

DIESSE DIAGNOSTICA SENESE SpA
53035 Monteriggioni (SIENA) – Italy – Strada dei Laghi, 39
Tel. +39 0577319554 FAX +39 0577319020



Sede Legale e Amministrazione
Via A. Solari, 19 20144 Milano - Italy

QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL TOSCANA VIRUS IgG -IgM

Code 91067

LOT.NO 092 **EXPIRY** 2025-01

REAGENTS

LABEL	DESCRIPTION	LOT No.	EXP	No
PF92001	005260 STRIPS IgG	108	2025-08	3
PF93000	005280 STRIPS IgM	668	2025-01	3
PF92006	005270 IgG CONJUGATE	085	2025-06	2
PF92007	005290 IgM CONJUGATE	086	2025-06	2
PF92002	005220 POSITIVE CONTROL IgG	081	2025-09	1
PF93910	005240 NEGATIVE CONTROL IgG/IgM	179	2025-06	2
PF92004	005200 CUT-OFF IgG	082	2025-09	1
PF92008	005230 ANTIGEN	075	2025-01	6
PF93621	006030 DILUENT 10	165	2025-05	1
PF93603	1035 WASHING BUFFER 10x	468	2025-06	1
PF93619	1034 SUBSTRATO	383-1	2025-05	1
PF93602	1032/RISK0 STOP SOLUTION	218-6	2025-06	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
- IgG		
Neg. Control	0.007	$\leq 0.6 \times \text{Cut-off}$
Cut-off Control	0.430	≥ 0.200
Positive Control	1.650	$\geq 1.5 \times \text{Cut-off}$
CV%		$\leq 15\%$
- IgM		
Neg. Control	0.023	< 0.150

The test has been carried out in accordance with the package insert

TESTED BY: Katia Tanzini 

APPROVED BY: (RESPONSIBLE HEAD, Quality Control Reagents) 

DATE 25/03/2024

WARNING: POTENTIAL BIOHAZARDOUS MATERIAL!

This kit may contain some reagents made with human serum or plasma. All serum or plasma used has been tested by an FDA approved method and found non-reactive for HIV-1/2, HCV and HBsAg. Because no method can offer complete assurance that HIV-1/2, HCV, HBsAg or other infectious agents are absent, reagents should be handled with maximum attention.

**CERTIFICATE OF ANALYSIS**

KIT: TOSCANA VIRUS IgG-IgM Code 91067
LOT: 092
DATE OF TEST: 22/03/2024

METHOD: ACCORDING TO THE PACKAGE INSERT

		FOUND	EXPECTED
1. CONTROL OF COMPLETE KIT IgG			
A) Blank		0.044	<0,100
B) Average OD of Negative Control		0.007	≤0.6xCut-off
C) Average OD of Cut-off Control		0.430	≥0.200
D) Average OD of Positive Control		1.650	≥1,5 x Cut-off
E) HOMOGENEITY OF CUT-OFF	No.	6	
	OD 450 nm	0.474	
	CV%	15%	≤15%

2. CONTROL OF COMPLETE KIT IgM

A) Blank	0.048	≤0.100
B) Average OD of Negative Control	0.023	≤0.150
C) Calculation of Cut-off (OD Negative control +250)	0.273	≥0.200

3. PRECISION OF FILLING PROCESS

☒ SATISFACTORY ☐ UNSATISFACTORY

FINAL RESULT: **ACCEPTED**

Date: 22-03-2024

Signed: 
Released: Q.C.Manager