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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	152-B	2024-06	2023-03

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93000	007060	MICROPLATE STRIPS	668	2024-06	48 det.
PF91585	007070	CONJUGATE	142-1	2024-06	1
PF93900/VZC	C5310	NEGATIVE CONTROL	788-2	2024-09	1
PF92385	006930	POSITIVE CONTROL	129-2	2024-09	1
PF91985	006920	CUT OFF CONTROL	139-2	2024-09	1
PF91685	006950	ANTIGEN (3 mL)	119	2026-03	3
PF93611	009660	DILUENT 2	229	2024-09	1
PF93603	1035	WASHING BUFFER 10x	457-1	2024-08	1
PF93602	1032/RISK0	STOP SOLUTION	215-5	2024-08	1
PF93619	1034	SUBSTRATE-HS	375	2024-09	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.041	< 0,6 Cut Off
CUT OFF CONTROL	0.335	≥ 0.200
POSITIVE CONTROL	2.084	> 1,5 Cut Off
CV %	7%	≤ 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: 15.06.2023

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.	152
DATE OF TEST	23/03/2023

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE	FOUND	EXPECTED
A) UNIFORMITY BETWEEN PLATES		
1st PLATE	OD 450 nm 2.086 CV% 7%	<20%
2nd PLATE	OD 450 nm 1.841 CV% 5%	<20%
B) UNIFORMITY WITHIN PLATE		
	OD 450 nm 2.041 CV% 8%	<15%
2. BULK CONTROL date: 17/03/2023		
A) Average OD of Cut Off Control	OD 450 nm 0.370	≥ 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: 23/03/2023		
A) Blank	OD 450 nm 0.043	≤ 0.100
B) Average OD of Negative Control	OD 450 nm 0.034	< 0,6 Cut Off
C) Average OD of Cut Off Control	OD 450 nm 0.364	≥ 0.200
D) Average OD of Positive Control	OD 450 nm 2.225	> 1,5 Cut Off
E) HOMOGENEITY OF CUT-OFF	No. 6 OD 450 nm 0.406 CV% 9%	≤15%
F) PRECISION OF FILLING PROCESS		



SATISFACTORY



UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 23.03.2023

Signed: *[Signature]*
Released: Q.C.Manager