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Sede Legale e Amministrazione
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QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL RUBELLA IgM

Code 91031

LOT.NO 289-C



2024-06



2023-03

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93031	006450	MICROPLATE	728	2024-09	1
PF91530	006440	CONJUGATE	202	2024-06	1
PF93900/RVM	C5060	NEGATIVE CONTROL	787	2024-09	1
PF92032	005430	POSITIVE CONTROL	191	2024-09	1
PF91831	005440	CUT OFF CONTROL	192	2024-09	1
PF91631	006460	ANTIGEN	195	2026-03	6
PF93611	009660	DILUENT 2	229	2024-09	1
PF93603	1035	WASHING BUFFER 10x	457-1	2024-08	1
PF93602	1032/RISK0	STOP SOLUTION	215-7	2024-08	1
PF93619	1034	SUBSTRATE-HS	375	2024-09	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.179	< 0,6 Cut Off
CUT OFF CONTROL	0.550	≥ 0.200
POSITIVE CONTROL	2.287	> 1,5 Cut Off
CV %	4%	≤ 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:

22.06.2023

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 - 011-V



CODE 91031
CODE 91177

QUALITY CONTROL CERTIFICATE

Annex: Method Evaluation

NAME KIT	RUBELLA IgM
LOT.	289
DATE OF TEST	16/05/2023

METHOD: ACCORDING TO THE PACKAGE INSERT

	FOUND	EXPECTED
1. MICROPLATE CONTROL		
A) UNIFORMITY BETWEEN PLATES		
1st PLATE	OD 450 nm 1.941 CV% 4%	< 20%
2nd PLATE	OD 450 nm 1.755 CV% 3%	< 20%
B) UNIFORMITY WITHIN PLATE	OD 450 nm 1.759 CV% 3%	<15%
2. BULK CONTROL date: 20/03/2023		
A) Average OD of Cut Off Control	OD 450 nm 0.450	≥ 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: 16/05/2023		
A) Blank	OD 450 nm 0.060	≤ 0.100
B) Average OD of Negative Control	OD 450 nm 0.179	< 0,6 Cut Off
C) Average OD of Cut Off Control	OD 450 nm 0.550	≥ 0.200
D) Average OD of Positive Control	OD 450 nm 2.287	> 1,5 Cut Off
E) HOMOGENEITY OF CUT-OFF	N° Replicate 6 OD 450 nm 0.610 CV% 4%	≤ 15%
F) PRECISION OF FILLING PROCESS		



SATISFACTORY



UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 16.05.2023

Signed:
Released: Q.C. Manager