TurbiMAX CRP

(Turbilatex / Immunoturbidometric)

ORDERING INFORMATION:

Ref. No.	Pack Size	Presentation
AVCRPT- 50	50 ml	Two Liquid Reagents with Calibrator
AVCRPT- 250	5 x 50 ml	

INTENDED USE

Kit is use for the Quantitative determination of C - reactive protein (CRP) in human Serum.

PRODUCT FEATURES :

1. Quantitative Immunoturbidometric Assay.
2. Two liquid stable reagents (Turbilatex and Diluent).
3. Linearity : 75 mg/L.
4. Liquid Stable Calibrator provided.
5. No Prozone effect was detected upon 800 mg/L.

CLINICAL SIGNIFICANCE

CRP is an acute-phase protein present in normal serum, which increases significantly after most forms of tissue injuries, bacterial and virus infections, inflammation and malignant neoplasia. During tissue necrosis and inflammation resulting from microbial infections, the CRP concentration can rise up to 300 mg/L in 12-24 hours.

PRINCIPLE

CRP-Turbilatex is a quantitative turbidimetric test for the measurement of C-reactive protein (CRP) in human serum. Latex particles coated with specific 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 a calibrator of known CRP concentration.

STORAGE AND STABILITY

All the components of the kit are stable until the expiration date on the labels when stored at 2-8ºC and the contaminations is prevented during their use.

KIT COMPONENTS

1. Diluent Reagent R1
2. Turbi Latex Reagent R2
3. CRP Calibrators : Concentration as stated on the label

COMPOSITION

Diluent (R1)	Tris buffer 100 mmol/L, pH 8.2. Sodium azide 0.95 g/L.
Latex (R2)	Latex particles coated with goat IgG anti-human CRP, pH 7.3. Sodium azide 0.95 g/L.
CRP-CAL	Calibrator: C-Reactive protein

REAGENT RECONSTITUTION & STABILITY

Reagent are liquid stable no need for reconstitution.

When the reagent is stored properly at 2-8°C & the contamination avoided, it is stable up to the expiry date mention on the label & kit box.

MATERIAL REQUIRED BUT NOT PROVIDED

Laboratory Instrumentation, Spectrophotometer UV/VIS with thermostatic cuvette holder or clinical chemistry analyzer: semi auto, calibrated micropipettes, glass or high quality polystyrene cuvettes, test tube/rack, heating bath controls, saline.

REAGENT DETERIORATION

Discard reagent if blank reagent absorbance exceeds 1.3 at 546 nm against Distilled water.

WARNING & PRECAUTIONS

- Reagent may contain some non reactive and preservative components. It is recommended to handle carefully, avoiding contact with skin and ingestion.
- Specimen should be considered infectious and handled appropriately.
- Contamination by soap or glycerol will affect this assay.
- Perform the test according to the general " Good Laboratory Practice" GLP.

SPECIMEN COLLECTION & STORAGE

Fresh serum. Stable 7 days at 2-8ºC or 3 months at –20ºC.
The samples with presence of fibrin should be centrifuged before testing.
Do not use highly hemolized or lipemic samples.

SYSTEM PARAMETERS :

Reaction Type	:	Fixed Time / Initial Rate / Two Point Kinetic
Reaction Direction	:	Increasing
Sample Volume	:	10 µl
Working Reagent Volume	:	1000 µl
Wave Length	:	546nm (530-550 nm)
Calibrator Conc.	:	**Printed on the vial**
Flow Cell Temp.	:	37°C
Linearity	:	75
Zero setting with	:	Distilled Water
Units	:	mg/L
Delay	:	10 sec.
Interval	:	120 sec

TEST PROCEDURE

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

Reagent	C	T
Reagent(R1)	800 µl	800 µl
CRP Calibrator	10 µl	-
Sample	-	10 µl
Reagent(R2)	200 µl	200 µl

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 10 sec.
Final absorbance A2 - exactly 120 sec. after A1
Determine ΔA for Calibrator (C) and Test (T)

CALCULATIONS :

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

EXPECTED VALUES

Normal values up to 6 mg/L.
Each laboratory should establish its own reference range.

Note:

1. In case of decreasing reaction observed, clean the flow cell with distilled water and Re-Run the sample.
2. If decreasing reaction observed again then sample value should be reported as less than 1mg/L.

QUALITY CONTROL & CALIBRATION

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

Each laboratory should establish its own Quality Control scheme.

Calibration

The sensitivity of the assay and the target value of the calibrator have been standardized against the Reference Material CRM 470/RPPHS (Institute for Reference Materials and Measurements, IRMM).

PERFORMANCE CHARACTERISTICS

1. Linearity limit: 75 mg/L

2. Sensitivity/ Limit of Detection (LOD)
The lower limit of detection is 0.6 mg/L

3.Interferences:
Bilirubin (20 mg/dl), lipemia (10 g/l) and rheumatoid factors (300 IU/ml) do not interfere. Hemoglobin (≥ 5 g/l), interferes. .

4. Precision:

Intra-Assay

N=10	Mean (mg/L)	SD (mg/L)	CV%
Control serum 1	15.08	0.46	3.08
Control serum 2	28.93	0.77	2.65
Control serum 3	56.66	0.79	1.4

Inter-Assay

N=10	Mean (mg/L)	SD (mg/L)	CV%
Control serum 1	14.88	0.7	4.72
Control serum 2	29.35	0.82	2.79
Control serum 3	57.38	1.49	2.59

5. Method Comparison:
Results obtained using this reagent (y) were compared to those obtained using a commercial reagent (x) with similar characteristics. 65 samples ranging from 1 to 75 mg/l of CRP were assayed. The correlation coefficient (r) was 0.98 and the regression equation y=0.892x + 0.282.

The results of the performance characteristics depend on the analyzer used.

LIMITATION
0.6 - 75 mg/L, under the described assay conditions. Samples with higher concentrations should be diluted 1/5 in saline (10 parts serum sample + 40 parts saline ex: 10µl serum sample+40 µl saline) and retested again and the results should be multiplied by 5.The linearity limit depends on the sample / reagent ratio, as well as the analyzer used. It will be higher by decreasing the sample volume, although the sensitivity of the test will be proportionally decreased.

WASTE DISPOSAL
Reagents must be disposed off in accordance with local regulations.

NOTES
Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

REFERENCE

1. Lars-Olof Hanson et al. Current Opinion in Infectious 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. Sacand 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.

Symbols Used on Pack

REF	Catalogue Number		Warning/Caution
LOT	Batch No.	IVD	In vitro diagnostic device
	Manufacturing Date		Storage Limit
	Expiry Date		Consult instruction for use
	Manufacturer		Keep away from sunlight
	Keep Dry		Do not use if package is damaged
	Contains sufficient no. of test		

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