**Model SOP**

**Standard Operating Procedure**

**Name of the facility / activity : TTI Testing of Blood unit for Anti HCV**

**Antibodies by Rapid Method.**

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| **SOP no.** | **Effective Date** | **Pages** | **Prepared by** | **Authorised by** |
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| **LOCATION** : TTI Laboratory | | | | |
| **SUBJECT** : TTI Testing | | | | |
| **FUNCTION** : Rapid visual test for the qualitative detection of antibodies to Hepatitis C  virus in Human Serum / Plasma. | | | | |
| **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. Test Kit ( HCV Tridot Device )
   3. Kit insert
   4. Blotting paper
   5. Paper napkin

***Specimen***

* Clotted blood / serum sample

1. **PROCEDURE:**

**Recommendations for the user**

1. **The procedural sequence of additions should be strictly adhered to avoid any discrepant results.**
2. Bring all the reagents and specimens to room temperature (20-25°C) before beginning the test, as the immunological sequence of reactions which take place during different procedural steps shows best performance at room temperature. DO NOT HEAT OR REPEATEDLY FREEZE/THAW SPECIMEN.
3. Place the required number of HCV TRI-DOT test devices at the working area.
4. Cut open the pouch and take out the device for performing the test. Write the sample identification number to be tested on the device for correct correlation with results.
5. While adding sample/reagents to the device, be sure to ALLOW EACH SOLUTION TO SOAK IN BEFORE ADDING THE NEXT SOLUTION. However, drops of each solution should be added in continuous stream to wet the entire area of membrane. If the sample does not soak-in within 40-60 seconds, observe the sample for any suspended particulate matter.

If present, centrifuge the sample at 10,000 r.p.m. for 15 mins. and use a fresh device to re-run the test. Refer to "SAMPLE / SPECIMEN PROCESSING".

1. All solutions and sample should be added to the CENTRE OF MEMBRANE.
2. For consistent results ensure FREE FALLING OF DROPS on the membrane holding the vial/dropper vertically for proper volume.
3. Disinfect and DISCARD THE USED DEVICES IMMEDIATELY AFTER READING RESULT considering it as potentially infectious.

**ASSAY PROCEDURE**

**Step No. 1**

Add 3 drops of Buffer Solution to the centre of the device.

**Step No. 2**

Hold the dropper vertically downwards and add 1 drop of patient's sample (50 01 serum or plasma) using the sample dropper provided. (use a separate sample dropper for each specimen to be tested).

**Step No. 3**

Add 5 drops of Buffer Solution.

**Step No. 4**

Add 2 drops of Protein-A conjugate.

**Step No. 5**

Add 5 drop of Buffer Solution.

**Step No. 6**

Read result immediately and discard the device immediately 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 RESULT**

* 1. Appearance of only one dot at the control region “C” indicates that the sample is NON-REACTIVE for antibodies to HCV.

**REACTIVE RESULT**

* + 1. Appearance of two dots, one at the control region “C” & other at the test region “T1”, indicates that the sample is REACTIVE for antibodies to HCV.
    2. Appearance of two dots, one at the control region “C” & other at the test region “T2” indicates that the sample is REACTIVE for antibodies to HCV.
    3. Appearance of all the three donts, one each at “C” “T1” & “T2” region indicates that the specimen is REACTIVE for antibodies to HCV.

**INVALID RESULT**

If no dot appears after the completion of test, either with clear background or with complete pinkish / purplish 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 retested on a fresh device (Refer sample / specimen processing).

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**