TurbiMAX Immunoglobulin E (IgE) Total

Latex Enhanced Turbidimtric Immuno Assay(LETIA)

ORDERING INFORMATION

Ref. No:	Pack Size	Presentation
AVIGET-25	25 ml	Two Liquid Reagents
AVIGET-100	100 ml	Two Liquid Reagents

INTENDED USE:

TurbiMAX Immunoglobulin E (IgE) Total is an in-vitro diagnostic kit for the quantitative determination of Immunoglobulin E in human Serum.

PRODUCT FEATURES

1. Latex Enhanced Turbidimetric Immuno Assay(LETIA)
2. Liquid Stable Two Reagents
3. 5 Level Calibrator set provided.
4. Measurement at 546 nms (540-630 nms)
5. Test Procedure time 5 minutes at 37°C
6. Linearity : 2000 IU/mL
7. Adaptable to Semi and Automated Analyzers

CLINICAL SIGNIFICANCE

Immunoglobulin E (IgE) are a particular type of antibodies, molecules involved in the immune reaction of the human being. IgE are constituted as all the immunoglobulins by a couple of heavy chains (H) and one light chain (L). The light chain is same as that of other immunoglobulins, while the heavy chains are characteristics of IgE and are of ε type: these ones are structurally very similar to the μ heavy chains of IgM. They are synthesized by B lymphocytes and more precisely by plasma cells which are in the submucosa habit of respiratory and intestinal systems.

Basically, the IgE production is stimulated by a particular sub population of T helper lymphocytes, the TH2: the differentiation of T lymphocytes into TH2 is stimulated by the presence of particular antigens, as that ones on the surface of parasite and helminth, and by allergens. TH2 lymphocytes start immediately to produce interleukin 4 and 5 (IL-4 ed IL-5), that stimulate the isotypic switch of B lymphocytes into immunoglobulin E (IgE) secreting cells.

The IgE mechanism of action is particular compared to the others immunoglobulins: after their production they connect at once their Fc part to FcεRI receptor (type I receptor for the Fc fragment of the ε chains) that is found on the basophilic and mast cells surfaces.

So IgE is functioning then as a receptor of the same mast cell: if IgE enters in contact with the antigen for which it is specific, it will stimulate the degranulation of the mast cell and the release of histamine and of lipidic mediators (prostaglandin, thromboxanes, leukotrienes) in the intercellular space, producing an allergic reaction.

Basically, IgE are a second barrier to the infections, after IgA; they have the function to protect the human organism from infections due to parasites, particularly to helminths. IgE are also the main responsible for the allergies, the most spread illnesses from hypersensitivity presents in the industrial countries populations.

PRINCIPLE

Quantitative determination of IgE may be done by an immunoturbidimetric method, by automatic analyzers or in manual.Mixing a sample with a precise Antigen to a solution having the corresponding anti-serum (Antibody), in a well-defined ratio, it is possible to have turbidity. Using multipoint Calibrator (6 Level Calibration, it is possible to prepare a Calibration Curve to refer, generally not rectilinear and not crossing the origin. Plotting Calibration Curve with the absorbance values and concentration of each calibrator it is possible to determine the concentration of human serum sample

STORAGE AND STABILITY

All the components of the kit are stable until the expiration date on the labels when stored at 2-8ºC and the contaminations is prevented during their use. Do not freeze the latex and diluent.

KIT COMPONENTS

1. Buffer Reagent R1
2. Latex Reagent R2
3. IgE Calibrator : Concentration as stated on the label

COMPOSITION

R1 - BUFFER

Buffer PBS modif.	>25 mmol/L

R2 - Anti-IgE LATEX

anti-IgE (goat) Latex	
NaN3	< 0.1%

REAGENT RECONSTITUTION & STABILITY

Reagent are liquid stable no need for reconstitution.
When the reagent is stored properly at 2-8°C & the contamination avoided, it is stable up to the expiry date mention on the label & kit box.

CALIBRATION

For calibration use 5 level calibrator set which is provided with the kit.

MATERIAL REQUIRED BUT NOT PROVIDED

Laboratory Instrumentation, Spectrophotometer UV/VIS with thermostatic cuvette holder or clinical chemistry analyzer: semi auto, calibrated micropipettes, glass or high quality polystyrene cuvettes, test tube/rack, heating bath controls, saline.

REAGENT DETERIORATION

Discard if blank reagent absorbance exceeds 1.2 at 546 nm against distilled water.

WARNING & PRECAUTIONS

- Reagent may contain some non reactive and preservative components. It is recommended to handle carefully, avoiding contact with skin and ingestion.
- Specimen should be considered infectious and handled appropriately.
- Contamination by soap or glycerol will affect this assay.
- Perform the test according to the general " Good Laboratory Practice" GLP

SPECIMEN COLLECTION & STORAGE

Unhaemolysed fresh serum.
Samples collection incompliance with CLSI (NCCLS)
Freeze the soonest, if samples are not tested the same day.

