CRP Kit

CliniQuant-TIA

Meril Diagnostics

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

REF	Pack Size	R1 Buffer Reagent	R2 Antiserum Reagent	R3 Calibrator
CRPTIA-01	1 x 40 / 1 x 10ml	1 x 40ml	1 x 10ml	1 x 1ml

INTENDED USE

CliniQuant-TIA CRP Kit is intended for the quantitative determination of C-Reactive Protein in human serum by turbidimetric immunoassay.

INTRODUCTION

C-reactive protein (CRP) is an acute phase protein synthesized in the liver. Its rate of synthesis increases within hours of acute injury or the onset of inflammation and may reach as high as 20 times the normal levels. A rapid fall of CRP indicates recovery. The degree of elevation of CRP level directly reflects the mass of activity of inflamed tissue. Its ability to fall to normal levels on resolution of the condition renders quantified CRP values to be a good indicator to allow rapid selection of appropriate anti-inflammatory therapy in several rheumatic diseases which are clinically difficult to assess. Apart from indicating inflammatory disorders, CRP levels helps in differential diagnosis, in the management of neonatal septicemia and meningitis where standard microbiological investigations are difficult. CRP levels rise invariably after major surgery, but fall to normal within 7-10 days. Absence of this fall is indicative of septic or inflammatory postoperative complications. Serum CRP concentration provides useful information in patients with myocardial infarction there being an excellent correlation between peak levels of CRP and creatine phosphokinase.

PRINCIPLE OF THE TEST

CliniQuant-TIA CRP is a turbidimetric assay for determination of C-reactive protein in human serum and is based on the principle of agglutination reaction. When the activation buffer mixed with sample is allowed to react with the CliniQuant-TIA CRP reagent, an insoluble complex is formed in the presence of CRP imparting turbidity which can be measured at 340 nm. The concentration of CRP is dependent on the intensity of turbidity.

KIT COMPONENTS

R1- Buffer : Phosphate buffered saline (pH 7.43), Polyethylene glycol (40 g/l), Sodium azide (0.09 %)

R2 - Anti serum Reagent : Phosphate buffered saline (pH 7.43), Polyclonal goat anti-human CRP (variable), Sodium azide (0.09 %)

R3 - Calibrator : Dilution of human plasma and pleural fluid containing high levels of CRP with phosphate buffered saline, liquid and stabilized. Contains 0.09 % sodium azide

MATERIALS REQUIRED BUT NOT PROVIDED

1. Micropipettes of appropriate volume (the use of accurate pipettes with disposable plastic tips is recommended).
2. 0.9% Saline
3. Vortex mixer
4. Water bath (37°C)
5. Appendorfs or test-tubes.
6. Instrumentation: Semi auto analyzer

STORAGE OF TEST KIT

Unopened test kits should be stored at 2-8 °C upon receipt. The test kit may be used throughout the expiration date on the kit (1 year from the date of manufacture). Do not freeze.

SPECIMEN COLLECTION, PREPARATION, TRANSPORT AND STORAGE

1. No special preparation of the patient is required prior to specimen collection by approved techniques.
2. Only serum should be used for testing.
3. Should a delay in testing occur, store the sample at 2-8°C.
4. Samples can be stored for upto a week at 2-8°C, provided they are not contaminated.
5. Do not use hemolysed, icteric or highly turbid serum. Turbid or particulate serum samples must be clarified by centrifugation at 2000 rpm for 15 minutes. Use the clear supernatant for testing.

PRECAUTIONS AND WARNINGS

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. Sodium azide has been reported to form lead or copper azide in laboratory plumbing which may explode on percussion. Flush drains with water thoroughly after disposing of fluids.
5. Follow good laboratory practice to avoid microbial contamination of reagents as this may reduce the life of the product and cause erroneous results.
6. Ensure that the assay is incubated at the mentioned temperature in the protocol.
7. Each donor unit used in the preparation of standards and controls was found to be negative for the presence of HIV1 and HIV2 antibodies, as well as for the hepatitis B surface antigen and anti-hepatitis C antibodies, using a method approved by FDA.
8. Do not use reagents beyond the expiry date.
9. In case of skin contact with any of the reagents, wash thoroughly with running water.
10. Shake the R2: Antiserum reagent well before use to improve test performance.
11. The calibration curve must be validated periodically with known controls.

