

Department:	Laboratory and Blood Bank (Serology)		
Document:	Internal Policy and Procedure		
Title:	C-Reactive Protein		
Applies To:	All Laboratory Staff		
Preparation Date:	January 06, 2025	Index No:	LB-IPP-173
Approval Date:	January 20, 2025	Version :	2
Effective Date:	February 20, 2025	Replacement No.:	LB-IPP-173(1)
Review Date:	February 20, 2028	No. of Pages:	03

1. PURPOSE:

1.1 This SOP is meant to be a guideline and to help the laboratory technician to perform and measure C- reactive protein based on latex slide agglutination method.

2. DEFINITONS:

2.1 C-reactive protein (CRP) is a substance produced by the liver in response to inflammation.

3. POLICY:

3.1 CRP is mainly used as a marker of inflammation. It is done to check for infection after surgery to identify and keep track of infectious diseases that cause inflammation and to see how well the treatment is working.

3.2 It is useful in assessing patients with Inflammatory Bowel Disease, Arthritis, Autoimmune Disease, Pelvic Inflammatory Disease, Lupus, Tuberculosis, Pneumonia and Cancer.

4. PROCEDURE:

4.1 Principle of CRP test:

4.1.1 C-reactive protein reagent kit is based on an immunological reaction between CRP antisera bound to biologically inert latex particles & CRP in the test specimen. When serum containing greater than 0.6 mg/dl CRP is mixed with the latex reagent, visible agglutination occurs.

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 μ L) of positive control, negative control, and serum on successive fields.

4.3.1.3 Re-suspend the CRP 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 as observed with negative control.

4.4.2 POSITIVE – indicated by observable agglutination in the reaction mixture.

4.5 Interpretation:

- 4.5.1 A positive reaction is indicated by any observable agglutination in the reaction mixture within 2 minutes. 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) = 6 * D Where : D is the highest dilution at which agglutination occurs (*6 is the conversion factor).

4.6 Results reporting:

- 4.6.1 Qualitative Test:
 - 4.6.1.1 Negative results are released as negative or < 6 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 (12 mg/l)	1/4 (24 mg/l)	1/8 (48mg/l)	1/16 (96mg/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

6. RESPONSIBILITIES:

- 6.1 All technician assigned in Serology lab.
- 6.2 The final report must be signed by section supervisor.

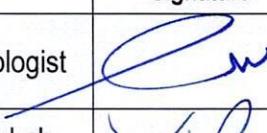
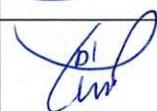
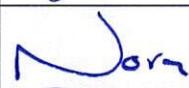
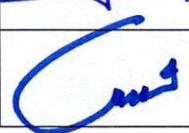
7. APPENDICES:

- 7.1 N/A

8. REFERENCES:

- 8.1 CRESCENT CRP kit Pamphlet
- 8.2 Medical Laboratory Technology Methods & Interpretations 4th edition by Ramnik Saad

9. APPROVALS:

	Name	Title	Signature	Date
Prepared by:	Dr. Fatma Hassan Ahmed	Clinical Pathologist		January 06, 2025
Reviewed by:	Dr. Kawther M. Abdou	Consultant & Lab. Medical Director		January 08, 2025
Reviewed by:	Ms. Noora Melfi Alanizi	Laboratory & Blood Bank Director		January 09, 2025
Reviewed by:	Mr. Abdulelah Ayed Al Mutairi	QM&PS Director		January 12, 2025
Reviewed by:	Dr. Tamer Mohamed Naguib	Medical Director		January 14, 2025
Approved by:	Mr. Fahad Hazam Alshammari	Hospital Director		January 20, 2025