CRP LATEX TEST KIT

Catalogue Number	Product Description
CRP/010	Test Kit 50
CRP/012	Test Kit 100

INTENDED USE
The Plasmatec CRP Latex test kit is for the qualitative and semi-quantitative estimation of C-Reactive Protein (CRP) in human serum samples.

WARNINGS AND PRECAUTIONS
For *in vitro* diagnostic use only
For professional use only
Health and Safety warnings:
All patient samples and reagents should be treated as potentially infectious and the user must wear protective gloves, eye protection and laboratory coats when performing the test.
Non disposable apparatus must be sterilised after use by an appropriate method. Disposable apparatus must be treated as biohazardous waste and autoclaved or incinerated.
Spillages of potentially infectious material should be absorbed and disposed of as above. The site of spillage must be sterilised with disinfectant or 70% alcohol.
Do not pipette by mouth.
Control reagents contain human serum. The human serum used has been tested and found to be negative for HIV, HCV and HbsAg. Nonetheless the reagent must be treated as potentially infectious and appropriate precautions should be taken when handling and on disposal. The product also contains aqueous buffer salts including sodium azide as preservative - see material safety data sheet
Analytical precautions:
Do not modify the test procedure.
Do not dilute or modify the reagents in any way.
Allow all reagents and samples to reach room temperature (18 - 30ºC) before use.
Resuspend test and control cells gently but thoroughly.
Do not interchange reagents from different kit batches.

COMPOSITION
Kit contents:
Latex reagent sufficient for 50/100 slide tests (Yellow label). The latex reagent should be well shaken to ensure homogeneity.
Positive Control (Red label). This serum is human positive CRP serum. This reagent is ready for use and will give positive results when tested with the Plasmatec CRP latex test.
Negative Control (Blue label). This control is a negative CRP control serum. This reagent is ready for use and will give a negative result when tested with the Plasmatec CRP latex reagent.
10x Concentrate. Glycine Diluent Buffer (Green label). Add one part to nine parts distilled water before use. On dilution the diluent has a pH between 8.0 and 8.2.
Pipette/ Stirrers/ Reusable agglutination slide.
Pack insert.

STORAGE AND SHELF LIFE
Store reagents, upright at 2-8ºC.
DO NOT FREEZE ANY OF THE REAGENTS
Do not use reagents after the stated expiry date.
Discard reagents if they become contaminated or do not demonstrate the correct activity with controls.

MATERIALS AND EQUIPMENT REQUIRED BUT NOT PROVIDED.
Small glass or plastic test tubes / Serological pipettes

SPECIMEN AND SAMPLE PREPARATION
Use fresh serum obtained by centrifugation of clotted blood. The sample may be stored at 2-8? C for 48 hours before performing the test. For longer periods of time the serum must be frozen. Haematic, lipaemic or contaminated serum must be discarded.

PROCEDURE
Principle:
Latex particles coated with goat anti-human CRP antibodies are agglutinated when mixed with samples containing CRP.
CRP is a serum constituent originally defined by its ability to precipitate Pneumococcus C polysaccharide. Characteristically, CRP appears in the serum of individuals in response to various inflammatory conditions and tissue necrosis and disappears as the causative conditions subside.
It is routinely found in cases of bacterial infection[1-4], active rheumatic fever[5] and many malignant diseases and is often seen in association with cases of rheumatoid arthritis, viral infections and tuberculosis. CRP has also been detected in patients following blood transfusions and surgical operations[6] as well as in patients with burns, pemphigus vulgaris and other bullaous lesions.

Qualitative method
1. Allow each component to reach room temperature.
2. Gently shake the latex reagent to disperse the particles.
3. Place a drop of undiluted serum onto the circle of the test slide using the disposable pipettes provided.
4. Add one drop of the latex reagent next to the drop of serum.
5. Using the other end of the pipette (broad end) spread the reagent and serum sample over the entire area of the test circle.
6. Gently tilt the test slide backwards and forwards approximately once every two seconds for two minutes. Positive and negative controls should be included at regular intervals. Both are ready for use and do not require further dilution. At the end of the test rinse the test slide with distilled water and dry. Normal laboratory precautions should be maintained while handling patients samples.

INTERPRETATION OF RESULTS
Presence of agglutination indicates a level of CRP in the sample equal or > 6mg/l. The lack of agglutination indicates a CRP level < 6mg/l in the sample.

Semi-quantitative determination
The semi-quantitative test can be performed in the same way as the quantitative test using dilutions of the serum in saline, phosphate buffered saline or glycine saline as follows:-

Dilutions	1/2	1/4	1/8	1/16
Sample serum	100? l	-	-	-
Saline	100? l	100? l	100? l	100? l
	?	100? l ?	100? l ?	100? l
Volume of sample	50? l	50? l	50? l	50? l
6xNº. Of dilution	6x2	6x4	6x8	6x16
Mg/I.U./ml	12	24	48	96

Normal Levels :- Adults < 6mg/l

RESULTS
The titre is expressed as the reciprocal of the highest dilution showing macroscopic agglutination: e.g. if this occurs in dilution 3, the titre is 48.

INTERPRETATION OF RESULTS
The elevation of CRP levels above normal indicates tissue damage, inflammation, or both with great reliability.
The Plasmatec CRP latex has been standardised to detect serum CRP levels at or above 6?g/ml, which is considered the lowest concentration of clinical significance.
The regular monitoring of CRP levels is often used as a means of assessing disease activity and of guiding therapy.
CRP determination is considered to be a greater practical significance than any other indicator of inflammatory disease. The erythrocyte sedimentation rate (ESR) for example, may become elevated as a result of non-inflammatory conditions. In these circumstances inflammatory disease may be excluded if CRP is absent.

PERFORMANCE CHARACTERISTICS
Analytical sensitivity: 6 (5-10) mg/L
Prozone effect: No prozone effect was detected up to 1600 mg/L
Diagnostic sensitivity: 95.6%
Diagnostic specificity: 96.2%

LIMITATIONS OF THE METHOD
High CRP concentration samples may give negative results (prozone effect). Re-test the sample again using a sample drop of 20 µL.
Haemoglobin (10 g/L), bilirubin (20 mg/dL) and lipemia (10 g/L), do not interfere. Rheumatoid factors (100 IU/mL), interfere. Other substances may interfere[7].
Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

INTERNAL QUALITY CONTROL
Control sera provided should be used to verify the test procedures.

REFERENCES

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4. Crockson, R.A., at al., Clin. Chrim. Acta 14: 435 (1966)
5. Hayashi, H., and Loggrippo, G.A., H. Ford Hosp. Med. J. 20:90 (1972)