SYMBOL KEYS

	Temperature limitation		Manufacturer		This way up	SC	Smart card (RFID)
	Use by		Consult Instructions for use	Σ	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	Anti-Human Albumin 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™

MA

IMMUNNOTURBIDIMETRIC ASSAY FOR DETERMINATION OF MA ON TURBOSMART™

SUMMARY

Urinary albumin excretion between 30-300 mg/day (Microalbuminuria), far below the levels found in clinical Proteinuria (> 300 mg/day) is a strong predictor of development of Diabetic nephropathy and vascular complications. Diabetic nephropathy leads to progressive loss of renal function or end stage renal disease (ESRD) and may necessitate need for dialysis or transplantation in most cases. The progression of Microalbuminuria is closely associated with progressive hypertension and loss of blood glucose control. The early presence of Microalbuminuria can be reversed by strict metabolic control and timely intervention of drugs early in the course of disease can arrest the progression of diabetic renal disease. Quantitative values of albumin are useful for differentiating Microalbuminuria from clinical proteinuria and the effective monitoring of intervention strategies.

Annual screening of Microalbuminuria is recommended by 'WHO' and 'International Diabetes Foundation' in all patients with IDDM over the age of 12 years and who have had diabetes for five years or more.

Microalbuminuria is also a significant risk marker of cardiovascular diseases. Its presence can be regarded as an index of increased cardiovascular vulnerability and a signal for correction of known risk factors.

Information regarding the concentration of albumin in urine for the detection of Microalbuminuria can be obtained by using **turbosmart™ MA** reagents.

PRESENTATION

REF	108750020	108750060
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

turbosmart™ MA assay contains:

1. R1 **turbosmart™ MA** Activation Buffer (R1): Ready to use.
2. R2 **turbosmart™ MA** anti-human albumin Reagent (R2): A ready to use solution of anti-human albumin antibody.
3. SC **turbosmart™ MA RFID**: Card with MA master calibration curve calibrated with a standard traceable to the IFCC reference material CRM 470.

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™ MA is a turbidimetric immunoassay for the detection of albumin in urine and is based on the principle of agglutination reaction. The test specimen is mixed with the activation buffer (R1) and **turbosmart™ MA** anti-human antibody solution (R2) and allowed to react. Presence of albumin in the test specimen forms an insoluble complex producing a turbidity, which is measured at wavelength ~ 650 nm. The resulting turbidity corresponds to the concentration of albumin 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. **As the reagents and RFID card within lots have been matched, reagents or RFID cards from different lots must not be interchanged.**

5. It is recommended that the reagent performance and RFID card calibration must be validated periodically with known controls such as **Turbodyne™ MA** control (REF: 108570005).
6. Do not use damaged or leaking reagents.
7. The reagents can be damaged due to microbial contamination or on exposure to extreme temperatures.
8. **Always use fresh clean disposable micropipette tips to aspirate the reagents for testing to prevent contamination.**

SPECIMEN COLLECTION AND PREPARATION

Though random urine specimen can be used, preferably first morning urine specimen should be collected in clean dry glass or plastic containers free from detergents and even traces of proteins. Specimen should be tested immediately preferably within 12 hours of collection. Specimen can be, stored upto 2 days at 2- 8°C provided they are not contaminated. Specimen should be free from particulate matter. Turbid or particulate urine specimen must be clarified by centrifugation at 2000 rpm for 10 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. Hold the RFID card against the sign indicated on the **turbosmart™** instrument as described in the user manual to transfer the card data into the instrument.
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 250µl R1 to the cuvette using fresh clean disposable micropipette tips. Then add 20µl sample and incubate the cuvette for 5 minutes.
5. Place the cuvette with R1 + sample in the **turbosmart™** reading chamber.
6. Press "Testing". The instrument will mix the sample and then indicate to add R2.
7. Pipette 100µl R2 reagent with the **turbosmart™** 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 **turbosmart™ MA** is 25-300 mg/L. The exact range is dependant on the calibrator value used for calibration which is lot specific.

Detection limit / Analytical Sensitivity

Detection limit: 25 mg/L

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

Precision

Intra-assay precision	n	Mean mg/L	SD	CV (%)
Sample 1	10	100.2	4.6	4.6
Sample 2	10	50.2	2.4	4.8
Sample 3	10	197.3	10.8	5.5

Inter-assay precision	n	Mean mg/L	SD	CV (%)
Sample 1	10	101.1	3.4	3.4
Sample 2	10	50.3	2.7	5.4
Sample 3	10	201.1	13.7	6.8

Interference

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

REFERENCE VALUES

The reference values of urinary albumin in normal population are < 25 mg/L. The reference values vary with regards to the time of collection of the urine sample.

REMARKS

1. Microalbuminuria is classified as: Albumin excretion rate: 20-200 mg/L, Albumin/Creatinine ratio: 2.5 - 25 mg/mmol, Albumin/Creatinine ratio: 30-300 mg/g, Albumin concentration (early morning urine): 30-300 mg/L.
2. For determining albumin excretion rate, ideally a 24-hr urine must be used as a sample.
3. Usage of well-calibrated pipettes and correct procedure is critical for achieving correct results.
4. Microalbuminuria also occurs in response to acute inflammatory conditions such as Ischaemia, trauma and thermal injury, surgery, pancreatitis and inflammatory bowel diseases. In many of these conditions the albumin excretion increases within minutes or hours of the initiating stimulus and only lasts for 24 - 72 hours.
5. Albumin excretion has also been associated with urinary tract infections.
6. Use only urine as test specimen. Do not use serum.
7. Contaminated and turbid urine samples could produce erroneous albumin values.
8. Albumin excretion is increased after physical activity. It is therefore recommended to use urine sample that has been produced at rest whenever random urine specimen is used.
9. As albumin excretion is subject to physiological fluctuations it is necessary to take two measurements in consecutive days, in case of contradictory results three measurements on different days must be done preferably within a week.
10. Liquid intake of the patient must be in the normal range i.e. 1.5 - 2 litres/day.
11. To diagnose incipient nephropathy, microalbuminuria must be present in at least 2 out of 3 specimens over a 3-6 month period.
12. It is recommended that results of the tests should be correlated with clinical findings to arrive at the final diagnosis.
13. 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.
14. 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. Microalbuminuria, Br. Med. Journal, 1992: 304, pgs 1196-1197.
2. Martin B Mattock, G. Viberti et. al., Diabetes, Vol. 41, June 1992, pgs 736-741.
3. C.E. Mogensen, Microalbuminuria as a predictor of clinical diabetic nephropathy, Kidney International, Vol.31 (1987), pgs 673-689.
4. K Borch-Johnsen, H. Wenzel, G. C. Viberti, C. E. Mogensen et.al., Is screening and intervention for microalbuminuria worthwhile in patients with insulin dependent diabetes, Br. Med. Jour., 1993: 306, pgs 1722-1725.
5. Data on file: Tulip Diagnostics (P) Ltd.