**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 2 x 20 mL
- Tris hydrochloride buffer (100 mM)
- R2: Latex Suspension 1 x 6.6 mL

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 < 0.1% w/v 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 bottles 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 bottles have been opened, store tightly capped at 2-8°C, 37 °C, 300 seconds

**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 M29-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 BIOMEDICAL 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
- Reagent 2 (R-2) Latex Suspension 1 x 6.6 mL

**Materials Required But Not Supplied**

KAMIYA BIOMEDICAL COMPANY

Materials Required But Not Supplied

Calibrators:
- Cat. No. KAI-092

**ASSAY CODE (2 POINT) : (27) - (50)**

**SAMPLE VOLUME (8) ( ) (NO)**

**R-1 VOLUME (300) ( ) (NO)**

**R-2 VOLUME (50) ( ) (NO)**

**WAVELENGTH (800) (570)**

**CALIB. METHOD (NONLINEAR) (4) (5)**

**STD.(1) Conc.-POS. ( ) - (1)**

**STD.(2) Conc.-POS. ( ) - (2)**

**STD.(3) Conc.-POS. ( ) - (3)**

**STD.(4) Conc.-POS. ( ) - (4)**

**STD.(5) Conc.-POS. ( ) - (5)**

**STD.(6) Conc.-POS. ( ) - ( )**

**SD LIMIT (999)**

**DUPLICATE LIMIT (10000)**

**SENSITIVITY LIMIT (0)**

**ABS. LIMIT (SLOPE) (32000) (INCREASE)**

**PROZONE LIMIT (-320000) (LOWER)**

**EXPECTED VALUE (-999999) (999999)**

**PANIC VALUE (-999999) (999999)**

**INSTRUMENT FACTOR (1.00)**

*1-5: Input concentration of calibrators.

Parameters for other automated analyzers are available.

**CALIBRATION**

A multi-point calibration curve should be made using the K-ASSAY® Total IgE Calibrator. It is recommended that the user determine calibration curve frequency as this depends on the instrument and type/number of other assays being performed. Initially, calibration should be performed each day.

**QUALITY CONTROL**

It is recommended that at least two levels of control (with known concentrations of IgE) be included in all assay runs.

**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 calibrator value, dilute with saline (containing 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>30.25</td>
<td></td>
</tr>
</tbody>
</table>

Precision Assay: Between Runs

<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:

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

Interference

<table>
<thead>
<tr>
<th>Substance</th>
<th>Interference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bilirubin F</td>
<td>No interference up to 18.5 mg/dL</td>
</tr>
<tr>
<td>Bilirubin C</td>
<td>No interference up to 21.6 mg/dL</td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>No interference up to 467 mg/dL</td>
</tr>
<tr>
<td>RF</td>
<td>No interference up to 500 IU/mL</td>
</tr>
<tr>
<td>Sodium Citrate</td>
<td>No interference up to 15 mg/mL</td>
</tr>
<tr>
<td>Sodium Heparin</td>
<td>No interference up to 150 U/mL</td>
</tr>
<tr>
<td>EDTA-2Na</td>
<td>No interference up to 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

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOT</td>
<td>Lot Number</td>
</tr>
<tr>
<td>GT</td>
<td>Reagent</td>
</tr>
<tr>
<td>EX</td>
<td>Expiration or “Use By” Date</td>
</tr>
<tr>
<td>REF</td>
<td>Catalog Number</td>
</tr>
<tr>
<td>IVD</td>
<td>For In Vitro Diagnostics Use</td>
</tr>
<tr>
<td>2-8°C</td>
<td>Temperature Limitation. Store between 2 and 8 degrees C</td>
</tr>
<tr>
<td>M</td>
<td>Manufacturer</td>
</tr>
<tr>
<td>J</td>
<td>Consult Package Insert for Instructions for Use</td>
</tr>
<tr>
<td>EC</td>
<td>Authorized Representative in the European Community</td>
</tr>
</tbody>
</table>