

Rubella Virus

Overview

Clinical

Rubella virus is transmitted by the respiratory route and it is known that the virus replicates in the nose, throat and the local lymph nodes. Rubella virus poses significant risks to pregnant women, as it can infiltrate the placenta and affect the developing fetus. The infection typically manifests with a transient rash. While joint pain and arthritis are uncommon in children, they can afflict as many as 70% of adult patients.

Congenital rubella syndrome stems from infection during early pregnancy, spanning from just before conception to the first 8-10 weeks of gestation. In up to 90% of cases, this infection can lead to multiple fetal defects, affecting various organs and significantly increasing the likelihood of miscarriage or stillbirth. Infants who survive congenital rubella syndrome may encounter severe developmental disabilities¹.

Epidemiology

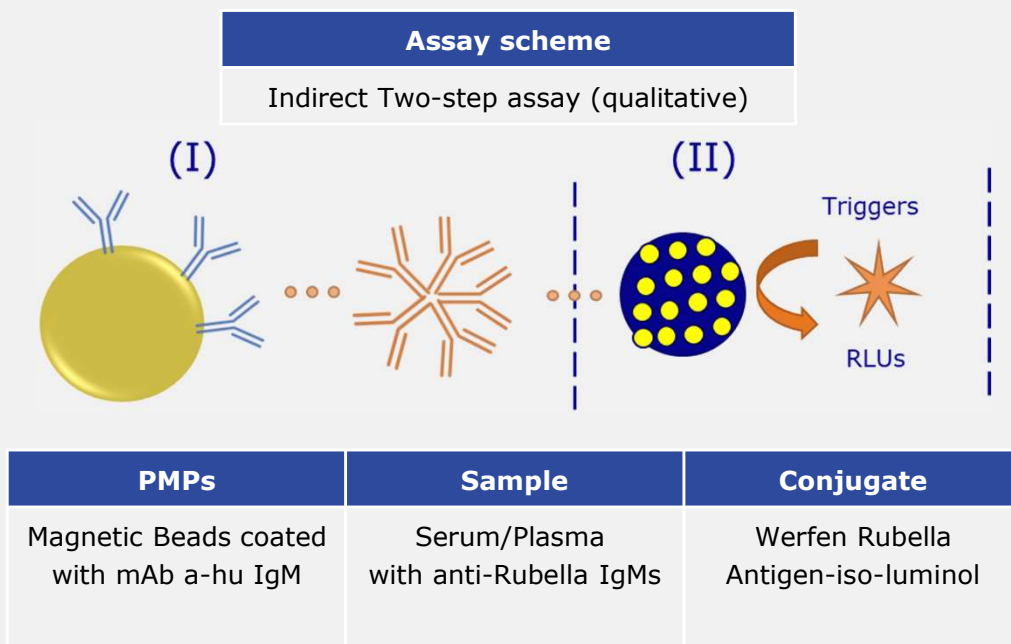
In 2022, the estimated number of measles cases was over 9 million².

Regarding congenital rubella syndrome, it is estimated in 100.000 cases worldwide³.

Rubella IgM CLIA

Assay Scheme

Qualitative detection of antibodies (IgM) to Rubella Virus in human serum or plasma



1. Rubella. WHO Factsheet October 2019. Accessed March 2024 . <https://www.who.int/news-room/fact-sheets/detail/rubella>

2. Fast Facts on Global Measles, Rubella, and Congenital Rubella Syndrome (CRS). November 23. Accessed March 2024 <https://www.cdc.gov/globalhealth/measles/data/fast-facts-global-measles-rubella.html>

3. World Health Organization. Rubella Vaccines: WHO Position Paper. Wkly. Epidemiol. Rec. 2020. Accessed March 2024. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10458369/pdf/vaccines-11-01358.pdf>

Evaluation of Rubella IgM CLIA vs reference assay

Rubella IgM CLIA Assay	Reference Method			Total
	IND	NEG	POS	
IND	0	0	2	2
NEG	1	248	2	251
POS	0	3	50	53
Total	1	251	54	306

Table 2: External evaluations were performed in a clinical laboratory. Samples were characterized by another commercially available MEIA Rubella IgM method and was tested with Rubella IgM CLIA assay. IND results were not used in calculations

N	Resolved Sensitivity		Resolved Specificity		Resolved Overall Agreement	
	Value	95% CI	Value	95% CI	Value	95% CI
303	98.0%	89.6% to 100.0%	98.8%	96.5% to 99.8%	98.7%	96.6% to 99.6%

Table 3: The discrepant samples were tested with a commercially available CLIA Rubella IgM method and one of them was resolved as negative in favor of Werfen Rubella IgM CLIA. After this additional testing, the results on table 3 were obtained for resolved sensitivity, specificity and overall agreement

Cross-reactivity Test with Rubella IgM CLIA

Cross-reactivity	
Cross-reactant type	Agreement
Anti-Toxo IgM (<i>Toxoplasma gondii</i>)	5/5
Anti-CMV IgM (Cytomegalovirus)	5/5
Anti-HIV (Human Immunodeficiency Virus)	6/6
HAMA (Human Anti-Mouse Antibodies)	5/5
SLE (Systemic Lupus Erythematosus)	10/10
ANA (Anti-Nuclear Antibodies)	6/6
Anti-EBV (Epstein-Barr Virus)	6/6
Anti-PV B19 (Parvovirus B19)	6/6
Anti-HSV-1 (Herpes Simplex Virus type 1)	5/5
Anti-VZV (Varicella Zoster Virus)	5/5

Table 4. Cross-reactant sample testing. 54 specimens with potential cross-reactivity with the Rubella CLIA IgM assay were tested against commercially available Rubella IgM assay. Table above is showing the agreement between methods

Werfen's Biomaterial offering

Rubella Ag (ref 3000-5202 / 3000-5204)

Storage: -70°C

Source: Tissue Culture (Virus Strain HPV-77)

Storage buffer: Sucrose / SDS/NTE

Purification method: Ultracentrifugation

Protein concentration: 0.5 – 1.5 mg/mL

Preservative: None

The content within this brochure is provided for informational purposes.

Contact oem@werfen.com for further technical information and product availability