**INTENDED USE**

The Spectrum Toxo IgG/IgM Rapid Test is a lateral flow chromatographic immunoassay for the simultaneous detection and differentiation of IgG and IgM anti-Toxoplasma gondii (T. gondii) in human serum or plasma. This kit is intended to be used as a screening test and as an aid in the diagnosis of infection with T. gondii. Any reactive specimen with the Spectrum Toxo IgG/IgM Rapid Test must be confirmed with alternative testing method(s) and clinical findings.

**SUMMARY AND EXPLANATION OF THE TEST**

T. gondii is an obligate intracellular protozoan parasite with a worldwide distribution. Serological data indicates that approximately 30% of the population of most industrialized nations is chronically infected with the organism.

A variety of serological tests for antibodies to T. gondii have been used as an aid in diagnosis of acute infection and to assess previous exposure to the organism. These tests are: the Sabin-Feldman dye test, direct agglutination, indirect hemagglutination, latex agglutination, indirect immunofluorescence and ELISA. Recently, a lateral flow immunochromatographic immunoassay such as the Spectrum Toxo IgG/IgM Rapid Test has been introduced to the clinic for the instant detection of T. gondii infection.

**TEST PRINCIPLE**

The Spectrum Toxo IgG/IgM Rapid Test is a lateral flow chromatographic immunoassay. The test cassette consists of: 1) a burgundy colored conjugate pad containing recombinant T. gondii antigens conjugated with colloidal gold (T. gondii conjugates) and rabbit IgG-conjugates, 2) a nitrocellulose membrane strip containing two test bands (M and G bands) and a control band (C band). The M band is pre-coated with monoclonal anti-human IgM for detection of IgM anti-T. gondii antibody. The G band is pre-coated with reagents for detection of IgG anti-T. gondii antibody, and the C band is pre-coated with goat anti-rabbit IgG.

**SPECIMEN COLLECTION AND HANDLING**

For in-Vitro diagnostic use

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1. Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer® by venipuncture).
2. Separate the plasma by centrifugation.
3. Carefully withdraw the plasma into a new pre-labeled tube.

**REAGENT PREPARATION AND STORAGE INSTRUCTIONS**

All reagents are ready to use as supplied. Store unused test devices unopened at 2°C-30°C. Do not freeze the kit. Do not expose the kit over 30°C. The positive and negative controls should be kept at 2°C-8°C or the temperature indicated. If stored at 2°C-8°C, ensure that the test device is brought to 15°C-30°C before opening. The test device is stable through the expiration date printed on the sealed pouch.

**ASSAY PROCEDURE**

1. Bring the specimen and test components to room temperature if refrigerated or frozen. Mix the specimen well, prior to assay, once thawed.
2. When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.
3. Be sure to label the device with the specimen’s ID number.
4. Fill the plastic dropper with the specimen. Holding the dropper vertically, dispense 1 drop (about 30-45 µL) of specimen into the sample well. Then add 1 drop (about 30-45 µL) of Sample Diluent immediately.
1. **Clinical Performance For IgG Test**
   A total of 302 samples from susceptible subjects were tested by the Spectrum Toxo IgG/IgM Rapid Test and by a commercial IgG EIA kit. Comparison of the results for all subjects is shown in the following table:

<table>
<thead>
<tr>
<th>Spectrum Toxo IgG/IgM Rapid Test</th>
<th>IgG EIA</th>
<th>Positive</th>
<th>Negative</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>2</td>
<td>0</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Negative</td>
<td>2</td>
<td>298</td>
<td>300</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>2</td>
<td>298</td>
<td>302</td>
<td></td>
</tr>
</tbody>
</table>

   Relative Sensitivity: 100%, Relative Specificity: 99.3%, Overall Agreement: 99.3%

2. **Clinical Performance For IgM Test**
   A total of 324 samples from susceptible subjects were tested by the Spectrum Toxo IgG/IgM Rapid Test and by a commercial IgM EIA kit. Comparison of the results for all subjects is shown in the following table:

<table>
<thead>
<tr>
<th>Spectrum Toxo IgG/IgM Rapid Test</th>
<th>IgM EIA</th>
<th>Positive</th>
<th>Negative</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>22</td>
<td>2</td>
<td>24</td>
<td></td>
</tr>
<tr>
<td>Negative</td>
<td>3</td>
<td>297</td>
<td>300</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>25</td>
<td>299</td>
<td>324</td>
<td></td>
</tr>
</tbody>
</table>

   Relative Sensitivity: 91.6%, Relative Specificity: 99.0%, Overall Agreement: 98.5%

**Limitations of Test**

1. The Assay Procedure and the Interpretation of Assay Result sections must be followed closely when testing for the presence of antibodies to T. gondii in serum or plasma from individual subjects. Failure to follow the procedure may give inaccurate results.
2. The Spectrum Toxo IgG/IgM Rapid Test is limited to the qualitative detection of antibodies to T. gondii in human serum or plasma. The intensity of the test line does not have a linear correlation with the antibody titer in the specimen.
3. A negative result for an individual subject indicates absence of detectable anti-T. gondii antibodies. However, a negative test result does not preclude the possibility of exposure to or infection with T. gondii.
4. A negative result can occur if the quantity of the anti-T. gondii antibodies present in the specimen is below the detection limits of the assay or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
5. Some specimens containing unusually high titers of heterophile antibodies or rheumatoid factor may affect expected results.
6. If the symptoms persist when the result from Spectrum Toxo IgG/IgM Rapid Test is negative or non-reactive, it is recommended to re-sample the patient a few days later or test with an alternative test device.
7. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

**References**