Prestige Diagnostics
Clinical Diagnostics & Point of Care Products

CRP (C-REACTIVE PROTEIN) VISILATEX – SLIDE ASSAY

CAT NO	DESCRIPTION	PACK SIZE
LATCRP4	CRP VISILATEX – LATEX REAGENT ONLY	1L

Intended Use:

CRP Visilatex is a rapid slide agglutination procedure intended to be used for the direct detection and semi quantitation of C-Reactive Protein (CRP) in human serum. This reagent is for In vitro diagnostic use by trained professionals only.

Summary and Principle:

A suspension of latex particles coated with specific anti-human C-reactive protein antibodies is added to a test sample. The presence or absence of a visible agglutination indicates the presence or absence of CRP in the samples tested.

Reagent Composition:

CRP Latex Reagent	**Polystyrene Latex particles coated with anti-human C-Reactive Protein antibody stabilized in a buffered saline**
	Sodium Azide 0.95g/l
Positive Control	**Serum Base with CRP Concentration equivalent to > 20 mg/l**
Negative Control	**Serum base with preservative**

Warnings and Precautions:

- The reagent contains sodium azide. Do not allow contact with skin or mucous membranes.
- Components of different human origin have been tested and found to be negative for the presence of antibodies to HIV 1+2 and HCV as well as for HBsAg. However, controls should be handled as potentially infectious.

Reagent Preparation and Stability:

Unopened reagents are stable up to expiry when stored at 2 - 8°C.
The reagents and controls are provided liquid stable. Once opened store at 2 - 8°C tightly capped. Do not freeze.

Materials required but not provided:

Pipettes, saline solution (0.9% NaCl for semi quantitation), mechanical rotor adjustable to 100 rpm.

Specimen Collection:

Collect clear serum by separation after standard venepuncture technique. Samples that cannot be tested immediately may be stored at 2 - 8°C up to 1 week. For longer term storage keep serum samples at -20°C for up to 3 months.
Before use, bring all samples to room temperature (+25°C).

Procedure:

Qualitative Assay:

1. Ensure that the test reagents and the samples are at room temperature.
2. Mix the Latex reagent gently by aspirating and expulsion of the reagent using the dropper several times.
3. Place 1 drop of serum (40 µl) in one of the circles on the card. On separate additional circles place 1 drop of Positive control and Negative control.
4. Add 1 drop (40 µl) of CRP Latex reagent to each circle next to the sample or control to be tested.
5. Mix the contents of each circle with a disposable stirrer while spreading over the entire area enclosed by the ring. Use separate stirrers for each mixture.
6. Rotate the slide by means of a mechanical rotor (100 rpm) for a period of 2 minutes.
7. Observe immediately under a suitable light source for any degree of agglutination.

Interpretation:

- Non-Reactive: Smooth suspension with no visible agglutination as shown by Negative control.
- Reactive: Any degree of agglutination visible macroscopically.

Semi-Quantitative Assay:

1. For each sample to be tested pipette 40 µl of 0.9% saline into each of the circles of a reaction card. Do not spread the saline.
2. To circle 1 add 40 µl of sample. Mix well by repeated aspiration and expulsion then transfer 40 µl of the mixture to the saline solution in the second circle. Mix as above.
3. Continue with the 2-fold serial dilutions up to the last circle and discard 40 µl from the last circle. Final sample dilutions will be 1/2, 1/4, 1/8, 1/16, 1/32, 1/64.
4. Test each dilution as described in the steps 4-7 for the qualitative assay.

Interpretation:

- Non-Reactive: Smooth suspension with no visible agglutination as shown by negative control
- Reactive: Any degree of agglutination visible macroscopically. If the highest dilution is still reactive, repeat the test starting with a 1/16 dilution. As the diluent, use a 1/50 dilution of negative control serum in 0.9% saline solution to make the new dilution series starting at 1/16. The approximate CRP level present in the sample may be calculated by multiplying the titre of the last (highest) dilution giving positive agglutination analytical sensitivity (6 mg/l).

Expected Values:

In healthy adults the CRP concentration is generally below 6 mg/l. In a number of disease states the reference range is often exceeded within 4 to 8 hours after an acute event and can reach levels up to 500 mg/l. Since an elevated CRP level is always associated with pathological changes, determination of CRR is of great value in diagnosis, treatment and monitoring of inflammatory conditions.

Quality Controls:

Positive and Negative controls should be run daily following the steps outlined in the qualitative assay. The positive control should produce rapid and obvious agglutination. If it does not, discard the kit and use a fresh kit for further assays.

Performance Characteristics:

- The minimum detectable limit (analytical sensitivity) is ~ 6 mg/l as tested against a CRP Reference Material (ERM-DA 472/IFCC).
- Diagnostic Specificity: 96.2%.
- No prozone effect was observed up to 1600 mg/l.

Limitations:

- The presence of RF in the sample may cause false positive reactions.
- Weak or negative reactions may occur with marked antigen excess (prozone effect).

Note:

- The sensitivity of the test may be reduced at low temperatures. The best results are achieved at 15-25°C.
- Delays in reading results may result in over-estimation of the CRP concentration. Do not interpret results after 2 minutes.
- When the CRP concentration is very high in serum, prozone effect may result in false negative reactions with undiluted serum. The test may be repeated using 10 µl of serum sample. If the result is positive, use the titration procedure above.
- The result from this test should not be used as the sole criteria for the diagnosis of inflammation or infection, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

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Sources of Error:

- Bacterial contamination of controls and specimens as well as freezing and thawing of the antigen may lead to false positive results.
- Traces of detergent in the test cards may give false positive results. Wash used cards first under tap water until all reactants are removed and then with distilled water. Allow to air dry, avoiding the use of organic solvents as they may impair the special finish on the slide.
- The CRP latex antigen must not be used beyond its expiry date because prolonged storage can affect the sensitivity of the suspension.

References:

1. Hanson et al. Current Opinion in Infectious Diseases, 1997; 10: 196-201
2. Pepys MM. The Lancet, 1980; 21: 653-656
3. Yoshitsugy H et al. Journal of Clinical Laboratory Status, 1987; 1: 15-27.
4. Wadsworth C et al. Clinica Chimica Acta, 1984; 138: 309-318.
5. Young D.S.et al., Effect of Drugs on Clinical Laboratory Tests, 4th ed., AACC Press Washington DC 1995.

REF	Catalogue number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by Date
	Manufacturer		

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