**【Product Name】**
IgE (eCLIA)

**【Order Information】**

| REF NO. | Package Size |
|---|---|
| 0320511601 | 50T |
| 0320511602 | 2×50T |
| 0320511603 | 100T |
| 0320511604 | 2×100T |

**【Intended Purpose】**
IgE (eCLIA) is an immunoassay reagent for in vitro quantitative determination of immunoglobulin E (IgE) in human serum and plasma by fully automated immunoassay analyzer to aid diagnosis of allergic diseases.
Intended testing population: People suspected of having allergic diseases.

**【Summary】**
IgE (approximately 190,000 d) circulates as a monomer at a serum concentration that is highly age dependent. It constitutes approximately 0.0005% of the total serum immunoglobulins in adults. Meanserum IgE levels progressively increase in healthy children up to 10 to 15 years of age and then decrease from the second through eighth decades of life, and strongly associated with and suggestive ofatopicdisorders,suchasallergicrhinitis, extrinsic[1]. Type I allergy is a classical Th2-driven hypersensitivity disease based on IgE recognition of environmental allergens. Exposure of allergic individuals to exogenous allergens leads to immediate type inflammation caused by degranulation of mast cells via IgE-allergen immune complexes and release of inflammatory mediators, proteases and proinflammatory cytokines[2] Many allergens that trigger a type I reaction are low-molecular weight, highly watersoluble proteins that enter the body via the mucosa of the respiratory and digestive tracts. Even the tiniest amounts are sufficient to cause an IgE-mediated reaction in sensitized persons,such as anaphylaxis, acute urticaria, allergic rhinoconjunctivitis, and bronchial asthma.[3]. It is important to note, however, that elevated total IgE is not specific to allergic diseases. It can also be present in other non-allergic conditions, including parasitic infections, certain autoimmune disorders, immunodeficiencies (e.g., Hyper-IgE syndrome), and systemic lupus erythematosus (SLE)[2,4,5,6].Consequently, the total IgE test result must not be used as the sole diagnostic criterion. It must be interpreted in conjunction with the patient's clinical presentation, medical history, physical examination, and other specific diagnostic tests (e.g., allergen-specific IgE testing) [7].
For professionals use only.

**【Principle】**
Sandwich principle. Total duration of assay: 18 minutes.
10 µL of sample, biotinylated anti-IgE antibody, and anti-IgE antibody labeled with ruthenium complex react to form a sandwich complex. After addition of streptavidin-coated microparticles, the complex becomes bound to the solid phase via interaction of biotin and streptavidin. The reaction mixture is aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode. Unbound substances are then removed with system reagent. Application of a voltage to the electrode then induces chemiluminescent emission which is measured by a photomultiplier. Results are determined via a calibration curve which is instrument specifically generated by 2-point calibration and a master curve provided via the RFID.

**【Composition】**
The reagent pack consists of reagent components and IgE Control Material value sheet. Reagent components include MB, RA, RB, calibrators and control materials (Optional). Different reagent components of lot numbers should not be used interchangeably.

| Components | Ingredients | Content (50T) | Content (2×50T) | Content (100T) | Content (2×100T) |
|---|---|---|---|---|---|
| Magnetic Beads (MB) | Streptavidin-coated microparticles 0.75 mg/mL; 0.1M PBS; 0.05% ProClin™ 300 | 1×1.8 mL | 2×1.8 mL | 1×3.5 mL | 2×3.5 mL |
| Reagent B (RB) | Biotinylated anti-IgE antibody, 1.0 µg/mL, 0.1 M PBS; 0.05% ProClin™ 300 | 1×3.0 mL | 2×3.0 mL | 1×6.0 mL | 2×6.0 mL |
| Reagent A (RA) | Anti-IgE antibody labeled with ruthenium complex, 1.0 µg/mL; 0.1 M PBS; 0.05% ProClin™ 300; | 1×3.0 mL | 2×3.0 mL | 1×6.0 mL | 2×6.0 mL |
| Calibrators | IgE, 0.1 M HEPES; 0.05% ProClin™ 300 | Low: 1×1.0 mL<br>High: 1×1.0 mL | | | |
| Control Materials (Optional) | IgE, 0.1 M HEPES; 0.05% ProClin™ 300 | Low: 1×1.0 mL<br>High: 1×1.0 mL | | | |

