OnSite™ Rubella IgG/IgM Rapid Test

OnSite Rubella IgG/IgM Rapid Test

REF: R0243C

INTENDED USE

The OnSite Rubella IgG/IgM Rapid Test is a lateral flow immunochromatographic immunoassay. The test cassette consists of: 1) a burgundy colored conjugate pad containing rubella virus antigens conjugated with colloidal gold (rubella conjugates) and a control antibody conjugated with colloidal gold. 2) A nitrocellulose membrane strip containing three test lines (M, G1, G2 lines) and a control line (C line). The M line is pre-coated with mouse anti-human IgM for detection of IgM anti-rubella virus. The G1 and G2 lines are pre-coated with mouse anti-human IgG for detection of different IgG anti-rubella virus. The C line is pre-coated with a control line antibody.

When an adequate volume of test specimen and sample diluent are dispensed into the sample wells, the specimen migrates by capillary action across the cassette. IgM anti-rubella virus, if present in the specimen, will bind to the rubella conjugates. The immunocomplex is then captured on the membrane by the pre-coated mouse anti-human IgM forming a burgundy colored line, indicating an IgM anti-rubella virus positive test result. IgG anti-rubella virus, if present in the specimen, will bind to the rubella conjugates. The immunocomplex is then captured on the membrane by the pre-coated mouse anti-human IgG forming a burgundy colored line and/or G2 test lines, indicating an IgG anti-rubella virus positive test result. An IgG anti-rubella virus titer <250 IU/mL produces a burgundy colored G1 test line. An IgG anti-rubella virus titer <250 IU/mL produces burgundy colored G1 and/or G2 test line. Absence of any test lines (M, G1 or G2) suggests a negative result. The test contains an internal control (C line) which should exhibit a burgundy colored line of the immunocomplex of the control antibodies, regardless of color development on the test lines (G1, G2 and M). If the C line does not develop, the test results invalid, and the specimen must be retested with another device.

TEST PRINCIPLE

The OnSite Rubella IgG/IgM Rapid Test is a lateral flow chromatographic immunnoassay. The test cassette consists of: 1) a burgundy colored conjugate pad containing rubella virus antigens conjugated with colloidal gold (rubella conjugates) and a control antibody conjugated with colloidal gold. 2) A nitrocellulose membrane strip containing three test lines (M, G1, G2 lines) and a control line (C line). The M line is pre-coated with mouse anti-human IgM for detection of IgM anti-rubella virus. The G1 and G2 lines are pre-coated with mouse anti-human IgG for detection of different IgG anti-rubella virus. The C line is pre-coated with a control line antibody.

When an adequate volume of test specimen and sample diluent are dispensed into the sample wells, the specimen migrates by capillary action across the cassette. IgM anti-rubella virus, if present in the specimen, will bind to the rubella conjugates. The immunocomplex is then captured on the membrane by the pre-coated mouse anti-human IgM forming a burgundy colored line, indicating an IgM anti-rubella virus positive test result. IgG anti-rubella virus, if present in the specimen, will bind to the rubella conjugates. The immunocomplex is then captured on the membrane by the pre-coated mouse anti-human IgG forming a burgundy colored line and/or G2 test lines, indicating an IgG anti-rubella virus positive test result. An IgG anti-rubella virus titer <250 IU/mL produces a burgundy colored G1 test line. The G1 and G2 lines are pre-coated with mouse anti-human IgG for detection of different IgG anti-rubella virus. The C line is pre-coated with a control line antibody.

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OnSite Rubella IgG/IgM Rapid Test - Cassette (Serum / Plasma / Whole Blood)

**INTERPRETATION OF ASSAY RESULT**

1. **NEGATIVE RESULT:**
   - If only the C line develops, the test indicates that the levels of IgM and IgG anti-rubella virus in the specimen are below the detection limits of the assay. The result is negative or non-reactive.

2. **INVALID:**
   - If no C line is developed, the test is invalid regardless of color development on any of the test lines (M, G1, G2). Repeat the assay with a new device.

3. **POSITIVE RESULT:**
   - IgM Negative
   - IgG 15-250 IU/mL
   - IgM Positive
   - IgG 15-250 IU/mL
   - IgM Positive, IgG ≥ 250 IU/mL
   - IgM Positive, IgG ≥ 250 IU/mL

Specimens with positive results should be confirmed with alternative testing methods and clinical findings before a diagnosis is made.

