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Sede Legale e Amministrazione
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QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL VARICELLA ZOSTER IgM

Code 91079

LOT.NO

154



2025-03



2023-12

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93000	007060	MICROPLATE STRIPS	673	2025-05	48 det.
PF91585	007070	CONJUGATE	144	2025-03	1
PF93900/VZC	C5310	NEGATIVE CONTROL	811	2025-06	1
PF92385	006930	POSITIVE CONTROL	131	2025-06	1
PF91985	006920	CUT OFF CONTROL	141	2025-06	1
PF91685	006950	ANTIGEN (3 mL)	120	2026-03	3
PF93611	009660	DILUENT 2	232	2025-05	1
PF93603	1035	WASHING BUFFER 10x	468	2025-06	1
PF93602	1032/RISK0	STOP SOLUTION	218-6	2025-06	1
PF93619	1034	SUBSTRATE-HS	381-1	2025-04	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.042	< 0,6 Cut Off
CUT OFF CONTROL	0.324	≥ 0.200
POSITIVE CONTROL	1.771	> 1,5 Cut Off
CV %	5%	≤ 15%

*Evaluation of the method according to the package inset in the attached document
This batch has been manufactured and checked according to quality requirements.
Hereby, it is released to distribution.*

APPROVED BY: RESPONSIBLE HEAD, Quality Control Reagents

DATE: 11.01.2024

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 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.

IO 09 - 313-V



CODE 91079

CODE 91089

QUALITY CONTROL CERTIFICATE

Annex: Method Evaluation

NAME KIT VARICELLA IgM

LOT. 154

DATE OF TEST 09/01/2024

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE	FOUND		EXPECTED
A) UNIFORMITY BETWEEN PLATES			
1st PLATE	OD 450 nm	2.715	
	CV%	15%	<20%
2nd PLATE	OD 450 nm	2.817	
	CV%	8/%	<20%
B) UNIFORMITY WITHIN PLATE			
	OD 450 nm	2.707	
	CV%	7%	<15%
2. BULK CONTROL date: 22/12/2023			
A) Average OD of Cut Off Control	OD 450 nm	0.372	≥ 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: 09/01/2024			
A) Blank	OD 450 nm	0.051	≤ 0.100
B) Average OD of Negative Control	OD 450 nm	0.042	< 0,6 Cut Off
C) Average OD of Cut Off Control	OD 450 nm	0.324	≥ 0.200
D) Average OD of Positive Control	OD 450 nm	1.771	> 1,5 Cut Off
E) HOMOGENEITY OF CUT-OFF	No.	6	
	OD 450 nm	0.374	
	CV%	5%	≤15%
F) PRECISION OF FILLING PROCESS			

☒ SATISFACTORY

☐ UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 09.01.2024

Signed:

Released: Q.C. Manager