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Sede Legale e Amministrazione  
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### QUALITY CONTROL CERTIFICATE

**KIT NAME** ENZYWELL MUMPS IgM

Code	91076				
LOT.NO	160	2025-02	2023-11		

### REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93000	007680	MICROPLATE STRIPS	673	2025-05	48 det.
PF91565	007690	CONJUGATE	152	2025-02	1
PF93900/MPM	C5290	NEGATIVE CONTROL	806	2025-05	1
PF92365	007710	POSITIVE CONTROL	134	2025-05	1
PF91965	007700	CUT OFF CONTROL	143	2025-05	1
PF91665	007730	ANTIGEN	119-1	2026-02	3
PF93611	009660	DILUENT 2	232	2025-05	1
PF93603	1035	WASHINGBUFFER 10x	464	2025-04	1
PF93602	1032/RISKO	STOP SOLUTION	218-5	2025-06	1
PF93619	1034	SUBSTRATE-HS	380-1	2025-03	1

### CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.108	< 0,6 Cut Off
CUT OFF CONTROL	0.496	≥ 0.200
POSITIVE CONTROL	1.947	> 1,5 Cut Off
CV %	13%	≤ 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: 28.11.2023

### 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. 160  
DATE OF TEST 23/11/2023

#### 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:14/11/2023		
A) Average OD of Cut Off Control	OD 450 nm 0.381	≥ 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:23/11/2023		
A) Blank	OD 450 nm 0.047	≤ 0.100
B) Average OD of Negative Control	OD 450 nm 0.108	< 0,6 Cut Off
C) Average OD of Cut Off Control	OD 450 nm 0.496	≥ 0.200
D) Average OD of Positive Control	OD 450 nm 1.947	> 1,5 Cut Off
E) HOMOGENEITY OF CUT OFF	No. 7 OD 450 nm 0.543 CV% 13%	≤ 15%
F) PRECISION OF FILLING PROCESS		

SATISFACTORY

UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 23/11/2023

Signed:   
Released: Q.C.Manager