MAYO CLINIC LABORATORIES

Test Definition: RBPG

Rubella Antibodies, IgG, Serum

Overview

Useful For
Determining immune status to the rubella virus

Method Name
Multiplex Flow Immunoassay (MFI)

NY State Available
No

Specimen

Specimen Type
Serum

Specimen Required
Supplies: Sarstedt Aliquot Tube, 5 mL (T914)
Collection Container/Tube:
Preferred: Serum gel
Acceptable: Red top
Submission Instructions: 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
0.4 mL

Reject Due To

Gross hemolysis	Reject
Gross lipemia	Reject
Gross icterus	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

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, as well as 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 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

The reported antibody index (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.

Positive: AI value of 1.0 or higher
-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

Immunoglobulin G-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 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), 100 prospective serum samples were analyzed in a blinded fashion by the SeraQuest Rubella IgG EIA (Quest Int., Doral, FL) and the BioPlex Rubella IgG assay. Samples with discordant results after initial testing were repeated by both assays during the same freeze/thaw cycle. The results are summarized below:

		SeraQuest Rubella IgG EIA	
		Positive	Negative
BioPlex Rubella IgG	Positive	83	0
	Negative	4*	13

*Same result upon repeat testing
Sensitivity: 95.4% (83/87); 95% Confidence Interval (95% CI): 89.9%-99.2%
Specificity: 100% (13/13); 95% CI: 73.4%-100%
Overall Percent Agreement: 96.0% (96/100); 95% CI: 89.8%-98.8%

Clinical Reference

1. AAP Committee on Infectious Diseases: Rubella. In: Pickering LK, Baker CJ, Kimberlin DW, eds. Red Book. 2012 Report of the Committee on 1. AAP Committee on Infectious Diseases: Rubella. In: Pickering LK, Baker CJ, Kimberlin DW, eds. Red Book. 2012 Report of the Committee on Infectious Diseases. 29th ed. American Academy of Pediatrics; 2012
2. Best JM: Rubella. Semin Fetal Neonatal Med. 2007;12(3):182. doi:10.1016/j.siny.2007.01.017
3. Duszak RS: Congenital rubella syndrome-major review. Optometry. 2009;80(1):36. doi:10.1016/j.optm.2008.03.006
4. Notifiable Diseases and Mortality Tables. MMWR Morb Mortal Wkly Rep. 2016;65(3):ND-38

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,

antihuman 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 re-suspended in wash buffer. The bead mixture then passes through a detector that 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.

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 Clinical Diagnostics Group, Hercules, CA)

PDF Report
No

Day(s) Performed
Monday through Saturday

Report Available
Same day/1 to 3 days

Specimen Retention Time
14 days

Performing Laboratory Location
Mayo Clinic Jacksonville Clinical Lab

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
86762

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
RBPG	Rubella Ab, IgG, S	5334-8

Test Definition: RBPG

Rubella Antibodies, IgG, Serum

Result ID	Test Result Name	Result LOINC® Value
RBG	Rubella Ab, IgG, S	40667-8
DEXG2	Rubella IgG Antibody Index	5334-8