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.

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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™

IgE

IMMUNOTURBIDIMETRIC ASSAY FOR DETERMINATION OF IgE IN HUMAN SERUM ON TURBOSMART™

SUMMARY

Allergy a hypersensitivity reaction is mediated by immunological mechanisms that can be antibody or cell mediated. In majority of cases the antibody typically responsible for an allergic reaction belongs to IgE isotype and the individual is said to suffer from an IgE mediated allergic disease. IgE bind to the surface of mast cells and basophilic granulocytes. The subsequent binding of allergens to the cell-bound IgE causes the release of histamines and other vasoactive substances by these cells, thereby initiating events that are described as an allergic reaction. IgE is present in trace amounts in normal serum and has a very short half-life. IgE levels exhibit a slow increase during childhood, reaching adult levels in the second decade of life. Usually the total IgE level increases with number of allergies that a person has and with the amount of exposure to relevant allergens. Measurement of serum IgE is useful to determine if the allergic reaction is IgE mediated or non-IgE mediated. IgE levels can increase in atopic diseases, neoplasm, immunodeficiencies and parasitic infections. Estimation of total circulating IgE would also be useful in early detection of allergy in infants and as a means of predicting future atopic manifestations. Several studies indicate an increase in IgE levels in parasitic infections and a significant fall in IgE concentration after effective therapy.

turbosmart™ IgE is an immunoturbidimetric assay for the measurement of total IgE in human serum.

PRESENTATION

REF	108760020	108760060
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™ IgE Activation buffer:** Ready to use.
2. R2 **turbosmart™ IgE Latex Reagent:** Ready to use uniform suspension of polystyrene latex particles coated with anti IgE.
3. SC **turbosmart™ IgE RFID: Card with Master calibration curve** calibrated with a standard traceable to the International Reference Preparation of IgE 75/502 from WHO.

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™ IgE is a turbidimetric immunoassay for the determination of immunoglobulin IgE in human serum and is based on the principle of agglutination reaction. The test specimen is mixed with the Activation buffer (R1) and **turbosmart™ IgE** Latex reagent (R2) and allowed to react. The presence of IgE in the test specimen results in the formation of an insoluble complex producing a turbidity, which is measured at ~ 650 nm wavelength. The extent of turbidity, corresponds to the concentration of IgE in the specimen.

NOTE

1. In vitro diagnostic reagent for laboratory and professional use only. Not for medicinal use.
2. All the reagents derived from human source have been tested for HBsAg and HIV antibodies and are found to be non-reactive. However handle the material as if infectious.
3. Reagent contains 0.09% Sodium Azide as preservative. Avoid contact with skin and mucosa. On disposal flush with large quantities of water.
4. The reagents can be damaged due to microbial contamination or on exposure to extreme temperatures.
5. Gently swirl each of the reagent vials to attain homogeneity prior to use for obtaining better performance.

6. Do not use vortex mixer for mixing reagents. Gently mix reagents and samples during test procedures.
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 reagent performance and RFID card calibration must be validated periodically with known controls such as **Turbodyne™ IgE** control (Ref: 108610002).
9. Do not use damaged or leaking reagents.
10. 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 delay in testing occur, store the sample at 2-8^{0}C, provided they are not contaminated. Samples can be stored for up to a week. Do not use hemolysed, icteric, or turbid serum specimen.

ADDITIONAL MATERIAL REQUIRED

turbosmart™ analyser, Cuvettes, Stopwatch, well calibrated micropipettes, disposable tips and incubator.

TEST PROCEDURE

1. Bring reagent and sample to room temperature before use.
2. Select the IgE test from the Measure Menu of Instrument.
3. Load the **turbosmart™ IgE** 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 IgE 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 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 100µl 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 **turbosmart™ IgE** reagent has been designed to measure IgE concentrations in the range 30IU/ml-2000IU/ml under the described assay condition. The exact range is dependant on the calibrator value used for calibration which is lot specific. The measuring range depends on sample to reagent ratio and the analyzer used for testing. An increase in sample volume would result in improved sensitivity but decrease in linearity whereas a decrease in sample volume would result in increased linearity and decrease in sensitivity.

Detection limit / Analytical Sensitivity

Detection limit: 30 IU/ml. The detection limit represents the lowest measurable IgE concentrations that can be distinguished from zero.

Precision

Intra-assay precision	n	Mean IU/ml	SD	CV (%)
Sample 1	10	255.2	9.6	3.7
Sample 2	10	96.8	4.7	4.9
Sample 3	10	402.3	20.4	5.0

Inter-assay precision	n	Mean IU/ml	SD	CV (%)
Sample 1	10	253.9	11.1	4.4
Sample 2	10	103.2	4.8	4.6
Sample 3	10	407.5	13.4	3.3

Interference

No interference was observed with Hemoglobin (500mg/dl), Bilirubin-C (60 mg/dl), Bilirubin-F (60mg/dl), Lipemia 15g/L and Rheumatoid factors 600 IU/ml.

REFERENCE VALUES

The suggested reference values for IgE:

Age	IgE Reference Range
< 1 year	1.4 - 53.2 IU/ml
1-4 years	0.4 - 351.6 IU/ml
5-10 years	0.5 - 393.0 IU/ml
11-15 years	1.9 - 170.4 IU/ml
> 15 years	2.0 - 305.9 IU/ml

The above reference range is for guideline only. As the spread of IgE values is extremely wide in subjects with and without known allergic diseases it is recommended that each laboratory should define its own reference range for the relevant population.

REMARKS

1. Markedly lipemic, hemolysed, and contaminated serum samples could produce non-specific IgE values.
2. Use of plasma rather than serum can lead to erroneous IgE values.
3. Do not read results beyond four minutes.
4. While total serum IgE levels are useful in confirming the clinical diagnosis of allergic diseases, a normal or low value does not rule out the possibility of IgE mediated conditions.
5. Serum IgE concentration is dependent upon multiple factors: including if the patient is sensitized, how many times the patient has been exposed to a specific allergen etc.
6. It is recommended that results of the test should be correlated with clinical findings to arrive at final diagnosis. All the clinical findings especially specific allergy testing should be taken into consideration while determining the clinical status of the patient.
7. IgE levels in adults without a tendency to develop atopies are usually less than 100 IU/ml.
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.

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6. Data on file: Tulip Diagnostics (P) Ltd.