SYSTEM PARAMETERS:

Reaction Type (Mode)	Fixed Time- Non Linear- Multi Standard
Reaction Direction	Increasing
Delay Time	30 Seconds
Measuring Time	300 Seconds
Wave Length	546 nm (540-630 nms)
Flow Cell Temp.	37°C
Blank	Distilled Water Blank
Reagent Volume	400 µl (R1) + 100 µl (R2)
Sample Volume)	20 µl
Calibrator Concentration	Printed on the Vials Labels)
Linearity	2000 IU/mL

TEST PROCEDURE :

Reagent	Calibrator	Sample/Control
Reagent R1	400 µl	400 µl
Calibrator	20 µl	----
Serum Sample	----	20 µl
Reagent R2	100 µl	100 µl

Read absorbance (A) at 546 nms (540-630 nms) for all the Calibrators/ Controls and Samples

Calculations with Calibrators/ Calibration Curve/ Result Interpretation:

Calculate the ∆Absorbance of Calibrators = Abs of Calibrator
Plot the ∆ absorbances of all the Calibrators versus their respective concentrations on a non linear graph paper. IgE Results for the samples and controls are determined using the prepared calibration curve.

∆Abs of Sample ie Abs of Sample
IgE in the sample is calculated by interpolation of Abs of Sample on the calibration curve.

CALCULATION
The concentration of IgE in unknown samples is derived from a calibration curve using an appropriate mathematical model such as logit/log or spline. The calibration curve is obtained with 5 calibrators at different levels and NaCl solution (9 g/l) for determination of the zero value. Stability of calibration: 4 weeks

EXPECTED VALUES
Normal Values IgE: 3 - 423 IU/mL.
Since the normal values depend on age, sex, diet, geographic area and other factors, each laboratory should establish its own normal values for this procedure.

QUALITY CONTROL & CALIBRATION
IgE Controls are recommended for daily quality control. The control intervals and limits should be adapted to each laboratory's individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the limits

PERFORMANCE CHARACTERESTICS:
1. Linearity
Linearity : 2000 IU/mL

2. Sensitivity/ Limit of Detection (LOD)
The lower limit of detection is 3.0 IU/mL

3.Interferences:
Interference test criterion: recovery ± 30% of initial value. No interference found on samples with: - total bilirubin up to 20 mg/dL;
- haemoglobin up to 600 mg/dL;
- lipemia [Intralipid] up to 1000 mg/dL;
- ascorbic acid up to 50 mg/dL.

4. Precision: determined on 20 replications of 2 samples. The results obtained are following:

Intra-Assay

N=20	Mean (mg/dl)	SD (mg/dl)	CV%
Control serum 1	106.6	3.2	3.0
Control serum 2	197.2	2.8	1.4

Inter-Assay

N=20	Mean (mg/dl)	SD (mg/dl)	CV%
Control serum 1	103.4	3.4	3.28
Control serum 2	198.1	2.9	1.46

5. Method Comparison:
a group of 20 sera has been tested using this procedure and using a similar reagent available on the market. The comparison gave these results:
Linear regression equation y = 1.0037x - 4
Correlation coefficient r = 0.9993 n = 20

LIMITATIONS (calibration curve): 3-3500 IU/mL, under the described assay conditions. Samples with higher concentrations should be diluted 1/5 in saline (10 parts serum sample + 40 parts normal saline ex: 10µl serum sample+40 µl saline) and retested again and the results should be multiplied by 5. The linearity limit and measurement range depends on the sample to reagent/ratio, as well as the analyzer used. It will be higher by decreasing the sample volume, although the sensitivity of the test will be proportionally decreased.

WASTE DISPOSAL
Reagents must be disposed off in accordance with local regulations.

NOTES
A) Applications on routine analyzers may be totally different from what developed as manual determination; in addition the procedures are specific for each analyzer.
B) Very deep attention must be given to interfering substances: certain drugs and other substances are able to influence levels of IgE
C) The clinical diagnosis cannot be done correctly using the result of only one test, but have to be done integrating critically the results of different laboratory tests and clinical data.
D) The calibration curve has to be always repeated at each change of the lot of the Reagent and/or calibrator.

REFERENCES:

1. Textbook of Clinical Chemistry, Ed. by N.W. Tietz, W.B. Saunders Co., Philadelphia (1999).
2. Young D.S., Effect of drugs on Clinical Lab. Test, 5th Ed. AACC Press (2000).
3. CLSI(NCCLS) C49-A/H56-A: Collection, Handling, Transport and Storage for Body Fluids. Quick Guide.
4. Imagawa M. et al., Clin. Chim. Acta, 117, 199 (1981).

Symbols Used on Pack

REF	Catalogue Number		Warning/Caution
LOT	Batch No.	IVD	In vitro diagnostic device
	Manufacturing Date		Storage Limit
	Expiry Date		Consult instruction for use
	Manufacturer		Keep away from sunlight
	Keep Dry		Do not use if package is damaged
	Contains sufficient no. of test		

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