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	Latex 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™ RF

IMMUNOTURBIDIMETRIC ASSAY FOR DETERMINATION OF SERUM RF ON TURBOSMART™

SUMMARY

In Rheumatoid arthritis (RA), diagnostically useful autoantibodies termed as Rheumatoid Factors (RF) can be detected which are immunoglobulins of the class IgG, IgM, IgA, and IgE. IgM class RF with specificity to human IgG Fc is the most useful prognostic marker for RA.

RF play a role in perpetuating the rheumatoid inflammatory process, the severity of joint damage could be predicted according to the strength of RF reactivity. A significant decline of RF with the remission of disease activity has also been demonstrated. Therefore, quantified serial determinations of RF are more meaningful for the diagnosis, prognosis, and assessment of therapeutic efficacy of rheumatoid arthritis.

Initial RF positivity has been a sensitive predictor for later joint destruction. Quantified measurement of initial RF level and especially repeated measurements of RF at regular intervals seems to add significantly to the prognostic value of RF in distinguishing between progressive and non-progressive disease in early RA.

turbosmart™ RF is a turbidimetric immunoassay for quantitative detection of rheumatoid factors of the IgM class in human serum.

PRESENTATION

REF	108720020	108720060
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™ RF Activation buffer:** Ready to use.
2. R2 **turbosmart™ RF Latex Reagent:** Ready to use uniform suspension of polystyrene latex particles coated with suitably modified Fc fraction of human IgG.
3. SC **turbosmart™ RF RFID: Card with Master calibration curve** calibrated with a standard traceable to the W.H.O., International Reference Preparation of Rheumatoid Arthritis Serum.

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™ RF is a quantitative immunoassay for the determination of rheumatoid factors and is based on the principle of agglutination reaction. The test specimen is mixed with **turbosmart™ RF** activation buffer (R1) and latex reagent (R2) and allowed to react. Presence of RF in the test specimen results in formation of an insoluble complex resulting in an increase in turbidity, which is measured at wavelength ~ 650 nm. The increase in turbidity corresponds to the concentration of RF 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 and Anti-HIV 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™ RF** latex reagent well before use to disperse the latex particles uniformly to improve test performance.
5. Do not use vortex mixers for mixing. Gently mix the reagents and samples during test procedures.

6. **As the reagents and RFID card within lots have been matched, reagents or RFID cards from different lots must not be interchanged.**
7. It is recommended that the reagent performance and Smart card calibration must be validated periodically with known controls such as **Turbodyne™ RF** control (Ref: 108540005).
8. Do not use damaged or leaking reagents.
9. The reagents can be damaged due to microbial contamination or on exposure to extreme temperatures
10. **Always use fresh 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 RF test from the Measure Menu of Instrument.
3. Load the **turbosmart™ RF** 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 RF 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 225µl R1 to the cuvette using fresh clean disposable micropipette tips.
6. Then add 5µl 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 25 µl 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™ RF** is 15-120 IU/ml. The exact range is dependant on the calibrator value used for calibration which is lot specific.

Detection limit / Analytical Sensitivity

Detection limit: 15 IU/ml
The detection limit represents the lowest measurable RF concentrations that can be distinguished from zero.

Precision

Intra-assay precision	n	Mean IU/ml	SD	CV (%)
Sample 1	10	41.1	6.0	14.6
Sample 2	10	69.7	4.0	5.9
Sample 3	10	101.6	4.6	4.5

Inter-assay precision	n	Mean IU/ml	SD	CV (%)
Sample 1	10	42.2	3.0	6.8
Sample 2	10	71.3	4.6	6.4
Sample 3	10	102.4	6.1	6.0

Interference

No interference was observed by Glucose upto 500 mg/dl, Albumin upto 50 g/dl, Bilirubin upto 50 mg/dl, Haemoglobin upto 500 mg/dl and Triglycerides upto 1000 mg/dl.

REFERENCE VALUES

The reference values of RF in normal population are < 20 IU/ml.
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. Samples with values beyond the linearity limit have to be diluted with isotonic saline and retested. The values obtained must be multiplied with the dilution factor for calculating the result.
3. Markedly lipemic, hemolysed, and contaminated serum samples could produce erroneous RF values.
4. Use of plasma rather than serum can result in erroneous RF values.
5. Rheumatoid factors are not exclusively found in rheumatoid arthritis but sometimes in syphilis, systemic lupus erythromatosus, hepatitis, and hypergammaglobulinemia also.
6. It is recommended that results of the test should be correlated with clinical findings to arrive at final diagnosis.
7. **turbosmart™ RF** assay is sensitive to the presence of IgM RF with heterogeneous specificity.
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. Amy M. Wasserman et.al., Diagnosis and Management of Rheumatoid Arthritis, American Family Physician, Vol.84, No.11, Dec 1, 2011, pgs 1245-1252.
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.