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Sede Legale e Amministrazione
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QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL RUBELLA IgM

Code 91031

LOT.NO 291-B



2025-03



2024-01

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93031	006450	MICROPLATE	729	2025-03	1
PF91530	006440	CONJUGATE	204-1	2025-04	1
PF93900/RVM	C5060	NEGATIVE CONTROL	814-1	2025-07	1
PF92032	005430	POSITIVE CONTROL	193-1	2025-07	1
PF91831	005440	CUT OFF CONTROL	194-1	2025-07	1
PF91631	006460	ANTIGEN	195	2026-03	6
PF93611	009660	DILUENT 2	233	2025-07	1
PF93603	1035	WASHING BUFFER 10x	473	2025-08	1
PF93602	1032/RISK0	STOP SOLUTION	218-6	2025-06	1
PF93619	1034	SUBSTRATE-HS	383-1	2025-05	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.256	< 0,6 Cut Off
CUT OFF CONTROL	0.462	≥ 0.200
POSITIVE CONTROL	2.074	> 1,5 Cut Off
CV %	9%	≤ 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:

30.05.2024

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 - 011-V



CODE 91031
CODE 91177

QUALITY CONTROL CERTIFICATE

Annex: Method Evaluation

NAME KIT RUBELLA IgM
LOT. 291
DATE OF TEST 30/01/2024

METHOD: ACCORDING TO THE PACKAGE INSERT

	FOUND	EXPECTED
1. MICROPLATE CONTROL		
A) UNIFORMITY BETWEEN PLATES		
1st PLATE	OD 450 nm 2.017 CV% 2%	< 20%
2nd PLATE	OD 450 nm 2.012 CV% 4%	< 20%
B) UNIFORMITY WITHIN PLATE	OD 450 nm 1.896 CV% 4%	< 15%
2. BULK CONTROL date: 25/01/2024		
A) Average OD of Cut Off Control	OD 450 nm 0.393	≥ 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: 30/01/2024		
A) Blank	OD 450 nm 0.051	≤ 0.100
B) Average OD of Negative Control	OD 450 nm 0.168	< 0,6 Cut Off
C) Average OD of Cut Off Control	OD 450 nm 0.428	≥ 0.200
D) Average OD of Positive Control	OD 450 nm 2.034	> 1,5 Cut Off
E) HOMOGENEITY OF CUT-OFF	N° Replicate 6 OD 450 nm 0.480 CV% 14%	≤ 15%
F) PRECISION OF FILLING PROCESS		

☒ SATISFACTORY

☐ UNSATISFACTORY

FINAL RESULT: ACCEPTED
Date: 2.2.2024

Signed:
Released: Q.C. Manager