High-Q CRP Ultra Wide Range

Latex Enhanced Turbidimetric Immuno Assay (LETIA)

Pariksha Biotech
A game changer in IVD

HIGH®
Command on Quality

Intended Use:

For the quantitative measurement of C-Reactive protein in human serum and lithium heparin or EDTA plasma samples by immunoturbidimetry. Measurement of C-Reactive protein is useful in the detection and evaluation of infection, tissue injury inflammatory disorders.

Test Summary:

CRP (C-Reactive protein) is a cytokine-induced, acute phase protein and that increases in concentration as result of the inflammatory process, most notably in response to pneumococcal bacterial infections, histolytic disease and a variety of disease states. Originally discovered by Tillet et al in 1930 in patient sera with acute infection, CRP has come to be used as a mark er or general diagnostic indicator of infections and inflammation. In healthy persons, serum and plasma levels are usually below 5 mg/L, whereas this threshold is often exceeded within a few hours after an acute inflammatory event, with CRP values reaching 20 to 500 mg/L. The assay of CRP is more sensitive than the erythrocyte sedimentation rate (ESR) and the leukocyte count and CRP levels rise and return to reference intervals more rapidly after the disease has subsided.

Increase in CRP values are non-specific and should not be interpreted without a complete clinical assessment.

Test Principle:

The CRP Ultra Wide Range Reagent kit is a latex-enhanced turbidimetric in vitro immunoassay. CRP in the sample binds to the specific anti-CRP antibody, which has been adsorbed to latex particles and agglutinates. The agglutination is detected as an absorbance change when read on an automated clinical chemistry analyzer (at 546 nm). The magnitude of the change is proportional to the quantity of CRP in the sample . The actual concentration is then determined by interpolation from a calibration curve prepared from calibrators of known concentrations.

Reagents Composition

Component	Ingredients	Concentration
Reagent 1	Glycine buffer solution	125 mMoL
Reagent 2	Latex particles sensitized with anti-CRP antibodies (rabbit polyclonal)	0.20 w/v %
CRP Calibrator	C-Reactive Protein (Lot Specific)	Concentration on the labels

CRP Calibrator Concentration has been standardized against the Reference Material ERM-DA 474/IFCC.

Warnings and Precautions for use

1. For *in vitro* diagnostic use.
2. Do not use the reagents beyond the expiration date printed on the label.
3. CRP Ultra Wide Range Reagents must be used with the CRP Ultra Wide Range Calibrator.
4. **Caution** : Reagent 1 and 2 contains < 0.1% sodium azide as an antimicrobial agent. Sodium azide may react with lead and copper plumbing to form potentially explosive metal azide buildup. Flush with copious amounts of water when discarding material.
5. Powder-free gloves should be worn. Avoid direct skin contact.

   See Material Safety Data Sheet for additional information.

Reagent Presentation, Storage and Stability

Reagent 1: Liquid.
Reagent 2: Liquid. Mix contents gently prior to use.

Reagents are stable till the expiry dates mentioned on the label when stored at 37 °C

Specimen:

Serum, EDTA plasma, and lithium heparinized plasma are the recommended sample types. Use standard sample collection and preparation methods.

If not analyzed promptly, serum or plasma specimens may be stored at -20°C

Analytical Specificity:

Limitations/Interfering Substances

The following do not interfere with the CRP Ultra assay:

Hemoglobin	up to 500 mg/dL
Conjugated bilirubin	up to 30 mg/dL
Unconjugated bilirubin	up to 30 mg/dL
Triglycerides	up to 3000 mg/dL
Intrafat	up to 5%
Rheumatoid factor	up to 560 IU/mL

Procedure: Fixed Time

Pipette into test tubes labeled Calibrator (C) and Test (T).

Reagent	(Calibrator)	(Test Sample)
Reagent -1	0.4 ml	0.4 ml
CRP Calibrator	5 µl	-
Sample	-	5 µl
Reagent -2	0.1 ml	0.1 ml

Mix well and read absorbances of Calibrator (C) and Test (T) against distilled water at 546 nm (530-550 nm) as follows:

Initial absorbance A1 -exactly after 5 sec.
Final absorbance A2 - exactly 120 sec. after A1
Determine Δ A for Calibrator (C) and Test (T)

Calculations :

$$\text{CRP Conc.: (mg/L)} = \frac{\text{(A2-A1) Sample}}{\text{(A2-A1) Calibrator}} \times \text{Calibrator Concentration}$$

System Parameters :

Reaction Type	: Fixed Time / Initial Rate / Two Point Kinetic
Reaction Direction	: Increasing
Sample Volume	: 5 µl
R1	: 0.4 ml
R2	: 0.1 ml
Wave Length	: 546 nm (530-550 nm)
Calibrator Conc.	: Concentration Lot Specific, Verify on the labels
Flow Cell Temp.	: 37ºC
Linearity	: 150
Zero setting with	: Distilled Water
Units	: mg/L
Delay	: 5 sec.
Interval	: 120 sec

Quality Control

Control Sera are recommended to monitor the performance of manual and automated assay procedures.

