

## IMMUNOGLOBULIN E (IgE) SYSTEM PACK

(Latex Immunosubidimetry Method )

B Auto 400, Unicorn 480, Bonavera Chem 400, Beaconic B400 & Beaconic chem 400 (Fully Auto Biochemistry Analyzer)



Code	Product Name	Pack Size
UNI39	IMMUNOGLOBULIN E (IgE) SYSTEM PACK	1x30 + 1x15 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  $\Delta A$  and the concentration of the calibrator, calculate the absorbance change value  $\Delta A$  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 Run to 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 400, Unicorn 480, Bonavera Chem 400, Beaconic B400& Beaconic chem 400 (Fully Auto Biochemistry Analyzer)

Test Name	IgE
Full Name	IgE
Pri Wave	578 nm
Sec Wave	None
Assay/point	2 Point end
Start	10
End	33
Decimal	2
Unit	IU/mL
Linearity Range Low	25 IU/mL
Linearity Range High	1600 IU/mL
Sample Volume	4.0 µl
Reagent 1 (R1) Volume	160 µl
Reagent 2 (R2) Volume	80 µl
Substrate Depleted	-
Linearity	1600 IU/mL
Out Of Linearity Range	-
Calibration Type	Spline
Points	6
Blank Type	Reagent
Concentration Blank	0.00
Concentration Std	Refer calibrator vial label

#### Symbols Used On Labels

- REF Catalogue Number
  Manufacturer
-  i See Instruction for Use
 LOT Lot Number
- CONT Content
  Storage Temperature
-  Expiry Date
 IVD In Vitro Diagnostics

BEA/24/IGE/UN/IFU Ver-02  
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