C-reactive protein (CRP) is an acute phase protein synthesized in the liver. Its rate of synthesis increases within hours of acute injury or the onset of inflammation and may reach as high as 20 times the normal levels. A rapid fall of CRP indicates recovery. The degree of elevation of CRP level directly reflects the mass or activity of inflamed tissue. And its ability to fall to normal levels on resolution of the condition renders quantified CRP values to be a good indicator to allow rapid selection of appropriate anti-inflammatory therapy in several rheumatic diseases, which are, clinically difficult to assess.

Apart from indicating inflammatory disorders, CRP levels helps in differential diagnosis, in the management of neonatal sepsis and meningitis where standard microbiological investigations are difficult. CRP levels rise invariably after major surgery, but fall to normal within 7-10 days. Absence of this fall is indicative of septic or inflammatory postoperative complications. Serum CRP concentration provides useful information in patients with myocardial infarction there being an excellent correlation between peak levels of CRP and creatine phosphokinase.

**Ready to use uniform suspension of polystyrene latex particles coated with anti-CRP antibody.**

**Calibrated with a standard traceable to the W.H.O. International Reference Standard (85/506) for Human C-reactive protein.**

**Store the reagents at 2-8°C. DO NOT FREEZE.**

**2. The shelf life of the reagent and activation buffer is as per the expiry date mentioned on the respective vial labels.**

**3. Once opened the reagents are stable for 75 days when stored at 2-8°C provided the reagents are not contaminated.**

**4. Store the Turbodyne™ CRP SMART CARD: Card with Master calibration curve calibrated with a standard traceable to the W.H.O. International Reference Standard (85/506) for Human C-reactive protein. Each batch of reagents undergoes rigorous quality control at various stages of manufacture for its specificity, sensitivity, and performance.**

**REAGENT STORAGE AND STABILITY**

1. **Store at 2-8°C. DO NOT FREEZE.**
2. **The shelf life of the reagent and activation buffer is as per the expiry date mentioned on the respective vial labels.**
3. **Once opened the reagents are stable for 75 days when stored at 2-8°C provided the reagents are not contaminated.**
4. **Store the Turbodyne™ SC card at a clean dry place. The Turbodyne™ SC card is valid upto the use of labelled number of tests within 75 days from its first insertion in the Turbodyne™ SC analyzer.**

**PRINCIPLE**

Turbodyne™ CRP is a turbidimetric immune assay for the determination of C-reactive protein in human serum and is based on the principle of agglutination reaction. The test specimen is mixed with activation buffer (R1), Turbodyne™ CRP latex reagent (R2) and allowed to react. Presence of CRP in the test specimen results in the formation of an insoluble complex producing a turbidity, which is measured at ~650 nm wavelength. The increase in turbidity corresponds to the concentration of CRP in the test specimen.

**NOTE**

1. **In vitro diagnostic reagent for laboratory and professional use only. Not for medicinal use.**
2. **The reagents that are derived from human source have been tested for HBAg, HIV and HCV antibodies and are found to be non-reactive. However handle the material as if infectious.**
3. **Reagents contain 0.09% Sodium Azide as a preservative. Avoid contact with skin and mucosa. On disposal flush with large quantity of water.**
4. **Gently mix the Turbodyne™ CRP reagents well before use to disperse the latex particles uniformly to improve test performance.**
5. **As the reagents and Smart card in lots within have been matched reagents or Smart cards from different lots must not be interchanged.**
6. **It is recommended that the reagent performance and Smart card calibration must be validated periodically with known controls such as Turbodyne™ CRP. (Ref: 108550005).**
7. Do not use damaged or leaking reagents.
8. The reagents can be damaged due to microbial contamination or exposure to extreme temperatures.
9. Always use clean disposable micropipette tips to aspirate the reagents to prevent contamination.

**SPECIMEN COLLECTION AND PREPARATION**

No special preparation of the patient is required prior to specimen collection by approved techniques. Only serum should be used for testing. Should a delay in testing occur, store the samples at 2 - 8°C. Samples can be stored for up to three days at 2 - 8°C, provided they are not contaminated. Do not use hemolyzed, icteric, or highly turbid sera. Turbid or particulate serum samples must be clarified by centrifugation at 2000 rpm for 15 minutes. Use the clear supernatant for testing.

**ADDITIONAL MATERIAL REQUIRED**

Turbodyne SC analyser, stopwatch, well-calibrated micropipettes, disposable tips, incubator.

**TEST PROCEDURE**

1. Bring reagent and sample to room temperature before use.
2. Insert the Turbodyne CRP smart card in the card reader slot of the Turbodyne SC.
3. The instrument will indicate to place cuvette with R1 + sample in the reading chamber.
4. Take a disposable cuvette (provided in the kit) and add 300 µl R1 to the cuvette using fresh clean disposable micropipette tips. Then add 5 µl sample and incubate the cuvette for 3 - 5 minutes.
5. Place the cuvette with R1 + sample in the Turbodyne SC reading chamber.
6. Press “Testing”. The instrument will mix the sample and then indicate to add R2.
7. Pipette 40 µl R2 reagent with the Turbodyne SC electronic Pipette to the cuvette with R1 + sample.
8. The reaction will start and the counter will start in the display. Results will be displayed on completion of reaction.

**SPECIFIC PERFORMANCE CHARACTERISTICS**

**Measuring Range**

The Measuring Range of Turbodyne CRP is 0.6 - 10 mg/dl.

**Detection limit / Analytical Sensitivity**

Detection limit: 0.6 mg/dl

The detection limit represents the lowest measurable CRP concentrations that can be distinguished from zero.

**Precision**

<table>
<thead>
<tr>
<th>Intra-assay precision</th>
<th>n</th>
<th>Mean mg/dl</th>
<th>SD</th>
<th>CV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample 1</td>
<td>10</td>
<td>2.1</td>
<td>0.1</td>
<td>5.0</td>
</tr>
<tr>
<td>Sample 2</td>
<td>10</td>
<td>5.0</td>
<td>0.3</td>
<td>6.3</td>
</tr>
<tr>
<td>Sample 3</td>
<td>10</td>
<td>6.9</td>
<td>0.4</td>
<td>5.9</td>
</tr>
</tbody>
</table>

**Interference**

No interference was observed with Bilirubin up to 50 mg/dl, Glucose up to 400 mg/dl, Haemoglobin up to 500 mg/dl, Creatinine up to 6 gms/L, and Urea up to 2 gms/L.

**REFERENCE VALUES**

The reference value of CRP in normal population are < 0.6 mg/dl. Each laboratory should define its own reference range for relevant population.

**REMARKS**

1. Usage of well-calibrated pipette and correct procedure is critical for achieving correct results.
2. Markedly lipemic, hemolyzed, and contaminated serum samples could produce non-specific CRP values.
3. Use of plasma rather than serum can lead to erroneous CRP values.
4. Elevated levels of CRP are found to be present at the 1st trimester of pregnancy and persist until delivery.
5. CRP levels are elevated in women who are on oral contraceptives.
6. The commonly used anti-inflammatory drugs or immunosuppressive drugs, including steroids do not affect CRP response, unless the disease activity is affected and it covers an exceptionally broad incremental range up to 3000 times.
7. Since CRP production is a non-specific response to tissue injury, it is recommended that results of the test should be correlated with clinical findings to arrive at the final diagnosis.
8. Values above linearity will be flagged “Exceed”. Such samples must be diluted 1:4 with normal saline and retested. The result obtained must be multiplied with the dilution factor.

**WARRANTY**

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

**BIBLIOGRAPHY**

6. Data on file - Tulip Diagnostics (P) Ltd.