Traceability: This method has been standardized against the 3rd international standard substances for IgE (WHO 11/234).
See the control material value sheet for the target values and ranges of control materials.
Supporting instruments and materials required but not provided in this pack (provided by Lifotronic)
Additional materials for Automated ECL Immunoassay Analyzer eCL8000, eCL8000i, eCL8000p, eCL8000x:
- REF 679005, Auffer, 480 mL, or REF 679004, Auffer, 6×480 mL
- REF 679007, Buffer, 480 mL, or REF 679006, Buffer, 6×480 mL
- REF 679009, Concentrated Washing Buffer, 1 L, or REF 679008, Concentrated Washing Buffer, 6×1 L
- REF 679011, Assay Cup, 300 T, or REF 679012, Assay Cup, 3000 T

Additional materials for Automated ECL Immunoassay Analyzer eCL8600, eCL8600i, eCL8600p, eCL8800, eCL8800i, eCL8800p:
- REF 0320501804, Auffer, 2×1 L, or REF 0320501805, Auffer, 4×1 L
- REF 0320501904, Buffer, 2×1 L, or REF 0320501905, Buffer, 4×1 L
- REF 0320507502, PreClean, 2×800 mL, or REF 0320507503, PreClean, 4×800
- REF 0320510001, Assay Cup/Assay Tip, 6×6×105, or REF 0320120111, Assay Cup/Assay Tip, 12×2×105

Additional materials for Automated ECL Immunoassay Analyzer eCL9000, eCL9600, eCL9900, eCL9900i:
- REF 0320501801, Auffer, 2×2 L, or REF 0320501806, Auffer, 4×2 L
- REF 0320501901, Buffer, 2×2 L, or REF 0320501906, Buffer, 4×2 L
- REF 0320507501, PreClean, 2×2 L, or REF 0320507504, PreClean, 4×2 L
- REF 0320510001, Assay Cup/Assay Tip, 6×6×105, or REF 0320510002, Assay Cup/Assay Tip, 1×6×105

**【Applicable Instrument】**
Automated ECL Immunoassay Analyzers: eCL8000, eCL8000i, eCL8000p, eCL8000x, eCL8600, eCL8600i, eCL8600p, eCL8800, eCL8800i, eCL8800p, eCL9000, eCL9600, eCL9900, eCL9900i.

**【Storage and Shelf life】**
Store at 2ºC-8°C.
Do not freeze.
Store the reagent kit upright in order to ensure complete availability of the microparticles during automatic mixing prior to use.

| *Stability of the reagents* | |
|---|---|
| Unopened store at 2ºC~8ºC | 18 months |
| Store at 2ºC~8ºC after opening | 8 weeks |
| Stored on the analyzers at 2ºC~15ºC | 8 weeks |

The calibrators and control materials are stable up to the stated expiration date.

| *Stability of the calibrators and control materials* | |
|---|---|
| Unopened store at 2ºC~8ºC | 18 months |
| Store at 2ºC~8ºC after opening | 8 weeks |

**【Specimen collection, handling and storage】**
It is recommended to use human serum samples or plasma samples collected with heparin lithium, heparin sodium, EDTA-K2 and EDTA-K3 blood collection tubes.
Samples should be collected in accordance with the standard operation of World Health Organization guidelines for blood collection. After the sample is completely coagulated, centrifugation should be performed to remove residual cellular substances. The sample should be free of air bubbles during testing. Lipid layer covering the sample after centrifugation should be removed. It is not recommended to use hemolyzed samples.
Samples can be stored for 24 hours at 18ºC~28ºC, 8 days at 2ºC~8ºC, and 6 months at -25ºC~-15ºC. Samples can be freeze-thawed only three times.

**【Testing Procedure】**
**Testing procedure and precautions**
Before testing, the system operation manual of the measuring instrument should be carefully read, so as to obtain relevant information such as system operating procedures, sample management, safety precautions and maintenance, and materials required for testing should be prepared. IgE testing procedures should be set up in accordance with the system operating procedures.
Before using the reagent, put it into the analyzer 30 minutes in advance to automatically stir the magnetic bead particles and keep them in suspension.
Recommended environment temperature for testing: 10~30ºC, relative humidity: ≤80.0%.

