

Monoclonal Antibody to Human IgG

Cat. No. AXIGG01MAB

Monoclonal Antibody

STORE AT -20 °C

Validated Assay Configuration – The following configuration represents the AssayProven™ recommended reagent combination for the validated application listed below.

VALIDATED APPLICATION	Rubella IgG — CLIA; Toxoplasma IgG — CLIA
CAPTURE REAGENT	AXRUB01RAG (Rubella IgG); AXTOX01RAG (Toxoplasma IgG)
DETECTION REAGENT	AXIGG01MAB
PERFORMANCE EVALUATION MATERIAL	Clinical serum samples

Product Characteristics

SPECIES OF ORIGIN	Mouse
PRODUCTION SYSTEM	Ascites
RECOMBINANT	No
ISOTYPE	IgG1
MOLECULAR WEIGHT	150 kDa
FULL-LENGTH PROTEIN	Yes
APPEARANCE	Liquid
FORMAT	Liquid
CONCENTRATION	As reported
METHOD TO DETERMINE CONCENTRATION	OD280
LYOPHILIZED	No
RECONSTITUTION METHOD	Not applicable
SONICATION REQUIRED PRIOR TO USE	No

Biological Characteristics

IMMUNOGEN	Human IgG (FC)
IMMUNOGEN SEQUENCE	Not characterized
AMINO ACID SEQUENCE	Not characterized
TAG PROTEIN	Not applicable
EPITOPE	Not characterized
CROSS-REACTIVITY	Not characterized
IMMUNOREACTIVITY	Immunoreactivity of each production lot is qualified against an internal reference standard, with acceptance criteria of $\pm 10\%$ relative signal under standardized assay conditions.

Quality Attributes

PURITY	$\geq 90\%$
METHOD TO DETERMINE PURITY	SDS-PAGE
PURIFICATION METHOD	Protein A chromatography
MAXIMUM BIOBURDEN	Not characterized

Binding Characteristics

ASSOCIATION RATE CONSTANT (K_a)	Not characterized
DISSOCIATION RATE CONSTANT (K_d)	Not characterized
EQUILIBRIUM DISSOCIATION CONSTANT (K_D)	Not characterized
BINDING DETERMINATION METHOD	Not characterized

Formulation

BUFFER / PH	10 mM phosphate buffer with 150 mM sodium chloride, pH 7.4
PRESERVATIVE	0.1% ProClin 300

Storage & Stability

STORAGE TEMPERATURE	-20 °C
SHELF LIFE	3 years
STABILITY AT 2–8 °C	>21 days
STABILITY AT -20 °C	3 years
STABILITY AT -40 °C	Not characterized
STABILITY AT -80 °C	Not characterized

Other Technical characteristics

ISOELECTRIC POINT (pI)	Not characterized
INACTIVATION METHOD	Not applicable

Notes & Safety Information

SAFETY INFORMATION	Refer to the appropriate Safety Data Sheet (SDS) for additional information.
NOTES	This reagent has been manufactured under ISO 13485 quality management system and is suitable for research or further manufacturing use only. Centrifuge before opening to ensure complete recovery of vial contents.

Performance Validation Report

The following pages contain the applicable AssayProven™ Performance Validation Report.

AssayProven™ Recommended Rubella IgG Pair

Recommended Pair Summary

Multiple antibody combinations were screened under standardized assay conditions to identify the optimal antibody pair for chemiluminescent immunoassay development. The recommended AssayProven™ Rubella IgG antibody pair demonstrated the best overall analytical performance, including strong correlation with the Abbott Rubella IgG assay using clinical serum samples, supporting its suitability for chemiluminescent immunoassay development.

