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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 089

EXPIRY 2024-01

REAGENTS

LABEL	DESCRIPTION	LOT No.	EXP	No
PF92001	005260 STRIPS IgG	102	2024-04	3
PF93000	005280 STRIPS IgM	666	2024-04	3
PF92006	005270 IgG CONJUGATE	082	2024-02	2
PF92007	005290 IgM CONJUGATE	083	2024-02	2
PF92002	005220 POSITIVE CONTROL IgG	078	2024-05	1
PF93910	005240 NEGATIVE CONTROL IgG/IgM	174	2024-02	2
PF92004	005200 CUT-OFF IgG	079	2024-05	1
PF92008	005230 ANTIGEN	075	2024-01	6
PF93621	006030 DILUENT 10	162	2024-04	1
PF93603	1035 WASHING BUFFER 10x	452	2024-02	1
PF93619	1034 SUBSTRATO	368	2024-04	1
PF93602	1032/RISK0 STOP SOLUTION	215-1	2024-08	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
- IgG		
Neg. Control	0.001	$\leq 0,6 \times \text{Cut-off}$
Cut-off Control	0.394	$\geq 0,200$
Positive Control	2.089	$\geq 1,5 \times \text{Cut-off}$
CV%	4%	$\leq 15\%$
- IgM		
Neg. Control	0.007	$< 0,150$

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

TESTED BY: Katia Tanzini

APPROVED BY: (RESPONSIBLE HEAD, Quality Control Reagents)

DATE 29.11.2022

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: **089**
DATE OF TEST: **25/11/2022**

METHOD: ACCORDING TO THE PACKAGE INSERT

	<i>FOUND</i>	<i>EXPECTED</i>
1. CONTROL OF COMPLETE KIT IgG		
A) Blank	0.052	<0,100
B) Average OD of Negative Control	0.001	$\leq 0.6 \times \text{Cut-off}$
C) Average OD of Cut-off Control	0.394	≥ 0.200
D) Average OD of Positive Control	2.089	$\geq 1,5 \times \text{Cut-off}$

E) HOMOGENEITY OF CUT-OFF	No.	6	
	OD 450 nm	0.445	
	CV%	4%	$\leq 15\%$

2. CONTROL OF COMPLETE KIT IgM

A) Blank	0.051	≤ 0.100
B) Average OD of Negative Control	0.007	≤ 0.150
C) Calculation of Cut-off (OD Negative control +250)	0.257	≥ 0.200

3. PRECISION OF FILLING PROCESS

☒ SATISFACTORY ☐ UNSATISFACTORY

FINAL RESULT: **ACCEPTED**

Date: 26/11/2022

Signed: 
Released: Q.C.Manager