Rubella Virus

Overview

Clinical

Rubella virus is transmitted by the respiratory route and 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 disabilities[1].

Epidemiology

In 2022, the estimated number of measles cases was over 9 million[2].

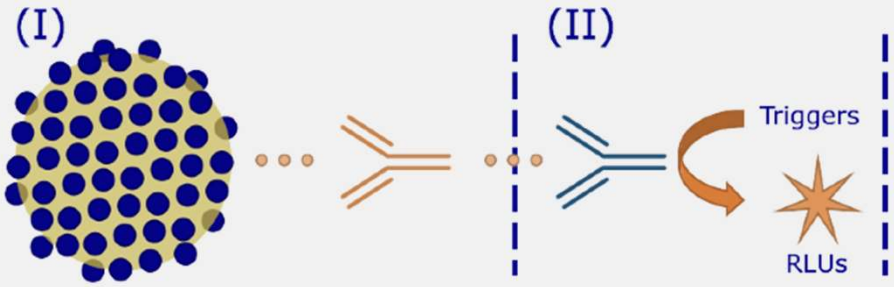
Regarding congenital rubella syndrome , it is estimated in 100.000 cases worldwide[3].

Rubella IgG CLIA

Assay Scheme

Quantitative detection of antibodies (IgG) to Rubella Virus in human serum or plasma

Assay scheme
Indirect Two-step assay (quantitative)



PMPs	Sample	Conjugate
Magnetic Beads coated with Werfen's Rubella Ag	Serum/Plasma with anti-Rubella IgGs	mAb a-hu-IgG-iso-luminol

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 IgG CLIA vs reference assay

	Reference Method			
Rubella IgG CLIA Assay	**IND**	**NEG**	**POS**	**Total**
IND	**2**	**0**	**11**	13
NEG	**3**	**70**	**3**	76
POS	**1**	**2**	**252**	255
Total	6	72	266	344

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

		Resolved Sensitivity		Resolved Specificity		Resolved Overall Agreement	
N		**Value**	**95% CI**	**Value**	**95% CI**	**Value**	**95% CI**
325		**98,8%**	**96.6% to 99.8%**	**100%**	**94.9% to 100.0%**	**99.1%**	**97.3% to 99.8%**

Table 3: The discrepant samples were tested with a commercially available CLIA Rubella IgG method and the 2 false positive resolved either as negative or indeterminate in favor of Werfen Rubella IgG CLIA. After this additional testing, the results on table 3 were obtained for resolved sensitivity, specificity and overall agreement

Cross-reactivity Test with Rubella IgG CLIA

Cross-reactivity	
Cross-reactant type	**Agreement**
Anti-Toxo IgG (*Toxoplasma gondii*)	3/3
Anti-CMV IgG (Cyomegalovius)	16/16
Anti-HIV (Human Immunodeficiency Virus)	6/6
HAMA (Human Anti-Mouse Antibodies)	4/4
SLE (Systemic Lupus Erythematosus)	1/1
ANA (Anti-Nuclear Antibodies)	10/10
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. 62 specimens with potential cross-reactivity with the Rubella CLIA IgG assay were tested against commercially available Rubella IgG assay. Table above is showing the agreement between methods

Werfen's Biomaterial offering

Rubella Ag (ref 3000-5202 / 3000-5204)
Storage: -70ºC
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

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