C Reactive Protein (CRP) (Latex)

A rapid latex slide test for the detection of CRP in serum

REF: 514 000 50 test (Complete Kit)
REF: 514 001 100 test (Complete Kit)

REF: 514 002 50 test (latex with positive control)
REF: 514 003 100 test (latex with positive control)

REF: 514 004 50 test (latex only)
REF: 514 005 100 test (latex only)

Intended Use

Rapid latex agglutination test for the qualitative screening and semi-quantitative determination of C Reactive Protein (CRP) in human serum.

Background

Tissue-damaging associated with inflammatory diseases, infection and neoplasms are associated with a major accute phase response of the C-reactive protein (CRP) and other acute phase reactants.The CRP response frequently precedes clinical symptoms, including fever. Measuring changes in the concentration of CRP provides useful diagnostic information about how acute and how serious a disease is. It also allows the assessment of complications during the disease and judgement about the disease genesis.

Test Principle

Spectrum CRP latex reagent is a suspension of polystyrene particles sensitized with anti-human CRP. When the latex reagent is mixed with a serum containing C-reactive protein, visible agglutination occurs. The latex reagent has been produced so that agglutination will take place only when the level of CRP is greater than 6 mg/L.

Reagents

Spectrum CRP latex kit contains the following reagents:

Latex Reagent :
A suspension of polystyrene latex particles in glycine-saline buffer pH: 8.6 ± 0.1, coated with anti-human CRP antibodies.

Positive Control Serum (bottle with red cap):
Is prepared from a stabilized human serum pool containing CRP as an antigen.
Both reagents contain 0.9 g/L Sodium azide as a preservative.

Negative Control Serum (bottle with white cap):
Reagent contain 0.9 g/L Na azide as a preservative.

Slides

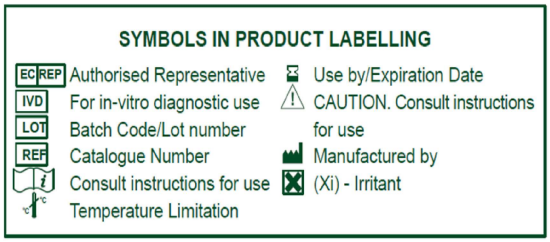
Note: Negative Control Serum and Slides are only included in Complete Kits REF: 514 000 (50 test) and REF: 514 001 (100 test).

Precautions and Warnings

All human blood components used to prepare controls have been tested for Hepatitis B surface antigen (HBsAg) and HTLV-III antibodies by FDA approved procedure and found to be non-reactive
No known test method for HBsAg or HTLV-III antibodies offers total assurance that a human derived product will not transmit hepatitis or HTLV-III virus. The user is therefore cautioned to handle reagents as if being capable of transmitting these diseases.

Storage and Stability

The reagents are stable up to the expiration date stated on the label when stored at 2 – 8 ^{O}C.Open vials are stable for 6 months at the specified temperature.



Deterioration

Latex reagent has a white uniform appearance after shaking ,reagent should be discarded in case of visible clumping.Do not use the latex reagent or controls in case of contamination.

Specimen Collection and Preservation

Use only serum specimens, plasma samples are not suitable for the test. Serum samples can be stored for 24 hrs at 2 – 8^{O}C, for longer storage it is recommended to store the samples at -20 ^{O}C.

Procedure

Qualitative Test (Screening)

1. Bring all reagents and specimens to room temperature.
2. Place one drop (50 µl) of the positive control and 50 µl of the patient serum into separate circles on the glass slide.
3. Shake the CRP latex reagent gently and add one drop (45 µl) on each circle next to the sample to be tested and control.
4. Mix well using disposable stirrer spreading the mixture over the whole test area and tilt the slide gently. Agitate for about 2 minutes with rotator or by hand and observe for the presence or abscence of agglutination.

Results and Interpretation

Negative result: No agglutination of the latex particles suspension within two minutes.

Positive result: An agglutination of the latex particles suspension will occur within two minutes, indicating a CRP level of more than 6 mg/L.

Semi-Quantitative Test

1. Serum to be titrated is serially diluted (1:2, 1:4, 1:8 etc) in 0.9 g/L saline solution.
2. Place one drop of positive control on slide. Do not attempt to dilute the CRP positive control serum for comparative or other purposes as no correlation exists between actual titre of the control and titre of unknown sera.
3. Place 50 µl of each serum dilution individually in successive circles on the slide and proceed as in screening methodology.

Results and Interpretation

The serum CRP titre can be defined as the highest dilution showing a positive result. The approximate CRP level (mg/L) present in the sample can be optained by the following formula:

CRP Titre (mg/L) = Highest dilution with positive reaction x Reagent sensitivity (6 mg/lL)

e.g. if the agglutination is present up to a titre 1:8, the approximate serum CRP level is 8 x 6 = 48 mg/L.

Expected Value

Up to 6 – 8 mg/L.

Limitations of the Procedure

Occasional agglutinations observed after 4 minutes have no diagnostic significance.

Highly haemolyzed and lipemic serum as well as plasma interfere with the test.

Performance charcteristics

1. **Analytical sensitivity:** 6 (5-10) mg/L, under the described assay conditions.
2. Prozone effect: No prozone effect was detected up to 1600 mg/L.
3. Diagnostic sensitivity: 95.6 %.
4. Diagnostic specificity: 96.2 %.

Interfering Substances

Haemolysis
No significant interference from haemoglobin up to 10 g/dL.

Icterus
No significant interference from free and conjugated bilirubin up to levels of 20 mg/dL

lipemia
No significant interference up to levels of 10 g/dL

Rheumatoid factor
No significant interference up to 300 IU/ml

Waste Disposal

This product is made to be used in professional laboratories.
Please consult local regulations for a correct waste disposal.
S56: dispose of this material and its container at hazardous or special waste collection point.
S57: use appropriate container to avoid environmental contamination.
S61: avoid release in environment. refer to special instructions/safety data sheets.

References

1. Bowman BH. In:Hepatic Plasma Protein. San Diego: Academic Press;1993:47-95.
2. Halbert, SP. Ann. N.Y. Acad. Sci., 103, 1027:1051; 1963.
3. Klein GL, Applied Microbiology, 21:999, 1971.
4. Klein GC: Manual of Clinical Immunology ASM 264-273: 1976.
5. Pepys MB et al. Lancet 1961 ; 1 : 653-660.
6. Rantz LD, DiCapri JM, Randall E. Am. J. Med. Sci., 24, 1952.

ORDERING INFORMATION	
CATALOG NO.	**QUANTITY**
514 000	50 test
514 001	100 test
514 002	50 test
514 003	100 test
514 004	50 test
514 005	100 test

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