

INTENDED USE

For the quantitative determination of C-Reactive Protein in Serum
Only for *In Vitro* Diagnostic use

ORDER INFORMATION

REF	CONT
TCRP 25T	1 x 7.5 ML
TCRP 50T	1 x 15 ML

CLINICAL SIGNIFICANCE

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

PRINCIPLE

CRP-turbilatex is quantitative latex based 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 samples that can be quantified by comparison from a calibrator of known CRP concentration.

KIT CONTENT

Reagent	25 tests/kit	50 tests/kit	Major ingredients
Reaction buffer (R1 reagent)	1x6.0ml	1x12.0ml	Phosphate Reaction buffer
CRP antibody latex combo (R2 reagent)	1x1.5 ml	1x3 ml	anti-human CRP polyclonal antibody combined with the surface of latex particle
Cuvette & Bead	25 no's	50 no's	/
Specification	1 copy	1 copy	/
Magnetic card	1 piece	1 piece	/

SAFETY PRECAUTIONS AND WARNINGS

1. For *in vitro* diagnostic use only.
2. DO NOT pipette by mouth. Avoid contact with skin and eyes. If spilt, thoroughly, wash affected areas with water. For further information, consult the CRP Reagent Material Safety Data Sheet.
3. Reagent contains Sodium Azide as a preservative. This may react with copper or lead plumbing to form explosive metal azides. Upon disposal, flush with large amounts of water to prevent azide build up.
4. Do not use the reagent after the expiration date printed on the kit.
5. 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 the calibrator cautiously as potentially infectious material.

SAMPLE COLLECTION AND PRESERVATION

Fresh serum: Stable for 7 days at 2-8°C or 3 months at -20°C.
Samples with presence of fibrin should be centrifuged before testing.
Do not use highly hemolysed or lipemic sample.

REAGENT STABILITY

All the component of the kit are stable until the expiry date on the label when stored tightly closed at 2-8°C and contaminants prevented during there use, Do not use expired reagents.

ASSAY PROCEDURE

1. THE REAGENT DOSE DISPENSING IN THE CUVETTE

Reagent	Dose
Reaction Buffer (R1 Reagent)	240µl
Sample	5µl
CRP antibody latex combo (R2 Reagent)	60µl

2. OPERATING STEP

- (1). When starting it shows "Read card", Put the corresponding lot magnetic card in the reader slot, reading the card correctly, the screening displays the reagent name and lot number, the instrument status indication light is working (yellow-green). Please check carefully.
- (2). After confirm the lot number, dispense 240µl reaction buffer (R1) to a cuvette and 5µl sample and mixing sticker. Do not produce bubbles when dispensing the sample.
- (3). **Without delay** put the cuvette in the detection well, gently press the cuvette until it contacts the bottom. The status indication light will be off when the analyzer detects the cuvette successfully
- (4). When the analyzer shows "Add [R2]", without delay immediately dispense 60µl CRP antibody latex combo (R2) in the cuvette. The analyzer will mix automatically and start to detect, it shows: "Testing..." it shows the result automatically and record the value
- (5). After detecting, move the cuvette. The status indication light will be working (yellow- green). Return to step (2) to detect next sample.
- (6). If moving the cuvette out in the process of detecting, the screen shows "Give up testing".
- (7). If the result shows >152.00mg/L, may use Normal saline to dilute the sample 1:5 (add 400µl Normal saline in 100µl sample), input dilution multiply 5, the analyser can calculate the sample concentration automatically.

QUALITY CONTROL

To ensure adequate quality control, Normal and abnormal control with assayed values should be run as unknown samples.

REFERENCE INTERVAL

Normal value: up to 6 mg/L

BIBLIOGRAPHY

1. Alouf Jodeph E. Pharma Ther 1980;11:661-717.
2. M Fasani et al eur J Lab Med 1994;Vol 2 no 1-67.
3. Todd E W J Exp Med 1932;55-267-280.