Overview

Useful For
Evaluating patients with suspected brucellosis

Reflex Tests

<table>
<thead>
<tr>
<th>Test ID</th>
<th>Reporting Name</th>
<th>Available Separately</th>
<th>Always Performed</th>
</tr>
</thead>
<tbody>
<tr>
<td>BRUTA</td>
<td>Brucella Ab, Agglutination, S</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

Testing Algorithm
If *Brucella* antibody screen, IgG and IgM is positive or equivocal, then confirmation will be performed at an additional charge.

Method Name
Enzyme-Linked Immunosorbent Assay (ELISA)

NY State Available
Yes

Specimen

Specimen Type
Serum

Specimen Required

Container/Tube:

Preferred: Serum gel

Acceptable: Red top

Specimen Volume: 1.5 mL

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

Specimen Minimum Volume
1.1 mL

Reject Due To

<table>
<thead>
<tr>
<th>Condition</th>
<th>Acceptance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemolysis</td>
<td>Mild OK; Gross reject</td>
</tr>
<tr>
<td>Lipemia</td>
<td>Mild OK; Gross reject</td>
</tr>
<tr>
<td>Icterus</td>
<td>NA</td>
</tr>
</tbody>
</table>
Test Definition: BRUGM
Brucella Ab Screen, IgG and IgM, S

Specimen Stability Information

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

Clinical and Interpretive

Clinical Information

Worldwide, brucellosis remains a major disease in humans and domesticated animals. *Brucella* infects goats (*B. melitensis*), cattle (*B. abortus*), swine (*B. suis*), and dogs (*B. canis*). The disease has a limited geographic distribution. Few cases occur in the United States, with the bulk occurring in the Mediterranean region, Western Asia, and parts of Latin America and Africa.

Three species of *Brucella* commonly cause disease in humans: *B. melitensis*, *B. suis*, and *B. abortus*. The acute disease often presents with fever, chills, and malaise; the chronic form also causes abscesses in bone, brain, spleen, liver, and kidney.

Reference Values

IgG SCREEN

Negative (reported as positive, negative, or equivocal)

IgM SCREEN

Negative (reported as positive, negative, or equivocal)

Interpretation

In the acute stage of the disease there is an initial production of IgM antibodies, followed closely by production of IgG antibodies. IgG-class antibodies may decline after treatment; however, high levels of circulating IgG-class antibodies may be found without any active disease. Chronic brucellosis shows a predominance of IgG-class antibodies with little or no detectable IgM.

Rising levels of specific antibody in paired sera can be regarded as serological evidence of recent infection. The presence of specific IgM in a single specimen may also indicate a recent infection, although IgM-class antibodies may persist for months following acute disease.

The CDC recommends that specimens testing positive for IgG or IgM by enzyme-linked immunosorbent assay (ELISA) be confirmed by a *Brucella*-specific agglutination method.

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 obtained 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 ELISA 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.

If results of ELISA are negative and a recent infection is suspected, a new specimen should be tested after 7 to 14 days.

**Cautions**

This test utilizes antigen derived from *Brucella abortus* strain W99. However, significant cross-reactivity exists for other *Brucella* species and, therefore, the assays should not be used to differentiate infection at the species level.

*B canis*, a rare cause of brucellosis, may not be detected by this method.

Detection of specific IgM or IgG-class antibody to *B melitensis* and *B suis* by this method has not been determined.

Enzyme-linked immunosorbent assay (ELISA) tests are intended to be used as a screen only. Positive results should be followed up using an agglutination assay for confirmation. Results must be used in conjunction with symptoms, patient history, and other clinical findings.

*B 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 CDC 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**

According the manufacturer's package insert, 127 patient samples testing positive with the Rose-Bengal test were also examined with the Euroimmun anti-*Brucella abortus* enzyme-linked immunosorbent assay (ELISA), and 160 blood donors were tested. Data from these studies were as follows for anti-*B abortus*:

- IgG: sensitivity, 78.0%; specificity, 98.0%
- IgM: sensitivity, 56.0%; specificity, 98.0%

**Clinical Reference**

**Method Description**

Serum is tested using an enzyme-linked immunosorbent assay (ELISA) Test Kit containing microtiter strips with wells coated with *Brucella abortus* antigens (strain W99). In the first reaction step, diluted patient samples are incubated in the wells. Specific IgG or IgM antibodies, if present in the serum, will bind to the antigens. To detect the bound antibodies, a second incubation is carried out using an enzyme-labeled antihuman IgG or antihuman IgM (enzyme conjugate). After addition of the substrate, tetramethylbenzidine (TMB)/hydrogen peroxide and a sulphuric acid stop solution, the resulting color reaction is measured photometrically at a wavelength of 450nm. (Package insert: Anti-*Brucella abortus* ELISA Test Instruction, Euroimmun Medizinische Labordiagnostika, Lubeck, Germany 7/7/2011)

**PDF Report**

No

**Day(s) and Time(s) Test Performed**

Monday, Wednesday, Friday; 9 a.m.

**Analytic Time**

Same day/1 day/ Additional days for agglutination test result if reflex testing is required.

**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 or approved 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 x 2-*Brucella* antibody, IgG and IgM

86622-*Brucella* total antibody, agglutination (if appropriate)

**LOINC® Information**

<table>
<thead>
<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>BRUGM</td>
<td>Brucella Ab Screen, IgG and IgM, S</td>
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<td>23686</td>
<td>Brucella Ab Screen, IgM, S</td>
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<td>23687</td>
<td>Interpretation</td>
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