TRUEchemie CRP 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

CRP is quantitative latex based turbidimetric test for the measurement of C - reactive protein (CRP) in human serum/plasma. 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 samples that can be quantified by comparison from a calibrator of known CRP concentration.

PACK SIZE

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

REAGENTS COMPOSITION

CRP Reagent (R1) : Tris buffer, preservative
CRP Buffer Reagent (R2) : Latex particles coated with specific anti-human CRP
CRP Calibrator : Ready to use. CRP concentration is stated on the vial label

STORAGE AND STABILITY

All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8 ºC and contaminations are prevented during their use. Do not use reagents over the expiration date.

Reagent deterioration: Do not freeze the reagents, frozen Latex or Diluent could change the functionality of the test.

Calibrator: Calibrator stored at 2-8 ºC and are stable till the expiry date mentioned on the label.

REAGENT PREPARATION

Ready to use reagents.
CRP calibrator – Ready to use.

SAMPLE/ SPECIMEN STORAGE

Use fresh Serum/Plasma (Do not use lipemic or hemolyzed sample).
If the test cannot be carried out on the same day, the serum/plasma may be stored at 2-8°C for 48 hours. If stored for a longer period, the sample should be frozen.
Samples with presence of fibrin should be centrifuged before testing.

WARNINGS AND PRECAUTIONS

1. For in vitro diagnostic use. To be handled by entitled and professionally educated person. Reagents of the kit are not classified as dangerous but contain less than 0.1% sodium azide.
2. Components from human origin have been tested and found to be negative for the presence of HBsAg, HCV, and HIV. However, handle cautiously as potentially infectious.
3. Avoid ingestion. DO NOT PIPETTE BY MOUTH
4. Dispose of all specimens and materials used to perform the test as bio-hazardous waste.

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 546 nm
6. Disposable gloves

TEST PROCEDURE

1. Bring the working reagent and the photometer (cuvette holder) to 37 ºC.
2. Assay conditions:
   Wavelength: 546 nm (530-550 nm)
   Temperature: 37 ºC
   Cuvette light path: 1 cm

	Blank (µL)	**Calibrator (µL)**	**Sample (µL)**
Distilled water	1000	-	-
CRP Reagent (R1)	-	800	800
CRP Buffer Reagent (R2)	-	200	200
Calibrator	-	10	-
Sample	-	-	10

Blank the Photometer with Distilled water.
Mix well and read absorbance of calibrator and sample against distilled water at 546 nm as follows:
Initial absorbance A_1 – Exactly after 10 sec.
Final absorbance A_2 – Exactly after 120 sec. after A_1
Determine Δ A for Calibrator(C) and Sample(S)
$\Delta AC = \Delta AC_2 - \Delta AC_1$
$\Delta AS = \Delta AS_2 - \Delta AS_1$

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

Up to 6 mg/ L.
Each laboratory should establish its own reference range. It is recommended that results of the test should be correlated with clinical findings to arrive at the final diagnosis.

AUTOMATED PROCEDURE

Appropriate Program sheet is available for different analyzers upon request.

CALIBRATION

Use TRUEchemie CRP Calibrator, which is ready to use.

Calibration stability : 4 weeks

Re-calibrate when control results are out of specified tolerances, when using different lot of reagent and when the instrument is adjusted.

PERFORMANCE CHARACTERISTIC

Linearity limit: Up to 90 mg/L, under the described assay conditions. If the concentration is greater than linearity (90 mg/L), dilute the sample with normal saline and repeat the assay. Multiply the result with dilution factor.
The linearity limit depends on the sample / reagent ratio, as well as the analysers used. It will be higher by decreasing the sample volume, although the sensitivity of the test will be proportionally decreased.

Detection limit: Values less than 1.0 mg/L give non-reproducible results.
Prozone limit : No prozone effect was detected up to 1000 mg/L.
Sensitivity: 1.0 mg/L

Precision: (%CV)

Intra assay precision	**n**	**Mean (mg/L)**	**SD**	**CV (%)**
Low	20	22.8	0.78	3.43
Medium	20	47.37	0.48	1.01
High	20	74.89	1.80	2.40

Inter-assay precision	**n**	**Mean (mg/L)**	**SD**	**CV (%)**
Low	20	24.54	0.86	3.49
Medium	20	47.60	1.26	2.66
High	20	74.79	0.76	1.01

The reagent was tested for 20 days, using three different CRP concentrations. The coefficient of variation was <5%.

Accuracy:

Control	**Assigned**	**Measured**
Randox Level 1	24.7	23.67
Randox Level 2	48.8	47.48
Randox Level 3	72.5	74.84

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

Method Comparison: Results obtained using TRUEchemie CRP reagent (y) did not show systematic differences when compared with another commercial reagent (x) with similar characteristics. The results obtained is below: The correlation coefficient (r^2) was 0.99 and the regression equation is y=0.985X-0.6841. The results of the performance characteristics depend on the analyzer used.

Interferences: No significant interferences were observed for Hemoglobin: ≤ 5 g/L; Bilirubin: ≤ 20 mg/dL; Lipemia: ≤ 10 g/L

SYSTEM PARAMETERS

Mode	:	Fixed kinetic
Calibrator concentration	:	Stated on vial
Wave length	:	546 nm(530-550nm)
Units	:	mg/L
Flow cell Temp	:	37 °C
Reagent volume	:	800 µL (R1) + 200 µL (R2)
Sample volume	:	10 µL
Delay time	:	10 sec.
Read time	:	120 sec. (2min.)
Normal range	:	up to 6 mg/L
Sensitivity	:	1.0 mg/L
Linearity	:	up to 90 mg/L
Reaction slope	:	Increasing

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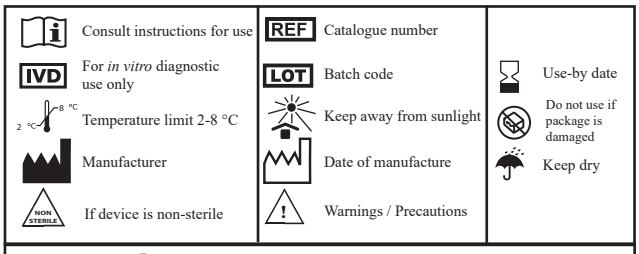

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