### TEST:
**Rubella IgG EIA**

| **Synonym:** | Anti-Rubella IgG; German Measles IgG antibody; Rubella immunity test |
| **Laboratory/Phone:** | Vaccine Preventable Disease/443-681-3889 |
| **Specimen:** | Serum |
| **Specimen identification:** | Label container with patient’s last name, first name, DOB, specimen type, date and time of collection. |
| **Specimen Volume Required:** | 1-2 ml |
| **Specimen Volume Minimum:** | 1 ml |
| **Collect:** | Venipuncture; Red top vacuum tube, transfer serum to sterile tube with leak-proof cap. |
| **Form:** | DHMH 4677 (MMRV Immunity Screen; Rubella Immunity Screen). |
| **Transport Conditions:** | 2-8°C-Refer to serology test guideline. |
| **Packaging and Shipping:** | Follow packaging and shipping instructions. |
| **Specimen Rejection:** | Discrepancy between name on tube and name on form, unlabeled hemolytic; lexemic; gross bacterial contamination. Specimens collected > 7 days prior to submission. Refer to serology guideline. |
| **Availability:** | Service available only to government facilities Monday to Friday. |

### Results and Interpretation:

- **Negative:** Indicates no detectable IgG antibody to Rubella virus. A negative result indicates no current or previous infection with Rubella virus. Such individuals are presumed to be susceptible to primary infection. However, specimen taken too early during a primary infection may not have detectable levels of IgG antibody. If primary infection is suspected, another specimen (convalescent) should be taken in 8-14 days and tested concurrently in the same assay with the original (acute) specimen to look for seroconversion. If acute specimen is negative and convalescent specimen is positive, seroconversion has taken place and a primary rubella virus infection is indicated.

- **Equivocal:** Equivocal results are indeterminate. Patient may or may not have immunity to Rubella Virus. It is not acceptable proof of immunity.

- **Positive:** Indicates evidence of Rubella IgG antibodies and suggests past or current infection with Rubella virus. Antibodies obtained via acquired immunity or immunization and probable protection from clinical infection. (Immunity).

### Reference Range:

- Negative.

### Additional Information:

For more information, see the CDC link at: [http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/rubella.pdf](http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/rubella.pdf)

### Turnaround Time:

2-6 working days

### Method:

ELISA

### Purpose of Test:

For detection of IgG antibodies to Rubella virus. The test can be used to evaluate single sera for immune status or paired sera to demonstrate seroconversion.

### Interfering Substances:

Test results in an immune compromised patients should be interpreted with caution.

### Testing Site:

Central Laboratory 1770 Ashland Avenue, Baltimore, MD 21205.

### Comment:

LIMITATIONS: A diagnosis should not be made on the basis of anti-Rubella results alone. Test results should be interpreted in conjunction with the clinical evaluation and the results of other diagnostic procedures. The antibody titer of a single serum specimen cannot be used to determine a recent infection. Paired samples (acute and convalescent) should be collected and tested concurrently to demonstrate seroconversion. Samples collected too early in the course of an infection may not have detectable levels of IgG. In such cases, a second sample may be collected after 2-7 weeks and tested concurrently with the Original sample to look for seroconversion. A positive rubella IgG test in neonates should be interpreted with caution since passively acquired maternal antibody can persist for up to 6 months.
TEST: Rubella IgM Antibody EIA

Synonym: Anti-Rubella IgM; Rubella IgM antibody for Rubella/German Measles

Laboratory/Phone: Vaccine Preventable Disease/443-681-3889

Specimen: Serum

Specimen identification: Label container with patient’s last name, first Name, DOB, specimen type, date and time of collection.

Specimen Volume Required: 1-2 ml

Specimen Volume Minimum: 1 ml

Collect: Venipuncture; Red top vacuum tube, transfer serum to sterile tube with leak-proof cap.

Form: DHMH 4677 (Other test) -- Prior authorization by Epidemiology is required (410 767-6628)

Transport Conditions: 2-8°C-Refer to serology test guideline.

Packaging and Shipping: Follow packaging and shipping instructions.

Specimen Rejection: Discrepancy between name on tube and name on form, unlabeled hemolytic, lipemic; gross bacterial contamination. Refer to serology guideline.

Availability: Monday to Friday. Test available only to DHMH epidemiologist to investigate outbreak.

Results and Interpretation:

Negative: Indicates no detectable Rubella IgM antibodies. A negative result indicates no current infection with rubella virus. However, specimens taken too early during a primary infection may not have detectable levels of IgM antibody. If a primary infection is suspected, another specimen should be taken within 7 days and tested concurrently in the same assay with the original specimen to look for seroconversion.

Equivocal: Equivocal specimens are indeterminate. Another specimen should be collected after 7 days and retested.

Positive: Indicates evidence of Rubella IgM antibodies. This suggests primary or reactivated infection with Rubella.

Reference Range: Negative.

Additional Information: For more information, see the CDC link at: http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/rubella.pdf

Turnaround Time: 2-6 working days

Method: ELISA

Purpose of Test: Test available only to DHMH epidemiologist to investigate outbreak. For the detection of IgM antibodies to Rubella virus.

Interfering Substances: Test results in an immune compromised patients should be interpreted with caution.

Testing Site: Central Laboratory 1770 Ashland Avenue, Baltimore, MD 21205.

Comment:

LIMITATIONS: Results of the Rubella IgM ELISA are not by themselves diagnostic and should be interpreted in light of the patient’s clinical condition and results of other diagnostic procedures. Rubella virus specific IgG antibody may compete with IgM for binding sites and cause false negative results. Rheumatoid factor, if present along with specific IgG, will cause false positive results. The Sample Diluent contains an absorbent which will remove IgG from the test specimen, and significantly reduce the possibility of false positive or negative results. Heterotypic IgM antibody responses may occur in patients infected with Epstein-Barr virus, and sera from patients with infectious mononucleosis may have false positive results in the rubella IgM ELISA. Samples taken too early during the course of a primary infection may not have detectable levels of rubella specific IgM. A negative result does not rule out a primary infection. It cannot distinguish the difference between vaccine-induced antibody and antibody resulting from a natural infection. False positive anti-rubella IgM results may be obtained from patients with autoimmune disease. The performance of the Rubella IgM EIA has not been validated using neonatal samples.