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

QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL VARICELLA ZOSTER IgG

Code 91078

LOT.NO 132-A

EXPIRY 2023-10

REAGENTS

CODE	LABEL	DESCRIPTION	LOT No.	EXP	No
PF93230	006910	MICROPLATE STRIPS	137	2024-06	48 det.
PF93563	007080	CONJUGATE	128	2023-10	1
PF93910	1036	NEGATIVE CONTROL	173-1	2023-11	1
PF92085	006880	POSITIVE CONTROL	116	2024-01	1
PF91885	006870	CUT-OFF CONTROL	117	2024-01	1
PF93619	1034	SUBSTRATE-HS	364-1	2023-11	1
PF93611	009660	DILUENT 2	224	2023-10	1
PF93603	1035	WASHING BUFFER 10x	450-1	2023-11	1
PF93602	1032/RISK0	STOP SOLUTION	214-3	2024-02	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.040	$\leq 0,6$ CUT-OFF
CUT-OFF CONTROL	0.402	≥ 0.200
POSITIVE CONTROL	1.941	$\geq 1,5$ CUT-OFF
CV %	9%	$\leq 15\%$

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

TESTED BY: Simone Baiocchi

Simone Baiocchi

APPROVED BY: (RESPONSIBLE HEAD, Quality Control Reagents)

Alvise

DATE: 11/08/2022

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 IgG**
LOT: **132**
DATE OF TEST: **09/08/2022**

Code 91078
91088

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE		FOUND	EXPECTED
A) UNIFORMITY BETWEEN PLATES			
1st PLATE	OD450 nm	1.412	
	CV%	5%	<20%
B) UNIFORMITY WITHIN PLATE			
	OD 450nm	1.422	
	CV%	5%	≤15%
2. CONTROL OF COMPLETE KIT			
A) OD 450 nm Substrate Blank		0.050	≤0,100
OD 450 nm Negative Control		0.040	(≤ 0.6xCut-off)
OD 450 nm Cut-off Control		0.402	>0.200
OD 450 nm Positive Control		1.941	(≥ 1,5 x Cut-off)
B) PANEL OF HUMAN SERA			
Average OD of Negative Sera		Accepted	< Cut-off
Average OD of Positive Sera		Accepted	> Cut-off
C) HOMOGENEITY OF CUT-OFF	No.	6	
	OD 450 nm	0.452	
	CV%	9%	≤15%
D) PRECISION OF FILLING PROCESS			

☒ SATISFACTORY ☐ UNSATISFACTORY

FINAL RESULT: **ACCEPTED**

Date: 09/08/2022

Signed:

Released: Q.C.Manager

Aggiornamento 07.2012