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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	156-C
	2024-04
	2023-01

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93000	007680	MICROPLATE STRIPS	666	2024-04	48 det.
PF91565	007690	CONJUGATE	149	2024-04	1
PF93900/MPM	C5290	NEGATIVE CONTROL	779-1	2024-07	1
PF92365	007710	POSITIVE CONTROL	131-1	2024-07	1
PF91965	007700	CUT OFF CONTROL	140-1	2024-07	1
PF91665	007730	ANTIGEN	118	2025-12	3
PF93611	009660	DILUENT 2	228-1	2024-07	1
PF93603	1035	WASHINGBUFFER 10x	457	2024-08	1
PF93602	1032/RISKO	STOP SOLUTION	215-3	2024-08	1
PF93619	1034	SUBSTRATE-HS	371	2024-06	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.076	< 0,6 Cut Off
CUT OFF CONTROL	0.316	≥ 0.200
POSITIVE CONTROL	1.909	> 1,5 Cut Off
CV %	5%	≤ 15%

Evaluation 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: 20.04.2023

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 - 305-V



CODE 91076

CODE 91085

QUALITY CONTROL CERTIFICATE

Annex: Method Evaluation

NAME KIT	MUMPS IgM
LOT.	156
DATE OF TEST	06/02/2022

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE	FOUND	EXPECTED
A) UNIFORMITY BETWEEN PLATES		
1st PLATE	OD 450 nm 1.799	
	CV% 4%	< 20%
2nd PLATE	OD 450 nm 1.772	
	CV% 6%	< 20%
B) UNIFORMITY WITHIN PLATE		
	OD 450 nm 1.792	
	CV% 7%	< 15%
2. BULK CONTROL date: 25/01/2023		
A) Average OD of Cut Off Control	OD 450 nm 0.339	≥ 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: 06/02/2023		
A) Blank	OD 450 nm 0.048	≤ 0.100
B) Average OD of Negative Control	OD 450 nm 0.076	< 0,6 Cut Off
C) Average OD of Cut Off Control	OD 450 nm 0.344	≥ 0.200
D) Average OD of Positive Control	OD 450 nm 2.186	> 1,5 Cut Off
E) HOMOGENEITY OF CUT OFF	No. 6	
	OD 450 nm 0.392	
	CV% 11%	≤ 15%
F) PRECISION OF FILLING PROCESS		

☒ SATISFACTORY

☐ UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 06.02.2023

Signed:

Released: Q.C.Manager