

Monoclonal Antibody to Human IgE

Cat. No. AXIGE02RAB

Recombinant 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	FIA
CAPTURE REAGENT	AXIGE01RAB
DETECTION REAGENT	AXIGE02RAB
PERFORMANCE EVALUATION MATERIAL	Clinical serum samples

Product Characteristics

SPECIES OF ORIGIN	Mouse
PRODUCTION SYSTEM	HEK293 cells
RECOMBINANT	Yes
ISOTYPE	Not characterized
MOLECULAR WEIGHT	Not characterized
FULL-LENGTH PROTEIN	Yes
APPEARANCE	Clear 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	Immunoglobulin E
IMMUNOGEN SEQUENCE	Not characterized
AMINO ACID SEQUENCE	Not characterized
TAG PROTEIN	Not characterized
EPITOPE	Not characterized
CROSS-REACTIVITY	No cross-reactivity with Immunoglobulin G, A, M
IMMUNOREACTIVITY	Not characterized

Quality Attributes

PURITY	≥95%
METHOD TO DETERMINE PURITY	SDS-PAGE
PURIFICATION METHOD	Affinity purification
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 PBS, pH 7.5
PRESERVATIVE	0.05% sodium azide

Storage & Stability

STORAGE TEMPERATURE	-20 °C
SHELF LIFE	3 years
STABILITY AT 2–8 °C	2 weeks
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 Total IgE Pair

Recommended Pair Summary

Multiple antibody combinations were screened under standardized assay conditions to identify the optimal antibody pair for fluorescence immunoassay development. The recommended AssayProven™ Total IgE antibody pair demonstrated the best overall analytical performance, including excellent analytical sensitivity, no observed cross-reactivity with other major immunoglobulin classes, and strong correlation with the Roche Elecsys Total IgE assay, supporting its suitability for fluorescence immunoassay development.

Category	Target	Format	Item Type	Cat. #	Description	Function
Allergy	Total IgE	FIA	Antibody	AXIGE01RAB	mAb to Human IgE	Capture
			Antibody	AXIGE02RAB	mAb to Human IgE	Detector

Method: 2-step sandwich assay

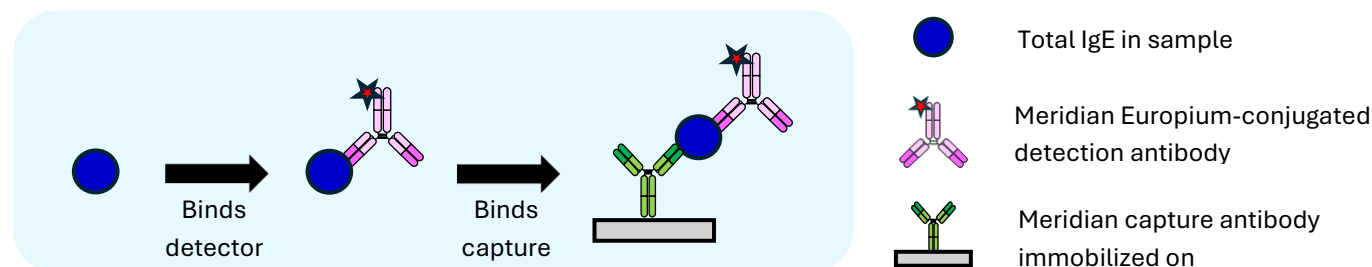


Figure 1. Schematic diagram of a 2-step sandwich fluorescence immunoassay using AssayProven™ pairs.

Correlation Performance

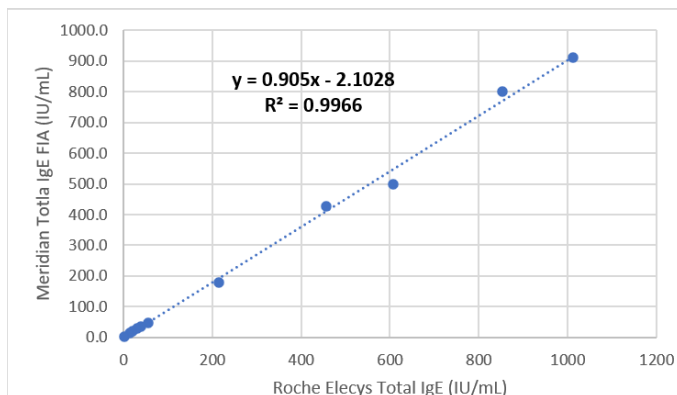


Figure 2. Correlation between the Meridian Total IgE FIA assay and the Roche Elecsys Total IgE assay using clinical serum samples (n = 13).

Analytical & Clinical Performance

Sample	Limit of Detection
Serum	2.0 IU/mL

Table 1. Analytical sensitivity (LoD) of the AssayProven™ Total IgE antibody pair.

Substance	Highest Concentration Evaluated
Immunoglobulin G	20 mg/mL
Immunoglobulin A	20 mg/mL
Immunoglobulin M	20 mg/mL

Table 2. No cross-reactivity was observed between the AssayProven™ Total IgE antibody pair and major immunoglobulin classes.