

DIESSE DIAGNOSTICA SENESE SpA
53035 Monteriggioni (SIENA) – 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 MUMPS IgM

Code 91076

LOT.NO 154-D EXPIRY 2023-12

REAGENTS

CODE	LABEL	DESCRIPTION	LOT No.	EXP	No
PF93000	007680	MICROPLATE STRIPS	664	2023-12	48 det.
PF91565	007690	CONJUGATE	147	2024-01	1
PF93900/MPM	C5290	NEGATIVE CONTROL	768	2024-04	1
PF92365	007710	POSITIVE CONTROL	129	2024-04	1
PF91965	007700	CUT-OFF CONTROL	138	2024-04	1
PF91665	007730	ANTIGEN	117	2024-11	3
PF93611	009660	DILUENT 2	226	2024-04	1
PF93603	1035	WASHINGBUFFER 10x	452	2024-02	1
PF93602	1032/RISK0	STOP SOLUTION	215-1	2024-08	1
PF93619	1034	SUBSTRATE-HS	368	2024-04	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.126	< 0,6 CUT-OFF
CUT-OFF CONTROL	0.297	≥ 0.200
POSITIVE CONTROL	1.994	> 1,5 CUT-OFF
CV %	9%	≤ 15%

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

TESTED BY: Katia Tanzini

APPROVED BY: RESPONSIBLE HEAD, Quality Control Reagents

DATE: 12.01.2023

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:	MUMPS IgM	Code 91076
LOT:	154	91085
DATE OF TEST:	21/10/2022	

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE	<i>FOUND</i>	<i>EXPECTED</i>
A) UNIFORMITY BETWEEN PLATES		
1st PLATE	OD450 nm	1.521
	CV%	12% <20%
2nd PLATE	OD 450nm	1.529
	CV%	9% <20%
B) UNIFORMITY WITHIN PLATE		
	OD 450nm	1.763
	CV%	12% ≤15%
2. CONTROL OF COMPLETE KIT		
A) OD 450 nm Substrate Blank	0.064	≤0,100
OD 450 nm Negative Control	0.126	(≤ 0.6xCut-off)
OD 450 nm Cut-off Control	0.297	>0.200
OD 450 nm Positive Control	1.994	(≥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.	10	
OD 450 nm	0.361	
CV%	9%	≤ 15%
D) PRECISION OF FILLING PROCESS		

☒ SATISFACTORY

☐ UNSATISFACTORY

FINAL RESULT: **ACCEPTED**

Date: 29.10.2022

Signed: 
Released: Q.C.Manager

Aggiornamento 11.2008