



**RAPID LATEX KIT**  
**DIRECTIONS FOR USE**

**CRP Latex Kit: For Detection Of C-Reactive Protein (CRP) In Serum.**

**SUMMARY**

C-Reactive Protein (CRP) usually appears in serum of individuals in response to inflammatory conditions and tissue necrosis and disappears when causative conditions subside. It is routinely found in cases of bacterial infection, active rheumatic fever and many malignant diseases and is often seen in association with rheumatoid arthritis, viral infections and tuberculosis. CRP has also been detected in patients following blood transfusions and surgical operations as well as in patients with burns, pemphigus vulgaris and other bullous lesions.

**INTENDED PURPOSE**

The reagent is a latex test reagent intended to be used to qualitatively and semi-quantitatively determine the presence or absence of CRP in the serum or plasma of patients when tested in accordance with the recommended techniques stated in this IFU.

**PRINCIPLE**

When used by the recommended techniques, latex particles in the reagent will agglutinate (clump) in the presence of CRP. No agglutination (no clumping) generally indicates absence of CRP (see **Limitations**).

**KIT DESCRIPTION**

Lorne CRP Latex Test Kit is for the detection of CRP. Test reagent consists of latex particles coated with rabbit Anti-CRP (IgG). The reagents do not contain or consist of CMR substances, or endocrine disrupting substances or that could result in sensitisation or an allergic reaction by the user. All the latex reagents are supplied at optimal dilution for use with all recommended techniques without need for further dilution or addition. For lot reference number and expiry date see **Vial Labels**.

**STORAGE**

Do not freeze. Reagent vials should be stored at 2 - 8°C on receipt. Prolonged storage at temperatures outside this range may result in accelerated loss of reagent reactivity.

**SPECIMEN COLLECTION**

Specimens should be drawn with or without anticoagulant using an aseptic phlebotomy technique. If testing is delayed specimens can be stored at 2-8°C for 7 days or for up to 3 months at or below -20°C. Specimens must be free from bacterial contamination, fibrin, gross lipaemia and gross haemolysis.

**PRECAUTIONS**

1. The kit is for *in vitro* diagnostic use only.
2. Do not use kit past expiration date (see **Vial and Box Label**).
3. Protective clothing should be worn when handling the reagents, such as disposable gloves and a laboratory coat.
4. The reagents in this kit have been processed to reduce the bio-burden, but are not supplied sterile. Once a vial has been opened the contents should remain viable up until the expiry date.
5. Materials used to produce the kit were tested at source and found to be negative for HIV 1+2 and HBsAg using approved microbiological tests. However, no known tests can guarantee that products derived from human or animal sources are free from infectious agents. Care must be taken in the use and disposal of each vial and its contents.

**DISPOSAL OF KIT REAGENT AND DEALING WITH SPILLAGES**

For information on disposal of kit reagent and decontamination of a spillage site see **Material Safety Data Sheets**, available on request.

**CONTROLS AND ADVICE**

1. It is recommended that the CRP Positive and Negative Controls are tested in parallel with each batch of tests. Tests must be considered invalid if controls do not show expected results.
2. All the reagents must be allowed to reach 18-25°C before use.
3. Shake the reagents well before use to ensure homogeneity.
4. Do not interchange components between different kits.
5. Use of kit and interpretation of results must be carried out by properly trained and qualified personnel in accordance with the requirements of country where kit is in use. The user must determine the suitability of the kit for use in other techniques.

**KIT COMPONENTS SUPPLIED**

1. CRP Latex Reagent (White cap, 5 mL): Latex particles coated with goat IgG anti-human CRP, pH, 8.2, containing a preservative.
2. CRP Positive Control (Red cap, 1 mL): Human serum with a CRP concentration > 20 mg/L containing a preservative.
3. CRP Negative Control (Blue cap, 1 mL): Animal serum containing a preservative.
4. Pipette stirrers.
5. Disposable agglutination slide.

**MATERIALS AND EQUIPMENT REQUIRED BUT NOT SUPPLIED**

1. Serological Pipettes.
2. Mechanical rotator capable with adjustable speed of 80-100 rpm.
3. Vortex mixer.
4. Small Glass or Plastic Test Tubes.
5. Distilled or Deionised Water.
6. 9 g/L saline solution.

**RECOMMENDED QUALITATIVE TECHNIQUE**

1. Allow the reagents and samples to reach room temperature. The sensitivity of the test may be reduced at low temperatures.
2. Place 50 µL of the sample (Note 1) and one drop of each Positive and Negative controls into separate circles on the slide test.
3. Swirl the CRP Latex Reagent thoroughly but gently before use and add one drop (50 µL) next to the samples to be tested.
4. Mix the drops with a stirrer, spreading them over the entire surface of the circle. Use different stirrers for each sample.
5. Place the slide on a rotary shaker at 80-100 r.p.m. for 2 minutes. False positive results could appear if the test is read after more than two minutes.

