

IMMUNOGLOBULIN-E (IgE)

(Immunoturbidimetric Method)

Intended Use

IgE is a reagent kit used for the determination of IgE level in human serum or plasma. The reagents are for *in-vitro* diagnostic use.

Principle

When an antigen-antibody reaction occurs between IgE and anti-IgE antibody which has been coated on latex particles, agglutination results. This agglutination is detected as an absorbance change, with the magnitude of the change being proportional to the quantity of IgE in the sample. The actual concentration is then determined by interpolation from a calibration curve prepared from calibrators of known concentration.

Reagent provided

- 1. R1 – IgE Buffer
- 2. R2 – IgE Latex
- 3. Calibrator.

Reagent storage and stability

The reagent and calibrator are stable till the expiry date stated on the container label.

Specimen collection and preservation

Follow standard laboratory procedures to collect serum samples. It is recommended to perform test immediately after sample collection. If the test cannot be done immediately, store sample at 2-4°C for upto 3 days or at -20°C for up to 1 month. Avoid repeated freezing and thawing.

Assay guidelines for Analyzers

Reaction type	Fixed Time
Reaction slope	Increasing
Flow cell Temperature	37°C
Wavelength	578 nm
Blank	Distilled water
Delay Time	20 sec.
Read Time	180 sec.
Sample volume	9 µl
Reagent volume	360 µl (R1) + 180 µl (R2)
Calibrator. concentration	As on vial
Sensitivity	25 IU/mL
Linearity	Up to 1650 IU/ml

Assay guidelines for Manual procedure (Multi Point Calibration with 6 Level Calibrator)

Reagents	Calibrator (C)	Test (T)
R1 IgE Buffer	360 µl	360 µl
Mix well, incubate at 37°C for 5 min, then add		
R2 IgELatex	180 µl	180 µl
Mix, aspirate the assay mixture. The First Reading should be recorded at 20 seconds (A1) followed by second reading at 180 seconds (A2) at 37°C, 578nm. (ΔA = A2-A1)		

Calculate

$$\text{Immunoglobulin E (mg/dL)} = \frac{\Delta A \text{ of Sample}}{\Delta A \text{ of calibrator}} \times \text{calibrator concentration}$$

Plot the Δ absorbance of all the calibrators versus their respective concentration on a non-linear graph paper, IgE Results for the samples are determined using the prepared calibration curve.

Normal Range

Less than 1 year old	1.35-19.5IU/mL
1-3 years	5.24-30.0IU/mL
4-6 years	5.20-112.0IU/mL
6-9 years	13.12-142.0IU/mL
10-12 years	11.2-172.0IU/mL
13-18 years	25.0-126.0IU/mL
Adult	28.0-140.0IU/mL

Note: Expected range varies from population to population and each laboratory should establish its own normal range.

Method Linearity: The Test is linear upto 1650IU/mL However, for IgE concentration 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 with dilution factor.

Quality Control

To ensure adequate quality control, it is recommended that each batch should include a normal and an abnormal commercial reference control serum. It should be realized that the use of quality control material checks both instrument and reagent functions together. Factors which might affect the performance of this test include proper instrument function, temperature control, cleanliness of glassware and accuracy of pipetting.

References

1. CLSI (NCCLD) C49-A.H56-laboratoryjna. Urban & Partner, 126-127, (2001)
2. Friedman RB, young DS. Effects of Disease on Clinical Laboratory Tests 2nd Edition, AACCC Press 1989
3. Renz H. Atopy and allergy. In: ThomasL, ed. Clinical Laboratory Diagnostics. Use and Assessment of Clinical Laboratory Results. 1st Edition, TH-Books, Frankfurt/Main, Germany, 1998.

Symbols

IVD	In Vitro Diagnostics.		Caution.		Keep away from sun light.		Date of Manufacture.
LOT	Batch No.		Read Instructions.		Fragile.		Product Expiry Date.
CONT	Content.		Storage Temperature.		Keep Dry.		Manufactured By.
REF	Catalogue No.						



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