LORNE LABORATORIES LTD.

GREAT BRITAIN

TURBILATEX KIT

DIRECTIONS FOR USE

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

SUMMARY

C-Reactive Protein (CRP) is an acute phase protein present in normal serum, that increases significantly after most forms of tissue injury. It 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 and viral infection, active rheumatic fever and many malignant diseases and is often seen in association with rheumatoid arthritis 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 bullaous lesions.

PRINCIPLE

CRP Turbilatex is a quantitative turbidimetric test for the measurement of CRP in human serum or plasma. Latex particles coated with specific Anti-Human CRP are agglutinated when mixed with samples containing CRP. The agglutination causes a change in absorbance, dependent on the CRP concentration in the patient sample. The CRP concentration can be quantified by comparing the absorbance change against the absorbance change of a calibrator of known CRP concentration (see **Limitations**).

KIT DESCRIPTION

Lorne CRP Latex Test Kit is for the detection of CRP. Test reagent consists of latex particles coated with goat Anti-CRP (IgG). 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. Each kit component is stable until the expiry date on the individual vial labels when stored at the temperature indicated on the individual vial labels. 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 2-8ºC for 7 days or for up to 3 months at or below –20ºC. 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. Materials used to produce the kit were tested at source and found to be negative for HIV 1+2, HCV 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 control sera are used to monitor the performance of manual and automated assay procedures. It is recommended that ASO/CRP/RF Level L (catalogue number 1102114) and ASO/CRP/RF Level H (catalogue number 1102115) is used. Tests must be considered invalid if controls do not show expected results.
2. All the reagents must be allowed to reach 18-25ºC 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) Diluent (R1): Tris buffer 20 mmol/l, pH 8.2, Sodium azide 0.95 g/L.
2) Latex (R2): Latex particles coated with goat IgG anti-human CRP, pH 7.3, Sodium azide 0.95 g/L.
3) CRP-Cal: Calibrator. CRP concentration is stated on the label.
4) Optional: Ref: 1102114 Control serum ASO/CRP/RF level L(ow).
5) Optional: Ref: 1102115 Control serum ASO/CRP/RF level H(igh).

MATERIALS AND EQUIPMENT REQUIRED

- SPINLAB 180 autoanalyser.
- Laboratory equipment.

SPINLAB 180 APPLICATION

Name	CRP	Ref. male low	*
Abbr. Name	CRP	Ref. male high	*
Mode	Twopoints	Ref. female low	*
Wavelength	546 nm	Ref. female high	*
Units	mg/L	Ref. Ped. low	*
Decimals	1	Ref. Ped. high	*
Low Conc.	2 mg/L	Panic value low	*
High Conc.	150 mg/L	Panic value high	*
Calibrator Name	CAL CRP	Control 1	*
Prozone check	No	Control 2	*
		Control 3	*
		Correlat. Factor	1.000
		Correlat. offset	0.000

Dual Mode

Sample blank	No
R1 bottle (ml)	25 ml
normal volume	240 µl
Rerun volume	240 µl
Sample	
normal volume	3.0 µl
Rerun volume	3.0 µl
R2 bottle (ml)	5 ml
normal volume	60 µl
Rerun volume	60 µl
Predilution	No
Slope blank	No
Point one, two	6,130 sec.

Reagent blank	No
Low absorbance	-0.100 Abs
High absorbance	3.000 Abs
R. Abs. L. Limit	-0.100 Abs
R. Abs. H. Limit	3.000 Abs
Substrate Depletion	3.000 Abs

LIMITATIONS

1. Hemoglobin (≥ 5 g/L) interferes. Bilirubin (≤ 20 mg/dL), lipemia (≤ 10 g/L) and Rheumatoid Factors (≤ 300 IU/mL) do not interfere. Other substances may interfere[7].
2. False positive or false negative results may also occur due to:
   a) Contamination of test materials
   b) Improper storage of test materials or omission of reagents
   c) Deviation from the recommended techniques

SPECIFIC PERFORMANCE CHARACTERISTICS

1. The kit has been characterised by all the procedures mentioned in the **Recommended Techniques**.
2. Use CRP calibrator reference 1107002. Reconstitute the calibrator with 1.0 ml of distilled water. Mix gently and incubate for 10 minutes at room temperature before use.
3. The CRP-latex sensitivity and the target value of the calibrator have been standardised against Reference Material CRM 470/RPPHS (Institute for Reference Materials and Measurements, IRMM).
4. Normal values are up to 6 mg/L. Each laboratory should establish its own reference range.

DISCLAIMER

1. The user is responsible for the performance of the kit by any method other than those mentioned in the **SPINLAB 180 APPLICATION**.
2. Any deviations should be validated prior to use using established laboratory procedures.

BIBLIOGRAPHY

1. Lars-Olof Hanson et al. Current Opinion in Infect Diseases 1997; 10:196-201.
2. Chetana Vaishnavi. Immunology and Infectious Diseases 1996; 6: 139-144.
3. Yoshitsugy Hokama et al. Journal of Clinical Lab. Status 1987; 1:15-27.
4. Kari Pulki et al. Scand J Clin Lab Invest 1986; 46: 606-607.
5. Werner Müller et al. Journal of Immunological Methods 1985; 80: 77-90.
6. Shogo Otsuji et al. Clin Chem 1982; 28/10: 2121-2124.
7. Young DS. Effects of drugs on clinical laboratory test, 4th ed. AACC Press, 1995

AVAILABLE KIT SIZES

Kit Size	Catalogue Number
100 Tests Per Kit	151150A

For the availability of other sizes, please contact:

Lorne Laboratories Limited
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Danehill
Lower Earley
Berkshire RG6 4UT
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TABLE OF SYMBOLS

LOT	Batch Number	IVD	*In-vitro* Diagnostic
REF	Catalogue Reference		Store At
	Expiry Date		Manufacturer
	Read Pack Insert		