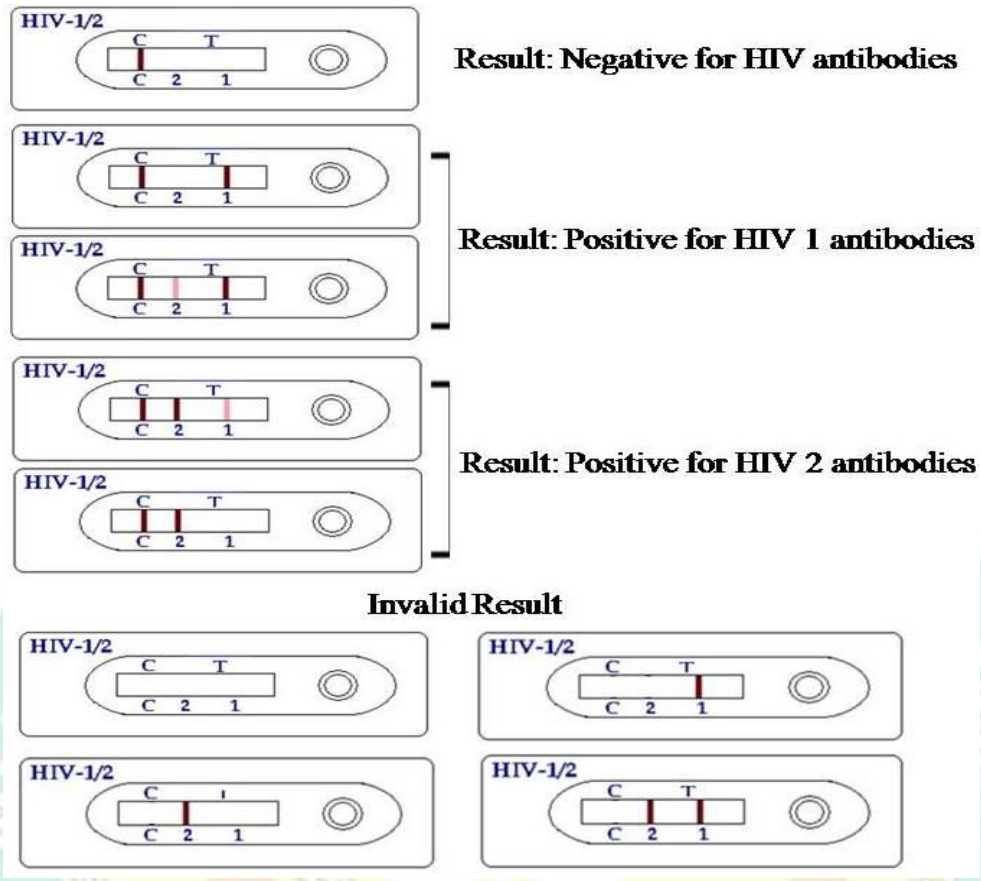
- If only the control band (C) is developed within the result window, the test indicates that no detectable HIV antibodies are present in the specimen, the result is negative.

Positive result:

- The presence of two lines as control line (C) and test line 1 (1) within the window indicates a positive result for HIV-1.
- The presence of two lines as control line (C), and test line 2 (2) within the window indicates a positive result for HIV-2.
- The presence of three lines as control line (C), test line 1 (1) and test line 2 (2) within the window indicates a positive result for HIV-1 and /or HIV-2.

Invalid test

No presence of control line (C) within the result window indicates an invalid result regardless of color development on '1' and '2' bands as indicated below. Repeat the assay with a new device.



9 PRECAUTIONS:

- For reliable performance and proper sensitivity of the test, all reagents should always be stored properly and used before expiration date.
- Repeat the test in case of very faint band or invalid test or if have any doubt for test band.

10 REFERENCES:

10.1MERISCREEN HIV 1-2 WB – Kit Insert

10.2 Training manual of Technical Officers, NACO, Regd. No.891/98

10.3 National guidelines for HIV testing, NACO, Ministry of health and Family welfare, Government of India, July 2015

11 APPENDICES AND FORMS:

NA

12 VALIDITY STATEMENT

This SOP is valid for one year from the date of issue.

Proprietary statement: This document contains information. It is provided to institution staff under AIIMS Rajkot only. Do not share verbally or otherwise without written consent of the Prof & Head, Department of Clinical Microbiology, AIIMS, Rajkot.

DOC. NO.	TITLE	ISSUE NO.
AIIMS/Rajkot/Micro/ SOP/4	SOP on Sample storage	1.0
Effective Date:20/06/2022		

Name	Designation	Function	Signature
Dr Mayuri Bhise	Assistant Professor	Preparation	
Dr Ashwini Agrawal	Prof & Head	Review and Approval	

Distribution List:
Laboratory

REVISION SUMMARY			
Revision No.	Issue No.	Effective Date	Revision History
0	1.0	20/06/2022	NA

1 INTRODUCTION

This standard operating procedure defines the procedures to be followed to store the serum samples send to the Microbiology Lab (ICTC)

2. PURPOSE

To define methods for storage of serum samples after testing is performed.

3. SCOPE

The ICTC- Laboratory staff will follow this SOP.

4. RESPONSIBILITY

It is the responsibility of the Laboratory staff (ICTC)to follow this SOP for storage of the samples after HIV testing is over.

5. PROCEDURE:

5.1. ICTC samples & Serology

- Store the serum samples in leak proof vials with proper labels at 2-8 °C
- Check the outside of the vials for visible contamination.
- Keep the tested reactive serum samples in a separate box with appropriate label.

5.2 Indeterminate/HIV-2 Samples

- Store the indeterminate/HIV-2 samples at 2-8 °C in separate box till they are sent for confirmation at referral center

6 REFERENCES:

6.1 Kit Insert

6.2 Training manual of Technical Officers, NACO, Regd. No.891/98

6.3 National guidelines for HIV testing, NACO, Ministry of health and Family welfare, Government of India, July 2015

7 APPENDICES AND FORMS:

NA

8 VALIDITY STATEMENT

This SOP is valid for one year from the date of issue.