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Sede Legale e Amministrazione
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QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL MUMPS IgG

Code 91075

LOT.NO 123

 2024-08

 2023-08

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93210	007600	MICROPLATE STRIPS	153	2024-08	48 det.
PF93561	007610	CONJUGATE	115	2024-11	1
PF93910	1036	NEGATIVE CONTROL	176-1	2024-11	1
PF92065	007630	POSITIVE CONTROL	105	2025-02	1
PF91865	007620	CUT OFF CONTROL	114	2025-02	1
PF93619	1034	SUBSTRATE-HS	376-2	2024-10	1
PF93611	009660	DILUENT 2	229	2024-09	1
PF93603	1035	WASHING BUFFER 10x	457-1	2024-08	1
PF93602	1032/RISK0	STOP SOLUTION	218	2025-06	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.004	$\leq 0,6$ Cut Off
CUT OFF CONTROL	0.380	≥ 0.200
POSITIVE CONTROL	1.911	$\geq 1,5$ Cut Off
CV %	7%	$\leq 15\%$

*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: 19.09.2023

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 - 304-V



CODE 91075

CODE 91084

QUALITY CONTROL CERTIFICATE

Annex: Method Evaluation

NAME KIT MUMPS IgG
LOT. 123
DATE OF TEST 12/09/2023

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE	FOUND	EXPECTED
A) UNIFORMITY BETWEEN PLATES		
1st PLATE	OD 450 nm 1.700 CV% 4%	< 20%
2nd PLATE	OD 450 nm N/A CV% N/A	< 20%
B) UNIFORMITY WITHIN PLATE	OD 450 nm 1.658 CV% 6%	< 15%
2. BULK CONTROL date:05/09/2023		
A) Average OD of Cut Off Control	OD 450 nm 0.344	≥ 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:12/09/2023		
A) Blank	OD 450 nm 0.049	≤ 0.100
B) Average OD of Negative Control	OD 450 nm 0.004	≤ 0,6 Cut Off
C) Average OD of Cut Off Control	OD 450 nm 0.380	≥ 0.200
D) Average OD of Positive Control	OD 450 nm 1.911	≥ 1,5 Cut Off
E) HOMOGENEITY OF CUT OFF	No. 6 OD 450 nm 0.430 CV% 7%	≤ 15%
F) PRECISION OF FILLING PROCESS		



SATISFACTORY



UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date:

19.09.2023

Signed:

Released: Q.C.Manager