Immunoglobulin E FS*

Diagnostic reagent for quantitative in vitro determination of immunoglobulin E (IgE) in serum or plasma on DiaSys respons®920

Order Information
Cat. No. 1 7239 99 10 921
4 twin containers for 80 tests each
Cat. No. 1 7239 99 10 926
2 twin containers for 80 tests each

Method
Particle enhanced immunoturbidimetric test

Principle
Determination of IgE concentration by photometric measurement of antigen-antibody-reaction of antibodies against human IgE and IgE present in the sample.

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 stored at 2 – 8 °C, protected from light and contamination is avoided. DiaSys respons containers provide protection from light. Do not freeze the reagents!

Warnings and Precautions
1. The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes!
2. Reagent 1 and reagent 2 contain animal material. Handle the product as potentially infectious according to universal precautions and good laboratory practice.
3. To avoid carryover interference, please take care of efficient washing especially after use of interfering reagents. Please refer to the DiaSys respons®920 Carryover Pair Table. Carryover pairs and automated washing steps with the recommended cleaning solution can be specified in the system software. Please refer to the user manual.
4. Heterophile antibodies in patient samples may cause falsified results.
5. In very rare cases, samples of patients with gammopathy might give falsified results [6].
6. 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.
7. For professional use only!

Waste Management
Please refer to local legal requirements.

Reagent Preparation
The reagents are ready to use. The bottles are placed directly into the reagent rotor.

Specimen
Serum, heparin plasma or EDTA plasma
Stability [1]:
7 days at 20 – 25°C
7 days at 4 – 8°C
6 months at -20°C
Discard contaminated specimens. Freeze only once.

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

Calibrator information

<table>
<thead>
<tr>
<th>Cat. No.</th>
<th>Kit size</th>
</tr>
</thead>
<tbody>
<tr>
<td>TruCal IgE (5 Levels)</td>
<td>1 7230 99 10 059</td>
</tr>
<tr>
<td>TruLab Protein Level 1</td>
<td>5 9500 99 10 046</td>
</tr>
<tr>
<td>TruLab Protein Level 2</td>
<td>5 9510 99 10 046</td>
</tr>
</tbody>
</table>

Performance Characteristics

Measuring range from 35 up to 900 IU/mL IgE, at least up to the concentration of the highest calibrator (in case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rener function).

Limit of detection** 10 IU/mL IgE
No prozone effect up to 17000 IU/mL IgE

On-board stability 30 days
Calibration stability 7 days

Interfering substance Interferences IgE [%IU/mL]
Hemoglobin up to 1000 mg/dL 86.1
up to 1200 mg/dL 151
up to 60 mg/dL 54.4
up to 40 mg/dL 197
up to 60 mg/dL 56.4
up to 60 mg/dL 191
Lipemia (triglycerides) up to 400 mg/dl 59.1
up to 1600 mg/dl 176

For further information on interfering substances refer to Young DS [2].

Within run (n=20) Sample 1 Sample 2 Sample 3
Mean [IU/mL] 82.2 119 482
Coefficient of variation [%] 2.34 2.16 1.47
Between run (n=20) Sample 1 Sample 2 Sample 3
Mean [IU/mL] 81.3 120 484
Coefficient of variation [%] 3.33 2.41 2.29

Method comparison (n=89)
Test x DiaSys IgE FS (Hitachi 917)
Test y DiaSys IgE FS (respons®920)
Slope 0.972
Intercept 8.88 IU/mL
Coefficient of correlation 0.997

** according to NCCLS document EP17-A, vol. 24, no. 34

Reference Range [3,4]

<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 year(s)</td>
<td>60 IU/mL</td>
</tr>
<tr>
<td>6 – 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
# Immunoglobulin E FS

Application for serum and plasma

## Test Details

### Test Names
- **Test**: IgE
- **Report Name**: Immunoglobulin E

### Units
- **Unit**: IU/mL

### Wavelength
- **Primary**: 578
- **Secondary**: 0

### Curves
- **Assay Type**: 2-point
- **Curve Type**: 4P Logit-Log

### Sample Replicates
- **M1 Start**: 18
- **M1 End**: 16
- **M2 Start**: 28
- **M2 End**: 26

### Dilution Ratios
- **Sample Replicates**: 1
- **Standard Replicates**: 3
- **Control Replicates**: 1
- **Delta Abs. / Min.**: 0.0000

### Calculations
- **Technical Minimum**: *
- **Technical Maximum**: *
- **Prozone Limit %**: 97
- **Linearity Limit %**: 0
- **Y = aX + b**: a = 1.0000, b = 0.0000

### Reference Ranges

<table>
<thead>
<tr>
<th>Category</th>
<th>Normal (IU/mL)</th>
<th>Upper Limit (IU/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>0.00</td>
<td>100.00</td>
</tr>
<tr>
<td>Panic</td>
<td>0.00</td>
<td>0.00</td>
</tr>
</tbody>
</table>

* Technical Limits are automatically defined by software via upper and lower calibrator level.
** Enter calibrator value.

## Sample Volumes

- **Normal**: 3.00 µL, Dilution Ratio: 1 X
- **Increase**: 6.00 µL, Dilution Ratio: 1 X
- **Decrease**: 3.00 µL, Dilution Ratio: 6 X
- **Standard Volume**: 3.00 µL

## Reagent Volumes and Stirrer Speed

- **RGT-1 Volume**: 160 µL, R1 Stirrer Speed: Low
- **RGT-2 Volume**: 80 µL, R2 Stirrer Speed: Low

## Test Details

### Test Names
- **Test**: IgE
- **Sample Type**: Serum

### Reference Range
- **Category**: Male

- **Lower Limit (IU/mL)**: Normal = 0.00, Panic = 0.00
- **Upper Limit (IU/mL)**: Normal = 100.00

## Sample Types

- **Serum**
- **Urine**
- **CSF**
- **Plasma**
- **Whole Blood**
- **Other**