IGE (IMMUNOGLOBULIN E)

Latex Enhanced Turbidimetric Method

Intended use:

This reagent can be used by medical institutions to determine the content of IgE in human serum samples in vitro for assistant diagnosis. IgE is a secretory immunoglobulin with a molecular weight of 196000. It consists of two light chains and two heavy chains. It is produced by plasma cells in the lamina propria of nasopharynx, tonsil, bronchus, gastrointestinal mucosa, etc. It is the main antibody causing type I allergy. The most obvious basic biological characteristic is homologous cytoplasm. Human IgE can only sensitize human and monkey cells, but can not make them allergic. Other animals are allergic. IgE is the most unstable to heat in immunoglobulin. Among the five kinds of immunoglobulins, the half-life of IgE is the shortest, and it has the highest decomposition rate and the lowest synthesis rate. Therefore, the content of IgE in serum is the lowest. The value of IgE in serum of normal people is about 10-340IU/ml, which is generally slightly higher in males than in females. In allergic constitution or hypersensitive patients, the IgE in serum is obviously higher than that in normal people Asthma is several times higher than normal people, so IgE in the serum is too high, often suggesting the existence of genetic allergy, or type I allergy.

Principle Of The Method

When the latex particles coated with IgE antibody are mixed with the samples containing IgE antigen, agglutination reaction occurs, which results in the change of absorbance. The size of latex particles is proportional to the content of IgE antigen in the samples. The content of IgE in the sample can be quantitatively determined by comparing the change of absorbance with the calibration product of known concentration.

Reagent concentration:

Reagent 1:

PBS Buffer Solution	0.1 mol/ L
PEG	Appropriate Amount
NaN_3	1 %
Surface Active Agent	Appropriate Amount

Reagent 2:

IgE Antibody	>0.2g/L
PBS Buffer Solution	0.1mol/L
NaN_3	1%
Stabilizer	Appropriate Amount
Surface Active Agent	Appropriate Amount

Preperation and stability:

R1: Ready for use

R2: Ready for use

The kit was stable for 18 months at 2 - 8℃. Pay attention to refrigeration during transportation and refrigeration should not be allowed in summer transportation. The reagent was opened and stored at 2-8℃ for 4 weeks.

Sample Requirements

It is suitable for fresh serum or plasma samples. If the samples collected on the same day can not be determined in time, please keep them at - 20℃ and thaw them quickly at 37℃ before use.When bilirubin was less than 60 mg/dL, fat emulsion was less than 500 mg/dL and hemoglobin was less than 750 mg/dL, no interference was found.

Measuring Range and Properties

Reagent appearance: R1 colorless clear transparent without foreign body; R2 milky white and without foreign body

Linearity range: 25-1000IU/ml

Precision:

CV within batches ≤10%,

CV between batches ≤15%.

Testing Procedure

1.Double reagents can be used directly after opening without preparation.

2.Test conditions

Basic parameters of automatic biochemical instruments

Wavelength:	570 nm
Assay mode:	Two-point endpoint method or fixed-time method： 5 min / 5 min
Sample:	5 uL
Reagent 1 ; Reagent 2	200 uL : 100 uL
Six-point calibration, using a non-linear computing model, such as Spline	
Reaction Direction : Unit :	Increase IU/ml

The automatic biochemical analyzer has its own program parameter input method. The basic parameters mentioned above need to be combined with the program parameter input method of the automatic biochemical analyzer. The reagent can be automatically measured only after the parameters of the computer are input.

3.Calibration instructions： 5 points liquid, balance to room temperature for direct use after taking out.

4. Result calculation ： The corresponding A is calibrated by the calibrator concentration. The FER concentration in the sample is read out from the calibration curve through the ΔA of the sample.

Interpretation of Test Results

The linearity of this kit depends on the ratio of samples and reagents, reducing the amount of specimens can increase linearity, but decrease the reagent sensitivity.Excessive sample size will affect the standard curve.

2. The first metering should be performed 40 seconds after the addition of R2, and the second metering is performed 300 seconds after the addition of R2.

3. When used for diagnostic and therapeutic purposes, the results of this test should always be combined with history, symptoms and other clinical outcomes for patients explained.

Reference Value

Normal reference range: ≤340 IU/ml

This reference value comes from the third edition of the National Practice Rules for Clinical Laboratory.

It is suggested that each laboratory verify this reference range or establish its own reference range.

Quality Control

Used to Bioanalytic IgE Control Set 2 x 1 ml #B10859

Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

Calibration

Used to Bioanalytic IgE Calibrator Set 5 x 0.5 ml #B11952

IgE Calibrator Set Calibration stability: 30 days, may differ from analyzers models.

Calibration frequecy

A two – point calibration is recommended in case of:

1-change of lot

2- quality control requirements

Precautions

1.This kit is a kind of Latex Enhanced Immunotransmittance Turbidimetric Reagent.Sub-wavelength is not recommended in it.

2.This product can only be used for In Vitro diagnostic

3.Do not mix different batches of reagents, recalibrate before using new kit with different lots.

4. No freezing! The frozen reagent may lead to changes in the determination performance.

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References

1. Chapman MD. Allergen nomenclature. Clin Allergy Immunol 2008; 21: 47–58. PubMed
2. Turgeon, Immunology and serology in laboratory medicine, C.V. Mosby Company, 1990, pg. 259-260.
3. Clinics: Allergic Diseases – Allergic Reactions to Latex Among Health Care Workers. Mayo Clin Proc 67:1075-1079, 1992.

Order information (Cat No.) :

CR664	B24195	B27196	B30196	B33196	B36195
B21195	B25195	B28195	B31196	B34195	B37195
B21196	B25196	B28196	B32195	B35195	B80195
B22195	B27195	B30195	B33195	B35196	

Manufacturer

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SYMBOLS

IVD	for in vitro diagnostic use only
LOT	lot of manufacturing
REF	code number
	storage at temperature interval
	expiration date (year/month)
	warning, read enclosed documents
	Read the directions

CE IVD

ISO 9001:2015
ISO 13485:2016