Programme Parameter for MERILYZER CliniQuant

Reading Mode	Sample blank non-linear
Calibrator Conc.	(mg/dl) See vial label
Filter – 1 (nm)	340
Temperature	37 °C
Volume (µl)	450
Delay Time (Sec)	5
Reaction Direction	Increase
Standard nos.	6
Reference Low	0
Reference High	1

CE
Meril Diagnostics Pvt. Ltd., Second Floor, D1-D3, Meril Park, Survey No. 135/2/B & 174/2, Muktanand Marg, Chala, Vapi-396191, Gujarat, India. T+91-260-3052100, F +91-260-3052125, W www.merillife.com
EC REP Obelis s.a., Bd General Wahis 53, 1030, Brussels, Belgium. T +(32) 2 732-59-54, F +(32) 2 732-60-03, E mail@obelis.net

TEST PROCEDURE

Bring reagents and specimen to room temperature before use.

Preparation of calibration curve

The concentration of R3: Calibrator is as mentioned on the vial label.

Dilute the calibrator serially as mentioned below for preparation of calibration curve.

Test Tube No.	1	2	3	4	5	6
Calibrator dilution No.	D1	D2	D3	D4	D5	D6
0.9% Saline	-	100 µl	100 µl	100 µl	100 µl	100 µl
Calibrator	100 µl	100 µl	100 µl	100 µl	100 µl	100 µl

The above five dilutions of the calibrator including the highest (D1) and lowest (D6) concentrations of measuring range must be used for the preparation of the calibration curve.

"The calibration curve so obtained is valid only for the same lot of reagents.

Test procedure:

(Note: During calibration on instrument with programming facilities, increasing concentration of standards must be used for preparing the calibration curve).

1. Pipette 800 µl Buffer (R1) and mix 64 µl standards, controls and samples.
2. Read optical density (OD1) of samples, controls and standards at 340 nm.
3. Add 200 µl of antiserum to the above
4. Mix and incubate for 5 minutes at 37°C.
5. Read the optical densities (OD2) of samples, controls and standards at 340 nm.

Calculate ΔOD'S, plot a standard curve and read the concentration of controls and sample.

RESULTS

1. Calculate ΔOD's, plot a standard curve and read the concentration of controls and samples.
2. Interpolate ΔOD of the diluted test specimen on the calibration curve and obtain the CRP concentration 'C' of the diluted test specimen.
3. Multiply the albumin concentration 'C' with the dilution factor (F) of the test specimen for obtaining the concentration of CRP in the neat test specimen.

Concentration of CRP in the neat test specimen in mg/dl = C x F (Where 'F' is the dilution factor of the test specimen)

PERFORMANCE CHARCTERISTICS

1. Linearity

The measuring range is 0 to 32 mg/dl.

2. Sensitivity/ Limit of detection (LOD)

The limit of detection is 0.08 mg/dl.

3. Accuracy

mg/dl

Control	Assigned	Measured
Level 1	2.63 (2.1 – 3.16)	2.5
Level 2	5.26 (4.21 – 6.31)	5.02
Level 3	7.15 (5.72 – 8.58)	7.06

4. Precision

Intra-assay precision

	Mean	SD	CV
n = 30	mg/dl	mg/dl	%
sample 1	0.68	0.02	3.25
sample 2	5.62	0.03	0.57

Inter-assay precision

	Mean	SD	CV
n = 60	mg/dl	mg/dl	%
sample 1	0.71	0.04	5.25
sample 2	5.51	0.12	2.11

REFERENCE VALUES

The reference value for CRP was determined to be 0-1 mg/dl with CliniQuant-TIA CRP. It is recommended that each laboratory must define its own reference range.

WARRANTY

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

BIBLIOGRAPHY

1. M.B.Pepys, G.M.Hirschfield., C-reactive protein: a critical update., The journal of Clinical Investigation, volume 111.,2003.
2. L.Wu, T.Han, X.Fan et al., Serum C-reactive protein as a possible marker to predict delayed hemorrhage after colonoscopic polypectomy., Med Sci Monit; 18(8): CR480-485., 2012.
3. K.Seo, J.Lee, J.Ahn et al., C-reactive protein as an indicator of inflammatory responses to experimentally induced cyctitis in dogs., J. Vet Sci, 13(2):79-185, 2013.
4. Y.j.li, Z.M.Li, Y.Xia et al., Serum C-reactive proteinc (CRP) as a simple and Independent Prognostic Factor in Extranodal Natural Killer/T-Cell Lymphoma, Nasal Type., PLOS ONE., volume 8, issue 5, e64158.,2013.
5. S.J.Semple., C-reactive protein- biological functions, cardiovascular disease and physical exercise. SAJSM, vol. 18 No. 1, 2006.
6. Data on file: Meril Diagnostics.

IFU/CRPTIA01/00
06-11-2018

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

EC REP Authorized European Representative in the European Community