**IMMUNOGLOBULIN E (IgE)**

**Intended Use**

In vitro diagnostic reagents for the quantitative determination of Immunoglobulin E (IgE) in human serum by the Immunoturbidimetric procedure.

**Background**

The Immunoglobulin E (IgE) has a molecular weight of approx. 190,000 g/mol and is produced by the organism in small quantities. Allergic diseases are a sign of hypersensitivity of the body. The type I hypersensitivity reaction, also called immediate hypersensitivity, is IgE mediated and is characterised by an immediate reaction following contact with the antigen. Antigens facilitating an IgE response include components of grass pollen, components of food, parasites and secretions from insects. This antigen induces the mucosal B-cells, in conjunction with T-helper cells, to produce specific IgE. The IgE molecules bind via Fc receptors to mast cells, which thus becomes sensitized. The next time when the antigen comes into contact with the sensitised mast cells, the bound IgE antibodies become cross-linked, leading to degranulation of the mast cells and release of mediators (as Histamine). The mediators bring about clinical signs typical for allergy, such as rhinitis, urtecaria, asthma and eczema. IgE is formed mainly in the lymph nodes and mucous membranes of the respiratory and gastrointestinal tracts. IgE molecules cannot pass through the placental barrier and do not activate complement. IgE determinations are indicated in the diagnosis and monitoring of allergic diseases. Elevated IgE levels also occur in parasitosis and immunodeficiency syndromes, such as acquired T-cell deficiency or the Wiskott-Aldrich syndrome. In infants and small children with recurrent respiratory syndromes, such as acquired T-cell deficiency or the Wiskott-Aldrich syndrome. In infants and small children with recurrent respiratory tract diseases (bronchitis, pseudogroup attacks), the determination of IgE is of prognostic relevance, also in some mielomas of IgE type.

**Test Principle**

The Spectrum IgE test is used for the quantitative in vitro determination of total immunoglobulin IgE in serum and plasma samples. Anti-IgE antibodies covalently bound to latex particles react with the antigen (IgE) in the sample to form an antigen-antibody reaction complex, which can be measured turbidimetrically after particle aggregation.

**Reagents**

**Buffer**

Phosphate buffer, pH 7.0, containing protein stabilizers and < 0.1 % sodium azide as preservative. Free of polyethyleneglicol.

**Latex reagent**

Suspension of latex microparticules covalently bound anti-IgE antibodies suspended in a neutral aqueous solution, with < 0.1 % sodium azide as preservative. Free of polyethyleneglicol.

**Precautions and Warnings**

For in vitro diagnostic use only. Do not pipette by mouth. Reagents containing sodium azide must be handled with precaution. Sodium azide can form explosive azides with lead and copper plumbing.

**System Parameter**

- **Wavelength**: 600 nm
- **Optical path**: 1 cm
- **Assay type**: Turbidimetric
- **Temperature**: 37 °C
- **Incubation time**: 4 min.

**Procedure**

The reagents are ready to use as supplied. Latex reagent should be gently shaken (invert the recipient 3-4 times) before each use.

- **Volume**
  - R1/Buffer reagent: 200 µl
  - R2/Latex reagent: 75 µl

- **Volume sample**: 13 µl

**Step 1:** mix R1 and R2, add sample and read 1st reading immediately after mixing.

**Step 2:** after 4 min read 2nd reading.

**Note:** Volume, time and wavelength are recommended. Adjust them depending of analyser features.

This reagent is intended to be used in clinical chemistry analysers. Adaptations for some of them are available.

**Calibration and Quality Control**

Standardization: use Spectrum Calibrators. The method was standardized against IRP 75/502. For quality control use BioLatex Control or other suitable control material. Each laboratory should establish corrective measures to be taken if values fall outside the limits. Control must be assayed and evaluated as for patient samples.
Calculation

The turbidimetric analysers automatically calculate the IgE concentration of each sample.

Expected Values

The serum IgE concentration in healthy, non-atopic test subjects is very age dependent.

<table>
<thead>
<tr>
<th>Age</th>
<th>IU/ml</th>
</tr>
</thead>
<tbody>
<tr>
<td>New-borns</td>
<td>&lt; 1.5</td>
</tr>
<tr>
<td>Infants&lt;1 year</td>
<td>&lt; 15</td>
</tr>
<tr>
<td>Children (1-5 years of age)</td>
<td>&lt; 60</td>
</tr>
<tr>
<td>Children (6-9 years of age)</td>
<td>&lt; 90</td>
</tr>
<tr>
<td>Children (10-15 years of age)</td>
<td>&lt; 200</td>
</tr>
<tr>
<td>Adults</td>
<td>&lt; 100</td>
</tr>
</tbody>
</table>

These data are to be interpreted as a guide. Each laboratory should establish its own reference intervals.

References

Kjellman N IM, Johansson SGO, Roth A. Clinical Allergy 1976; 6:51-59
Debelic, M. Clinical Significance of total and specific IgE in bronchial asthma. Allergol Immunopathol 1976;4: 361-70.
Sonderdruck aus DG Klinische Chemie Mitteilungen 1995; 26: 207

ORDERING INFORMATION

<table>
<thead>
<tr>
<th>CATALOG NO.</th>
<th>QUANTITY</th>
</tr>
</thead>
<tbody>
<tr>
<td>548 001</td>
<td>100 test</td>
</tr>
</tbody>
</table>