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	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™

D-dimer

IMMUNNOTURBIDIMETRIC ASSAY FOR DETERMINATION OF PLASMA D-DIMER ON TURBOSMART™

SUMMARY

During coagulation sequence of reactions occurs in the body in response to variety of external and or internal stimuli. The enzymatic cascade reaction terminates in the conversion of FIBRINOGEN to FIBRIN, by the enzyme THROMBIN. The fibrin gel is then converted to a stable fibrin clot by thrombin activated Factor XIII.

Finally, the fibrin network is dissolved by the enzyme PLASMIN to generate cross-linked fibrin degradation products (XL FDP). D-Dimer comprising of two D fragments cross linked together, is the smallest plasmin resistant molecular unit present within the cross linked fibrin degradation products.

Detection of D-Dimer is invaluable as a diagnostic marker for thrombotic conditions such as DIC, DVT and PE. The role of the pretest clinical probability score and/or the D-Dimer concentration in the diagnostic management of deep venous thrombosis has been supported by several different studies. The strategy of combining clinical assessment with D-Dimer testing in the initial evaluation of outpatients with suspected deep venous thrombosis is a potentially powerful means to rule out the DVT rapidly and safely, without the need for ultrasonography.

D-Dimer levels can also be used to monitor thrombolytic therapy with t-PA and with streptokinase, thrombotic complications in pregnancy, acute myocardial infarction, sickle cell crisis, severe septic infections, liver disease, DIC accompanying snake bite and prognosis and response to therapy in cancer. D-Dimer testing has been evaluated as a predictive factor for recurrences of VTE after discontinuation of oral anticoagulant therapy.

turbosmart™ D-dimer is a quantitative Immunoturbidimetric assay for the determination of D-Dimer in human plasma.

PRESENTATION

REF	108770020	108770060
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™ D-dimer assay contains:

1. R1 **turbosmart™ D-dimer Activation Buffer (R1):** ready to use buffer.
2. R2 **turbosmart™ D-dimer Latex Reagent (R2):** A uniform suspension of polystyrene latex particles coated with mouse monoclonals Anti D-Dimer Antibody. The cross-linked fibrin degradation products, D-Dimer, D-Dimer E, and high molecular weight derivatives are all recognized by **turbosmart™ D-dimer** latex reagent. No binding was found to the fibrinogen degradation products X, Y, D, and E to 20 mg/L or to fibrinogen upto 1000 mg/L.
3. SC **turbosmart™ D-dimer RFID:** Card with D Dimer Master Calibration curve.

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™ D-dimer is a turbidimetric immunoassay for the determination of D-Dimer and is based on the principle of agglutination reaction. The test specimen is mixed with **turbosmart™ D-dimer** latex reagent (R2) and activation buffer (R1) and allowed to react. Presence of D-Dimer 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 D-Dimer 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™ D-dimer** 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 within lots have been matched, reagents from different lots must not be interchanged.
7. **As the reagents and RFID card within lots have been matched, reagents or RFID cards from different lots must not be interchanged.**
8. It is recommended that the performance of the reagents and **RFID card** calibration must be validated periodically with known controls such as **Turbodyne™ D-dimer** control (Ref: 108580005).
9. Do not use damaged or leaking reagents.
10. The reagents can be damaged due to microbial contamination or on exposure to extreme temperatures.
11. **Always use fresh clean disposable micropipette tips to aspirate the reagents to prevent contamination.**

SAMPLE COLLECTION AND PREPARATION

No special preparation of the patient is required prior to sample collection. Plasma samples are recommended for use with **turbosmart™ D-dimer** test. Fresh EDTA, citrate or heparinised anticoagulated plasma specimens are suitable for performing the test.

Sample storage : 20-25°C - 8 hours
2-8°C - 4 days
Frozen (-20°C) : 2 months
Thaw frozen specimens at 37°C and centrifuge plasma before 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 D-Dimer test from the Measure Menu of Instrument.
3. Load the **turbosmart™ D-dimer** 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 D-Dimer 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 180µl 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 60µl 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

The **turbosmart™ D-dimer** reagent has been designed to measure **D-Dimer** concentrations in the range 100 - 9999 ng/ml. The exact range is dependant on the calibrator value used for calibration which is lot specific. The **turbosmart™ D-dimer** assay is linear between the measuring range under the described assay conditions. The linearity limit of the measuring range depends on the sample to reagent ratio as well as the analyzer used. It will be higher by decreasing the sample volume, though the detection limit of the assay will be proportionately decreased.

Detection limit / Analytical Sensitivity

Detection limit: 500 ng/ml
The detection limit represents the lowest measurable **turbosmart™ D-dimer** concentrations that can be distinguished from zero.

Precision

Intra-assay precision	n	Mean ng/ml	SD	CV (%)
Sample 1	10	1010	43.9	4.4
Sample 2	10	2071	108.6	5.2
Sample 3	10	4047	278.5	6.9

Inter-assay precision	n	Mean ng/ml	SD	CV (%)
Sample 1	10	1009	63.7	6.3
Sample 2	10	2016	135.5	6.7
Sample 3	10	4115	279.2	6.8

Interference

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

REFERENCE VALUES

The reference values of D-Dimer in normal population with **turbosmart™ D-dimer** were estimated to be < 500 ng/ml DD units. 1 DD unit is equivalent to 2 FEU units. 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. When ΔA obtained for the test specimen is greater than the ΔA of the standard with highest concentration then, it indicates that the concentration of **D-Dimer** in the test specimen is beyond the measuring range of the **turbosmart™ D-dimer** assay. Such specimens should be rerun with further dilutions.
3. Markedly lipemic, hemolysed, and contaminated plasma samples could produce erroneous **D-Dimer** 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

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