**PERFORMANCE CHARACTERISTICS**

1. **Analytic Sensitivity of IgG Detection**
   - Twelve groups of matrix spiked with IgG anti-rubella virus to the WHO 1st International Standard (RUBI-1-94) concentrations of 0, 5, 10, 15, 30, 60, 100, 160, 200, 250, and 300 IU/mL. The specimens were run on the OnSite Rubella IgG/IgM Rapid Test. Defined as the 95% detection level, the limit of detection or sensitivity for the OnSite Rubella IgG/IgM Rapid Test G1 and G2 test lines is 15 IU/mL and 250 IU/mL, respectively.
   - LOD for G1 test line
   - LOD for G2 test line

2. **Accuracy of IgG Detection**
   - A total of 214 specimens were collected and tested with the OnSite Rubella IgG/IgM Rapid Test and by a commercial IgG anti-rubella virus ELISA with positive cut off level at 10 IU/mL. Comparison for all subjects is shown in the following table:

<table>
<thead>
<tr>
<th>Reference</th>
<th>Positive</th>
<th>Negative</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reference</td>
<td>173</td>
<td>174</td>
<td>347</td>
</tr>
<tr>
<td>Positive</td>
<td>174</td>
<td>0</td>
<td>174</td>
</tr>
<tr>
<td>Negative</td>
<td>0</td>
<td>173</td>
<td>173</td>
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</tbody>
</table>

Relative Sensitivity: 98.3%, Relative Specificity: 95.0%, Overall Agreement: 97.7%

Among the 214 specimens, 3 specimens were detected to have IgG levels higher than 250 IU/mL. These specimens were all detected as positive on the OnSite Rubella IgG/IgM Rapid Test G1 and G2 test line.

3. **Positive Rate on the Random Clinical Specimens**
   - The positive rate of the OnSite Rubella IgG/IgM Rapid Test was evaluated with 10,000 clinical specimens. M, G1 and G2 positive rates were 0.3%, 87% and 7%, respectively.

4. **Boston Biomedia Inc (BBI) Mixed Titer Performance Panel**
   - The performance of the OnSite Rubella IgG/IgM Rapid Test and a commercially available IgM anti-rubella virus Rapid Test were evaluated using BBI Mixed Titer Performance Panel PTR-201. The results are shown in the following table:

<table>
<thead>
<tr>
<th>BBI Reference Panel: Abbott EIA-Rubella</th>
<th>Number</th>
<th>OnSite Rubella IgG/IgM Rapid Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>IgM Positive</td>
<td>5</td>
<td>M Positive, G1 Positive, G2 Positive</td>
</tr>
<tr>
<td>IgG ≥ 15 IU/mL</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>15 IU/mL ≥ IgG ≥ 250 IU/mL</td>
<td>14</td>
<td>0</td>
</tr>
<tr>
<td>IgG ≥ 250 IU/mL</td>
<td>6</td>
<td>0</td>
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</table>

5. **Cross-Reactivity**
   - The reported IgM anti-rubella virus positive rate is 0.3-1.7%.

6. **EXPECTED VALUES**
   - IgM and IgG anti-rubella virus positive rates vary depending on the age of the population studied, the local vaccination programs. The reported IgG anti-rubella positive rates at ≥10-15 IU/mL and >200 IU/mL are 89-94% and 3.4%, respectively.
   - The reported IgM anti-rubella virus positive rate is 0.3-1.7%.

7. **STANDARDIZATION**
   - The OnSite Rubella IgG/IgM Rapid Test has been calibrated against the World Health Organization 1st International Standard, anti-rubella immunoglobulin (RUBI-1-94).

8. **LIMITATIONS OF TEST**
   - The test procedure and the interpretation of assay result sections must be followed closely when testing for the presence of antibodies to rubella virus in serum, plasma or whole blood in various subjects. Failure to follow the procedure may lead to inaccurate results.
   - The OnSite Rubella IgG/IgM Rapid Test is limited to the qualitative detection of antibodies to rubella virus in human serum, plasma or whole blood. The intensity of the test line does not reflect correlation with the titer of rubella antibody in the specimen.
   - A negative or non-reactive test result does not preclude the possibility of exposure to or infection with rubella virus. A negative or non-reactive result can occur if the titer of rubella virus antibody present in the specimen is below the level detectable by the assay or if rubella virus antibody was not present during the stage of disease in which the sample was collected.

9. **REFERENCES**

**TABLES**

<table>
<thead>
<tr>
<th>Conditions</th>
<th>Test Positive</th>
<th>Test Negative</th>
<th>Overall Agreement</th>
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<tbody>
<tr>
<td>HAV</td>
<td>2</td>
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<td>100%</td>
</tr>
<tr>
<td>HBV</td>
<td>0</td>
<td>18</td>
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<tr>
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<td>97.7%</td>
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</table>

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