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Sede Legale e Amministrazione
Via A. Solari, 19 20144 Milano - Italy

QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL MEASLES IgM

Code 91073

LOT.NO 154 EXPIRY 2024-02

REAGENTS

CODE	LABEL	DESCRIPTION	LOT No.	EXP	No
PF93000	008090	MICROPLATE STRIPS	666	2024-04	48 det.
PF91575	008100	CONJUGATE	146	2024-02	1
PF93900/MVM	C5270	NEGATIVE CONTROL	771	2024-05	1
PF92375	008110	POSITIVE CONTROL	130	2024-05	1
PF91975	008120	CUT-OFF CONTROL	135	2024-05	1
PF91675	008140	ANTIGEN	117	2025-07	3
PF93611	009660	DILUENT 2	226	2024-04	1
PF93603	1035	WASHING BUFFER 10x	452	2024-02	1
PF93602	1032/RISK0	STOP SOLUTION	215-1	2024-08	1
PF93619	1034	SUBSTRATE-HS	368	2024-04	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.058	< 0,6 CUT-OFF
CUT-OFF CONTROL	0.350	≥ 0.200
POSITIVE CONTROL	1.429	> 1,5 CUT-OFF
CV %	5%	≤ 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: 12.02.23

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: MEASLES IgM Code 91073
 LOT: 154 91081
 DATE OF TEST: 03/01/2023

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE		FOUND	EXPECTED
A) UNIFORMITY BETWEEN PLATES			
1st PLATE	OD450 nm	1.799	
	CV%	4%	<20%
2nd PLATE	OD 450nm	1.772	
	CV%	6%	<20%
B) UNIFORMITY WITHIN PLATE			
	OD 450nm	1.792	
	CV%	7%	≤ 15%
2. CONTROL OF COMPLETE KIT			
A) OD 450 nm Substrate Blank		0.048	≤ 0,100
OD 450 nm Negative Control		0.058	(≤ 0.6xCut-off)
OD 450 nm Cut-off Control		0.350	>0.200
OD 450 nm Positive Control		1.429	(≥1,5 x Cut-off)
B) PANEL OF HUMAN SERA			
Average OD of Negative Sera		accepted	< Cut-off
Average OD of Positive Sera		accepted	> Cut-off
C) HOMOGENEITY OF CUT-OFF	No.	8	
	OD 450 nm	0.397	
	CV%	5%	≤ 15%

D) PRECISION OF FILLING PROCESS

SATISFACTORY



UNSATISFACTORY



FINAL RESULT: **ACCEPTED**

Signed:

Released: Q.C.Manager

Date: 09.01.2023