**Model SOP**

**Standard Operating Procedure**

**Name of the facility / activity : HIV Testing of Blood Unit by Rapid Method**

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| **SOP no.** | **Effective Date** | **Pages** | **Prepared by** | **Authorised by** |
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| **LOCATION** : TTI Testing Laboratory | | | | |
| **SUBJECT** : HIV Testing | | | | |
| **FUNCTION** : Samples tested for Anti HIV Antibodies by Rapid Method | | | | |
| **DISTRIBUTION**: Supervisor in charge of TTI testing laboratory  Master File | | | | |

1. **SCOPE & APPLICATION:**

HIV is a mandatory test for blood unit screening before it is transfused. This is carried out on all donor units’ samples.

1. **RESPONSIBILITY:**

It is the responsibility of technician from TTI Testing lab to carry out the test and report as required.

1. **Material Required:**
   1. Disposable gloves
   2. Kit with test cards available ( HEPACARD)
   3. Kit insert
   4. Blotting paper
   5. Paper napkin

***Specimen***

* Clotted blood / serum sample

1. **PROCEDURE:**

**Assay Procedure**

Take care of the following points before starting the test.

* 1. Bring all the reagents and specimens to room temperature (250C-300C) before beginning the test. The immunological sequence of reactions which take place during different procedural steps shows best performance at room temperature. DO NTO HEAT OR REPEATEDLY FREEZE / THAW SPECIMEN
  2. Place the required number of HIV TRI-DOT test devices at the working area.
  3. Tear off the pouch and take out the device for performing the test. Writ the sample number to be tested on the device.
  4. While adding sample / reagents to the device, be sure to ALLOW EACH SOLUTION TO SOAK IN BEFORE ADDING THE NEXT SOLUTION.
  5. However drops of each solution should be added in continuous stream to wet the entire area of membrane.
  6. If the solution does not soak-in within 40-60 seconds; observe the sample for any suspended particulate matter. If it is present, centrifuge the sample at 10,000 r.p.m. for 15 min. and use a fresh device to re-run the test. Refer to “SPECIMEN / SAMPLE PROCESSING”.
  7. All solutions and sample should be added to the CENTRE OF MEMBRANE.
  8. For consistent results ensure FREE FALLING OF DROPS on the membrane.
  9. Do not use kit components beyond the expiration date.
  10. The liquid conjugate should not be subjected to frequent temperature fluctuations.
  11. The procedural sequence of reagent addition should be strictly adhered to avoid any discrepant results.

**TEST PROCEDURE**

* + 1. Add 3 drops of Buffer Solution to the centre of the device.
    2. Hold the dropper vertically and add 1 drop of patient’s sample (serum or plasma) using the sample dropper provided (use a separate sample dropper for each specimen to be tested).
    3. Add 5 drops of Buffer Solution.
    4. Add 2 drops of Liquid Conjugate directly from the conjugate vial.
    5. Add 5 drops of Buffer Solution and read results.

Read result immediately and discard the device considering it to be potentially infectious.

IMPORTANT: IT IS IMPORTANT TO ALLOW EACH SOLUTION TO SOAK IN THE TEST DEVICE BEFORE ADDING THE NEXT SOLUTION.

**INTERPRETATION OF RESULTS**

**NON-REACTIVE**

If only One DOT (only the Control Dot) the specimen is non reactive for antibodies either to HIV-1 or HIV-2. Interpret sample as non-reactive.

**REACTIVE**

1. If two DOTS, one for the control and the other for HIV-1, the specimen is reactive for antibodies to HIV-1.
2. If two DOTS, one for the control and the other for HIV-2, the specimen is reactive for antibodies to HIV-2.
3. If all the three DOTS, one each for control, HIV-1 & HIV-2, the specimen is reactive for antibodies to HIV-1 & HIV-2.

**INVALID TEST**

If not DOT appears after the test is complete, either with clear background or with complete pinkish/ purple background the test indicates ERROR. This may indicate a procedural error or deterioration of specimen / reagents or particulate matter in the specimen. The specimen should be tested on a new device.

1. **DOCUMENTATION:**

**In the daily worksheet and rapid testing documentation its important to write;**

* 1. The date on which the test is run.
  2. The name of the kit used.
  3. Lot No. and expiry date of the kit.
  4. Initials of the technologist who performed the test.
  5. Initials of the Supervisor who verifies the result.
  6. Reactive units are marked in red.

Transfer the results to TTI register and in case of reactive samples immediately issue instructions or make sure personally to remove the unit along with the components prepared.

1. **REFERENCES:**
2. Technical Manual of the American Association of Blood Banks – 15th Edition, 2005.
3. Kit insert.
4. **END OF DOCUMENT**