Pariksha Biotech
A game changer in IVD

IgE Total Estimation Kit

High-Q Immunoglobulin E (IgE) Total (Premium)

Latex Enhanced Turbidimtric Immuno Assay(LETIA)

HIGH Command on Quality

Intended Use:

Kit for the quantitative determination of Immunoglobulin E in Human Serum

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 Latex Enhanced Turbidimetric Immuno Assay 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 (5 Level Calibrator i t 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

Attention:

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) A lot of factors, as ambient temperature, the working reagent temperature, wash accuracy and the type of spectrophotometer, may affect the tests performances.
E) The calibration curve has to be always repeated at each change of the lot of the Reagent and/or calibrator.

Reagents

Components of the kit:

R1 - Buffer

Buffer PBS modif. >25 mmol/L

R2 - Anti-IgE Latex

anti-IgE (goat) Latex

NaN3 < 0.1%

Stability: the Reagents are stable up to the expiry date mentioned on the labels, stored at 2-8°C.

Preparation of the reagents:

All the reagents are ready-to-use. Mix gently before use and let the reagents reach the room temperature.

Samples:

Un hemolysed fresh serum.
Samples collection in compliance with CLSI (NCCLS)
Freeze the soonest, if samples are not tested the same day.
Freeze only once. Absolutely do not re freeze

Assay Procedure: (Multi Point Calibration with 5 Calibrator Levels)

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 (546-630 nms)
Flow Cell Temp.	37°C
Blank	Distilled Water Blank
Reagent Volume	400 µl (R1) + 100µl (R2)
Sample Volume)	20 µl
Calibrator Concentration	(On the Vials Lot Specific)
Linearity	2000 IU/mL

Procedure :

Reagent	Calibrator	Sample/Control
IgE R1	400 µl	400 µl
Calibrators 1,2,3,4,5	20 µl	----
Serum Sample	----	20 µl
Mix and incubate for 5 Minutes at 37 °C		
IgE R2	100 µl	100 µl

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

Calculations with Calibrators/ Calibration Curve/ Result Interpretation:

Calculate the Δ Absorbance of Calibrators = Abs of Calibrator
Plot the Δ 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.

Δ 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

Attention:

The kit is tested for a manual spectrophotometer and for HITACHI, COBAS and MINDRAY systems. The applications on automatic analyzers could be completely different by what has been developed as manual determination.

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Reference Values:
Since the normal values depend on age, sex, diet, geographic area and other factors, each laboratory should establish its own normal values. Published studies show that it is difficult to determine "normal" values for the IgE serum concentration. Furthermore, the circulation of IgE is brief, as their life span is short. **As a guideline, 80% of the values corresponding to a normal and non atopic population are less than 209 IU/mL.**

Normal Reference Values IgE: Up to 209 IU/mL

Up to 209 IU/mL. (Normal and Non Atopic Population)

209 - 425 IU/mL(Atopic IgE mediated non serious allergies)

> 425 IU/mL (Chronic atopic IgE mediated serious allergies that are pathologic in nature where the intense treatment is required)

Analytical Performances: (validated on MINDRAY Bs300)
The performances of the Reagent **IMMUNOGLOBULIN E (IgE) Total** has been tested with a MINDRAY BS300 analyzer. The data, while representing the characteristics of the product, could be different for each laboratory and for different analyzers.

Method Linearity: the test is linear up to 2000 IU/mL However, for IgE concentrations higher than the maximum value of the calibrator, it is recommended to dilute the sample 1:5 with saline solution, test again and multiply the result x 5.

Method Sensitivity (LoD): the sensitivity limit, that is the minimum concentration that can be distinguished by zero, is 15.0 IU/mL

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.

Within-run Precision: determined on 20 replications of 2 samples. The results obtained are following:

Sample	Mean (mg/dL) ± 2s	CV %
Human 1	106.7 6.2	3.2
Human 2	197.2 5.6	1.4

Run-to-run Precision: determined for 5 days with 20 replications for each days, for two samples. The results obtained are the following:

Sample	Mean (mg/dL) ± 2s	CV %
Human 1	103.4 6.4	3.1
Human 2	198.1 7.4	1.9

Accuracy: 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

References:

1. Textbook of Clinical Chemistry, Ed. by N.W. Tietz, W.B. Saunders Co., Philadelphia (1999).

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Ordering information

Cat No:	Pack Size	Presentation
P- IgE	25 ml	Two Liquid Reagents and Calibrator Set

Product Features

- Latex Enhanced Turbidimetric Immuno Assay(LETIA)
- High Avidity Anti IgE Antibodies are used for high functional affinity there by better linearity
- Liquid Stable Two Reagents
- 5 Point Calibrator Set provided
- Measurement at 546 nms (546-630 nms)
- Test Procedure time 5 minutes at 37°C
- High Linearity : 2000 IU/mL
- Adaptable to Semi and Automated Analyzers

Symbols used with IVD devices

	Date of manufacture		Manufactured by
IVD	In vitro diagnostic medical device		Keep away from sunlight
	Do not freeze		This way up
	Use-by date		Do not use if package is damaged
	Keep dry	LOT	Batch Code
	Consult instructions for use	R	Reagent
eIFU Indicator	Consult electronic instructions for use	CAL	Calibrator Material
REF	Catalogue number		
	Caution		

Manufactured by :-
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Pariksha's world inside
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