Category	Target	Format	Item Type	Cat. #	Description	Function
TORCH	Rubella IgG	CLIA	Antigen	AXRUB01RAG	Rubella Virus Antigen	Capture
			Antibody	AXIGG01MAB	mAb to Human IgG	Detector

Method: 2-step sandwich assay

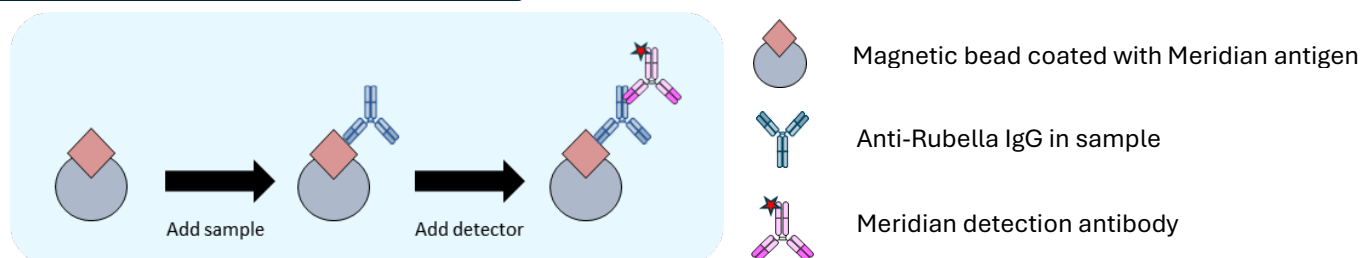


Figure 1. Schematic diagram of a 2-step sandwich chemiluminescent immunoassay using AssayProven™ pairs.

Correlation Performance

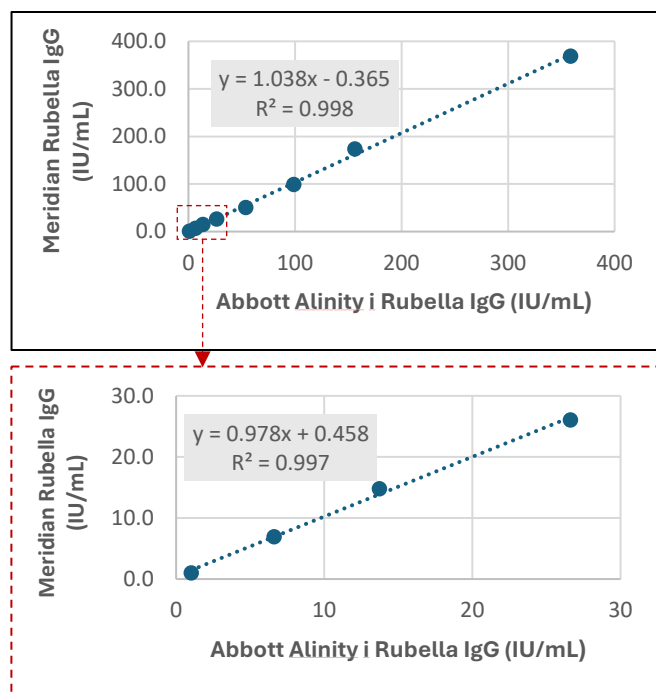


Figure 2. Correlation between the Meridian Rubella IgG assay and the Abbott Alinity I Rubella IgG assay using clinical serum samples.

Correlation Data

Abbott (IU/mL)	Meridian Pair (IU/mL)
1	1
6.6	6.9
13.7	14.7
26.6	26
54	50.2
98.8	98.6
156.3	173.9
358.6	368.5

Table 1. Correlation of Meridian Rubella IgG assay with the Abbott Alinity I Rubella IgG assay using clinical serum samples.

AssayProven™ Recommended Toxoplasma IgG Pair

Recommended Pair Summary

Multiple antibody combinations were screened under standardized assay conditions to identify the optimal antibody pair for chemiluminescent immunoassay development. The recommended AssayProven™ Toxoplasma IgG antibody pair demonstrated the best overall analytical performance, including strong correlation with the Roche Toxoplasma IgG assay using clinical serum samples, supporting its suitability for chemiluminescent immunoassay development.