**INTERPRETATION OF QUALITATIVE RESULTS**

1. **Positive:** Visible agglutination of latex particles constitutes a positive result and within the accepted limitations of the test procedure, indicates a level of CRP in the specimen > 6 mg/l.
2. **Negative:** No visible agglutination of latex particles constitutes a negative result and within the accepted limitations of the test procedure, indicates a level of CRP in the specimen < 6 mg/l.

**RECOMMENDED SEMI-QUANTITATIVE TECHNIQUE**

1. The semi-quantitative test can be performed in the same way as the qualitative test using dilutions of the serum.
2. Make doubling dilutions of the specimen using 9 g/L saline solution as follows:

Dilution	Serum	Saline
1/2	100 µl undiluted serum	100 µl
1/4	100 µl 1/2 diluted serum	100 µl
1/8	100 µl 1/4 diluted serum	100 µl
1/16	100 µl 1/8 diluted serum	100 µl

3. Test the specimen dilutions in the same way as for the quantitative technique above.
4. Agglutination of the sera indicates:

Dilution	CRP Levels (mg / l)
1/2	12 (6 x 2)
1/4	24 (6 x 4)
1/8	48 (6 x 8)
1/16	96 (6 x 16)



**Lorne Laboratories Limited**  
Unit 1 Cutbush Park Industrial Estate  
Danehill  
Lower Earley  
Berkshire, RG6 4UT  
United Kingdom  
Tel: +44 (0) 118 921 2264  
Fax: +44 (0) 118 986 4518  
E-mail: info@lornelabs.com

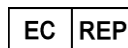
5. Normal levels of CRP in adults are < 6 mg/l.

#### NOTES

1. High CRP concentration samples may give false negative results (pro-zone effect). Re-test the sample again using a drop of 20 µl.

#### RESULTS

The titre is expressed as the reciprocal of the highest dilution showing macroscopic agglutination: e.g. if this occurs in dilution 1/8, the titre is 48.



Advena Ltd. Tower Business Centre, 2<sup>nd</sup> Flr.,  
Tower Street, Swatar, BKR 4013, Malta

#### INTERPRETATION OF SEMI-QUANTITATIVE RESULTS

The elevation of CRP levels above normal indicates tissue damage, inflammation, or both with greater reliability. Regular monitoring of CRP levels is often used as a means of assessing disease activity and of guiding therapy. CRP determination is considered of greater practical significance than other indicators of inflammatory disease. Erythrocyte sedimentation rate (ESR) may become elevated as a result of non-inflammatory conditions. In these circumstances inflammatory disease may be excluded if CRP is absent.

#### STABILITY OF THE REACTIONS

Slide tests should be interpreted immediately after the 2-minute rotation period to avoid the possibility that a negative result may be incorrectly interpreted as positive due to drying of the reagent.

#### LIMITATIONS

- Reactions read beyond the two-minute interval may be invalid.
- The results obtained from this assay must be considered a part of the differential diagnosis and medical history of the patient.
- There is no relationship between the strength of reactivity and C-reactive protein levels.
- Hemoglobin ( $\leq 10$  g/L), bilirubin ( $\leq 20$  mg/dL) and lipemia ( $\leq 10$  g/L), do not interfere. Rheumatoid factors ( $\geq 100$  IU/mL), interfere. Other substances may interfere<sup>7</sup>.
- False positive or false negative results may also occur due to:
  - Contamination of test materials
  - Improper storage of test materials or omission of reagents
  - Deviation from the recommended techniques

#### SPECIFIC PERFORMANCE CHARACTERISTICS

- The kit has been characterised by all the procedures mentioned in the **Recommended Techniques**.
- Prior to release, each lot of Lorne CRP Latex Test Kit is tested by **Recommended Techniques** to ensure suitable reactivity.
- The CRP-latex sensitivity is calibrated to the Reference Material ERM-DA 474/IFCC.
- Analytical sensitivity:** 6 (5-10) mg/L, under the described assay conditions.
- Prozone effect:** No prozone effect was detected up to 1600 mg/L (Note 1).
- Diagnostic sensitivity:** 95.6 %.
- Diagnostic specificity:** 96.2 %.

#### DISCLAIMER

- The user is responsible for the performance of the kit by any method other than those mentioned in the **Recommended Techniques**.
- Any deviations should be validated prior to use using established laboratory procedures.

#### BIBLIOGRAPHY

- David S.Jacobs et al. Laboratory Test Handbook, 3<sup>rd</sup> edition, Lexi-Comp Inc, 1994.

#### AVAILABLE KIT SIZES

Kit Size	Catalogue Number
100 Tests Per Kit	850100A