TurbiMAX hS CRP

Latex Enhanced Turbidimetric Immuno Assay (LETIA)

ORDERING INFORMATION:

Ref. No.	Pack Size	Presentation
AVHSCRPT- 50	50 ml	Two Liquid Reagents with Calibrator

INTENDED USE

TurbiMAX hs CRP is an in-vitro diagnostic kit for the high sensitivity C-reactive protein (hsCRP) assay quantitative determination of C-reactive protein (CRP) in human serum and plasma on automated clinical chemistry analyzers. Measurement of CRP is of use for the detection and evaluation of inflammatory disorders and associated diseases, infection and tissue injury.

PRODUCT FEATURES

1. Two liquid reagents (Turbilatex and Diluent).
2. 5 Liquid Calibrators provided
3. Linearity : 100 mg/L
4. Multi Point - Non Linear Assay
5. 4 Minutes Assay (5 Sec Delay and 240 Sec Measuring)

CLINICAL SIGNIFICANCE

CRP (C-reactive protein, MW=25106Da) is an acute phase protein whose concentration is seen to increase as a result of the inflammatory process, most notably in response to pneumococcal (bacterial) infectious, histolytic disease, and a variety of disease states. Originally discovered by Tillet et al. in 1930 in patient sera with acute infection, CRP has now to be used as a marker or general diagnostic indicator of infections and inflammation, in addition to serving as a monitor of patient response to therapy and surgery. Furthermore, regular measurements of CRP in infants can be a useful aid in the early diagnosis of infectious diseases.

PRINCIPLE

The hsCRP assay is based on a latex enhanced immunoturbidimetric assay. When an antigen-antibody reaction occurs between CRP in a sample and anti-CRP which has been sensitized to latex particles, agglutination results. This agglutination is detected as an absorbance change (546 nm) with the magnitude of the change being proportional to the quantity of CRP in the sample. The actual concentration is then determined by the interpolation from a calibration curve prepared from calibrators of known 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. hS CRP Calibrators (5) : 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 1.4 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

SAMPLES 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 Label**
Flow Cell Temp.	:	37°C
Linearity	:	100
Zero setting with	:	Distilled Water
Units	:	mg/L
Delay	:	5 sec.
Interval	:	240 sec

TEST PROCEDURE

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

Reagent	C	T
Reagent(R1)	800 µl	800 µl
CRP Calibrator (1, 2, 3, 4, 5)	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 5 sec.
Final absorbance A2 - exactly 240sec. after A1
Determine ΔA for Calibrator (C) and Test (T)

CALCULATIONS :

hS 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:

The assay reference interval was determined using serum specimens from 103 apparently healthy adults with ages of 18- 62 according to CLSI C28-A3 guideline. The serum specimens were tested in duplicate by the hsCRP method. EP Evaluator 8 Software was used to verify the reference interval.
C-Reactive Protein is a non-specific indicator for a wide range of disease processes.
Reference intervals may be affected by different factors.
Expected values <6 mg/L
Recommended Cardiac risk assessment categories:

Low Risk for CVD	< 1 mg/L
Intermediate Risk for CVD	1.0 to 3.0 mg/L
High Risk for CVD	> 3.0 mg/L

Newborns with no evidence of infection have CRP concentrations < 1 mg/L

RISK STRATIFICATION:
For patients with acute coronary syndromes, measurement of hsCRP may provide prognostic information.A value of CRP > 10 mg/L in the early period (6 - 24 hours after onset of symptoms), has been shown to be indicative of an increased risk for short term (30 days - 1 year) recurrent cardiac events substudy of 447 patients in the CAPTURE trial examined the clinical implications of elevated levels of CRP for risk stratification in patients with unstable angina. As shown in the following graph, patients with a CRP >10 mg/L experienced a higher event rate (mortality or MI) than patients with a CRP <10 mg/L

Because of the variation depending on age, sex, diet, and geographical location, each laboratory should determine its own expected values for the different patient groups as dictated by good laboratory practice.

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: 100 mg/L

2. Sensitivity/ Limit of Detection (LOD)
The lower limit of detection is 0.15 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=20	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=20	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 150 mg/l of hS 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
0.15 - 100 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 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. 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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