PRODUCT INFORMATION SHEET

AssayProven™

Polyclonal Antibody to Dengue NS1

Cat. No. AXDEN01PAB	Polyclonal 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	LFA
CAPTURE REAGENT	AXDEN02MAB
DETECTION REAGENT	AXDEN01PAB
PERFORMANCE EVALUATION MATERIAL	Viral culture supernatants

Product Characteristics

SPECIES OF ORIGIN	Rabbit
PRODUCTION SYSTEM	Rabbit Serum
RECOMBINANT	No
ISOTYPE	Not applicable
MOLECULAR WEIGHT	Not characterized
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

meridian LIFE SCIENCE®

Meridian Life Science, Inc.
5171 Wilfong Road
Memphis , TN 38134
USA

www.meridianlifescience.com
Tel: (+1) 901-382-8716
Email: info@meridianlifescience.com
Orders: orders@meridianlifescience.com

Biological Characteristics

IMMUNOGEN	Recombinant Dengue virus NS1 protein
IMMUNOGEN SEQUENCE	D0EPW9 (UniProt ID)
AMINO ACID SEQUENCE	Not characterized
TAG PROTEIN	Not applicable
EPITOPE	Not characterized
CROSS-REACTIVITY	No cross-reactivity with Chikungunya, Zika virus, Malaria, Influenza A, Influenza B, HBV, CMV, Salmonella, Rotavirus, and Legionella
IMMUNOREACTIVITY	Not characterized

Quality Attributes

PURITY	≥80%
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	PBS, pH 7.3
PRESERVATIVE	0.09% sodium azide

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Storage & Stability

STORAGE TEMPERATURE	−20 °C
SHELF LIFE	12 months
STABILITY AT 2–8 °C	12 months
STABILITY AT −20 °C	12 months
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.

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PRODUCT INFORMATION SHEET

AssayProven™

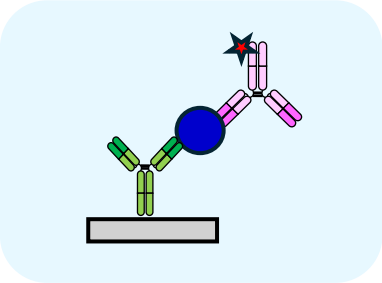
AssayProven™ Recommended Dengue Antibody Pair

Recommended Pair Summary

Multiple antibody combinations were screened under standardized assay conditions to identify the optimal antibody pair for lateral flow immunoassay development. The recommended AssayProven™ Dengue NS1 antibody pair demonstrated the best overall analytical performance, including excellent analytical sensitivity across all four dengue serotypes, high clinical specificity, and no detectable cross-reactivity with common infectious disease pathogens, supporting its suitability for lateral flow immunoassay development.

Category	Target	Format	Item Type	Cat. #	Description	Function
Infectious Disease	Dengue NS1	LFA	Antibody	AXDEN02MAB	mAb to Dengue NS1	Capture
			Antibody	AXDEN01PAB	pAb to Dengue NS1	Detector

Method: Sandwich lateral flow immunoassay (LFA)



Meridian capture antibody immobilized on membrane

Dengue NS1 in virus culture supernatant

Meridian detection antibody

Figure 1. Schematic diagram of a sandwich lateral flow immunoassay using AssayProven™ antibody pairs.

Analytical & Clinical Performance

Analyte (Virus Culture Supernatant)	Limit of Detection
Dengue type 1 (Hawaii)	4.44×10^{2} ($TCID_{50}$/mL)
Dengue type 2 (New Guinea C)	4.08×10^{2} ($TCID_{50}$/mL)
Dengue type 3 (H87)	6.56×10^{2} ($TCID_{50}$/mL)
Dengue type 4 (H241)	2.51×10^{3} ($TCID_{50}$/mL)

Table 1. Analytical sensitivity of the AssayProven™ Dengue NS1 antibody pair using dengue virus culture supernatants.

Clinical specificity:

98.7% (222/225) using 225 Dengue NS1-negative clinical samples, which were confirmed as negative using a commercial detection kit. (Dengue Virus NS1 ELISA, EUROIMMUN, EQ 266a-9601-1)

Potential cross-reactivity:

No cross-reactivity was observed using samples positive for Chikungunya, Zika virus, Malaria, Influenza A, Influenza B, HBV, CMV, Salmonella, Rotavirus, and Legionella.

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