SeroCHEK ™

BIOSS
See Life More Clearly

CRP

50 T, 100 T
12202002, 12202003

INTENDED USE: This reagent is intended for *in vitro* quantitative determination of C-reactive protein (CRP) in serum

-No prozone effect detected up to 1600 mg/L

-Rapid procedure, only 2 minutes test

-Excellent clarity, clear agglutination

CLINICAL SIGNIFICANCE

CRP is a classic acute phase protein of human serum, synthesized by hepatocytes. Normally it is present only in trace amounts in serum, but it can increase as much as 1,000 fold in response to injury or infection. The clinical measurement of CRP in serum therefore appears to be a valuable screening test for organic disease and a sensitive index of disease activity in inflammatory, infections and ischemic conditions.

PRINCIPLE

CRP latex kit is a rapid agglutination procedure for the direct detection and semi-quantitation (on slide) of C-reactive protein (CRP). The reagent, latex particles suspension coated with specific antihuman C-reactive protein antibodies, agglutinates in presence of CRP in patient serum.

REAGENTS & MATERIALS PROVIDED

CRP LATEX **1 x 2.5 mL / 1 x 5 ml**

Suspension of polystyrene particles coated with anti human CRP goat antibodies.

CRP POSITIVE CONTROL **1 x 0.5 mL**

Human pooled serum

CRP NEGATIVE CONTROL **1 x 0.5 mL**

Human pooled serum

PHYSIOLOGICAL SALINE BUFFER CONCENTRATE **1 x 5 mL**

Dilute 1:20 (v/v) with distilled water

ACCESSORIES:	**For 50 T**	**For 100 T**
1. Reaction slide	1	1
2. Plastic droppers	50	100
3. Applicator sticks	50	100
4. Rubber teat	1	1

PRECAUTION

Reagent components of human origin have been tested and found to be negative for the presence of antibody to HIV (1/2) as well as for HBsAg and HCV antibody. However, handle cautiously as potentially infectious.

The reagent and controls contain less than 0.1% sodium azide.

STORAGE AND STABILITY

When stored at 2-8^{0}C and protected from light, the reagent and the controls are stable until the expiry date stated on the label. DO NOT FREEZE.

Preparation of physiological saline buffer: Prepare physiological saline buffer by adding 95mL of distilled water to 5mL of physiological saline buffer concentrate (provided). It is stable up to expiry date, when stored at room temperature.

ANALYTICAL SENSITIVITY

The CRP latex sensitivity has been adjusted to detect a minimum of **6 (5-10) mg/L** in the undiluted samples.

SAMPLE

Fresh serum (free of haemolysis)

QUALITATIVE TEST

Allow all reagents as well as the sample to reach room temperature. Mix well before use.

1. Place 1 drop of serum sample on to the slide using a disposable serum dropper.
2. Add one drop of CRP-latex reagent to the above drop and mix well with disposable applicator stick.
3. Rock the slide gently to and fro for 2 minutes and examine immediately under good light source for agglutination, do not examine beyond 2 minutes.
4. For positive & negative controls follow the same procedures as mentioned above by taking control serum from respective vials.

RESULT AND INTERPRETATION

Positive result:

The presence of agglutination indicate concentration of CRP in the sample equal or greater than 6 mg/L (above normal)

Negative result:

The lack of agglutination indicates CRP level lower than 6 mg/L in the sample, (within the normal range)

SEMI – QUANTITATIVE TEST

In the case in which it is desired to find out the titre of a positive sample, it is possible by the serial dilution methodology.

1. Place 50 µL diluted saline Buffer onto each of five circles of the slide.
2. Using a 50 µL micro pipette add 50 µL serum sample to the drop of saline buffer in 1st circle.
3. Using the same micro pipette, mix the sample with saline by aspirating back & forth several times. Aspirate 50 µL from 1st circle and transfer to 2nd circle. Repeat the same operation up to 5th circle. Aspirate 50 µL from 5th circle and discard. Dilutions obtained as 1/2, 1/4, 1/8, 1/16, 1/32
4. Then add 1 drop of CRP latex reagent to the above circles. Mix and rock the slide gently to and fro for 2 minutes; observe the agglutination under good source of light.

CALCULATION

Concentration of CRP in serum can be calculated as follows:

CRP Conc. (mg/L) = sensitivity x titre (highest dilution serum showing agglutination)

Where, CRP sensitivity = 6 mg/L

NOTE:

1. Reaction time is critical, if reaction time exceeds two minutes, drying of reaction mixture may cause false positive results.
2. Freezing the CRP latex reagent will cause spontaneous agglutination.
3. Intensity of agglutination is not necessarily indicative of relative CRP concentration, therefore screening reaction should not be graded.
4. A false negative can be attributes to a prozone phenmenon (antigen excess). It is recommended therefore to check sample with dilution.
5. Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

PERFORMANCE CHARACTERISTICS

Diagnostic sensitivity : 95.6%

Diagnostic specificity : 96.2%

Prozone effect : No prozone effect detected up to 1600mg/mL.

INTERFERENCES

Bilirubin	up to 20 mg/dL
Hemoglobin	up to 10 g/L
Lipids	up to 10 gL
Rheumatoid factor	up to 100 IU/mL

Do not interfere. Other substances may interfere.

BIBLIOGRAPHY

1. Wadsworth, C.Wadsworth, E., Efficacy of latex agglutination methods for determination of C - reactive protein in Pediatric sera. Clin. Chem. Acta, 138, (1984), 309
2. Ballou S.P, Kushner, I.C. Reactive Protein and acute phase response. ADV Int. Med, 37, (1992), 313.
3. Young D.S., Effects of Drugs on Clinical Laboratory Test 4th ed. AACC Press, 1995.

SYMBOLS USED ON THE LABELS

SYMBOLS USED ON THE LABELS : IVD IN VITRO DIAGNOSTIC USE | SEE PACKAGE INSERT FOR PROCEDURE | LOT LOT NUMBER | MANUFACTURER'S ADDRESS | MANUFACTURING DATE | EXPIRY DATE | TEMPERATURE LIMIT

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