Overview

Useful For
Evaluating patients with suspected brucellosis

Method Name
Agglutination

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
0.25 mL

Reject Due To

<table>
<thead>
<tr>
<th>Gross hemolysis</th>
<th>Reject</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gross lipemia</td>
<td>Reject</td>
</tr>
<tr>
<td>Gross icterus</td>
<td>OK</td>
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</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>
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</table>

Clinical and Interpretive
Clinical Information

*Brucella* species are facultative intracellular, gram-negative staining bacilli capable of producing the disease "brucellosis" in humans. Human disease likely is acquired by contact with animals infected with the organism (*Brucella abortus*, *Brucella suis*, *Brucella melitensis*, and occasionally *Brucella canis*) either by direct contact or by ingestion of meat or milk. The signs and symptoms associated with brucellosis may include fever, night sweats, chills, weakness, malaise, headache, and anorexia. The physical examination may reveal lymphadenopathy and hepatosplenomegaly. A definitive diagnosis of brucellosis is made by recovering the organism from bone marrow, blood, fluid (including urine), or tissue specimens.

In cases of suspected brucellosis, serology may assist in the diagnosis and play a supplementary role to routine culture. Antibodies to *Brucella* species may not become detectable until 1 to 2 weeks following the onset of symptoms, so serum specimens drawn during acute disease may be negative by serology in patients with brucellosis. If serology is performed, the Centers for Disease Control and Prevention currently recommends that specimens testing positive or equivocal for IgG or IgM by a screening enzyme immunoassay (EIA) be confirmed by a *Brucella*-specific agglutination method.(1)

Reference Values

<1:80

Interpretation

The Centers for Disease Control and Prevention (CDC) recommends that specimens testing positive or equivocal for IgG or IgM by a screening enzyme immunoassay (EIA) be confirmed by a *Brucella*-specific agglutination method.(1)

Negative to a titer of 1:40 or higher can be seen in the normal, healthy population. A titer of 1:80 or greater is often considered clinically significant(2); however, a 4-fold or greater increase in titer between acute and convalescent phase sera is required to diagnose acute infection.

The CDC/Council of State and Territorial Epidemiologists case definition for human brucellosis states that the laboratory criteria for diagnosis includes 1) isolation of *Brucella* species from a clinical specimen, 2) four-fold or greater rise in *Brucella* agglutination titer between acute- and convalescent-phase serum specimens drawn more than 2 weeks apart and studied at the same laboratory, or 3) demonstration by immunofluorescence of *Brucella* species in a clinical specimen.

Positive results by a screening EIA that are not confirmed by *Brucella*-specific agglutination may represent false-positive screening results. If clinically indicated, a new specimen should be tested after 7 to 14 days.

Cautions

The tube agglutination assay was designed using antigen derived from *Brucella abortus*, and may not be positive in patients infected with other *Brucella* species (eg, *Brucella canis*).

Positive results by *Brucella* serology are not diagnostic of acute infection, as antibodies may persist for months to years following exposure. To diagnose acute infection, detection of *Brucella* species in culture is the recommended approach (see BRUCB / *Brucella* Culture, Blood).

*Brucella abortus* strain RB51 is used for vaccination of animals in the United States. There are currently no serologic tests to detect an antibody response to strain RB51 in humans. Per Centers for Disease Control and Prevention guidelines, routine clinical serology tests for *Brucella* do not detect an antibody response to strain RB51. Note that other strains besides RB51 may be used for vaccinating animals outside of the United States.(3)

Supportive Data

Prospective serum specimens (n=114) positive for IgG or IgM antibodies, or both, by a Food and Drug
Administration-approved screening enzyme immunoassay (EIA) (Euroimmun) were tested for Brucella antibodies using tube agglutination (TAT) reagents supplied by the National Veterinary Services (NVS) Laboratory. The results were compared to those obtained by an outside reference laboratory which uses reagents supplied by Remel. Overall percent agreement was 89.5% (102/114).

In addition to prospective sera, a panel of characterized serum specimens (n = 14) were tested. Overall agreement was 100% with the expected results.

Sera known to be positive for antibodies to Borrelia burgdorferi (n = 5), Chlamydia species (n = 1), Coxiella burnetti (n = 2), Rickettsia species (n = 1), or Epstein-Barr virus (n = 11) were tested by the Brucella Ames TAT and all 20 specimens were found to be negative (<1:80). In addition, a serum specimen containing rheumatoid factor (n = 1) was tested and found to be negative.

Clinical Reference

Performance

Method Description

PDF Report
No

Day(s) and Time(s) Test Performed
Monday, Wednesday; 10 a.m.

Analytic Time
2 days

Maximum Laboratory Time
7 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
86622

LOINC® Information

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<tr>
<th>Test ID</th>
<th>Test Order Name</th>
<th>Order LOINC Value</th>
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<tbody>
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<td>Brucella Ab, Agglutination, S</td>
<td>19053-8</td>
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<table>
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