TRUEchemie CRP (Immunoturbidimetry) Test Kit

(Immunoturbidimetric assay)

for the quantitative turbidimetric determination of C-Reactive Protein (CRP) in human serum or plasma

INTENDED USE

The TRUEchemie CRP Test kit is a quantitative turbidimetric test for the measurement of C-Reactive Protein (CRP) in human serum or plasma.

INTRODUCTION

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

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.

PACK SIZE

Kit Size	**25 mL**	**50 mL**
Cat No.	**ADX 911**	**ADX912**
Kit contents		
CRP Reagent (R1)	1 x 20 mL	1 x 40 mL
CRP Buffer Reagent (R2)	1 x 5 mL	1 x 10 mL
CRP Calibrator	1 x 0.5 mL	1 x 0.5 mL

REAGENTS COMPOSITION

1.CRP Reagent (R1) : Tris buffer
2.CRP Buffer Reagent (R2): Latex particles coated with specific rabbit anti-human CRP
3.CRP Calibrator : Human serum CRP concentration is stated on the vial label

STORAGE AND STABILITY

The components of the kit, stored at 2 - 8 °C, will remain stable until the expiry date stated on the label.
Working reagent: Stable for 30 days at 2-8 ºC. Shake the vial gently before use.
Reagent deterioration: Reagent should be clear and colorless. Any turbidity may be sign of deterioration and reagent should be discarded. Do not freeze the reagents, **frozen Latex or Diluent could change the functionality of the test.**
Calibrator: Stable till expiry when stored at 2-8 ºC

REAGENT PREPARATION

Ready-to-use reagents.

SAMPLE / SPECIMEN AND STORAGE

Fresh Serum (Do not use lipemic or hemolyzed sample).
Stable for 7 days at 2-8 ºC. Samples with presence of fibrin should be centrifuged before testing.

WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostics use.
2. Components from human origin have been tested and found to be negative for the presence of HBsAg, HCV, and antibody to HIV (1/2). However, handle cautiously as potentially infectious.
3. Avoid ingestion. DO NOT PIPETTE BY MOUTH.
4. The disposal of the residues has to be done as per local legal regulations.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Pipettes to accurately measure required volumes.
2. Test tubes/rack
3. Timer
4. 37 °C heating block or water bath
5. Photometer capable of accurately measuring absorbance at 540 nm

TEST PROCEDURE

1. Bring the working reagent and the photometer (cuvette holder) to 37 ºC.
2. Assay conditions:

Wavelength: 540 nm (530-550)
Temperature: 37 ºC
Cuvette light path: 1 cm

	Blank (mL)	**Calibrator (mL)**	**Sample (mL)**
Distilled water	1.000	-	-
CRP Reagent (R1)	-	0.800	0.800
CRP Buffer Reagent (R2)	-	0.200	0.200
Calibrator	-	0.005	-
Sample	-	-	0.005

Blank the Photometer with Distilled water.
Mix well and read absorbance of calibrator and sample against distilled water at 540 nm as follows:
Initial absorbance A_0 – Exactly after 10 sec.
Final absorbance A1 – Exactly after 120 sec. after A_0
Determine Δ A for Calibrator(C) and Sample(S)
$\Delta AC = \Delta AC_1 - \Delta AC_0$
$\Delta AS = \Delta AS_1 - \Delta AS_0$
Calculations:

$$\text{Serum/plasma C-reactive protein (mg/L)} = \frac{\Delta AS}{\Delta AC} \times \text{Calibrator concentration (mg/L)}$$

QUALITY CONTROLS

Control Sera are recommended to monitor the performance of manual and automated assay procedures. Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

NORMAL VALUES

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

AUTOMATED PROCEDURE

Appropriate Program sheet is available for different analyzers upon request.

CALIBRATION

Use TRUchemie CRP Calibrators, which are ready to use.
Re-calibrate when control result are out of specified tolerances, when using different lot of reagent and when the instrument is adjusted

LIMITATIONS

1. **Linearity limit:** Up to 150 mg/L, under the described assay conditions. If the concentration is greater than linearity (150 mg/L), dilute the sample with normal saline and repeat the assay. Multiply the result with dilution factor.
2. **Detection limit:** Values less than 2 mg/L give non-reproducible results.
3. **Prozone effect:** No prozone effect was detected up to 1000 mg/L.

INTERFERENCES

Bilirrubin (20 mg/dL), lipemia (10 g/L) and rheumatoid factors (300 IU/mL) do not interfere.
Hemoglobin (≥ 5 g/L), interferes. Other substances may interfere.

SYSTEMS PARAMETERS

Mode	:	Fixed kinetic
Calibrator concentration	:	Stated on vial
Wave length	:	540 nm(530-540nm)
Units	:	mg/L
Flow cell Temp	:	37 °C
Blank	:	Distilled water
Reagent volume	:	1.000 mL
Sample volume	:	0.005 mL
Delay time	:	10 sec.
Read time	:	120 sec. (2min.)
Low Normal	:	0
High Normal	:	6

REFERENCES

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.

Index of Symbols

Consult instructions for use	Catalogue number	Use-by date
For *in vitro* diagnostic use only	Batch code	Do not use if package is damaged
Temperature limit 2-8 °C	Date of manufacture	Keep dry
Keep away from sunlight	Manufacturer	European Conformity
If device is non-sterile	Warnings / Precautions	Authorized Representative