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CERTIFICATE OF ANALYSIS

Catalog #:

6075

Lot#

M42911022

Description:

Rubella Virus Grade III Antigen

Viral Strain:

HPV77

DOM:

23 MAY 2022

Source:

Grown in Vero Cells

Product manufactured in the United States using only domestic animal materials processed in U.S. facilities.

Format:

Liquid

Exp. Date:

23 MAY 2027

Bioburden:

Concentration:

Acceptable Range: < 100 CFU/mL

Testing Results: 0 CFU/mL

Protein

Assay: Total Protein by OD260/280nm Acceptable Results: 0.1 – 0.2 mg/mL

Testing Results: 0.13 mg/mL

Activity:

ELISA Assay: Reference Lot Number: M31581018

Testing Results: Midpoint Titer (test antigen): 52.173

Acceptable Range: -15% - +15% of Reference Antigen % of Reference: -5.35 %

Testing Results: Midpoint Titer (reference antigen): 55.122

Background ELISA Ratio: Acceptable ≤ 2

Test Result: 1

Sensitivity/Specificity Negative Control: Acceptable To Report

Test Result: Acceptable

Sensitivity/Specificity Medium Positive Control: Acceptable ≥ 3

Test Result: 12

Sensitivity/Specificity High Positive Control: Acceptable ≥ 8

Test Result: 20

Buffer:

10 mM Tris, 150 mM NaCl, 1.0 mM EDTA, pH 8.0 – 8.4

Preservative:

None

Storage:

Store at \leq -65°C. Avoid multiple freeze/thaw cycles.

Inactivation:

Product inactivated by UV irradiation and verified by Infectivity Testing (Plaque Assay)

Acceptable Range: ≤ 10 PFU/mL

Testing Results: 0 PFU/mL

Applications:

Each laboratory should determine an optimum working titer for use in its particular application.

Safety Notes:

Refer to the appropriate Safety Data Sheet (SDS) for additional information.

Quality Signature:

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03 AUG 2022