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Sede Legale e Amministrazione
20144 Milano (Italy) Via A. Solari 19 sc. 6

QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL VARICELLA ZOSTER IgM

Code 91079

LOT.NO 153



2024-10



2023-09

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93000	007060	MICROPLATE STRIPS	669	2024-10	48 det.
PF91585	007070	CONJUGATE	143	2024-12	1
PF93900/VZC	C5310	NEGATIVE CONTROL	800	2025-03	1
PF92385	006930	POSITIVE CONTROL	130	2025-03	1
PF91985	006920	CUT OFF CONTROL	140	2025-03	1
PF91685	006950	ANTIGEN (3 mL)	119	2026-03	3
PF93611	009660	DILUENT 2	231	2025-03	1
PF93603	1035	WASHING BUFFER 10x	459	2024-10	1
PF93602	1032/RISK0	STOP SOLUTION	218-3	2025-06	1
PF93619	1034	SUBSTRATE-HS	380	2025-03	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.059	< 0,6 Cut Off
CUT OFF CONTROL	0.457	≥ 0.200
POSITIVE CONTROL	1.970	> 1,5 Cut Off
CV %	9%	≤ 15%

*Evaluatin 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:

18.10.2023

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 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. 153
DATE OF TEST 16/10/2023

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE	FOUND		EXPECTED
A) UNIFORMITY BETWEEN PLATES			
1st PLATE	OD 450 nm	1.566	
	CV%	11%	<20%
2nd PLATE	OD 450 nm	N/A	
	CV%	N/A	<20%
B) UNIFORMITY WITHIN PLATE			
	OD 450 nm	1.693	
	CV%	11%	<15%
2. BULK CONTROL date: 05/10/2023			
A) Average OD of Cut Off Control	OD 450 nm	0.407	≥ 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: 16/10/2023			
A) Blank	OD 450 nm	0.045	≤ 0.100
B) Average OD of Negative Control	OD 450 nm	0.059	< 0,6 Cut Off
C) Average OD of Cut Off Control	OD 450 nm	0.457	≥ 0.200
D) Average OD of Positive Control	OD 450 nm	1.970	> 1,5 Cut Off
E) HOMOGENEITY OF CUT-OFF	No.	8	
	OD 450 nm	0.501	
	CV%	9%	≤15%
F) PRECISION OF FILLING PROCESS			



SATISFACTORY



UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 16.10.2023

Signed:

Released: Q.C.Manager