Test Definition: BRCMG

Brucella Antibody Screen, IgM and IgG, ELISA, Serum

Overview

Useful For

Evaluating patients with suspected brucellosis

Profile Information

Test Id	Reporting Name	Available Separately	Always Performed
BRCM	Brucella Ab Screen, IgM ELISA, S	No	Yes
BRCG	Brucella Ab Screen, IgG ELISA, S	No	Yes
BRCI	Brucella Ab Screen Interpretation	No	Yes

Reflex Tests

Test Id	Reporting Name	Available Separately	Always Performed
BRUTA	Brucella Ab, Agglutination, S	Yes	No

Testing Algorithm

If the *Brucella* antibody screen, IgM or IgG, result is either positive or equivocal, then confirmation by *Brucella* total antibody agglutination testing will be performed at an additional charge.

Method Name

BRCM. BRCG: Enzyme-Linked Immunosorbent Assay (ELISA)
BRCI: Technical Interpretation

NY State Available

Yes

Specimen

Specimen Type

Serum

Necessary Information

If patient is suspected of having Brucellosis infection, call 1-800-533-1710 to notify Customer Service so appropriate

safety precautions can be taken to minimize exposure risks.

Specimen Required

Collection Container/Tube:
Preferred: Serum gel
Acceptable: Red top
Submission Container/Tube: Sterile vial
Specimen Volume: 1 mL
Collection Instructions: Centrifuge and aliquot serum into a sterile, plastic vial.

Forms

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

Specimen Minimum Volume

0.4 mL

Reject Due To

Gross hemolysis	Reject
Gross lipemia	Reject
Heat-inactivated specimen	Reject

Specimen Stability Information

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

Clinical & Interpretive

Clinical Information

Brucellosis is a major disease in humans and domesticated animals and is a systemic bacterial infection caused by gram-negative coccobacilli of the genus *Brucella*. Brucellosis is a zoonotic disease, and a variety of domestic animals serve as reservoir species: *Brucella* infects goats (*Brucella melitensis*), cattle (*Brucella abortus*), swine (*Brucella suis*), and dogs (*Brucella canis*). Transmission to humans results from direct contact with infected animals, exposure to infectious aerosols, or ingestion of unpasteurized dairy products; human-to-human transmission does not occur. While few cases are reported in the US, the majority of cases occur 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*. Clinical manifestations

of brucellosis consist of fever, sweats, malaise, weight loss, headache, and weakness. The onset may be insidious or acute, generally beginning within 2 to 4 weeks after exposure. Any organ or system of the body may be involved, although death is uncommon. Presumptive diagnosis of brucellosis can be made by detection of high or rising titers of specific antibodies, typically to smooth lipopolysaccharide (S-LPS), a major antigenic virulence determinant. Serologic tests using S-LPS can detect antibody to the three major *Brucella* species due to this shared epitope. IgM antibodies appear during the first week of infection followed by a switch to IgG synthesis during the second week. A variety of serologic tests have been used for diagnosis of *Brucella* infection. Detection of anti-*Brucella* antibodies using enzyme-linked immunosorbent assay (ELISA) has been demonstrated to be a sensitive diagnostic approach. However, all specimens testing positive by ELISA should be confirmed by an agglutination method to increase assay specificity.

Reference Values

IgG SCREEN
Negative
Reference values apply to all ages.

IgM SCREEN
Negative
Reference values apply to all ages.

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.

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 Centers for Disease Control and Prevention (CDC) recommends that specimens testing positive for IgG or IgM by enzyme-linked immunosorbent assay (ELISA) be confirmed by a *Brucella*-specific agglutination method.(1)

The CDC/Council of State and Territorial Epidemiologists case definition for human brucellosis states that the laboratory criteria for diagnosis includes the following:
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
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 14 to 21 days.

If results of ELISA are negative and a recent infection is suspected, a new specimen should be tested after 14 to 21 days.

Cautions

This test utilizes antigen derived from *Brucella abortus* strain W99. However, significant cross-reactivity exists for other

Brucella species (except *Brucella canis*); 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 *Brucella melitensis* and *Brucella suis* by this method has not been determined.

Enzyme-linked immunosorbent assays 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 US. 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 US.(2)

Supportive Data

According to the manufacturer's package insert, 127 patient samples testing positive with the Rose-Bengal test were also examined with the Eurroimmun anti-*Brucella abortus* enzyme-linked immunosorbent assay, 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

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. Gunes H, Dogan M: False-positivity in diagnosis of brucellosis associated with Rev-1 vaccine. Libyan J Med. 2013;8:20417
3. Yagupsky P, Morata P, Colmenero JD. Laboratory diagnosis of human brucellosis. Clin Microbiol Rev. 2019;33(1):e00073-19. Published 2019 Nov 13. doi:10.1128/CMR.00073-19
4. Stoddard RA. Detection of *Brucella* spp. antibodies. In: Leber AL, Burnham CAD, eds. Clinical Microbiology Procedures Handbook. 5th ed. ASM Press; 2023:chap 13.3

Performance

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/hydrogen peroxide, and a sulfuric acid stop solution,

the resulting color reaction is measured photometrically at a wavelength of 450 nm.(Package insert: Anti-*Brucella abortus* ELISA Test Instructions. Euroimmun Medizinische Labordiagnostika; IgM: 01/2019, IgG: 08/2020)

PDF Report
No

Day(s) Performed
Tuesday, Thursday

Report Available
Same day/1 to 5

Specimen Retention Time
14 days

Performing Laboratory Location
Mayo Clinic Laboratories - Rochester Superior Drive

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 was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. It has not been cleared or approved by the US Food and Drug Administration.

CPT Code Information
86622 x 2-*Brucella* antibody, IgG and IgM
86622-*Brucella* total antibody, agglutination (if appropriate)

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
BRCMG	Brucella Ab Screen, IgM/IgG ELISA, S	91140-4

Result ID	Test Result Name	Result LOINC® Value
BRCM	Brucella Ab Screen, IgM ELISA, S	24388-1
BRCG	Brucella Ab Screen, IgG ELISA, S	24387-3
BRCI	Brucella Ab Screen Interpretation	66485-4