PRODUCT INFORMATION SHEET

AssayProven™

Monoclonal Antibody to TSH

Cat. No. AXTSH01RAB	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	AXTSH01RAB
DETECTION REAGENT	AXTSH02RAB
PERFORMANCE EVALUATION MATERIAL	Clinical serum and whole blood samples

Product Characteristics

SPECIES OF ORIGIN	Mouse
PRODUCTION SYSTEM	CHO cells
RECOMBINANT	Yes
ISOTYPE	IgG
MOLECULAR WEIGHT	150 kDa (50 kDa heavy chain, 25 kDa light chain)
FULL-LENGTH PROTEIN	Yes
APPEARANCE	Clear liquid
FORMAT	Liquid
CONCENTRATION	≥1 mg/mL
METHOD TO DETERMINE CONCENTRATION	OD280
LYOPHILIZED	No
RECONSTITUTION METHOD	Not applicable
SONICATION REQUIRED PRIOR TO USE	No

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Biological Characteristics

IMMUNOGEN	Human pituitary TSH
IMMUNOGEN SEQUENCE	Not characterized
AMINO ACID SEQUENCE	Not characterized
TAG PROTEIN	Not characterized
EPITOPE	Not characterized
CROSS-REACTIVITY	Not characterized
IMMUNOREACTIVITY	Not characterized

Quality Attributes

PURITY	≥90%
METHOD TO DETERMINE PURITY	SDS-PAGE
PURIFICATION METHOD	Affinity 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	20 mM phosphate buffer, pH 7.7
PRESERVATIVE	0.09% sodium azide

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Storage & Stability

STORAGE TEMPERATURE	−20 °C
SHELF LIFE	36 months
STABILITY AT 2–8 °C	12 months
STABILITY AT −20 °C	36 months
STABILITY AT −40 °C	Not characterized
STABILITY AT −80 °C	Not characterized

Other Technical characteristics

ISOELECTRIC POINT (pI)	7.3
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.

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AssayProven™ Recommended TSH Antibody 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™ TSH antibody pair demonstrated the best overall analytical performance, including excellent analytical sensitivity and strong correlation with the Roche Elecsys TSH assay in both serum and whole blood, supporting its suitability for fluorescence immunoassay development.

Category	Target	Format	Item Type	Cat. #	Description	Function
Thyroid	TSH	FIA	Antibody	AXTSH01RAB	mAb to TSH	Capture
			Antibody	AXTSH02RAB	mAb to TSH	Detector

Method: 2-step sandwich assay

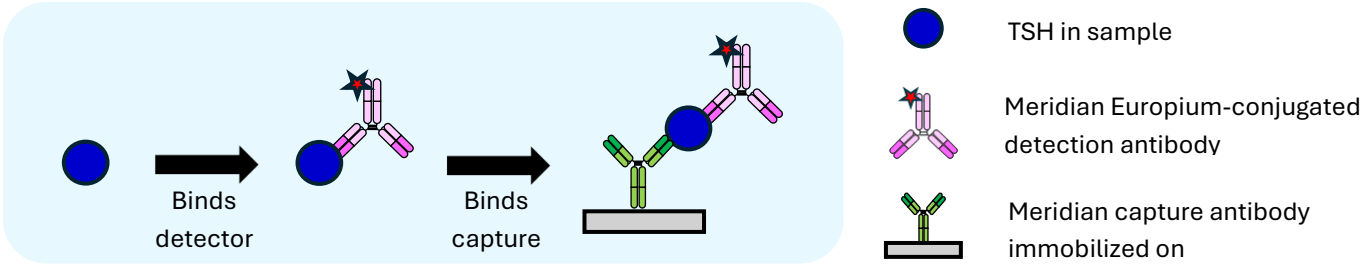


Figure 1. Schematic diagram of a 2-step sandwich fluorescence immunoassay using AssayProven™ pairs.

Correlation Performance

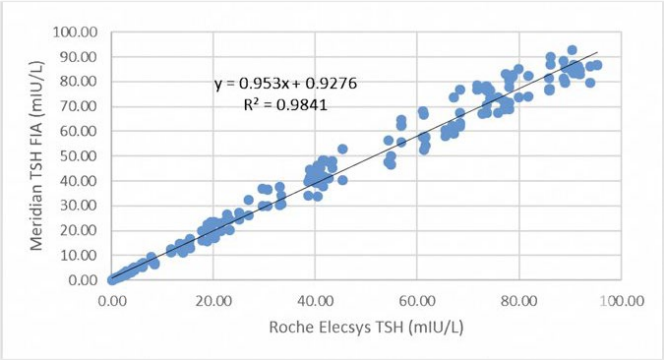


Figure 2. Correlation between the Meridian TSH FIA assay and the Roche Elecsys TSH assay using clinical serum samples (n = 120).

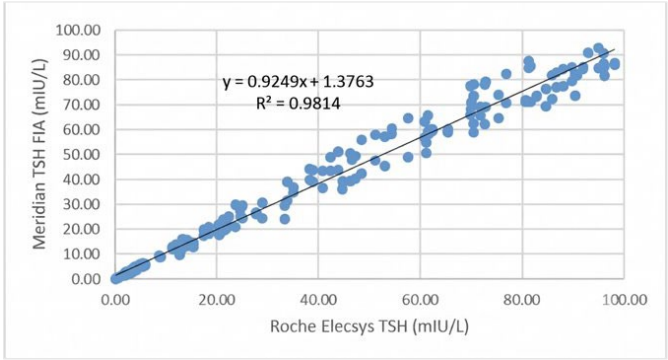


Figure 3. Correlation between the Meridian TSH FIA assay and the Roche Elecsys TSH assay using whole blood samples (n = 120).

Analytical & Clinical Performance

Sample	Limit of Detection
Serum	0.059 mIU/L
Whole blood	0.058 mIU/L

Table 1. Analytical sensitivity (Limit of Detection) of the AssayProven™ TSH antibody pair.

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