**Total IgE**

**For the Quantitative Determination of Circulating Total Human IgE**

**Cat. No. KAI-092**

**INTENDED USE**

The K-ASSAY® Total IgE is an *in vitro* diagnostic reagent for the quantitative determination of circulating total IgE in human serum or plasma by immunoturbidimetric assay for use as an aid in the clinical diagnosis of IgE-mediated allergic disorders in conjunction with other clinical findings. FOR IN VITRO DIAGNOSTIC USE.

**PRINCIPLE OF TEST**

Latex particles coated with antibody specific to human IgE form immune complexes in the presence of IgE from the sample. The immune complexes cause an increase in light scattering that is proportional to the concentration of IgE in the serum or plasma sample. The light scattering is measured by reading turbidity at 570 nm. The sample IgE concentration is determined versus IgE calibrators of known concentrations.

**KIT COMPOSITION**

**Reagents (Liquid Stable)**
- R1: Buffer Reagent
- R2: Antiserum Reagent
- Latex particles coated with goat anti-human IgE antibody

**WARNINGS AND PRECAUTIONS**

FOR IN VITRO DIAGNOSTIC USE. Rx only.

Not to be used internally in humans or animals. Normal precautions exercised in handling laboratory reagents should be followed.

Do not mix or use reagents from one test kit with those from a different lot number.

Do not use reagents past their expiration date stated on each reagent container label.

Do not pipette by mouth. Avoid ingestion and contact with skin.

Reagents in this kit contain sodium azide as a preservative. Sodium azide may form explosive compounds in metal drain lines. When disposing of reagents through plumbing fixtures, flush with copious amounts of water. For further information, refer to “Decontamination of Laboratory Sink Drains to Remove Azide Salts,” in the Manual Guide-Safety Management No. CDC-22 issued by the Centers for Disease Control, Atlanta, Georgia.

**REAGENT PREPARATION**

Reagents are ready to use and do not require reconstitution. Mix before using by gently inverting the bottles. After opening, gently invert Reagent 2 once a week.

**STORAGE AND STABILITY**

All reagents should be stored at 2-8°C and protected from light. Unopened reagents can be used for one year from the date of manufacture as indicated by the expiration date on the package and bottle labels if stored at 2-8°C. Once the reagent vials have been opened, store tightly capped at 2-8°C and use within 1 month. Discard reagents if they become contaminated. Evidence of obvious precipitation in reagent 2 (R-2) solution is cause to discard.

**SPECIMEN COLLECTION AND PREPARATION**

**Serum**

Blood should be collected from a patient and the serum separated as soon as possible. Soon after the blood is drawn, it should be allowed to clot, centrifuged, and the serum separated from the clot to a tube. It is recommended that specimen collection be carried out in accordance with NCCLS document H29-A2. Serum samples can be stored for 1 week at 4°C, or at -20°C for longer storage. Avoid repeated freeze/thaw cycles.

**Plasma**

Whole blood is collected in sodium citrate anticoagulant. After collection, immediately centrifuge. In the U.S., follow NCCLS guideline H3-A2. Plasma samples can be stored for 1 week at 4°C, or at -20°C for longer storage. Avoid repeated freeze/thaw cycles.

**AUTOMATED ANALYZER APPLICATION**

Suitable for two-reagent automated analyzers that can measure a rate reaction at an absorbance of 570 nm. Performance assessment was determined using the Hitachi 917. Customers should contact KAMIYA BIO MEDICAL COMPANY for information regarding performance verification of applications for other analyzers.

Refer to the instrument manual from the manufacturer regarding the following:

- Use or function
- Installation procedures and requirements
- Principles of operation
- Performance characteristics, operating instructions
- Calibration procedures including materials and / or equipment to be used
- Operational precautions, limitations, and hazards
- Service and maintenance information

**PROCEDURE**

**Materials Supplied**

- Reagent 1 (R-1) Buffer Reagent 2 x 20 mL
- 0.1 M Tris hydrochloride buffer
- Reagent 2 (R-2) Antiserum Reagent 1 x 6.6 mL
- Latex particles coated with goat anti-human IgE antibody

**Materials Required But Not Supplied**

- Calibrators: K-ASSAY® Total IgE Calibrator, Cat. No. KAI-093C
- Purified water

**Two Reagent Clinical Chemistry Analyzer**

- Capable of accurate absorbance readings at 570 nm
- Capable of accurately dispensing the required volumes
- Capable of maintaining 37°C

**Plastic tubes**

- Sample dilution: Saline with 0.09% Sodium Azide and 1% BSA

**Assay Procedure**

Note: Allow all reagents and specimens to warm to room temperature (18-25°C). Mix all reagents gently before using.

