**Model SOP**

**Standard Operating Procedure**

**Name of the facility / activity : HBsAg 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** : HBsAg Testing |
| **FUNCTION** : Samples tested for Hepatitis B Surface Antigen by rapid method |
| **DISTRIBUTION**: Supervisor in charge of TTI testing laboratory Master File |

1. **SCOPE & APPLICATION:**

HBsAg 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:**
	1. Bring the required number of Hepacard foil pouches and specimen to room temperature prior to testing.
	2. Take out HEPACARD device from the foil pouch. In case of 5 test pouch packing tightly reseal the pouch containing balance devices with clamp and rod so that devices are protected from moisture. Ensure the pouch is perfectly sealed otherwise the device will get deteriorated thus giving erratic results.
	3. Label the test card with donor number or identification number.
	4. Add 2 drops ( 70 micro litre ) of plasma/ serum specimen into the sample well using the dropper provided ( use separate micro tip or dropper for each sample0
	5. Read results at 10 minutes. However to confirm negative, results should be read in 10 minutes.

 (NO RESULT SHOULD BE READ AFTER 20 MINUTES)

**Interpretation of the results:**

**REACTIVE :**

Appearance of pink coloured line, one each in test region “T” and control region “C” indicates that the sample is REACTIVE for HBsAg. A difference of intensity in colour may occur between the Test line & Control line depending on the concentration of the HBsAg in the serum but this does not affect interpretation of the result. Depending on the concentration of HBsAg, positive results may be observed within 60 seconds. However, to detect concentration around 0.5 ng to 1ng/ml and to confirm a negative result, the test result should be read only at 20 minutes. If the conc. of HBsAg in the sample is very high, only test line may be observed. This is due to Hook’s effect. Such samples should be diluted 1:10 or 1:20 in normal saline & again re-run the test, Diluted sample should show both control & test line. In case, if control line does not appear or is faint dilute the sample further.

**NON-REACTIVE :**

Appearance of one distinct pink line in the control region “C” only, indicates that the sample is “NON REACTIVE” for HBsAg.

**INVALID:**

When neither control line nor the test line appears on the membrane, the test should be treated as invalid which may be because of following reasons:

a) Improper storage at temperature other than the recommended temperature.

b) Wrong procedure.

c) Long atmospheric exposure of the test device after opening the pouch.

The test should be repeated using a new HEPACARD and test sample.

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.**