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DIESSE

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

QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL VARICELLA ZOSTER IgG

Code	91078				
LOT.NO	136-A		2024-06		2023-03

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93230	006910	MICROPLATE STRIPS	139	2024-11	48 det.
PF93563	007080	CONJUGATE	131	2024-06	1
PF93910	1036	NEGATIVE CONTROL	175-2	2024-06	1
PF92085	006880	POSITIVE CONTROL	119-1	2024-09	1
PF91885	006870	CUT OFF CONTROL	121-1	2024-09	1
PF93619	1034	SUBSTRATE-HS	375-1	2024-09	1
PF93611	009660	DILUENT 2	228	2024-07	1
PF93603	1035	WASHING BUFFER 10x	457-1	2024-08	1
PF93602	1032/RISK0	STOP SOLUTION	215-7	2024-08	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.021	≤ 0,6 Cut Off
CUT OFF CONTROL	0.451	≥ 0.200
POSITIVE CONTROL	1.798	≥ 1,5 Cut Off
CV %	4%	≤ 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: 06.07.2023

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.

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DIESSE

CODE 91078
CODE 91088

QUALITY CONTROL CERTIFICATE

Annex: Method Evalution

NAME KIT	VARIGELLA IgG
LOT.	136
DATE OF TEST	06/04/2023

METHOD: ACCORDING TO THE PACKAGE INSERT

	FOUND		EXPECTED
1. SOLID PHASE			
A) UNIFORMITY BETWEEN PLATES			
1st PLATE	OD450 nm	2.098	
	CV%	4%	<20%
2nd PLATE	OD 450nm	1.908	
	CV%	4%	<20%
B) UNIFORMITY WITHIN PLATE			
	OD 450 nm	2.049	
	CV%	5%	< 15%
2. BULK CONTROL date: 31/03/2023			
A) Average OD of Cut Off Control	OD 450 nm	0.420	≥ 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: 06/04/2023			
A) Blank	OD 450 nm	0.046	≤ 0.100
B) Average OD of Negative Control	OD 450 nm	0.024	≤ 0,6 Cut Off
C) Average OD of Cut Off Control	OD 450 nm	0.418	≥ 0.200
D) Average OD of Positive Control	OD 450 nm	1.747	≥ 1,5 Cut Off
E) HOMOGENEITY OF CUT OFF	No.	6	
	OD 450 nm	0.464	
	CV%	3%	≤ 15%
F) PRECISION OF FILLING PROCESS			

[X] SATISFACTORY [ ] UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 06 04 23

Signed:

Released: Q.C.Manager