**Model SOP**

**Standard Operating Procedure**

**Name of the facility / activity : Rapid Plasma Reagin (RPR) card test for the diagnosis of syphilis in serum and plasma of blood donor sample.**

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| **SOP no.**  | **Effective Date** | **Pages** | **Prepared by**  | **Authorised by**  |
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| **LOCATION** : TTI Testing Laboratory |
| **SUBJECT** : Testing for syphillis |
| **FUNCTION** : Rapid plasma reagin (RPR) card test for the diagnosis of syphilis in serum  and plasma  |
| **DISTRIBUTION**: Supervisor in charge of TTI testing laboratory Master File |

1. **SCOPE & APPLICATION:**

Serological test for syphilis using VDRL carbon antigen.

It is qualitative test for screening donor's blood for syphilis. The antigen suspension used in the test must be prepared meticulously before to each run of test from a VDRL, antigen stock.

VDRL antigen is composed of a colourless alcoholic solution of beef cardiolipin,
cholesterol and lecithin. Patients with syphilis produce IgM and IgG antibodies to lipid
material released from the damaged tissue and from the organism. Antilipid antibodies react with the VDRL antigen suspension producing microflocculation.

1. **RESPONSIBILITY:**

It is the responsibility of technician from TTI Testing lab to carry out the test and report as required. The Medical Officer is responsible for cross checking all the test results and the entries in the register.

1. **Material Required:**
* Rotator / shaker
* Reagent kit
* Dispensing dropper with measuring needle
* Disposables 6 well test cards
* Disposable mixing sticks
* Insert
* Mircopipettes and disposable pipette tips
1. **PROCEDURE:**

**Principle : RPR card** test is a qualitative and semi-quantitative screening test for reagent antibody. The test is similar in principle to the classical VDRL test. The reagent used is a modified cardiolipin antigen, coated with micro particulate carbon particles. In addition, it contains a balance quantity of cholesterol and lecithin. In the presence of reagin antibodies, flocculation appears which can be visualised macroscopically.

**Method**

1. Dispense50 µl of sample or control on to a circle of the test card using a clean and dry pipette.
2. Using the wooden mixing stick provided, spread the sample over the entire area of the test circle.
3. Gently resuspend the RPR antigen with the help of the dispensing dropper provided, slowly suck the required quantity of the reagent. Add one drop of the reagent on to each test sample while holding the dropper in a vertical position. Do not restir the mixture on the test circle.
4. Rotate the card for 8 minutes either manually or on a mechanical rotator 800 rpm.
5. Read the result by visual inspection in good light.

 **INTERPRETATION OF RESULT**

**Positive result (reactive)** is indicated by the development of clearly visible clumps of the carbon particles either in the centre or at the edge of the test circle.

Negative result (non-reactive) is indicated when the carbon particles remains in a homogenous suspension in no aggregates are visible.



1. **DOCUMENTATION:**

Paste the printout in the VDRL file and also record the following details:

* 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 components.

1. **REFERENCE:**
2. Kit Package inserts.
3. Technical Manual of American Association of Blood Banks 15th edition 2005.
4. **END OF DOCUMENT**