Intended Use:
CRP is in vitro Medical Device Reagents/Kits for the detection and screening of C - reactive protein levels in various conditions including autoimmune disorder in human specimen. It is intended for *in vitro* diagnostics use by trained healthcare professionals in IVD laboratory only and not near patients.

Clinical Significance
C-Reactive Protein (CRP) is a normal alpha globulin, which increases in inflammatory processes. The name CRP is derived from the fact that this protein has the capacity to precipitate the somatic C-carbohydrate of Pneumococcus. Elevated CRP levels are usually observed in a variety of infections and inflammatory conditions where there is tissue destruction.
The CRP level measurement is useful in differential diagnostic of neonatal septicemia and meningitis. CRP levels are always elevated after myocardial infarction and surgery. The CRP test can also help in determining post-surgical complications.

PRINCIPLE
Uniform latex particles are coated with anti-human CRP. The specimen containing CRP on mixing with latex Reagent agglutinates, showing a positive test result. If CRP is absent, there will be no agglutination, indicating a negative test result.

Reagent Composition

R1 CRP LATEX	Latex particles coated with goat IgG anti-human CRP, pH 8.2, Preservative
R2 CRP Positive Control	Synthetic Positive control with , preservative
R3 Negative Control	Synthetic Negative control with , Preservative

Reagent Preparation
Reagents are ready to use.

Stability and Storage
1. Store the reagent at 2-8^{0}C. **DO NOT FREEZE.**
2. The shelf life of the reagent is as per the expiry date mentioned on the reagent vial labels.

Material provided with the kit
Reagents
CRP latex reagent, Positive Control, Negative Control

Accessories:
Glass slide, Plastic Droppers, Mixing sticks.

Additional Material Required
Stop watch, High intensity direct light source, Saline, Pipettes, Test tubes.

Notes
1. In vitro diagnostic reagent for laboratory and professional use only. Not for medicinal use.
2. All the reagents derived from human source have been tested for HBsAg and Anti HIV antibodies and are found to be non-reactive. However handle the material as if infectious.
3. Reagent contains 0.1% Sodium Azide as a preservative. Avoid contact with skin and mucosa. On disposal flush with large quantities of water.
4. The reagent can be damaged due to microbial contamination or on exposure to extreme temperatures. It is recommended that the Performance of the reagent be verified with the positive and negative controls supplied with the kit.
5. The Latex reagent should be shaken well prior to use, to ensure homogeneous suspension of latex
6. Only a clean and dry glass slide must be used. Clean the slide with distilled water and wipe dry.
7. Accessories provided with the kit only must be used for optimum results.

Calibration
The CRP-latex sensitivity is calibrated to the Reference Material ERM- DA 472/IFCC.

Sample and Stability
Only fresh serum must be used for testing. Should a delay in testing occur, store the sample at 2-8^{0}C. Samples can be stored for up to a week. Do not use hemolyzed serum.
Fresh serum, Stable7days at2-8ºC or3 months at -20ºC.Samples with presence of fibrin should be centrifuged before testing. Do not use highly hemolyzed or lipemic samples.

Procedure
Bring reagent and samples to room temperature before testing.

Qualitative Method
1. Pipette one drop of serum onto the glass slide using the disposable plastic droppers provided with kit.
2. Add one drop of CRP latex reagent to the drop of test sample on the slide.
3. Using a mixing stick, mix serum and the CRP latex reagent uniformly over the entire circle. Do not let the dropper tip touch the liquid on the slide.
4. Immediately start a stopwatch. Rock the slide gently, back and forth, observing for agglutination macroscopically at **two minutes**. Proceed similarly with each dilution.
5. Do not read the results beyond 2 minutes.

Semi Quantitative Method
Using normal saline prepare serial dilutions of the serum sample positive in the quantitative method 1:2, 1:4, 1:8, 1:16, 1:32, 1:64 and so on.
1. Pipette the diluted specimens onto the slide. Start with the 1:2 diluted test specimen.
2. Add a drop of CRP reagent to it. Mix well. Spread the mixture uniformly over the entire circle.
3. Immediately start a stopwatch. Rock the slide gently, back and forth, observing for agglutination macroscopically at **two minutes**. Proceed similarly with each dilution as test specimen.

Interpretation of Results

Qualitative Method
Agglutination is a positive test result and indicates the presence of detectable levels of CRP in the test specimen.

No agglutination is a negative test result and indicates absence of detectable levels of CRP in the test specimen.

Semi quantitative Method
Agglutination in the highest serum dilution corresponds to the amount of CRP in mg/dl present in the specimen.

Calculation

Concentration of CRP can be calculated as follows:

CRP (mg/dl) = S x D

Where,

S = Sensitivity of the reagent i.e., 0.6mg/dl.

D = Highest dilution of serum showing agglutination

Reference Values

Up to 6 mg/L. Each laboratory should establish its own reference range.

Performance Characteristics

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 (Note1).
3. Diagnostic sensitivity: 95,6%.
4. Diagnostic specificity: 96,2%.

Interference

Bilirubin (20 mg/dL), hemoglobin (10 g/L), and lipids (10 g/L), do not interfere. Rheumatoid factors (100 IU/mL), interfere. Other substances may interfere[7].

Remarks

1. Markedly lipemic, hemolysed and contaminated serum samples could produce non-specific results.
2. Use of plasma rather than serum can lead to false positive results.
3. CRP is found to be present after the first trimester of pregnancy and persists until delivery.
4. CRP levels increase in women who are on oral contraceptives.
5. CRP response is not affected by the commonly used anti-inflammatory or immunosuppressive drugs, including steroids, unless the disease activity is affected and it covers an exceptionally board incremental range up to 3000 times.
6. Do not read results beyond indicated testing time limits.
7. Since CRP production is a non-specific response to tissue injury, it is recommended that result of the test should be correlated with clinical findings to arrive at the final diagnosis.
8. In cases where an increase in CRP levels is suspected, but the screening test shows a negative result, semi quantization should be done to rule out prozone effect.

References

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For In vitro Diagnostic Use Only