Each laboratory should establish its own Quality Control scheme
Can be used on semi and fully auto analyzers

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Reference Values:

Normal values Adults up to 6.0 mg/L.

New Borns up to 3 weeks < 4.1 mg/L
Infants and Children < 2.8 mg/L

The normal range of CRP was evaluated in 612 healthy adults (305 men with the age distribution of 20-66 years and 307 women with the age distribution of 19-68 years) using the CRP Ultra Wide Range assay kit. Of the 612 adults, 90% had values <2.5 mg/L and 10% had values from 3.0-6.0 mg/L.

Each laboratory should establish its own reference range.

Calibration:

Only the CRP Ultra Wide Range Calibrators should be used to calibrate the CRP Ultra Wide Range assay. The assigned values of the CRP Ultra Wide Range Calibrators are standardized against ERM-DA 472/IFCC.

Quality Control:

Reliability of test results should be monitored routinely with quality control materials or serum pools that reasonably represent performance with patient specimens. Controls or serum pools should be used to monitor that the reagents are functioning properly and that correct procedures are being followed. An acceptable range for each lot of control material should be established by the laboratory. If control values are not within the expected range, follow normal troubleshooting procedures.
Quality Control values should be within the expected ranges.

Performance Chracterestics

Reportable Range:

Functional Sensitivity:

The functional sensitivity for the CRP Ultra Wide Range reagent was found to be 0.1 mg/L.
The functional sensitivity was determined as the lowest measurable CRP concentration with a CV less than 20%. The functional sensitivity was obtained from 20 replicated measurements of each of the equally spaced serial dilutions of CRP.

Lower Detection Limit:

The lower detection limit was found to be 0.10 mg/L. The lower detection limit was assessed using zero standard (saline) and serial dilutions of the lowest CRP Ultr a calibrator (10 mg/L). All the samples were assayed in 20 replicates and a mean value and SD were calculated for each sample. The lower detection limit was determined as the CRP concentration of which mean -2SD does not overlap with the mean +2SD of the zero standard (saline).

Specificity:

When sera containing known levels of CRP in the assay range were measured, the values obtained for the sera were in the range of the know concentration, plus or minus 10%.

Linearity

The CRP Ultra Wide Range method is linear up to 150.0 mg/L. Recovery of Linearity depends on the photometric absorption limit of the instrument that is used while performing the assay. Reducing the sample volume may yield better linearity

Specimens above the assay range may be diluted with physiological saline. Multiply the result by the dilution factor to obtain the CRP concentration for the sample.

Precision Studies:

Precision of the CRP Ultra Wide Range Reagent was determined using 3 levels of control material on the Roche Hitachi 917 analyzer.

Within-Run Precision

Control	n	Mean Recovery (mg/L)	Standard Deviation (mg/L)	CV
Level 1	21	0.46	0.03	5.74%
Level 2	21	2.28	0.05	1.99%
Level 3	21	9.81	0.11	1.16%

Total Precision

Serum pool/ Control	n	Mean Recovery (mg/L)	Standard Deviation (mg/L)	CV
Level 1	21	0.47	0.03	6.97%
Level 2	21	2.18	0.07	3.34%
Level 3	21	9.76	0.12	1.23%

Accuracy:

Comparative performance studies were conducted using the CRP Ultra Wide Range Reagent on the Roche Hitachi 917 clinical analyzer and a marketed CRP ne phelometric assay using 451 male and female serum samples, with concentrations between 0.03 and 23.9 mg/L.

The regression analysis is provided below:

CRP Ultra vs a nephelometric assay(n = 451)	
Slope	1.012
Intercept (units)	0.005
Correlation Coefficient (r)	0.999

Product Features

- Latex Enhanced Turbidimtric Immuno Assay (LETIA)
- Two liquid reagents (Turbilatex and Diluent).
- Linearity : Up to 150 mg/L
- Liquid Calibrator provided
- Greater delectability of Pediatric CRP Values
- No Prozone effect was detected upon 150 mg/L
- Bilirubin (500 mg/dl), Lipemia (3000 mg/dL) and Rheumatoid factors (560 IU/ml)
- Do not Interfere where as Hemoglobin (≥ 6 g/l) interferes.

Symbols used with IVD devices

	Date of manufacture		Manufactured by
IVD	In vitro diagnostic device		Keep away from sunlight
	Do not freeze		This way up
	Use by (yyyy-mm-dd or mm/yyyy)	R	Reagent
CAL	Calibrator Material	LOT	Batch code
2°C 8°C	Temperature limitation (store at)	CONTROL	Control
	Consult instructions for use		Keep dry Keep away from rain
REF	Catalog Number		

eIFU Indicator

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SCAN TO EXPLORE MORE

Manufactured in India by :
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