

Toxoplasma gondii Recombinant Antigen

Cat. No. AXTOX01RAG

Recombinant Antigen

STORE AT -20 °C

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

VALIDATED APPLICATION	CLIA
CAPTURE REAGENT	AXTOX01RAG
DETECTION REAGENT	AXIGG01MAB
PERFORMANCE EVALUATION MATERIAL	Clinical serum samples

Product Characteristics

SPECIES OF ORIGIN	Toxoplasma gondii
PRODUCTION SYSTEM	E. coli
RECOMBINANT	Yes
ISOTYPE	Not applicable
MOLECULAR WEIGHT	26.7 kDa
FULL-LENGTH PROTEIN	No
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	Not applicable
IMMUNOGEN SEQUENCE	Not applicable
AMINO ACID SEQUENCE	Not characterized
TAG PROTEIN	Not characterized
EPITOPE	Not applicable
CROSS-REACTIVITY	No cross-reactivity with HIV, HCV, syphilis
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	Affinity chromatography
MAXIMUM BIOBURDEN	Not characterized

Binding Characteristics

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

Formulation

BUFFER / PH	20 mM Tris with 150 mM sodium chloride, pH 8.0
PRESERVATIVE	None

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 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

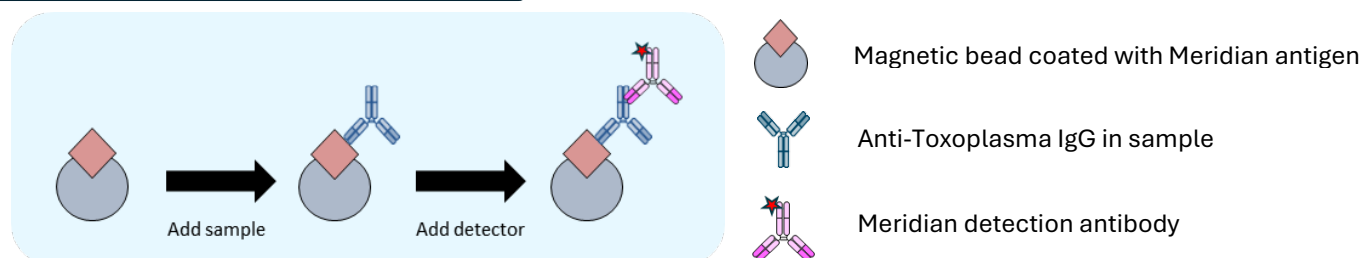


Figure 1. Schematic diagram of a 2-step sandwich chemiluminescent immunoassay using AssayProven™ pairs.

Correlation Performance

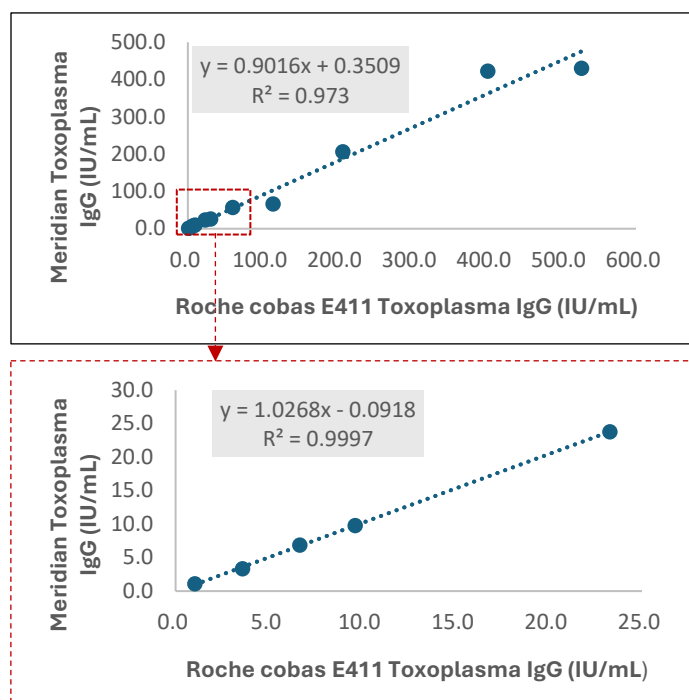


Figure 2. Correlation between the Meridian Toxoplasma IgG assay and the Roche cobas e411 Toxoplasma IgG assay using clinical serum samples.

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.