Allergic reactions, which are becoming more widespread, are usually diagnosed on the basis of medical history and clinical symptoms. In vitro and in vivo testing, however, play a key role in confirming clinical suspicions and tailoring treatment. The measurement of immunoglobulin E (IgE) in serum is widely used in the diagnosis of allergic reactions and parasitic infections. Many allergies are caused by the immunoglobulins of subclass IgE acting as a means of predicting future atopic manifestations. Before making any therapeutic determination it is important, however, to know whether the allergic reaction is IgE mediated or non-IgE mediated. Measurement of total IgE in serum sample, along with the specific IgE diagnostic information, can help to make that determination. Measurement of total circulating IgE may also be of value in the early detection of allergy in infants and as a means of predicting future atopic manifestations. Before deciding on any therapy it is important to take into consideration whether the reaction is IgE or non-IgE mediated. Measurement of total IgE in serum sample, along with the specific IgE diagnostic information, can help to make that determination. Measurement of total circulating IgE may also be of value in the early detection of allergy in infants and as a means of predicting future atopic manifestations.
11.0 QC PARAMETERS

In order for the assay results to be considered valid the following criteria should be met:
1. The Dose Response Curve should be within established parameters.
2. Four out of six quality control pools should be within the established ranges.

12.0 RISK ANALYSIS

The MSDS and Risk Analysis Form for this product is available upon request from Monobind Inc.

12.1 Assay Performance
1. It is important that the time of reaction in each well is held constant to achieve reproducible results.
2. Pipetting of samples should not extend beyond ten (10) minutes to avoid assay drift.
3. Highly Ipecam, hemolyzed or grossly contaminated specimen(s) should not be used.
4. If more than one (1) plating is used, it is recommended to repeat the dose response curve.
5. The addition of signal reagent initiates a kinetic reaction, therefore the signal reagent(s) should be added in the same sequence to eliminate any time-deviation during reaction.
6. Failure to remove adhering solution adequately in the aspiration or decantation wash step(s) may result in poor replication and spurious results.
7. Use components from the same lot. No intermixing of reagents from different batches.
8. Accurate and precise pipetting, as well as following the exact time and temperature requirements prescribed are essential.
9. Any deviation from Monobind IFU may yield inaccurate results.
10. It is important to calibrate all the equipment e.g. Pipettes, Readers, Washers and/or the automated instruments used with this device, and to perform routine preventive maintenance.
11. Risk Analysis - as required by CE Mark IVD Directive 98/79/EC for this and other devices, made by Monobind, can be requested via email from Monobind@monobind.com.
12.2 Interpretation
1. Measurements and interpretation of results must be performed by a skilled individual or trained professional.
2. Laboratory results alone are only one aspect for determining patient care and should not be the sole basis for therapy.
3. The reagents for the test system have been formulated to be used in lieu of a dose response curve but in the same manner and context as a dose response curve.
4. For valid test results, adequate controls and other parameters must be within the listed ranges and assay requirements.
5. If test kits are altered, such as by mixing parts of different kits, which could produce false test results, or if results are incorrectly interpreted, Monobind shall have no liability.
6. If computer controlled data reduction is used to interpret the results of the test, it is imperative that the predicted values for the calibrators fall within 10% of the assigned concentrations.
7. Serum IgE concentration is dependent upon a multiplicity of factors: including if the patient is sensitized, how many times the patient has been exposed to a specific allergen etc. Total IgE concentration alone is not sufficient to assess the clinical status. All the clinical findings especially specific allergy testing should be taken into consideration while determining the clinical status of the patient.
8. Specificity
The interpretation of IgE results by Monobind is performed by the use of a specific allergen. Total IgE concentration alone is not sufficient to assess the clinical status. All the clinical findings especially specific allergy testing should be taken into consideration while determining the clinical status of the patient.
9. A study of population from different age groups was conducted to evaluate the Monobind IgE AccuLIT® CLIA Test System. The results are presented in Table 1.

13.0 EXPECTED RANGES OF VALUES

A study of population from different age groups was conducted to evaluate the Monobind IgE AccuLIT® CLIA Test System. The results are presented in Table 1.

