

QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL MEASLES IgM

Code	91073		
LOT.NO	159	2025-07	2024-05

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93000	008090	MICROPLATE STRIPS	676	2025-11	48 det.
PF91575	008100	CONJUGATE	151	2025-08	1
PF93900/MVM	C5270	NEGATIVE CONTROL	824	2025-11	1
PF92375	008110	POSITIVE CONTROL	135	2025-11	1
PF91975	008120	CUT OFF CONTROL	140	2025-11	1
PF91675	008140	ANTIGEN	119	2027-04	3
PF93611	009660	DILUENT 2	233	2025-07	1
PF93603	1035	WASHING BUFFER 10x	475	2025-11	1
PF93602	1032/RISKO	STOP SOLUTION	220	2026-03	1
PF93619	1034	SUBSTRATE-HS	385	2025-08	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.089	< 0,6 Cut Off
CUT OFF CONTROL	0.536	≥ 0.200
POSITIVE CONTROL	1.756	> 1,5 Cut Off
CV%	4%	≤ 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: 12.06.24

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 - 308-V



CODE 91073
CODE 91081

QUALITY CONTROL CERTIFICATE

Annex: Method Evaluation

NAME KIT MEASLES IgM
LOT. 159
DATE OF TEST 10/06/2024

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE	FOUND	EXPECTED
A) UNIFORMITY BETWEEN PLATES		
1st PLATE	OD 450 nm	2.454
	CV%	10% < 20%
2nd PLATE	OD 450 nm	2.644
	CV%	8% < 20%
B) UNIFORMITY WITHIN PLATE		
	OD 450 nm	2.617
	CV%	11% < 15%
2. BULK CONTROL date: 28/05/2024		
A) Average OD of Cut Off Control	OD 450 nm	0.523 ≥ 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: 10/06/2024		
A) Blank	OD 450 nm	0.045 ≤ 0.100
B) Average OD of Negative Control	OD 450 nm	0.089 < 0,6 Cut Off
C) Average OD of Cut Off Control	OD 450 nm	0.536 ≥ 0.200
D) Average OD of Positive Control	OD 450 nm	1.756 > 1,5 Cut Off
E) HOMOGENEITY OF CUT OFF	No.	6
	OD 450 nm	0.581
	CV%	4% ≤ 15%
F) PRECISION OF FILLING PROCESS		

SATISFACTORY

UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 10/06/2024

Signed:

Released: Q.C.Manager