HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER
MATERNITY AND CHILDREN HOSPITAL

Department:	Laboratory and Blood Bank (Serology)		
Document:	Internal Policy and Procedure		
Title:	Rheumatoid Factor		
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 Rheumatoid Factor based on latex slide agglutination method.

2. DEFINITONS:

2.1 Rheumatoid Factor (RF) is an antibody that attaches to a substance in the body called IgG, forming a molecule known as an immune complex that can trigger different types of inflammation- related processes in the body. This is most often used to diagnose Rheumatoid arthritis. It may also be used to rule out or diagnose other inflammation- related conditions.

3. POLICY:

3.1 A rheumatoid factor test is one of a group of blood tests primarily used to help pinpoint a diagnosis of rheumatoid arthritis. These other tests may include: Anti-nuclear antibody (ANA) Anti-cyclic citrullinated peptide (anti-CCP) antibodies. C-reactive protein (CRP).

4. PROCEDURE:

4.1 Principle of RF Test:

4.1.1 The test is composed of polystyrene latex particles coated with human IgG, stabilized and suspended in Glycine buffer pH 8.2. If Rheumatoid Factor is present in serum, a clearly visible agglutinate forms within 2 mins when mixed with the latex.

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- 8°C and for longer period if frozen.

4.3 Procedure:

4.3.1 Qualitative:

4.3.1.1 Bring reagents and specimens to room temperature.

4.3.1.2 Place 1 drop (50 uL) of Positive control, Negative control, and serum on successive fields.

4.3.1.3 Re-suspend the RF latex reagent then add 1 drop to each field.

4.3.1.4 Mix well then gently rock the slide for 2 mins & read immediately.

4.3.2 Semi- Qualitative:

4.3.2.1 Set up at least 5 rings labelled as 1:2, 1:4, 1:8, 1:16, 1:32, etc.

4.3.2.2 Dilute sample according to dilution factor on successive wells with glycine saline (diluted 1:20).

4.3.2.3 Repeat the procedure as in qualitative method.

4.4 **Reading:**

4.4.1 NEGATIVE – indicated by a uniform milky suspension with no agglutination

4.4.2 POSITIVE – any observable agglutination in the reaction mixture.

4.4.3 WEAKLY REACTIVE- produces a very fine granulation or partial clumping; should be re-tested semi- quantitatively.

4.5 **Interpretation:**

4.5.1 A positive reaction is indicated by any observable agglutination in the reaction mixture. The highest dilution at which agglutination occurs gives the titer of the sample.

4.5.2 A high/ increasing amount of CRP in the blood suggests acute infection or inflammation.

4.5.3 Calculation:

4.5.3.1 Titer (mg/l) = 8 *D Where :D is the highest dilution at which agglutination occurs (*8 is the conversion factor)

4.6 **Results reporting:**

4.6.1 Qualitative Test:

4.6.1.1 Negative results are released as negative or < 8 mg/l.

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 last dilution of serum with visible agglutination:

Dilution	1/2 (16 mg/l)	1/4 (32 mgl/)	1/8 (64mg/l)	1/16 (128mg/l)
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 2 min.

4.7.2 The negative control should show NO agglutination within 2 min.

4.7.3 Otherwise repeat the test.

5. MATERIAL AND EQUIPMENT:

5.1 CRP Latex reagent
5.2 Positive control
5.3 Negative control
5.4 Glycine saline buffer
5.5 Slide with 6 circles
5.6 Dispenser pipette and mixing sticks
5.7 Shaker
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 CRESCENT CRP kit Pamphlet
8.2 Medical Laboratory Technology Methods & Interpretations 4th ed by Ramnik Saad

9. APPROVALS:

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