

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 090

EXPIRY 2024-06

REAGENTS

LABEL	DESCRIPTION	LOT No.	EXP	No
PF92001	005260 STRIPS IgG	104	2024-09	3
PF93000	005280 STRIPS IgM	668	2024-06	3
PF92006	005270 IgG CONJUGATE	083	2024-08	2
PF92007	005290 IgM CONJUGATE	084	2024-08	2
PF92002	005220 POSITIVE CONTROL IgG	079	2024-11	1
PF93910	005240 NEGATIVE CONTROL IgG/IgM	176	2024-11	2
PF92004	005200 CUT-OFF IgG	080	2024-11	1
PF92008	005230 ANTIGEN	075	2025-01	6
PF93621	006030 DILUENT 10	163	2024-06	1
PF93603	1035 WASHING BUFFER 10x	458	2024-09	1
PF93619	1034 SUBSTRATO	375-1	2024-09	1
PF93602	1032/RISK0 STOP SOLUTION	215-7	2024-08	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
- IgG		
Neg. Control	0.004	$\leq 0,6 \times \text{Cut-off}$
Cut-off Control	0.372	$\geq 0,200$
Positive Control	2.300	$\geq 1,5 \times \text{Cut-off}$
CV%	4%	$\leq 15\%$
- IgM		
Neg. Control	0.013	$< 0,150$

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

TESTED BY: Baiocchi Simone

APPROVED BY: (RESPONSIBLE HEAD, Quality Control Reagents)

DATE 05.07.2023

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.