Example 1

<table>
<thead>
<tr>
<th>Sample ID</th>
<th>Well</th>
<th>RLU</th>
<th>Mean RLU (B)</th>
<th>Conc (IU/ml)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A1</td>
<td></td>
<td>187</td>
<td>150</td>
<td>0</td>
</tr>
<tr>
<td>B1</td>
<td></td>
<td>111</td>
<td></td>
<td></td>
</tr>
<tr>
<td>C1</td>
<td></td>
<td>1914</td>
<td>1847</td>
<td>5</td>
</tr>
<tr>
<td>D1</td>
<td></td>
<td>1780</td>
<td>1817</td>
<td>25</td>
</tr>
<tr>
<td>E1</td>
<td></td>
<td>8019</td>
<td>1817</td>
<td>25</td>
</tr>
<tr>
<td>F1</td>
<td></td>
<td>8327</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note:

The data presented in Example 1 and Figure 1 is for illustration only and should not be used in lieu of a dose response curve prepared with each assay. In addition, the RLU’s of the calibrators have been normalized to 100,000 RLUs for the F calibrator (greatest light output). This conversion minimizes differences caused by efficiency of the various instruments that can be used to measure light output.

14.0 PERFORMANCE CHARACTERISTICS

14.1 Precision
The within and between assay precision of the IgE AccuLIT® CLIA Test System were determined by analyses on three different levels of control sera. The number, mean value, standard deviation (σ) and coefficient of variation for each of these control sera are presented in Table 2 and Table 3.

Table 2: Within Assay Precision (Values in IU/ml)

<table>
<thead>
<tr>
<th>Sample</th>
<th>N</th>
<th>X</th>
<th>σ</th>
<th>C.V.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1</td>
<td>20</td>
<td>76.3</td>
<td>6.4</td>
<td>8.4%</td>
</tr>
<tr>
<td>Level 2</td>
<td>20</td>
<td>172.2</td>
<td>7.1</td>
<td>4.1%</td>
</tr>
<tr>
<td>Level 3</td>
<td>20</td>
<td>389.5</td>
<td>8.6</td>
<td>2.2%</td>
</tr>
</tbody>
</table>

14.2 Sensitivity
The sensitivity (detection limit) was ascertained by determining the variability of the mIU/ml serum calibrator and using the 2σ (95% certainty) statistic to calculate the minimum dose. It was determined to be 0.023 IU/ml.

Table 3: Between Assay Precision (Values in IU/ml)

<table>
<thead>
<tr>
<th>Sample</th>
<th>N</th>
<th>X</th>
<th>σ</th>
<th>C.V.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1</td>
<td>20</td>
<td>78.0</td>
<td>7.0</td>
<td>9.5%</td>
</tr>
<tr>
<td>Level 2</td>
<td>20</td>
<td>185.1</td>
<td>6.6</td>
<td>3.5%</td>
</tr>
<tr>
<td>Level 3</td>
<td>20</td>
<td>394.2</td>
<td>11.6</td>
<td>2.9%</td>
</tr>
</tbody>
</table>

14.3 Accuracy
The Monobind IgE AccuLIT® CLIA Test System was compared with a reference method. Biological specimens with IgE levels in the low, medium and high ranges were used. The values ranged from 1 to 4500 IU/ml. The total number of such specimens was 166, each patient had no laboratory abnormality which could produce false test results, or if results are incorrectly interpreted. Monobind shall have no liability.

14.4 Specificity
The interpretation of IgE results by Monobind is performed by the use of a specific allergen. Total IgE concentration alone is not sufficient to assess the clinical status. All the clinical findings especially specific allergy testing should be taken into consideration while determining the clinical status of the patient.

14.5 High Dose Effect
Since the assay is sequential in design, high concentrations of IgE do not show the hook effect. Myeloma IgE patient samples with concentrations over 8 million IU/ml demonstrated extremely high levels of light intensity.

15.0 REFERENCES


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DCO: 1353 MP2575 Product Code: 2575-300

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