An example of an automated application:

<table>
<thead>
<tr>
<th>Sample</th>
<th>8.0 μL</th>
</tr>
</thead>
<tbody>
<tr>
<td>R1 (Buffer Reagent)</td>
<td>300 μL</td>
</tr>
<tr>
<td>37 °C, 300 seconds</td>
<td></td>
</tr>
<tr>
<td>R2 (Antiserum Reagent)</td>
<td>50 μL</td>
</tr>
<tr>
<td>37 °C, 300 seconds</td>
<td></td>
</tr>
</tbody>
</table>

Measure 2 Point End at 570 nm main, 800 nm sub

**CALCULATIONS**

IgE levels are determined by the analyzer using the prepared calibration curve.

**LIMITATIONS OF PROCEDURE**

Performance of this assay has only been evaluated on adult specimens. Since a reference range is only available for adult specimens, this assay should only be used for adults. The reference range was calculated using Japanese adults.

If the IgE value of a sample is greater than highest IgE value of a sample (contains 0.09% sodium azide and 1% BSA) and re-assay.
PERFORMANCE

Specificity
When a sample with a known value is assayed, the result is within ±10% of the assigned value.

Precision
The following results were obtained on a Hitachi 917 analyzer with pooled human serum:

<table>
<thead>
<tr>
<th>Sample</th>
<th>I</th>
<th>II</th>
<th>III</th>
<th>IV</th>
<th>V</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>10</td>
<td>10</td>
<td>10</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Mean (IU/mL)</td>
<td>105.3</td>
<td>174.1</td>
<td>350.5</td>
<td>1,117.8</td>
<td>1,908.6</td>
</tr>
<tr>
<td>Std. Dev.</td>
<td>1.06</td>
<td>2.85</td>
<td>7.68</td>
<td>13.26</td>
<td>30.25</td>
</tr>
<tr>
<td>C.V. %</td>
<td>1.01</td>
<td>1.63</td>
<td>2.2</td>
<td>1.2</td>
<td>1.6</td>
</tr>
</tbody>
</table>

Precision Assay: Within Run

<table>
<thead>
<tr>
<th>Sample</th>
<th>I</th>
<th>II</th>
<th>III</th>
<th>IV</th>
<th>V</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>10</td>
<td>10</td>
<td>10</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Mean (IU/mL)</td>
<td>105.4</td>
<td>177.6</td>
<td>663.7</td>
<td>2,147.5</td>
<td>3,304.7</td>
</tr>
<tr>
<td>Std. Dev.</td>
<td>2.72</td>
<td>3.24</td>
<td>11.22</td>
<td>33.56</td>
<td>16.67</td>
</tr>
<tr>
<td>C.V. %</td>
<td>2.58</td>
<td>1.82</td>
<td>1.69</td>
<td>1.56</td>
<td>0.50</td>
</tr>
</tbody>
</table>

Accuracy / Correlation

A comparison of the K-ASSAY Total IgE reagent and the Company X's Total IgE reagent was performed with the following results:

\[ y = 0.9851x + 10.618 \]
\[ r = 0.9928 \]
\[ n = 80 \]
\[ x = \text{Company X's Total IgE} \]
\[ y = \text{K-ASSAY Total IgE} \]

Assay Range

10 - 2,000 IU/mL (or value of highest calibrator)

Lower Limit of Detection

The lower limit of detection is 10 IU/mL.

MATRX COMPARISON

A comparison of serum vs. plasma was performed with the following results:

\[ y = 1.2072x + 10.297 \]
\[ r = 0.9989 \]
\[ n = 80 \]
\[ x = \text{Plasma IgE values (IU/mL)} \]
\[ y = \text{Serum IgE values (IU/mL)} \]

INTERFEERENCE

<table>
<thead>
<tr>
<th>Interferent</th>
<th>Interference up to</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bilirubin F</td>
<td>18.5 mg/dL</td>
</tr>
<tr>
<td>Bilirubin C</td>
<td>21.6 mg/dL</td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>467 mg/dL</td>
</tr>
<tr>
<td>RF</td>
<td>500 IU/mL</td>
</tr>
<tr>
<td>Sodium Citrate</td>
<td>15 mg/mL</td>
</tr>
<tr>
<td>Sodium Heparin</td>
<td>150 U/mL</td>
</tr>
<tr>
<td>EDTA-2Na</td>
<td>1.5 mg/mL</td>
</tr>
<tr>
<td>Chyle (Formazine Turb.)</td>
<td>No interference up to 2,120</td>
</tr>
</tbody>
</table>

EXPECTED VALUE

It is recommended that each laboratory establish its own expected range to reflect its patient population.

In our laboratory, the expected value of IgE in adults is less than 178 IU/mL for 413 normal plasma samples. The top 149 of the 413 samples were excluded due to the statistical prevalence of allergies in the normal population. The reference range cited in the Laboratory Test Handbook for U.S. populations is <300 IU/mL.

REFERENCES


LABELING SYMBOLS

- LOT: Lot Number
- REAG: Reagent
- EXP: Expiration or “Use By” Date
- CAT: Catalog Number
- XV: For In Vitro Diagnostics Use
- T: Temperature Limitation, Store between 2 and 8 degrees C
- H: Potential Human Biohazard
- M: Manufacturer
- P: Consult Package Insert for Instructions for Use
- EU REP: Authorized Representative in the European Community