Immunoglobulin E Assay Kit (IgE)

Method：Latex immuno turbidimetric Method

Cat .No.	Packing Size	Analyzer
EGSIGE	R1: 1×40 ml R2: 1×20 ml	For Hitachi917& OlympusAU640/400/600
ETGSIGE	R1: 1×20 ml R2: 1×10 ml	For Hitachi917& OlympusAU640/400/600

INTENDED USE

For in vitro quantitative determination of Immunoglobulin E in serum or plasma.

CLINICAL SIGNIFICANCE

Increased IGE content is commonly seen in allergic diseases (allergic rhinitis, exogenous asthma, hay fever, allergic dermatitis, chronic urticaria, drug and food allergies), parasitic infections, and patients with IGE type myeloma [1], ADIS[2], and non-Hodgkin's lymphoma [1].

ASSAY PRINCIPLE

IgE in the sample and specific IgE-antibody in the reagent react to form antigen-antibody complex and generate turbidity, which is proportional to the amount of IgE in the sample. Measuring the absorbance at a specific wavelength and compare with the calibration curve to calculate IgE concentration in the sample.

REAGENT COMPOSITION

Contents	Concentration
Reagent 1 (R1)	
2-(N-morpholine) ethylsulfonic acid (MES) buffer	50mmol/L
Preservative	0.1%
Reagent 2 (R2)	
Latex particle coated IgE antibody	0.1%
Preservative	0.1%

STORAGE AND EXPIRY DATE

1. Stable up to the expiry date when the reagent is sealed and stored in dark at 2-8 ℃.
2. Once opened, the reagents are stable for 28 days when refrigerated on the analyzer or refrigerator.
3. The production date and expiry date are shown on the label .
4. Reagents should not be frozen.

SAMPLE REQUIREMENT

Fresh serum,
EDTA potassium or heparin lithium anticoagulant plasma.It can be stored for 7 days at 2℃ ~ 8℃, and for a month at -20℃. The thawed specimen can only be used once.

ASSAY PROCEDURE

Test Condition（Hitachi 917）

Main wavelength	570 nm	Sample（S）	5 μl
Secondary wavelength	—	Reagent 1（R1）	200μl
Reaction temperature	37℃	Reagent 2（R2）	100μl
Optical diameter of colorimetric cup	1cm	Reaction type	End-point method

Operate procedure

Add into Cuvette：	
Sample（S）	5 μl
Reagent 1（R1）	200μl
Well mixed，37℃ incubate for 5 min，Add in.	
Reagent 2（R2）	100μl
H_2O	5μl
Well mixed，37℃ incubate for 90s, measure the original absorbance A1，incubate again for 210s，measure the absorbance A2，calculate ΔA=A2-A1。	

Note: Parameters above are only introduced with Hitachi 917 as an example. The parameters of different biochemistry analyzers are slightly different. Please read the manual carefully before setting parameters.

CALIBRATION

1.It is recommended to use Gcell IGE calibrator.
2. According to the requirements of the calibration procedure in the operation manual of biochemistry analyzer, each laboratory establishes its own calibration procedure according to the specific conditions.
3.Requirements for calibration and frequency: It is recommended to calibrate at least once every two weeks. When the following situations occur, it is recommended to re-calibrate: change the reagent batch number, the indoor quality control runs out of control, the biochemistry analyzer carries out major maintenance or replaces the main parts such as light source or cuvette.
4.The calibrator is liquid and can be used directly. The six point calibration USES purified water as the first point. After use, tighten the cap to avoid contamination and freeze storage.

QUALITY CONTROL

It is recommended to use Gcell IGE control. The absorbance of quality control should be within the labeled value range. If the results deviate from the scope, please find out the reason by following steps:
1 Check the parameter setting and light source.
2 Check the cleanliness of the cuvette and sampling needle.
3 Check whether water is contaminated or not. Bacterial growth can lead to incorrect results.
4 Check the reaction temperature.
5 Check the validity of the kit.

RESULT CALCULATION

To calibrate product concentration of the calibration curve is Δ A corresponding, IgE concentration in the samples by the Δ A readout from the calibration curve of the sample.

REFERENCE RANGE

Normally serum or plasma: <198 IU/mL.
Laboratories are suggested to establish its own reference interval according to age, sex, diet and region.

INTERFERENCES

The effect of Bilirubin ≤ 40 mg/dL, hemoglobin ≤ 500 mg/dL,

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and intralipid ≤ 5‰, is less than ±10%.

ACCURACY

The kit is tested with NIBSC 11/234 international reference material. The deviation of the results should ≤±15%.

SENSITIVITY

When the sample concentration is 500IU/mL, the absorbance change should ≤0.5000.

LINEARITY RANGE

In the range of [25.0,1000.0] IU/mL, the linearity correlation coefficient r ≥ 0.990. In the range of [25.0, 200.0] IU/mL, the absolute deviation should ≤ 30.0 IU/mL; In the range of (200.0, 1000.0] IU/mL, the relative deviation should ≤±15%.

PRECISION

Repeatability precision was obtained by testing control or sample for 20 times of repeated measurement. Intermediate precision was obtained by testing human samples or control for 2 batches per day, and each batch was measured for 2 times separately in morning and afternoon, for total 20 days. The results are as follows:

a）Repeatability Precision（N=20）

	Mean (IU/mL)	CV(%)
Control 1	110.84	2.36
Control 2	440.27	0.94

b) Intermediate Precision (N=80)

	Mean (IU/mL)	CV(%)
Control 1	98.65	3.49
Control 2	433.30	1.52

MATTERS FOR ATTENTION

1. The reagent contains preservatives. If it enters the eye, mouth or contact on the skin, please rinse it thoroughly with clean water immediately and go to the hospital if necessary.
2. The reagent contains preservatives, which can react strongly with copper, lead and other metals to form azide metal. Therefore, please dilute the waste liquid and flush the drain pipe to avoid residual when disposal.
3. Do not mix or exchange reagents with different batches in the process of detection.
4. Opened reagents should be sealed and stored according to the specified method. Expired product should not be used.
5. Please dispose test tubes and other instruments that have touched the test sample according to the relevant medical waste disposal regulations.
6. Calibrator and control use human matrix serum, passed the detection of HIV (HIV 1, HIV 2) antibodies, hepatitis B surface antigen (HbsAg) and hepatitis C virus (HCV). All of them are negative. Although the detection method is highly accurate, it can not be guaranteed that all infected donors are found, so the control should also be treated as infectious specimens.

REFERENCES

1. Linlin Zhao. Assay method and clinical meaning for serum IgE test [J]. Medical examination,2013,13(36):316.
2.Corinne Rancinan,MDM, IgE serum level:A prognostic marker for AIDS in HIV-infected adults?[J] J Allergy Clin Immunol 1998,102:329-30.

INDEX OF SYMBOLS

	Manufacture
REF	Catalogue Number
LOT	Lot number
	Date of manufacture
	Use by(Expiration date)
IVD	For In-Vitro Diagnostic use only
2℃ 8℃	Stored at 2-8℃
	Attention:See instruction for use
EC REP	Authorized Representative in the European Company

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