

DIESSE DIAGNOSTICA SENESE SpA
53035 Monteriggioni (SI), Italy, Strada dei Laghi 39
Tel. +39 0577319554 FAX +39 0577319020



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	139	 2025-05	 2024-03

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93230	006910	MICROPLATE STRIPS	142	2025-09	48 det.
PF93563	007080	CONJUGATE	134	2025-06	1
PF93910	1036	NEGATIVE CONTROL	179	2025-06	1
PF92085	006880	POSITIVE CONTROL	122	2025-09	1
PF91885	006870	CUT OFF CONTROL	124	2025-09	1
PF93619	1034	SUBSTRATE-HS	383	2025-05	1
PF93611	009660	DILUENT 2	233	2025-07	1
PF93603	1035	WASHING BUFFER 10x	468	2025-06	1
PF93602	1032/RISK0	STOP SOLUTION	218-6	2025-06	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.095	$\leq 0,6$ Cut Off
CUT OFF CONTROL	0.400	≥ 0.200
POSITIVE CONTROL	1.387	$\geq 1,5$ Cut Off
CV %	14%	$\leq 15\%$

*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:

19.06.2024

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 - 310-V



CODE 91078

CODE 91088

QUALITY CONTROL CERTIFICATE

Annex: Method Evaluation

NAME KIT VARIGELLA IgG

LOT. 139

DATE OF TEST 10/04/2024

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE	FOUND	EXPECTED
A) UNIFORMITY BETWEEN PLATES		
1st PLATE	OD450 nm 1.599	
	CV% 6%	<20%
2nd PLATE	OD 450nm N/A	
	CV% N/A	<20%
B) UNIFORMITY WITHIN PLATE		
	OD 450 nm 1.632	
	CV% 8%	< 15%
2. BULK CONTROL date: 03/04/2024		
A) Average OD of Cut Off Control	OD 450 nm 0.448	≥ 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: 10/04/2024		
A) Blank	OD 450 nm 0.045	≤ 0.100
B) Average OD of Negative Control	OD 450 nm 0.095	≤ 0,6 Cut Off
C) Average OD of Cut Off Control	OD 450 nm 0.400	≥ 0.200
D) Average OD of Positive Control	OD 450 nm 1.387	≥ 1,5 Cut Off
E) HOMOGENEITY OF CUT OFF	No. 6	
	OD 450 nm 0.445	
	CV% 14%	≤ 15%
F) PRECISION OF FILLING PROCESS		



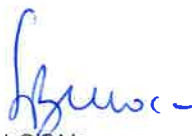
SATISFACTORY



UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 10.04.2024

Signed: 
Released: Q.C. Manager