Immunoglobulin E FS*

Diagnostic reagent for quantitative in vitro determination of immunoglobulin E (IgE) in serum or plasma on photometric systems

Order Information
Cat. No.       Kit size
1 7239 99 10 930  R1 2 x 20 mL + R2 2 x 10 mL
1 7230 99 10 059  5 x 1 mL TruCal IgE:
                   Calibrator set with 5 different levels

Summary [1]
The human immunoglobulin classes (IgG, IgA, IgM, IgE and IgD) are a group of functionally and structurally closely related glycoproteins. Human IgE has a molecular weight of about 190 000 Dalton and consists of two identical heavy chains and two identical light chains which are bound together by disulfide bonds in a characteristic Y-shaped form.
The original function of IgE is the specific defense of parasites. In the developed countries it plays a major role in the mediation of immediate type hypersensitivity reactions (type I according to Coombs and Gell). Harmless, polyvalent antigens (pollen, house dust mites), stimulate B cells at the site of entry to synthesize specific IgE which in part binds to mast cells. The half life of plasma IgE is 2-3 days while mast cell-bound IgE has a half life from months to years. During the next contact of the antigen with the sensitized mast cell, bound IgE are cross linked. The cell is degranulated and mediators (mainly histamine) are released which cause, for example, symptoms of hay fever, asthma, and atopic eczema.
Elevated IgE levels occur in atopic diseases, parasitic infection, diseases with T cell dysfunction (e.g. AIDS), certain malignant tumors (respiratory tract, gastrointestinal tract), hyper-IgE syndrome, graft-versus-host disease, and in severe burns.
Measurement of total IgE is mainly conducted in the field of the diagnosis of atopic diseases where highly increased IgE levels may occur. IgE testing is a good tool especially in differential diagnostic examination of clinical pictures with possible allergic background.

Method
Particle enhanced immunoturbidimetric test

Principle
Determination of the IgE concentration by photometric measurement of antigen-antibody-reaction of latex particles coated with antibodies to human IgE with IgE present in the sample.

Specimen
Serum, heparin plasma or EDTA plasma

Stability [2]:
7 days at 20 – 25°C
7 days at 4 – 8°C
6 months at −20°C

Only freeze once!
Discard contaminated specimens.

Reagents

Components and Concentrations
R1:  Glycine  pH 8.3    170 mmol/L
     NaCl         100 mmol/L
R2:  Glycine  pH 7.3    170 mmol/L
     Latex particles coated with anti-human IgE monoclonal antibody (mouse)
     NaCl         100 mmol/L

Storage Instructions and Reagent Stability
The reagents are stable up to the end of the indicated month of expiry if, after opening, stored at 2 – 8°C, protected from light and contamination is avoided. Do not freeze the reagents.

Warnings and Precautions
1. The reagents contain sodium azide (0.9 g/L) as preservative. Do not swallow. Avoid contact with skin and mucous membranes.
2. The reagents contain animal material. Handle the product as potentially infectious according to universal precautions and good laboratory practice.
3. In very rare cases, samples of patients with gammapathy might give falsified results [6].
4. Heterophile antibodies in patient samples may cause falsified results.
5. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient’s medical history, clinical examinations and other findings.
6. For professional use only!

Waste Management
Please refer to local legal requirements.

Reagent Preparation
The reagents are ready to use.

Materials required but not provided
NaCl solution 9 g/L
General laboratory equipment

Assay Procedure for Analyzers

Application sheets for automated systems are available on request.

Basic parameter for Hitachi 911

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wavelength</td>
<td>800/570 nm (bichromatic)</td>
</tr>
<tr>
<td>Temperature</td>
<td>37°C</td>
</tr>
<tr>
<td>Measurement</td>
<td>2 Point End</td>
</tr>
<tr>
<td>Sample/calibrator</td>
<td>5 µL</td>
</tr>
<tr>
<td>Reagent 1</td>
<td>200 µL</td>
</tr>
<tr>
<td>Reagent 2</td>
<td>100 µL</td>
</tr>
<tr>
<td>Addition Reagent 2</td>
<td>Cycle 15 (276 s)</td>
</tr>
<tr>
<td>Absorbance 1</td>
<td>Cycle 18 (335 s)</td>
</tr>
<tr>
<td>Absorbance 2</td>
<td>Cycle 24 (455 s)</td>
</tr>
<tr>
<td>Calibration</td>
<td>Spline</td>
</tr>
</tbody>
</table>

Note: For manual procedures the volumes of sample, calibrator and reagents have to be calculated appropriately and the timing has to be kept exactly.
Calculation
The IgE concentration in unknown samples is derived from a calibration curve using an appropriate mathematical model such as spline or logit/Log. The calibration curve is obtained with 5 calibrators at different levels and NaCl solution (9 g/L) for determination of the zero value.
Stability of calibration: 4 weeks

Calibrators and Controls
For the calibration of automated photometric systems, DiaSys TruCal IgE calibrator set is recommended. The assigned values of the calibrators have been made traceable to the WHO Reference Material NIBSC 75/502.
For internal quality control, a DiaSys TruLab Protein control should be assayed. Each laboratory should establish corrective action in case of deviations in control recovery.

Performance Characteristics

Measuring Range
The test has been developed to determine concentrations of IgE within a measuring range from 10 – 1000 IU/mL. When values exceed this range samples should be diluted 1 + 10 with NaCl solution (9 g/L) and the result multiplied by 11.

Prozone Limit
No prozone effect was observed up to an IgE value of 60000 IU/mL.

Specificity/Interferences
Due to its antibodies, DiaSys Immunoglobulin E FS is a specific immunoassay for human IgE. No interference was observed by conjugated and unconjugated bilirubin up to 60 mg/dL, hemoglobin up to 1500 mg/dL, lipemia up to 1200 mg/dL triglycerides and RF up to 800 IU/mL. For further information on interfering substances refer to Young DS [3].

Sensitivity/Limit of Detection
The lower limit of detection is 10 IU/mL.

Imprecision

<table>
<thead>
<tr>
<th>Age group</th>
<th>Upper limit of the normal range (95th percentile)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Newborns</td>
<td>1.5 IU/mL</td>
</tr>
<tr>
<td>1st year</td>
<td>15 IU/mL</td>
</tr>
<tr>
<td>1 – 5 years</td>
<td>60 IU/mL</td>
</tr>
<tr>
<td>5 – 9 years</td>
<td>90 IU/mL</td>
</tr>
<tr>
<td>10 – 15 years</td>
<td>200 IU/mL</td>
</tr>
<tr>
<td>Adults</td>
<td>100 IU/mL</td>
</tr>
</tbody>
</table>

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary

Literature

Manufacturer
DiaSys Diagnostic Systems GmbH
Alte Strasse 9   65558 Holzheim   Germany