**Calibration**
Calibration should be performed using lot-matching reagent and calibrators.
Before calibration, the reagent information should be imported into the analyzer via radio frequency identification reagent card (refer to instrument user manual).
Recalibration is recommended as follows :
(1) When using a new lot of reagent;
(2) When the same lot of reagents has been used on the analyzer for more than 4 weeks;
(3) If the quality control result exceeds the defined limit;
(4) When changing the buffers of different lot numbers.

**Quality Control procedure**
For quality control, use IgE Control Materials.
In addition, other suitable control material can be used.
Controls for the various concentration ranges should be run individually at least once every 24 hours when the test is in use, once per reagent kit, and following each calibration.
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 defined limits.
If necessary, repeat the measurement of the samples concerned.
Follow the applicable government regulations and local guidelines for quality control.
Please make sure that the correct values are used.

**Calculation**
The system software can automatically calculates the analyte concentration using particular algorithm, and the result unit is IU/mL.

**Specimen dilution**
Samples with IgE concentrations above the measuring range can be diluted with sample diluent. The recommended dilution ratio is 20 times (either automatically by the instrument or manually). If manual dilution, the result should be multiplied by the dilution ratio. If dilution by instrument, the instrument will automatically multiply the result by the dilution ratio.

**【Reference intervals】**
The IgE concentrations in healthy, non-atopic subjects are greatly dependent on age. By testing serum samples from 754 normal, apparently healthy individuals, the 95th percentile upper reference limit (95th URL) was determined using a nonparametric

| Age group | Sample Size | IU/mL |
|---|---|---|
| Neonates | 124 | 1.5 |
| Infants in 1st year of life | 124 | 15.0 |
| Children aged 1-5 years | 126 | 60.0 |
| Children aged 6-9 years | 127 | 90.0 |
| Children aged 10-15 years | 125 | 200.0 |
| Adults | 128 | 100.0 |

Due to the differences in geography, race, gender and age, it is recommended that each laboratory determine the applicability of reference range through tests, and establish the reference range of this laboratory if necessary.

**【Limitations】**

The test results are only for clinical reference and cannot be used alone as the basis for diagnosis or exclusion of cases.

1. The measuring range of the kit 0.1-2500 IU/mL. Values below the lower detection limit are reported as < 0.1 IU/mL. Values above the measuring range are reported as > 2500 IU/mL.
2. The measured result was unaffected by the high-dose hook effect at IgE concentrations up to 50000 IU/mL.
3. When the sample containing triglyceride ≤ 2200 mg/dL, bilirubin ≤ 37 mg/dL, hemoglobin ≤ 100 mg/dL, biotin ≤ 100 ng/mL, HAMA ≤100 ng/mL, the interference deviation of the measured results is within 10%. When the rheumatoid factor concentration reached 6000 IU/mL, the relative recovery of the test result is between 90% and 110%.
4. When the sample containing Acetaminophen 15.6 mg/dL, Acetylcysteine 15 mg/dL, Acetylsalicylic acid 3 mg/dL, Ampicillin-Na 7.5 mg/dL, Cefoxitin 660 mg/dL, Cetirizine 0.435 mg/dL, Cyclosporine 0.18 mg/dL, Diphenhydramine 0.0774 mg/dL, Doxycycline 1.8 mg/dL, Fexofenadine 0.116 mg/dL, Heparin 330 units/dL, Ibuprofen 21.9 mg/dL, Levodopa 0.75 mg/dL, Methyldopa 2.25 mg/dL, Metronidazole 12.3 mg/dL, Mometasone 0.000045 mg/dL, Phenylbutazone 32.1 mg/dL, Prednisolone 0.12 mg/dL, Rifampicin 4.8 mg/dL, Salicylic Acid 2.86 mg/dL, Theophylline 6 mg/dL, the interference deviation of the measured results is within ± 10%.
5. An interference was found for samples from patients treated with Xolair (omalizumab). Do not use samples from patients under treatment with Xolair (omalizumab) or similar drugs containing anti-IgE antibodies[8].

