C - Reactive Protein (CRP) Kit
CliniQuant
Latex Turbidimetry

Meril Diagnostics

For *in vitro* diagnostic use
Read this pack insert thoroughly before use

REF CRPLIT-01	R1 CRP Reagent	R2 CRP Reagent	R3 CRP Standard
Pack size	1 x 40 ml	1 x 10 ml	1 x 1 ml

INTENDED USE
This reagent is intended for quantitative determination of C-reactive protein (CRP) in human serum by latex turbidimetry.

CLINICAL SIGNIFICANCE
C-Reactive Protein (CRP) is an acute phase protein produced by the liver in response to inflammation, infection and tissue injury. Increased CRP concentrations occur much earlier than other acute phase reactants and this rapid response to trauma or infection is the distinguishing feature of CRP. In addition, CRP levels return to normal quickly at the end of an acute episode making CRP useful for both the detection of acute episodes as well as in treatment monitoring.

PRINCIPLE OF THE METHOD
Latex particles coated with specific rabbit anti-human CRP are agglutinated when mixed with samples containing CRP. The agglutination causes an absorbance change, dependent upon the CRP contents of the patient sample that can be quantified by comparison from calibrators of known CRP concentrations.

KIT COMPONENTS
R1 - CRP Reagent
R2 - CRP Reagent
R3 - CRP Standard

MATERIALS REQUIRED BUT NOT PROVIDED
Laboratory instrumentation, Spectrophotometer UV/VIS with thermostatic cuvette holder or clinical chemistry analyzer: semi automated, calibrated micropipettes, glass or high quality polystyrene cuvettes, test tube/rack, heating bath, controls, saline.

REAGENT PREPARATION , STORAGE & STABILITY
Reagent is ready to use. Mix reagent R2 well before processing.
Mix reagent 1 & reagent 2 in ratio of 4:1. Keep away from direct light sources.
Stability : up to expiration date on labels at 2-8°C. Do not freeze the reagent.

WARNINGS AND PRECAUTIONS
1. For *in vitro* use only.
2. This pack insert must be completely understood prior to operation. Do not modify the test procedure or substitute reagents from other manufacturers or other lots unless the reagent is stipulated as interchangeable. It is recommended to handle carefully by entitled and professionally educated person.
3. Do not pipette by mouth. Use disposable gloves while performing the assay. Wash hands thoroughly when finished.
4. Follow good laboratory practice to avoid microbial contamination of reagents as this may reduce the life of the product and cause erroneous results.
5. Do not use reagents beyond the expiry date.
6. In case of skin contact with any of the reagents, wash thoroughly with running water.

SPECIMEN
Fresh serum : Stable for 7 days at 2 - 8°C . Do not use hemolyzed or lipemic sample.

Programme Parameter for MERILYZER CliniQuant

Reading Mode	Fixed Time
Standard Conc.	lot specific
Filter – 1 (nm)	546 nm
Temperature	37 ° C
Volume (µl)	500
Delay Time (Sec)	10
Read Time (Sec)	120
Reaction Direction	Increase
Reference Low	0
Reference High	6
Linearity Limit	150

TEST PROCEDURE

Dispense	Blank	Standard	Sample
Working reagent	1ml	1ml	1ml
Distilled water	20 µl	-	-
Standard	-	20 µl	-
Sample	-	-	20 µl

Mix, incubate 10 seconds at 37°C, then record absorbance as A1. After exactly 120 seconds, record again absorbance as A2.

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RESULT CALCULATION

Serum :

CRP mg/L =A2-A1(Sample)/A2-A1(Standard) x Concentration of Standard

EXPECTED VALUES

Up to 6 mg/L.
It is recommended that each laboratory verifies this range or derives reference interval for the population it serves.

QUALITY CONTROL AND CALIBRATION

It is recommended to perform internal quality control with assayed normal and assayed abnormal to confirm the validity of the test and assure the accuracy of patient result.
Using the recommended Calibrator or the Standard included, calibrate the assay:
a. When using a new reagent or lot
b. When QC values are out of range

PERFORMANCE CHARACTERISTICS

1.Linearity

The linearity up to 150 mg/L

2.Sensitivity/ Limit of detection (LOD)

The limit of detection is 0.68 mg/L.
The limit of quantification is 2.09 mg/L.

3. Interferences

No interference has been observed for the following
Bilirubin up to 20 mg/dl.
Hemoglobin up to 500 mg/dl.
Triglycerides up to 500 mg/dl.

4.Precision

Intra-assay precision

	Mean	SD	CV
n = 20	mg/L	mg/L	%
Control L1	22.73	0.68	2.97
Control L3	59.05	1.11	1.88

Inter-assay precision

	Mean	SD	CV
n = 20	mg/L	mg/L	%
Control L1	22.89	1.03	4.48
Control L3	54.72	1.70	3.11

4.Methods Comparison

Comparison was done between CRP Reagent (y) & reference CRP Kit (x) using 20 samples gave following results:
$y = 1.0220x + 0.0462$
$r^2 = 0.9997$

LIMITATIONS

Samples with values above 150 mg/L should be diluted with 0.9% saline, re-run and multiply results by dilution factor.

WASTE DISPOSAL

This product is made to be used in professional laboratories. Please consult local regulations for correct waste disposal.

REFERENCES

1. Alouf Jodeph E.Pharma Ther 1980;11:661-717.
2. M Fasani et al eur J Lab Med 1994;Vol 2 no 1-67.
3. Todd E W J Exp Med 1932;55-267-280.

IFU/CRPLIT01/02
22-01-2021

Symbols used on Meril Diagnostics labels:

REF	Catalogue No.		Attention See Instruction for Use
LOT	Batch No.	IVD	*In vitro* Diagnostics
	Expiry Date		Consult Instruction for Use
	Manufacturer		Storage Temperature
	Keep Dry		Keep Away from Sunlight
	Manufacturing Date		Do not use if package is damaged