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

QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL VARICELLA ZOSTER IgM

Code	91079		
LOT.NO	149-C	2023-09	2022-07

REAGENTS					
CODE	LABEL	DESCRIPTION	LOT No.	EXP	No
PF93000	007060	MICROPLATE STRIPS	662	2023-09	48 det.
PF91585	007070	CONJUGATE	140	2023-10	1
PF93900/VZC	C5310	NEGATIVE CONTROL	752	2024-01	1
PF92385	006930	POSITIVE CONTROL	127	2024-01	1
PF91985	006920	CUT-OFF CONTROL	137	2024-01	1
PF91685	006950	ANTIGEN (mL 3.0)	116	2025-06	3
PF93611	009660	DILUENT 2	224-1	2023-10	1
PF93603	1035	WASHING BUFFER 10x	451-2	2024-01	1
PF93602	1032/RISK0	STOP SOLUTION	215	2024-08	1
PF93619	1034	SUBSTRATE-HS	365-1	2023-11	1

CONTROLS

FOUND RESULTS		EXPECTED RESULTS
NEGATIVE CONTROL	0.064	< 0,6 CUT-OFF
CUT-OFF CONTROL	0.378	≥ 0.200
POSITIVE CONTROL	2.056	> 1,5 CUT-OFF
CV %	8%	≤ 15%

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

TESTED BY: Katia Tanzini

APPROVED BY: RESPONSIBLE HEAD, Quality Control Reagents

DATE

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: VARICELLA IgM Code 91079
 LOT: 149 Code 91089
 DATE OF TEST: 04/08/2022

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE			FOUND	EXPECTED
A) UNIFORMITY BETWEEN PLATES				
1st PLATE	OD 450 nm		1.908	
	CV%		7%	<20%
2nd PLATE	OD 450 nm		1.884	
	CV%		3%	<20%
B) UNIFORMITY WITHIN PLATE				
	OD 450 nm		1.915	
	CV%		6%	<15%
2. BULK CONTROL date: 26/07/2022				
A) Average OD of Cut Off Control	OD 450 nm		0.389	≥ 0.200
B) Index of Negative and Positive Sera			accepted	According to specification
C) Sensitivity with working calibrators			accepted	According to specification
3. FINAL CONTROL date: 04/08/2022				
A) Blank	OD 450 nm		0.054	≤ 0.100
B) Average OD of Negative Control	OD 450 nm		0.064	< 0,6 Cut Off
C) Average OD of Cut Off Control	OD 450 nm		0.378	≥ 0.200
D) Average OD of Positive Control	OD 450 nm		2.056	> 1,5 Cut Off
E) HOMOGENEITY OF CUT-OFF	No.		8	
	OD 450 nm		0.432	
	CV%		8%	≤15%
F) PRECISION OF FILLING PROCESS				

☒ SATISFACTORY ☐ UNSATISFACTORY

FINAL RESULT: **ACCEPTED**

Date: 04.08.2022

Signed: 
 Released: Q.C.Manager