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Sede Legale e Amministrazione
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Pag 1/1

QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL MUMPS IgM

Code 91076

LOT.NO 162-A



2025-06



2024-05

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93000	007680	MICROPLATE STRIPS	673	2025-12	48 det.
PF91565	007690	CONJUGATE	154-1	2025-07	1
PF93900/MPM	C5290	NEGATIVE CONTROL	822-1	2025-10	1
PF92365	007710	POSITIVE CONTROL	136-1	2025-10	1
PF91965	007700	CUT OFF CONTROL	145-1	2025-10	1
PF91665	007730	ANTIGEN	118	2025-12	3
PF93611	009660	DILUENT 2	233	2025-07	1
PF93603	1035	WASHINGBUFFER 10x	473	2025-08	1
PF93602	1032/RISKO	STOP SOLUTION	218-6	2025-06	1
PF93619	1034	SUBSTRATE-HS	385	2025-08	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.060	< 0,6 Cut Off
CUT OFF CONTROL	0.390	≥ 0.200
POSITIVE CONTROL	2.261	> 1,5 Cut Off
CV %	11%	≤ 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:

05.06.2024

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 - 305-V



CODE 91076

CODE 91085

QUALITY CONTROL CERTIFICATE

Annex: Method Evaluation

NAME KIT MUMPS IgM
LOT. 162
DATE OF TEST 15/05/2024

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE	FOUND		EXPECTED
A) UNIFORMITY BETWEEN PLATES			
1st PLATE	OD 450 nm	2.715	
	CV%	15%	< 20%
2nd PLATE	OD 450 nm	2.817	
	CV%	8%	< 20%
B) UNIFORMITY WITHIN PLATE			
	OD 450 nm	2.707	
	CV%	7%	< 15%
2. BULK CONTROL date: 09/05/2024			
A) Average OD of Cut Off Control	OD 450 nm	0.403	≥ 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: 15/05/2024			
A) Blank	OD 450 nm	0.046	≤ 0.100
B) Average OD of Negative Control	OD 450 nm	0.058	< 0,6 Cut Off
C) Average OD of Cut Off Control	OD 450 nm	0.347	≥ 0.200
D) Average OD of Positive Control	OD 450 nm	1.853	> 1,5 Cut Off
E) HOMOGENEITY OF CUT OFF			
	No.	6	
	OD 450 nm	0.393	
	CV%	13%	≤ 15%
F) PRECISION OF FILLING PROCESS			



SATISFACTORY



UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 15.05.2024

Signed:

Released: Q.C.Manager