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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 134-A

EXPIRY 2024-03

REAGENTS

CODE	LABEL	DESCRIPTION	LOT No.	EXP	No
PF93230	006910	MICROPLATE STRIPS	139	2024-11	48 det.
PF93563	007080	CONJUGATE	130	2024-03	1
PF93910	1036	NEGATIVE CONTROL	175	2024-06	1
PF92085	006880	POSITIVE CONTROL	118	2024-06	1
PF91885	006870	CUT-OFF CONTROL	119	2024-06	1
PF93619	1034	SUBSTRATE-HS	368	2024-04	1
PF93611	009660	DILUENT 2	226	2024-04	1
PF93603	1035	WASHING BUFFER 10x	453	2024-04	1
PF93602	1032/RISK0	STOP SOLUTION	215-1	2024-08	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.034	$\leq 0,6$ CUT-OFF
CUT-OFF CONTROL	0.392	≥ 0.200
POSITIVE CONTROL	1.690	$\geq 1,5$ CUT-OFF
CV %	13%	$\leq 15\%$

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

TESTED BY: Silvia Sardelli

APPROVED BY: (RESPONSIBLE HEAD, Quality Control Reagents)

DATE: 08.02.2023

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 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** Code **91078**
 LOT: **134** 91088
 DATE OF TEST: **01/02/2023**

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE		<i>FOUND</i>	<i>EXPECTED</i>
A) UNIFORMITY BETWEEN PLATES			
1st PLATE	OD450 nm	2.098	
	CV%	4%	<20%
B) UNIFORMITY WITHIN PLATE			
	OD 450nm	2.049	
	CV%	5%	≤15%
2. CONTROL OF COMPLETE KIT			
A) OD 450 nm Substrate Blank		0.047	≤0,100
OD 450 nm Negative Control		0.034	(≤ 0.6xCut-off)
OD 450 nm Cut-off Control		0.392	>0.200
OD 450 nm Positive Control		1.690	(≥ 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	0.439	
	CV%	13%	≤15%
D) PRECISION OF FILLING PROCESS			

☒ **X**

SATISFACTORY

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FINAL RESULT: **ACCEPTED**

Date: **01.02.2023**

Signed:

Released: Q.C.Manager

Aggiornamento 07.2012