5.0 PREPARATION AND STABILITY OF REAGENTS

All reagents are ready to use. Latex must be mixed with very care, until the solution is homogenous. It is suggested to handle carefully it, avoiding contact with skin and swallow. Perform the test according to the general “Good Laboratory Practice” guidelines.

7.0 MATERIAL REQUIRED BUT NOT PROVIDED

Current laboratory instrumentation: Normal saline (0.9% NaCl), only for semiquantitative technique: automatic pipette, pipet, watch.

8.0 TEST PERFORMANCE

8.1 Interferences. No interferences are present with :
- Hemoglobin: ≤ 1000 mg/dl
- Bilirubin: ≤ 20 mg/dl
- Cholesterol: ≤ 1000 mg/dl

8.2 Sensibility. 180 IU/ml

8.3 Correlation. Evaluation performed on 118 samples, gave the following results with a equivalent method as reference:

<table>
<thead>
<tr>
<th>Dilution</th>
<th>MEDIA IVD sr/</th>
<th>TOC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>+</td>
<td>48</td>
<td>1</td>
</tr>
<tr>
<td>-</td>
<td>2</td>
<td>67</td>
</tr>
<tr>
<td>1+31</td>
<td>50</td>
<td>68</td>
</tr>
<tr>
<td>1+31</td>
<td>118</td>
<td></td>
</tr>
</tbody>
</table>

9.0 CALIBRATION AND CONTROLS

Controls, when provided with the kit, should always used to distinguish agglutination.

10.0 QUALITATIVE PROCEDURE

Allow the reagent and controls to reach room temperature (20 to 30°C). Gently shake the reagent vial to disperse and suspend the latex particles in the buffer solution. Vigorous shaking should be avoided.

1. Place 0.050 ml of the serum on one section of the disposable slide.
2. Place a drop of reagent next to the drop of serum.
3. Mix both drops with a stirrer covering the whole surface of the slide section.
4. Gently rotate the slide for 3 minutes manually or on a rotatory shaker (60-80 rpm).
5. Look for the presence or absence of agglutination after the aforementioned period of time.

11.0 SEMIQUANTITATIVE PROCEDURE

Preparation of the serum dilutions (see the following descriptive diagram for the technique):

<table>
<thead>
<tr>
<th>Dilution</th>
<th>ASO value (indiluted sample)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1+1</td>
<td>1</td>
</tr>
<tr>
<td>1+3</td>
<td>2</td>
</tr>
<tr>
<td>1+7</td>
<td>8</td>
</tr>
<tr>
<td>1+15</td>
<td>16</td>
</tr>
<tr>
<td>1+31</td>
<td>320</td>
</tr>
<tr>
<td>1+31</td>
<td>600</td>
</tr>
</tbody>
</table>

12.0 LIMITATIONS

Reading of the results should be done after 3 minutes from the beginning of the reaction. A reading obtained after this period of time may be incorrect. Existence of prozone at high titer levels is unknown.

13.0 EXPECTED VALUES

Although normal values can vary with age, season of the year and geographical area, the ‘upper limit of normal’ antistreptolysin-O titer for preschool children is less than 100 IU/ml and in school age children or young adults is usually between 168 and 250 IU/ml. In any case, the average can be established at less than 200 IU/ml. Because of this variation, titer above the upper limits may be indicative of streptococcal infection, but only a two dilution rise in titer between acute and convalescent stage specimens should be considered significant. Following acute streptococcal infection, the antistreptolysin-O titer will usually rise up to one week, increasing to a maximum level within 2 to 5 weeks and usually returning to the preinfection levels in approximately 6 to 12 months.

14.0 WASTE DISPOSAL

This product is made to be used in professional laboratories. Please consult local regulations for a correct waste disposal. Secure this material and its container at hazardous or special waste collection point. SS7 use appropriate container to avoid environmental contamination. SS8 avoid release in environment. Refer to special instructions/safety data sheet.

15.0 REFERENCES


16.0 SYMBOLS – DIRECTIVE CE 98/79

- Adenzima, consultare le istruzioni per l'uso
- Solo per uso diagnostico in vitro
- Ntitermazioni per kit
- Conservare a 2-8°C
- Usare entro
- Lotto
- Non ridistribuire
- Codice #
- Fabbricante
- MANUFACTURER

MeDia DiagnosticI
Forti - Italy
www.mediatrici.biz