

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 MEASLES IgG

Code 91072

LOT.NO 129



2025-01



2023-10

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93220	007440	MICROPLATE STRIPS	119	2025-04	48 det.
PF93562	007450	CONJUGATE	120	2025-01	1
PF93910	1036	NEGATIVE CONTROL	177-2	2025-03	1
PF92075	008070	POSITIVE CONTROL	110	2025-04	1
PF91875	008050	CUT OFF CONTROL	120	2025-04	1
PF93619	1034	SUBSTRATE-HS	380	2025-03	1
PF93611	009660	DILUENT 2	231	2025-03	1
PF93603	1035	WASHING BUFFER 10x	464	2025-04	1
PF93602	1032/RISK0	STOP SOLUTION	218-5	2025-06	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.028	$\leq 0,6$ Cut Off
CUT OFF CONTROL	0.464	≥ 0.200
POSITIVE CONTROL	1.720	$\geq 1,5$ Cut Off
CV%	9%	$\leq 15\%$

*Evaluation 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: 07.11.2023

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 - 307-V



CODE 91072

CODE 91080

QUALITY CONTROL CERTIFICATE

Annex: Method Evaluation

NAME KIT MEASLES IgG
LOT. 129
DATE OF TEST 31/10/2023

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE	FOUND		EXPECTED
A) UNIFORMITY BETWEEN PLATES			
1st PLATE	OD 450 nm	2.419	
	CV%	9%	< 20%
2nd PLATE	OD 450 nm	N/A	
	CV%	N/A	< 20%
B) UNIFORMITY WITHIN PLATE			
	OD 450 nm	2.187	
	CV%	12%	< 15%
2. BULK CONTROL date: 26/10/2023			
A) Average OD of Cut Off Control	OD 450 nm	0.438	≥ 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: 31/10/2023			
A) Blank	OD 450 nm	0.047	≤ 0.100
B) Average OD of Negative Control	OD 450 nm	0.028	≤ 0,6 Cut Off
C) Average OD of Cut Off Control	OD 450 nm	0.464	≥ 0.200
D) Average OD of Positive Control	OD 450 nm	1.720	≥ 1,5 Cut Off
E) HOMOGENEITY OF CUT OFF			
	No.	5	
	OD 450 nm	0.511	
	CV%	9%	≤ 15%
F) PRECISION OF FILLING PROCESS			

☒ SATISFACTORY

☐ UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 31.10.2023

Signed:

Released: Q.C.Manager