Category	Target	Format	Item Type	Cat. #	Description	Function
TORCH	Toxoplasma IgG	CLIA	Antigen	AXTOX01RAG	Recombinant Toxoplasma gondii	Capture
			Antibody	AXIGG01MAB	mAb to Human IgG	Detector

Method: 2-step sandwich assay

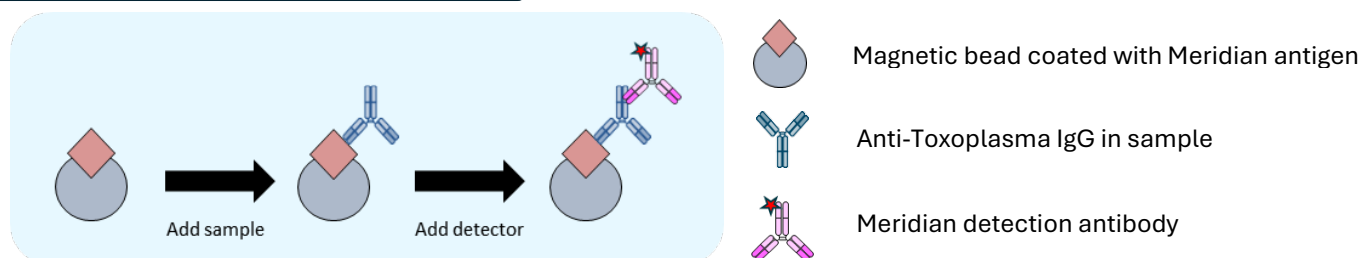


Figure 1. Schematic diagram of a 2-step sandwich chemiluminescent immunoassay using AssayProven™ pairs.

Correlation Performance

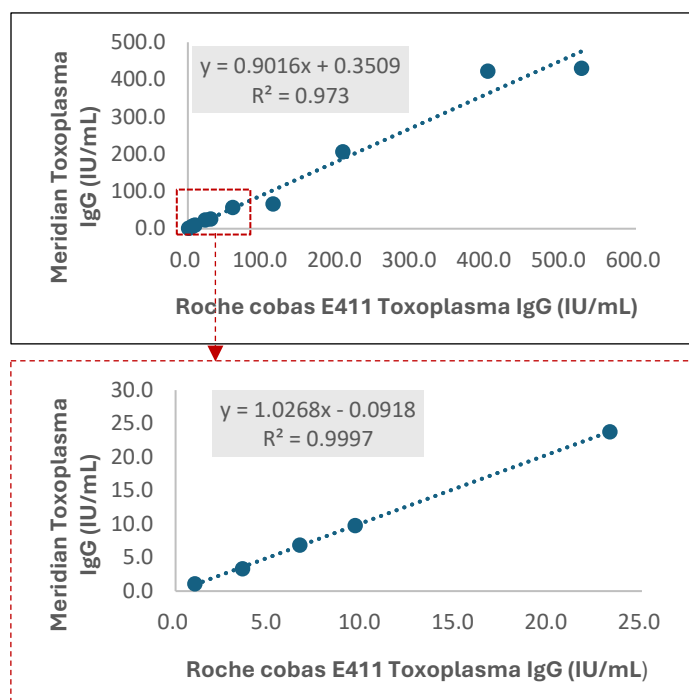


Figure 2. Correlation between the Meridian Toxoplasma IgG assay and the Roche cobas e411 Toxoplasma IgG assay using clinical serum samples.

Correlation Data

Roche (IU/mL)	Meridian pair (IU/mL)
1.0	1.1
3.6	3.3
6.7	6.9
9.6	9.8
23.3	23.8
30.7	25.9
60.1	57.2
114.3	66.2
207.7	206.3
401.8	422.3
527.4	430.7

Table 1. Correlation of the Meridian Toxoplasma IgG assay with Roche Toxoplasma IgG assay (cobas e411) using clinical samples.