SYMBOL KEYS

	Temperature limitation		Manufacturer		This way up	SC	Smart card (RFID)
	Use by		Consult Instructions for use		Contains sufficient for <n> tests	CT	Cuvettes
	Date of Manufacture	REF	Catalogue Number	EC REP	Authorised Representative in the European Community	R1	Activation Buffer
LOT	Batch Number/ Lot Number	IVD	*In vitro* Diagnostic Medical Device			R2	Antibody Reagent

TULIP DIAGNOSTICS (P) LTD.

REGD. OFFICE: GITANJALI, TULIP BLOCK, DR. ANTONIO DO REGO BAGH, ALTO SANTACRUZ, BAMBOLIM COMPLEX P.O., GOA-403 202, INDIA. Website: www.tulipgroup.com

MANUFACTURING UNIT: PLOT NOS. 92/96, PHASE II C, VERNA IND. EST., VERNA, GOA-403 722, INDIA.

EC REP

CMC Medical Devices & Drugs S.L., C/ Horacio Lengo No. 18, CP 29006, Malaga, Spain

1221/VER-01

CE

turbosmart™

CRP UV

IMMUNOTURBIDIMETRIC ASSAY FOR DETERMINATION OF SERUM CRP ON TURBOSMART™

SUMMARY

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 septicemia 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.

PRESENTATION

REF	108730020	108730060
Σ	20 Tests	60 Tests
R1	20 Tests	3 x 20 Tests
R2	20 Tests	3 x 20 Tests
SC	1 No.	1 No.
CT	20 Nos.	60 Nos.

REAGENT

1. R1 **turbosmart™ CRP UV Activation buffer:** Ready to use.
2. R2 **turbosmart™ CRP UV Antibody Reagent:** Ready to use anti-CRP antibody reagent.
3. SC **turbosmart™ CRP UV RFID: 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 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 provide the reagents are not contaminated.
4. Store the **turbosmart™** RFID card at a clean dry place. The **turbosmart™** RFID card data once transferred into **turbosmart™** analyzer is valid upto the use of labelled number of tests within 75 days.

PRINCIPLE

turbosmart™ CRP UV is a turbidimetric immunoassay 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), **turbosmart™ CRP UV** antibody 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 HBsAg, 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 preservative. Avoid contact with skin and mucosa. On disposal flush with large quantities of water.
4. Gently mix the **turbosmart™ CRP UV** reagents well before use to improve test performance.
5. **As the reagents and RFID card within lots have been matched, reagents or RFID cards from different lots must not be interchanged**
6. It is recommended that the reagent performance and RFID card calibration must be validated periodically with known controls such as **Turbodyne™ CRP UV** control (REF: 108670005).
7. Do not use damaged or leaking reagents.

8. The reagents can be damaged due to microbial contamination or on 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 upto three days at 2 - 8°C, provided they are not contaminated. Do not use hemolysed, 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

turbosmart™ analyser, stopwatch, well calibrated micropipettes, disposable tips, incubator.

TEST PROCEDURE

1. Bring reagent and sample to room temperature before use.
2. Select the CRP UV test from the Measure Menu of Instrument.
3. Load the **turbosmart™ CRP UV** test data from the RFID card (Provided with the kit) to the analyser as described in the Instrument User Manual. The Instrument is ready to perform the CRP test.
4. The instrument will indicate to place cuvette with R1 + sample in the reading chamber.
5. Take a disposable cuvette (provided in the kit) and add 200µl R1 to the cuvette using fresh clean disposable micropipette tips.
6. Then add 20µl sample and incubate the cuvette for 5 minutes.
7. Place the cuvette with R1 + sample in the **turbosmart™** reading chamber.
8. Long Press "Test"key. The instrument will mix the sample and then indicate to add R2.
9. Long press **turbosmart™** electronic Pipette to dispense 90µl R2 reagent to the cuvette with R1+sample.
10. 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 **turbosmart™ CRP UV** is 3 - 300 mg/L. The exact range is dependant on the calibrator value used for calibration which is lot specific.

Detection limit / Analytical Sensitivity

Detection limit: 3 mg/L
The detection limit represents the lowest measurable CRP concentrations that can be distinguished from zero.

Precision

Intra-assay precision	n	Mean mg/L	SD	CV (%)
Sample 1	10	20.56	2.20	10.75
Sample 2	10	50.08	4.06	8.11
Sample 3	10	100.87	5.12	5.08

Inter-assay precision	n	Mean mg/L	SD	CV (%)
Sample 1	10	20.54	1.88	9.15
Sample 2	10	49.51	4.16	8.40
Sample 3	10	102.20	5.20	5.09

Interference

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

REFERENCE VALUES

The reference values of CRP in normal population are < 6 mg/L.
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, hemolysed, 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 after the 1st trimester of pregnancy and persists 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 upto 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. Samples with values above measuring range must be diluted 1:4 with normal saline and retested. The result obtained must be multiplied with the dilution factor.
9. The measuring range of the assay is as indicated in the pack insert. Values outside the measuring range are extrapolated values and should not be considered as accurate.

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

1. R.D. Eastham et.al.,C-Reactive Protein in Rheumatic Heart Disease, Am. Rheum. Dis. (1958), 17 pgs 314-3182. Ward A.N..
2. Clinical Laboratory Diagnostics, Edited by Lothar Thomas, M.D., 1st Ed., 1998, TH-Books Verlagsgesellschaft mbH, Frankfurt, Germany, pgs 700-706.
3. Data on file : Tulip Diagnostics (P) Ltd.