**【Analytical Performance charateristics】**

**Lower limits of measurement**

Limit of Blank = 0.03 IU/mL
Limit of Detection= 0.1 IU/mL
Limit of Quantitation = 0.5 IU/mL.

**Accuracy**

The relative deviation shall not exceed ±10%.

**Linearity**

Within the range of 0.5~2500 IU/mL, the correlation coefficient (r) of the kit should be greater than 0.9900.

**Precision**

The precision of IgE are the Repeatability(%CV) ≤6%, the Within-Laboratory Precision(%CV) ≤10%, the Reproducibility(%CV) ≤10%.

Precision was determined using immunoassay reagent, samples in a protocol (EP05-A3) of the CLSI (Clinical and Laboratory Standards Institute). The following results were obtained:

| Sample | Mean (IU/mL) | Repeatability (%CV) | Within-Laboratory Precision (%CV) | Reproducibility (%CV) |
|---|---|---|---|---|
| Human serum 1 | 4.937 | 3.12% | 3.24% | 4.58% |
| Human serum 2 | 49.30 | 3.17% | 3.23% | 4.06% |
| Human serum 3 | 197.8 | 3.45% | 3.46% | 4.85% |

**Analytical specificity**

No cross-reactivities with the immunoglobulins G, A, D and M were detectable.

| Analog | Concentration (μg/mL) |
|---|---|
| IgG | 100 |
| IgA | 100 |
| IgD | 100 |
| IgM | 100 |

**Homogeneity of Calibrators and Control Materials**

Within-bottle homogeneity: coefficient of variation (CV) ≤ 5%
Between-bottle homogeneity: The coefficient of variation (CV) ≤8%.

**Measured values of control materials**

The measured results of supporting assigned control materials of the kit should be within the quality control range.

**Method comparison**

A comparison of the Lifotronic IgE assay (y) with the Roche Elecsys IgE II method (x) using clinical samples gave the following correlations:
Number of serum samples measured: 212
Linear regression:
y=1.007x+0.7995
r = 0.9976
The sample concentrations were between 0.1 and 2500 IU/mL.

**【Precautions and Warnings】**

1. When using this kit, the relevant operation precautions of the laboratory must be observed and it needs to be operated by a professional experimenter;
2. The test results of this kit can only be used as clinical reference, the patient's clinical evaluation should be based on the patient's clinical symptoms/signs, medical history, other laboratory test results and treatment response, etc.;
3. Due to methodological reasons or antibody specificity, the results of the same sample tested with reagents of different manufacturers may be different. Therefore, results obtained with different kits should not be directly compared, so as to prevent indicate the characteristics of the reagents in the test report issued to the clinician. If the reagent type is changed during series monitoring, continuous testing should be conducted, and the results should be compared with the original reagent results in parallel to re-determine the baseline value;
4. This product contains animal-derived substances, and may have potential biological risks. All samples and reaction wastes should be treated as the source of infection, and all wastes must be disposed of in accordance with local regulations.
5. Any serious incident that would be occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established..
6. The preservative ProClin™300 which contain Mixture of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H-isothiazol-3-one (3:1): May cause an allergic skin reaction. thus, proper personal protection should be adopt while handling the reagent: avoid breathing dust/fume/gas/mist/vapours/spray, wear protective gloves and contaminated work clothing should not be allowed out of the workplace. If skin irritation or rash occurs: get medical advice/attention, take off contaminated clothing and wash it before reuse, and dispose of contents/container to an approved waste disposal plant.
7. The Summary of Safety and Performance (SSP) could be obtained from EUDAMED when it's available. If the SSP is required, please send email to the Manufacturer.

**【Bibliography】**

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**【Symbols Explanation】**

| Symbol | Title of Symbol | Symbol | Title of Symbol |
|---|---|---|---|
| | Manufacturer | | Consult instructions for use |
| | Use-by date | IVD | In vitro diagnostic medical device |
| LOT | Batch code | Σ | Sufficient for <n> tests |
| SN | Serial number | | Biological risks |
| | Temperature limit | | This way up |
| EC REP | Authorized representative in the European Community | CE | Indicates this device is in compliance with Europe Directive. |
| REF | Catalogue number | P/N | Material code |
| | Warning | | Date of manufacture |
| UDI | Unique device identifier | | |

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