HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER
MATERNITY AND CHILDREN HOSPITAL

Department:	Laboratory and Blood Bank (Serology)		
Document:	Internal Policy and Procedure		
Title:	Rapid Plasma Reagin		
Applies To:	All Laboratory Staff		
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1. PURPOSE:

1.1 This SOP is meant to be a guideline and to help the laboratory technician to perform and measure RPR antigen based on latex slide agglutination method.

2. DEFINITONS:

2.1 RPR (A rapid plasma regain) is a non-treponemal antibody flocculation assay for the rapid detection of Syphilis caused by Treponema pallidum. It is also used to monitor patient response to antimicrobial therapy.

3. POLICY:

3.1 RPR test is a blood test used to screen you for syphilis. It works by detecting the nonspecific antibodies that your body produces while fighting the infection.

3.2 Syphilis is a sexually transmitted infection (STI) caused by the spirochete bacterium Treponema pallidum.

4. PROCEDURE:

4.1 Principle of RPR test:

4.1.1 The RPR antigen is a cardiolipin suspension containing charcoal micro-particles. It is prepared using VDRL antigen to which Choline chloride has been added to eliminate the need for inactivating serum. Some additive is also added to enhance the stability of suspension and the charcoal particles to enable the test to be read visibly. This antigen detects an antibody called Reagin present in the serum of Syphilitic patients. If a sample contains reagin, a flocculation of the antigen is produced which coagglutinate with the charcoal micro-particles giving black clumps of different size depending on the reagin titre.

4.2 Specimen Requirements:

4.2.1 Fresh serum samples should be collected in the manner routinely used for any clinical laboratory test.

4.2.2 Sample collected in plain tube (Yellow/ Red) only – 2 ml.

4.2.3 Sample must be at room temperature upon performing the test.

4.2.4 Sample is stable for no longer than 72 hours after collection if stored at 2- 8oC and for longer period if frozen.

4.3 Procedure:

4.3.1 Qualitative:

4.3.1.1 Bring all reagents & samples to Room Temperature before beginning the test.

4.3.1.2 The Positive and Negative controls should be run each day testing is done.

4.3.1.3 To prepare antigen for testing attach the hub of the dispensing needle to the fitting on the plastic dispensing bottle. Shake the antigen ampule to re-suspend the particles. Open the ampule. Squeeze the dispensing bottle to collapse it. Insert the needle into the ampule and withdraw the antigen suspension into the dispensing bottle.

4.3.1.4 All samples are initially tested undiluted.

4.3.1.5 Place 50 uL serum/Plasma onto a 18-mm circle of the RPR test card then spread to fill the entire circle using the inverted Dispensator (Closed end). Do not spread beyond the confines of the circle.

4.3.1.6 Gently shake the antigen dispensing bottle to re-suspend the particles.

4.3.1.6 Rotate the card for 8 mins at 100± 2 rpm.

4.3.1.7 Immediately remove the card from the rotator. Briefly rotate & tilt the card by hand to aid in differentiating non-reactive from minimally reactive results.

4.3.1.8 Perform the quantitative test on serum specimens showing any degree of reactivity (clumping) or "roughness".

4.3.2 Semi- Qualitative:

4.3.2.1 Make serial two-fold dilutions of the sample in 9 g/L saline solution.

4.3.2.2 Repeat the procedure as in qualitative method.

4.4 **Reading:**

4.4.1 Medium or large clumps indicates reactive result.

4.4.2 Small clumps indicate weakly reactive.

4.4.3 No clumping or very slight indicates non-reactive.

4.5 **Interpretation:**

4.5.1 A negative test is normal and means no antibodies to Syphilis have been detected. The screening test is most likely be positive in secondary & latent Syphilis. During primary and tertiary Syphilis, this test may be falsely negative.

4.5.3 Calculation:

4.5.3.1 N.A

4.6 **Results reporting:**

4.6.1 Qualitative Test:

4.6.1.1 Negative results are released as negative

4.6.1.2 Positive results are indicated by observable agglutination in the reaction mixture

4.6.2 Semi- Quantitative Test:

4.6.2.1 Record the highest dilution showing a positive result:

Dilution	1:2	1:4	1:8	1:16
Saline	50ul	50ul	50ul	50ul
Serum	50ul	50ul	50ul	50ul
	Mix and transfer 50ul to next well	Mix and transfer 50ul to next well	Mix and transfer 50ul to next well	Discard 50ul of the mixture

4.7 **Quality Control:**

4.7.1 The positive control should show agglutination within 8 min at titre ¼ .

4.7.2 The negative control should show NO agglutination within 8 min.

4.7.3 Otherwise repeat the test.

4.7.4 For all RPR positive samples do confirmatory test.

5. MATERIAL AND EQUIPMENT:

5.1 RPR Carbon Antigen
5.2 Positive control
5.3 Negative control
5.4 Disp. Needle 20ul
5.5 Dispensing Bottle
5.6 Disposable Test Cards
5.7 Shaker, Pipette
5.8 Kit insert

6. RESPONSIBILITIES:

6.1 All technician assigned in Serology lab
6.2 The final report must be signed by section supervisor and approved by lab pathologist

7. APPENDICES:

7.1 N/A

8. REFERENCES:

8.1 UDI test kit pamphlet
8.2 Medical Laboratory Technology Methods & Interpretations 4th ed by Ramnik Saad

9. APPROVALS:

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