



CERTIFICATE OF ANALYSIS

Catalog #: 6300 **Lot #** M32088018

Description: Rubella IgM MAX™ Antigen

Rubella viral infection (German Measles) is typically a mild and self-limiting disease that is most often contracted during childhood. Primary rubella infections are not common in adults, but if they occur, the infection may have serious consequences in pregnant women. Rubella Western Blot assays of IgM serum samples showed that false positive reactivity frequently is due to the reaction with Rubella capsid antigens. This may be due to cross-reactivity. Rubella IgM™ MAX Antigen was designed to be free of capsid proteins to address potential IgM cross-reactivity issues. Rubella IgM™ MAX Antigen is the envelope spike protein comprised of E1 and E2 in the native configuration. These antigens give greater specificity in the detection of Rubella IgM antibodies. Specific Rubella IgM antibodies appear early after infection and react with the envelope proteins (spike protein) in the acute stage of the Rubella viral (German Measles) infections. Rubella IgM™ MAX Antigen is prepared by a patented process (patent #6,670,117 and #6,872,396 B2) of extraction of Rubella antigens from cells infected with Rubella Virus strain HPV77. Although the primary intent for this antigen is for the detection of IgM antibodies it can also be used for IgG if desired.

Viral Strain: HPV77
Source: Propagated in VERO Cells
 Product manufactured in United States using only domestic animal materials processed in U.S. facilities.

Format: Liquid **Exp. Date:** 31 JAN 2023

Protein Concentration: UV/VIS (A260/A280)
 Acceptable Range: 0.40 – 0.60 mg/mL
 Testing Results: 0.44 mg/mL

Activity: ELISA Assay: Testing Results: Midpoint Titer (test antigen): 1724.15
 Acceptable Range: -15% - +50% of Reference Antigen % of Reference: 18.89%
 Testing Results: Midpoint Titer (reference antigen): 1450.21

Buffer: 0.1M Sodium Carbonate, 0.1M Sodium Chloride, pH 7.9 – 8.3

Identity Assay: Western Blot
 Acceptance: Only E1 and E2 bands shown **Testing Results:** Pass

Preservative: None

Applications: Antigen designed for Rubella IgM assays

Storage: Store at ≤ -65°C. Avoid multiple freeze/thaw cycles

Inactivation: Product inactivated by detergent and verified by Infectivity Testing (Plaque Assay)
 Acceptable Range: 0 PFU/mL
 Testing Results: 0 PFU/mL

Safety Notes: Refer to the appropriate Safety Data Sheet (SDS) for additional information. Since no test method can offer complete assurance that infectious agents are absent, this material should be handled with caution.


 Signature

05 March 2018
 Date

FOR RESEARCH OR FURTHER MANUFACTURING USE ONLY