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™

ASO

IMMUNOTURBIDIMETRIC ASSAY FOR DETERMINATION OF SERUM ASO ON TURBOSMART™

SUMMARY

The group A, β-hemolytic streptococci produce various exotoxins such as Streptolysin O, Streptolysin S that can act as antigens. The affected individuals produce specific antibodies against Streptolysin 'O' that has clinical significance namely Antistreptolysin 'O'. Antistreptolysin 'O' (ASO) can be detected 1 - 3 weeks after infection, attaining a maximum levels at around 3 - 6 weeks. Determination of these antibodies is very useful for the diagnosis of streptococcal infections and their relative effects such as rheumatic fever and acute glomerulonephritis.

PRESENTATION

REF	108740020	108740060
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™ ASO Activation buffer:** Ready to use.
2. R2 **turbosmart™ ASO Latex Reagent:** Ready to use uniform suspension of polystyrene latex particles coated with stabilized Streptolysin 'O'.
3. SC **turbosmart™ ASO RFID: Card with Master calibration curve that is** traceable to the International standard for Antistreptolysin 'O' (97/662).

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 provided 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™ ASO is a turbidimetric immunoassay for the determination of Antistreptolysin 'O' and is based on the principle of agglutination reaction. The test specimen is mixed with **turbosmart™ ASO** activation buffer (R1) and latex reagent (R2) and allowed to react. Presence of ASO 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 ASO 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 antibodies 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™ ASO** latex reagent well before use to disperse the latex particles uniformly 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 Smart card calibration must be validated periodically with known controls such as **Turbodyne™ ASO** control (Ref: 108560005).
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 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 ASO test from the Measure Menu of Instrument.
3. Load the **turbosmart™ ASO** 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 ASO 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 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™ ASO** is 75-600 IU/ml. The exact range is dependant on the calibrator value used for calibration which is lot specific.

Detection limit / Analytical Sensitivity

Detection limit: 75 IU/ml
The detection limit represents the lowest measurable ASO concentrations that can be distinguished from zero.

Precision

Intra-assay precision	n	Mean IU/ml	SD	CV (%)
Sample 1	10	199.5	3.2	1.6
Sample 2	10	302.9	17.1	5.6
Sample 3	10	403.6	20.7	5.1

Inter-assay precision	n	Mean IU/ml	SD	CV (%)
Sample 1	10	197.7	11.2	5.7
Sample 2	10	303.3	16.6	5.5
Sample 3	10	402.5	20.6	5.1

Interference

No interference was observed by Bilirubin upto 50 mg/dl Glucose upto 500 mg/dl, Haemoglobin upto 500 mg/dl, Triglycerides upto 1000 mg/dl and Albumin upto 10 g/dl.

REFERENCE VALUES

The reference values of ASO in normal population are < 200 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. Markedly lipemic, hemolysed, and contaminated serum samples could produce erroneous ASO values.
3. Use of plasma rather than serum can result in erroneous ASO values.
4. It is recommended that results of the test should be correlated with clinical findings to arrive at final diagnosis.
5. 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.
6. 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. Todd W.W., (1934), J. Path and Bact., 39, 299-320.
2. Klein G.C., (1980), Manual of Clin. Immunol.., 7th Ed., 431.
3. Spaun J., Bentzon M. W., Larsen S.O., et. al., (1961), Bull. WHO, 24, 271-279.
4. Klein G. C., et. al., (1971), Appl. Microbiol., 21, 999.
5. Clinical Laboratory Diagnostics, Edited by Lothar Thomas, M.D., 1st Ed., 1998, TH-Books Verlagsgesellschaft mbH, Frankfurt, Germany.
6. Data on file: Tulip Diagnostics (P) Ltd.