For Research Use Only. Not for use in Diagnostic Procedures.

2014-07-07

### INTENDED USE

The Salmonella IgG ELISA Kit is intended for the detection of IgG antibody to Salmonella in human serum or plasma. For research use only, not for use in diagnostic procedures.

### SUMMARY AND EXPLANATION

*Salmonella typhi* is the causative agent of typhoid fever, a contagious infection of the intestines that affects the whole body. In developing countries, typhoid often occurs in epidemics. Most people in the United States get typhoid as a result of visiting another country where the food or water supply has been contaminated. Symptoms usually start 1 to 3 weeks after exposure to the bacteria. Symptoms include: high fever, headache, sore throat, vomiting, diarrhea, skin rash, and weakness. The symptoms may take 2 weeks or more to go away. Typhoid is spread when a person drinks or eats food and water contaminated by human waste (stool or urine) containing *Salmonella* bacteria. A person who no longer has symptoms may still transmit the bacteria as a carrier.

### PRINCIPLE OF THE TEST

Diluted serum is added to wells coated with purified antigen. IgG specific antibody, if present, binds to the antigen. All unbound materials are washed away and the enzyme conjugate is added to bind to the antibody-antigen complex, if present. Excess enzyme conjugate is washed off and substrate is added. The plate is incubated to allow the hydrolysis of the substrate by the enzyme. The intensity of the color generated is proportional to the amount of IgG specific antibody in the sample.

<table>
<thead>
<tr>
<th>MATERIALS PROVIDED</th>
<th>96 Tests</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Microwells coated with <em>Salmonella typhi</em> antigen</td>
<td>128x8x1</td>
</tr>
<tr>
<td>2. Sample Diluent: 2 bottle (ready to use)</td>
<td>25 ml</td>
</tr>
<tr>
<td>3. Calibrator: 1 Vial (ready to use)</td>
<td>1 ml</td>
</tr>
<tr>
<td>4. Positive Control: 1 vial (ready to use)</td>
<td>1 ml</td>
</tr>
<tr>
<td>5. Negative Control: 1 vial (ready to use)</td>
<td>1 ml</td>
</tr>
<tr>
<td>6. Enzyme conjugate: 1 bottle (ready to use)</td>
<td>12 ml</td>
</tr>
<tr>
<td>7. TMB Substrate: 1 bottle (ready to use)</td>
<td>12 ml</td>
</tr>
<tr>
<td>8. Stop Solution: 1 bottle (ready to use)</td>
<td>12 ml</td>
</tr>
<tr>
<td>9. Wash concentrate 20X: 1 bottle</td>
<td>25 ml</td>
</tr>
</tbody>
</table>

### MATERIALS NOT PROVIDED

1. Distilled or deionized water
2. Precision pipettes
3. Disposable pipette tips
4. ELISA reader capable of reading absorbance at 450nm
5. Absorbance paper or paper towel
6. Graph paper
ASSAY PROCEDURE
Bring all specimens and kit reagents to room temperature (18-26 °C) and gently mix.
1. Place the desired number of coated strips into the holder.
2. Negative control, positive control, and calibrator are ready to use. Prepare 1:101 dilution of test samples, by adding 5 µl of the sample to 0.5 mL of sample diluent. Mix well.
3. Dispense 100 µl of diluted sera, calibrator and controls into the appropriate wells. For the reagent blank, dispense 100µl sample diluent in 1A well position. Tap the holder to remove air bubbles from the liquid and mix well. Incubate for 20 minutes at room temperature.
4. Remove liquid from all wells. Wash wells three times with 300 µl of 1X wash buffer. Blot on absorbance paper or paper towel.
5. Dispense 100 µl of enzyme conjugate to each well and incubate for 20 minutes at room temperature.
6. Remove enzyme conjugate from all wells. Wash wells three times with 300 µl of 1X wash buffer. Blot on absorbance paper or paper towel.
7. Dispense 100 µl of TMB substrate and incubate for 10 minutes at room temperature.
8. Add 100 µl of stop solution.
9. Read O.D. at 450 nm using ELISA reader within 15 min. A dual wavelength is recommended with reference filter of 600-650 nm.

INTERPRETATION
The following is intended as a guide to interpretation of S. typhi IgG test results; each laboratory is encouraged to establish its own criteria for test interpretation based on sample populations encountered.

Antibody Index Interpretation
<0.9 No detectable antibody to S. typhi IgG by ELISA.
0.9-1.1 Borderline positive. Follow-up testing is recommended if clinically indicated.
>1.1 Detectable antibody to S. typhi by ELISA

LIMITATIONS OF THE TEST
1. Lipemic or hemolyzed samples may cause erroneous results.