Immunoglobulin E (IgE) System Pack (Latex Immunoturbidimetry Method)

B Auto 200, Unicorn 230, Unicorn 120 , Bonavera Chem 200 , Beaconic chem 200, Beaconic B200, Beaconic analyzer 120& Bonavera chem 100(Fully Auto Biochemistry Analyzer)

Code	Product name	Pack size
BA239	Immunoglobulin E (IgE) System Pack (Latex Immunoturbidimetry Method)	1X20+1X10 ML

Intended use

For the quantitative determination of immunoglobulin E in human serum or plasma.

Clinical significance

Elevation of IgE is mainly seen in patients with allergic diseases, such as allergic rhinitis, bronchial asthma, atopic conjunctivitis, atopic dermatitis, allergic vasculitis, granuloma, vernal conjunctivitis, urticaria, etc. Reduction of IgE is mainly seen in patients with primary agammaglobulinemia, ataxia- telangiectasia, tumors, and using chemotherapy drugs. (for reference only)

Principle

When IgE in the sample and specific anti-IgE antibodies coated on latex particles combine, an agglutination reaction will occur. The turbidity of the agglutination reaction is proportional to the IgE concentration in the sample. The instrument can calculate the IgE concentration in the patient sample based on the curve established by the calibration.

Reagent Composition

Reagent 1: Diluent

Glycine buffer 150 mmol/L

NaCl 100 mmol/L

Bovine serum albumin 10g/L.

Reagent 2: latex

Latex suspension coated by anti-IgE antibody ＜0.5%,

NaCl 100 mmol/L.

Reagents are liquid, ready to used

Reagent 3: Ultima IgE Calibrator (6 levels Calibrator)

Calibrator are liquid, ready to used

Storage and stability

This kit stays stable for during its shelf life when stored in a dark condition at +2-+8°C (do not freeze). After being opened for the first time, the kit can be stored at +2-+8°C in an anti-pollution environment and stays stable for 30 days.

On board stability: Min 20 days if refrigerated (+8-+14°C) and not contaminated.

Specimen preparation

Fresh non-hemolyzed human serum or plasma.

Calculations

Establish a working curve between the absorbance change value ΔA and the concentration of the calibrator, calculate the absorbance change value ΔA of the sample, and check and get the IgE concentration value in the sample through the working curve.

Reference interval

Up to 200IU/mL

It is recommended that each laboratory should establish its own reference interval.

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 characteristics

1. Measuring range 25 IU/mL – 1600 IU/mL

Samples above this concentration should be diluted 1+1 with 0.9% NaCl solution and the result multiplied by 2.

2. Sensitivity: 25 IU/mL

3. Precision

Intra-assay precision Within run (n=20)	Mean (IU/mL)	SD (IU/mL)	CV (%)
Sample 1	460.94	5.04	1.09
Sample 2	758.37	4.74	0.63

Inter-assay precision Within run (n=20)	Mean (IU/mL)	SD (IU/mL)	CV (%)
Sample 1	104.94	0.74	0.70

Comparison

A comparison between Beacon IgE (y) and a commercially available test (x) using 20 samples gave following results:
y = 1.319x-32.364 r = 0.9988

General precautions

For in vitro diagnostic use only.

Diagnosis should only be made after taking clinical symptoms and the results of other tests into consideration.

Exercise the normal precautions required for handling all laboratory reagents.

Disposal of all waste material should be in accordance with local guidelines.

Precautions for measurement

Specimens should be treated as potentially infectious (HIV, Hepatitis B virus, Hepatitis C virus, etc.) and handled with appropriate caution.

Reagents with different lot numbers should not be interchanged or mixed.

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

Material safety data sheet available for professional user on request.

Parameter For B Auto 200,Unicorn 230,Unicorn 120,Bonavera Chem200,Beaconic chem 200,Beaconic B200,Beaconic analyzer 120 & Bonavera chem 100 (Fully Auto Biochemistry Analyzer)

Test Name	IgE
Full Name	IgE
PRI Wave	578
Sec Wave	None
Assay/point	2-point end
Start	19
End	34
Decimal	2
Unit	IU/mL
Linearity Range Low	25 IU/mL
Linearity Range High	1600 IU/mL
Sample Volume	5.0
Reagent 1 (R1) Volume	200
Reagent 1 (R2) Volume	100
Substrate Depleted/Abs.limit	-
Linearity	1600 IU/mL
Out Of Linearity Range	-
Calibration Type	Spline
Points	6
Blank Type	Reagent
Concentration Blank	0.0
Concentration STD	Refer calibrator vial label

Symbols used on labels

REF Catalogue Number

Manufacture

LOT Lot number

CONT Content

Expiry date

IVD In vitro diagnostics

See Instruction for use

Storage temperature