Overview

Useful For
Determination of immune status to the rubella virus

Method Name
Multiplex Flow Immunoassay (MFI)

NY State Available
Yes

Specimen

Specimen Type
Serum

Specimen Required

Container/Tube:

Preferred: Serum gel
Acceptable: Red top

Specimen Volume: 0.5 mL

Forms
If not ordering electronically, complete, print, and send a Microbiology Test Request (T244) with the specimen.

Specimen Minimum Volume
0.4 mL

Reject Due To

<table>
<thead>
<tr>
<th>Condition</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gross hemolysis</td>
<td>Reject</td>
</tr>
<tr>
<td>Gross lipemia</td>
<td>Reject</td>
</tr>
<tr>
<td>Gross icterus</td>
<td>Reject</td>
</tr>
<tr>
<td>Heat-inactivated specimen</td>
<td>Reject</td>
</tr>
</tbody>
</table>

Specimen Stability Information

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum</td>
<td>Refrigerated (preferred)</td>
<td>14 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Frozen</td>
<td>14 days</td>
<td></td>
</tr>
</tbody>
</table>

Clinical and Interpretive
Clinical Information
Rubella (German or 3-day measles) is a member of the Togavirus family and humans remain the only natural host for this virus. Transmission is typically through inhalation of infectious aerosolized respiratory droplets and the incubation period following exposure can range from 12 to 23 days.(1) Infection is generally mild, self-limited, and characterized by a maculopapular rash beginning on the face and spreading to the trunk and extremities, fever, malaise, and lymphadenopathy.(2)

Primary in utero rubella infections can lead to severe sequelae for the fetus, particularly if infection occurs within the first 4 months of gestation. Congenital rubella syndrome is often associated with hearing loss and cardiovascular and ocular defects.(3)

The United States 2-dose measles, mumps, rubella (MMR) vaccination program, which calls for vaccination of all children, leads to seroconversion in 95% of children following the first dose.(1) A total of 4 cases of rubella were reported to the Centers for Disease Control and Prevention in 2011 without any cases of congenital rubella syndrome.(4) Due to the success of the national vaccination program, rubella is no longer considered endemic in the United States (www.cdc.gov/rubella). However, immunity may wane with age as approximately 80% to 90% of adults will show serologic evidence of immunity to rubella.

Reference Values
Vaccinated: positive (> or =1.0 AI)
Unvaccinated: negative (< or =0.7 AI)
Reference values apply to all ages.

Interpretation
Positive: Antibody index (AI) value of 1.0 or higher

- The reported AI value is for reference only. This is a qualitative test and the numeric value of the AI is not indicative of the amount of antibody present. AI values above the manufacturer recommended cutoff for this assay indicate that specific antibodies were detected, suggesting prior exposure or vaccination.

- The presence of detectable IgG-class antibodies indicates immunity to the rubella virus through prior immunization or exposure. Individuals testing positive are considered immune to rubella infection.

Equivocal: AI value 0.8-0.9
Submit an additional sample for testing in 10 to 14 days to demonstrate IgG seroconversion if recently vaccinated or if otherwise clinically indicated.

Negative: AI value of 0.7 or lower
The absence of detectable IgG-class antibodies suggests the lack of a specific immune response to immunization or no prior exposure to the rubella virus.

Cautions
IgG-class antibodies to rubella virus may be present in serum specimens from individuals who have received blood products within the past several months, but who have not been immunized or experienced past infection with this virus.

Serum samples drawn early during acute phase of infection may be negative for IgG-class antibodies to this virus.
The presence of anti-rubella-IgG antibodies does not exclude the possibility of a recent or ongoing infection. Testing for IgM-class antibodies to rubella should be performed at a state health laboratory or at the Centers for Disease Control and Prevention (CDC) if the clinical presentation is suggestive of acute rubella infection.

Supportive Data

To evaluate the accuracy of the BioPlex Rubella IgG multiplex flow immunoassay (MFI), 500 prospective serum samples were analyzed in a blinded fashion by the SeraQuest Rubella IgG EIA (Quest International and the BioPlex Rubella IgG assay. Samples with discordant results after initial testing were repeated by both assays during the same freeze/thaw cycle. Further discrepancies were evaluated by the Rubella IgG VIDAS enzyme-linked fluorescent immunoassay (ELFA; bioMerieux, Inc.). The results are summarized below:

<table>
<thead>
<tr>
<th>BioPlex Rubella IgG</th>
<th>SeraQuest Rubella IgG EIA</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Positive</td>
<td>Negative</td>
</tr>
<tr>
<td>Positive</td>
<td>446</td>
<td>0</td>
</tr>
<tr>
<td>Negative</td>
<td>7</td>
<td>23</td>
</tr>
<tr>
<td>Equivocal</td>
<td>17</td>
<td>0</td>
</tr>
</tbody>
</table>

6/7 samples tested as equivocal by the VIDAS Rubella IgG ELFA.

Sensitivity: 94% (446/470); 95% CI: 92.5% to 96.6%

Specificity: 100% (23/23); 95% CI: 83.1% to 100%

Overall Percent Agreement: 94.4% (472/500); 95% CI: 92.0% to 96.1%

Clinical Reference


Performance

Method Description

The BioPlex 2200 Rubella IgG assay uses multiplex flow immunoassay technology. Briefly, serum samples are mixed and incubated at 37 degrees C with sample diluent and dyed beads coated with rubella antigen. After a wash cycle, anti-human IgG antibody conjugated to phycoerythrin (PE) is added to the mixture and incubated at 37 degrees C. Excess conjugate is removed in another wash cycle and the beads are resuspended in wash buffer. The bead mixture then passes through a detector which identifies the bead based on dye fluorescence and determines the amount of antibody captured by the antigen based on the fluorescence of the attached PE. Raw data is calculated in relative fluorescence intensity.
Test Definition: RBPG
Rubella Ab, IgG, S

Three additional dyed beads, an internal standard bead, a serum verification bead, and a reagent blank bead are present in each reaction mixture to verify detector response, the addition of serum to the reaction vessel and the absence of significant nonspecific binding in serum. (Package insert: BioPlex 2200 System MMRV IgG. Bio-Rad Laboratories; 11/30/2018)

PDF Report
No

Day(s) and Time(s) Test Performed
Monday through Saturday, 9 a.m.

Analytic Time
Same day/1 day

Maximum Laboratory Time
3 days

Specimen Retention Time
14 days

Performing Laboratory Location
Rochester

Fees and Codes

Fees
- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their Regional Manager. For assistance, contact Customer Service.

Test Classification
This test has been cleared, approved or is exempt by the U.S. Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

CPT Code Information
86762

LOINC® Information

<table>
<thead>
<tr>
<th>Test ID</th>
<th>Test Order Name</th>
<th>Order LOINC Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>RBPG</td>
<td>Rubella Ab, IgG, S</td>
<td>5334-8</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Result ID</th>
<th>Test Result Name</th>
<th>Result LOINC Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>RBG</td>
<td>Rubella Ab, IgG, S</td>
<td>40667-8</td>
</tr>
<tr>
<td>DEXG2</td>
<td>Rubella IgG Antibody Index</td>
<td>52986-7</td>
</tr>
</tbody>
</table>