

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 IgG

Code 91075

LOT.NO 119 EXPIRY 2023-07

REAGENTS

CODE	LABEL	DESCRIPTION	LOT No.	EXP	NO
PF93210	007600	MICROPLATE STRIPS	149	2023-09	48 det.
PF93561	007610	CONJUGATE	111	2023-07	1
PF93910	1036	NEGATIVE CONTROL	172-3	2023-08	1
PF92065	007630	POSITIVE CONTROL	101	2023-10	1
PF91865	007620	CUT-OFF CONTROL	110	2023-10	1
PF93619	1034	SUBSTRATE-HS	361	2023-07	1
PF93611	009660	DILUENT 2	223	2023-08	1
PF93603	1035	WASHING BUFFER 10x	448-1	2023-10	1
PF93602	1032/RISK0	STOP SOLUTION	214-1	2024-02	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.018	$\leq 0,6$ CUT-OFF
CUT-OFF CONTROL	0.486	≥ 0.200
POSITIVE CONTROL	2.088	$\geq 1,5$ CUT-OFF
CV %	3%	$\leq 15\%$

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

TESTED BY: Katia Tanzini

APPROVED BY: RESPONSIBLE HEAD, Quality Control Reagents

DATE 11.05.2022

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.

**CERTIFICATE OF ANALYSIS**

KIT: MUMPS IgG Code 91075
LOT: 119 91084
DATE OF TEST: 04/05/2022

METHOD: ACCORDING TO THE PACKAGE INSERT

FOUND **EXPECTED**

1. CONTROL OF COMPLETE KIT

A) OD 450 nm Substrate Blank	0.039	≤ 0.100
OD 450 nm Negative Control	0.018	$(\leq 0.6 \times \text{Cut-off})$
OD 450 nm Cut-off Control	0.486	> 0.200
OD 450 nm Positive Control	2.088	$(\geq 1.5 \times \text{Cut-off})$

B) PANEL OF HUMAN SERA		
Average OD of Negative Sera	accepted	$< \text{Cut-off}$
Average OD of Positive Sera	accepted	$> \text{Cut-off}$

C) HOMOGENEITY OF CUT-OFF	No.	6	
	OD 450 nm	0.525	
	CV%	3%	$\leq 15\%$

FINAL RESULT: ACCEPTED

Date: 04.05.22

Signed: 
Released: Q.C. Manager

Aggiornamento 11.2008