

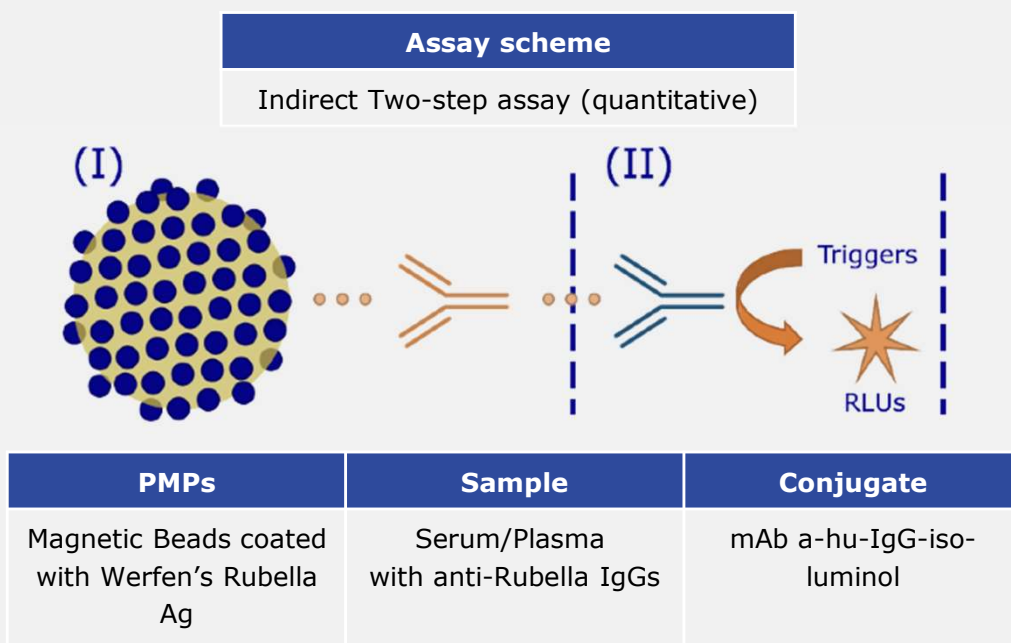
Overview

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.

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

Assay Scheme

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



werfen

Evaluation of Rubella IgG CLIA vs reference assay

Rubella IgG CLIA Assay	Reference Method			Total
	IND	NEG	POS	
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

N	Resolved Sensitivity		Resolved Specificity		Resolved Overall Agreement	
	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 (<i>Toxoplasma gondii</i>)	3/3
Anti-CMV IgG (Cyomegalovirus)	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: -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 immunoassay@werfen.com for further technical information and product availability