



CERTIFICATE OF ANALYSIS

KIT: MUMPS IgM Code 91076
 LOT: 153 91085
 DATE OF TEST: 29/06/222

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE		<i>FOUND</i>	<i>EXPECTED</i>
A) UNIFORMITY BETWEEN PLATES			
1st PLATE	OD450 nm	1.908	
	CV%	7%	<20%
2nd PLATE	OD 450nm	1.884	
	CV%	3%	<20%
B) UNIFORMITY WITHIN PLATE			
	OD 450nm	1.915	
	CV%	6%	≤15%
2. CONTROL OF COMPLETE KIT			
A) OD 450 nm Substrate Blank		0.046	≤0,100
OD 450 nm Negative Control		0.103	(≤ 0.6xCut-off)
OD 450 nm Cut-off Control		0.353	>0.200
OD 450 nm Positive Control		2.326	(≥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	0.399	
	CV%	10%	≤ 15%

D) PRECISION OF FILLING PROCESS

☒ SATISFACTORY

☐ UNSATISFACTORY

FINAL RESULT: **ACCEPTED**

Date: 30.06.22

Signed:
 Released: Q.C.Manager

Aggiornamento 11.2008

DIESSE DIAGNOSTICA SENESE SpA
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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 153-C EXPIRY 2023-09

REAGENTS

CODE	LABEL	DESCRIPTION	LOT No.	EXP	No
PF93000	007680	MICROPLATE STRIPS	662	2023-09	48 det.
PF91565	007690	CONJUGATE	146	2023-09	1
PF93900/MPM	C5290	NEGATIVE CONTROL	749	2023-12	1
PF92365	007710	POSITIVE CONTROL	128	2023-12	1
PF91965	007700	CUT-OFF CONTROL	137	2023-12	1
PF91665	007730	ANTIGEN	117	2024-11	3
PF93611	009660	DILUENT 2	224-1	2023-10	1
PF93603	1035	WASHINGBUFFER 10x	451-2	2024-01	1
PF93602	1032/RISK0	STOP SOLUTION	215	2024-08	1
PF93619	1034	SUBSTRATE-HS	365-1	2023-11	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.103	< 0,6 CUT-OFF
CUT-OFF CONTROL	0.353	≥ 0.200
POSITIVE CONTROL	2.326	> 1,5 CUT-OFF
CV %	10%	≤ 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: 23.09.2022

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.