MAYO CLINIC LABORATORIES

Test Definition: BRUTA

Brucella Total Antibody Confirmation, Agglutination, Serum

Overview

Useful For
Evaluating patients with suspected brucellosis

Method Name
Agglutination

NY State Available
Yes

Specimen

Specimen Type
Serum

Specimen Required
Collection Container/Tube:
Preferred: Serum gel
Acceptable: Red top
Submission Container/Tube: Plastic vial
Specimen Volume: 0.5 mL
Collection Instructions: Centrifuge and aliquot serum into a plastic vial.

Forms
If not ordering electronically, complete, print, and send Infectious Disease Serology Test Request (T916) with the specimen.

Specimen Minimum Volume
0.25 mL

Reject Due To

Gross hemolysis	Reject
Gross lipemia	Reject
Gross icterus	OK

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Refrigerated (preferred)	14 days	
	Frozen	14 days	

Clinical & Interpretive

Clinical Information

Brucella species are facultative intracellular, gram-negative staining bacilli capable of producing the disease "brucellosis" in humans. Human disease is likely 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 collected 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 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 collected more than 2 weeks apart and studied at the same laboratory
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 (Euroimmun) were tested for *Brucella* antibodies using tube agglutination (TAT) reagents supplied by the National Veterinary Services Laboratory. The results were compared to those obtained by an outside reference laboratory that used 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

1. Centers for Disease Control and Prevention (CDC): Public health consequences of a false-positive laboratory test result for *Brucella*-Florida, Georgia, and Michigan, 2005. MMWR Morb Mortal Wkly Rep. 2008 Jun 6;57(22):603-605
2. Welch RJ, Litwin CM: A comparison of *Brucella* IgG and IgM ELISA assays with agglutination methodology. J Clin Lab Anal. 2010;24(3):160-162
3. Gunes H, Dogan M: False-positivity in diagnosis of brucellosis associated with Rev-1 vaccine. Libyan J Med. 2013:8:20417

Performance

Method Description

Serially diluted serum is added to an antigen prepared from *Brucella abortus* strain 1119-3. Agglutination or flocculation is assessed after incubation at 37 degrees C for 48 hours.(Package insert: Animal and Plant Health Inspection Service National Veterinary Services Laboratories, Kirsh D: US Dept of Health, Education, and Welfare; 1973; Cooke FJ, Slack

MPE: Gram-negative coccobacilli. In: Cohen J, Powderly WG, Opal SM, eds. Infectious Diseases. 4th ed. Elsevier; 2017:1611-1627)

PDF Report
No

Day(s) Performed
Monday, Wednesday

Report Available
2 to 7 days

Specimen Retention Time
14 days

Performing Laboratory Location
Rochester

Fees & 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 account representative. For assistance, contact Customer Service.

Test Classification
This test has been cleared, approved, or is exempt by the US 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

Test ID	Test Order Name	Order LOINC® Value
BRUTA	Brucella Ab, Agglutination, S	19053-8

Result ID	Test Result Name	Result LOINC® Value
8112	Brucella Ab, Agglutination, S	19053-8