

QUANTITATIVE TURBIDIMETRIC TEST FOR DETERMINATION OF C-REACTIVE PROTEIN

For *In-Vitro* Diagnostic Use Only

Store at 2°C to 8°C

OVERVIEW

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.

INTENDED USE

Quantitative determination of C-Reactive Protein in human Serum/Plasma.

This test is for in vitro diagnostic use only.

PRINCIPLE

The CRP Turbilex is a quantitative turbidimetric test for the measurement of CRP in human serum or plasma. Latex particles coated with CRP are agglutinated when mixed with sample containing CRP. The agglutination causes an absorbance change, dependent upon the CRP content of the patient sample that can be quantified by comparison by comparison from calibrator of known CRP concentration.

CONTENTS OF KIT

1. Latex Diluent (R1)
2. Latex Reagent (R2)
3. CRP Calibrator (R3)
4. Pack inserts

OPTIONAL MATERIAL REQUIRED

1. Semi-automatic or Fully Automated Biochemistry Analyzer
2. PPEs (Disposable Gloves, Mask, Safety Goggles, Apron)
3. Biohazard Dust Bin.
4. Test Tubes
5. Micropipettes

PRECAUTIONS /KIT STORAGE AND STABILITY

1. Please read all the information in this package insert before performing the test.
2. Do not use after the expiration date.
3. Store in between temperature 2°C to 8°C.
4. Do not use if damaged or leaked.
5. Do not open until you are ready to start the test.
6. Keep out of the reach of children.

WARNINGS

1. Do not reuse the tested reagent.
2. Follow the instruction to get accurate results.
3. Use appropriate personal protective equipment.
4. Dispose the leftover and used reagents and samples hygienically in biohazard waste.
5. Treat samples and reagent reaction volume as potentially infectious. Avoid contact with skin.
6. For in vitro diagnostic use. Not to be taken internally.
7. Do not mix the specimen sample or interchange the different specimen.
8. Do not use the reagents of other lots in combination with the kit.
9. Discard the remaining reagent in the kit.
10. The manufacturer and distributor of this product shall not be liable for any losses, liability, claims, costs or damages whether direct or consequential arising out for related to an incorrect diagnosis.

SPECIMEN COLLECTION

1. Fresh serum or plasma shall be used.

2. Serum shall be separated from freshly collected blood in plain tube or clot activator tube.
3. Freshly collected EDTA blood can be used to separate plasma for testing.
4. The samples stored at 2-8°C for 2 to 3 days can also be used.
5. Do not use highly hemolyzed or lipemic samples.

REAGENT PREPARATION

Working reagent Preparation: Mix the reagent R1 & R2 gently before use.

Mix the reagent R1 & R2 with the proportion as follows

9 ml Diluent + 1 ml Latex reagent (900µl+100µl).

Prepare the required amount of reagent only.

CRP calibrator: Ready to use value mention on vial.

ONE POINT CALIBRATION (LINEAR RANGE UP TO 15 mg/dl)

CRP Calibrator is ready to use.

TEST PROCEDURE

	CAL	SAMPLE
Sample	-	10 µl
Standard	10 µl	-
Reagent	1000 µl	1000 µl

Note: Please make proportional increase or decrease in volume reagent and samples/calibrators/controls if required for available analyzer requirements.

1. Bring the kit component to room temperature before testing.
2. Take 450 µl of Diluent Reagent in cuvette and add 50 µl of latex reagent in it.
3. Put 5.0 µl of sample/control/calibrator in to the cuvette and mix. The sample and reagent quantity can be decreased or increased as per capacity of analyzer.
4. Please make proportional increase or decrease in volume reagent and samples/calibrators/controls if required for available analyzer requirements.
5. Immediately read the absorbance of the reaction.
6. Read the absorbance of the reaction again after exactly 120 seconds.
7. Calculate concentration and interpret the results as per formula.

Wavelength	540 nm
Cuvette	1 cm light path
Reaction Temperature	37 °c
Measurement	Against Distilled water
Reaction	2-point kinetics
Reaction Direction	Increasing
Sample / Reagent Ratio	1:100
Linearity	15 mg/dl

INTERPRETATION OF RESULTS

1. Concentration = $\frac{(A_2 - A_1)_{\text{Sample}}}{(A_2 - A_1)_{\text{Calibrator}}} \times \text{Concentration of calibrator}$

PERFORMANCE CHARACTERISTICS

INTERNAL EVALUATION

- 1 Total 188 samples were evaluated for specificity & sensitivity. sensitivity was found to be 100% (60/60) and relative specificity was found 100% (98/98).
2. The Positive predictive value (PPV) and Negative Predictive value (NPV) for the test was 100 %.

3. No cross reactivity found with High T3,T4,TSH, Pregnancy, High Bilirubin, High Cholesterol, HIV, HCV, HBsAg, Syphilis positive samples.

Lowest detection limit: 5.0 mg/ml

Sensitivity – 100 %

Specificity – 100 %

Cross Reactivity – No Cross Reactivity Observed

LINEARITY

The method is linear to a concentration of 15 mg/dl.

If the concentration exceeds this value, the sample should be diluted 1:3 with 0.9% saline solution and retested.

LIMITATIONS

1. As with all diagnostic tests, the test result must always be correlated with clinical findings.
2. The results of test are to be interpreted within the epidemiological, clinical and therapeutic context. When it seems indicated, reference correlation should be considered.
3. Any modification to the above procedure and / or uses of other reagents will invalidate the test procedure.

QUALITY CONTROL

Positive and Negative controls are recommended to monitor the performance of test procedure, as well as a comparative pattern for a better results interpretation.

REFERENCE VALUE

Reference Values: -

Each laboratory should establish its own reference range.

DISCLAIMER

The all precautions shall be taken to ensure the diagnostic ability and accuracy of this product. This product is utilized outside the control of manufacturer and distributors. The various factors including storage temperature, environmental conditions and procedure error may affect the results.

REFERENCES

1. M Fasani et al *eur J Lab Med* 1994; Vol 2 no 1-67.
2. Todd E *W.J exp Med* 1932;55:267-280

IVD	In Vitro Diagnostic Use
	Manufacturer
	Manufacturing Date
	Expiry Date
LOT	Lot Number
	Store at 2°C to 8°C
	Single Use
	Number of tests in the pack
	Do not use if pouch or kit damaged
	This side Up
	Read package insert before use



MANUFACTURED BY

ImmunoScience India Private Limited,

Gat No. 41, Kusgaon, Shivapur-Velhe Road, Tal- Bhor, Pune,
Maharashtra (India) – 412205.