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Sede Legale e Amministrazione
20144 Milano (Italy) Via A. Solari 19 sc. 6

QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL RUBELLA IgM

Code 91031

LOT.NO 290



2024-12



2023-09

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93031	006450	MICROPLATE	729	2025-03	1
PF91530	006440	CONJUGATE	203	2024-12	1
PF93900/RVM	C5060	NEGATIVE CONTROL	798	2025-03	1
PF92032	005430	POSITIVE CONTROL	192	2025-03	1
PF91831	005440	CUT OFF CONTROL	193	2025-03	1
PF91631	006460	ANTIGEN	195	2026-03	6
PF93611	009660	DILUENT 2	231	2025-03	1
PF93603	1035	WASHING BUFFER 10x	462	2025-02	1
PF93602	1032/RISK0	STOP SOLUTION	218-3	2025-06	1
PF93619	1034	SUBSTRATE-HS	380	2025-03	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.273	< 0,6 Cut Off
CUT OFF CONTROL	0.511	≥ 0.200
POSITIVE CONTROL	1.899	> 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: 12.10.2023

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. 290
DATE OF TEST 09/10/2023

METHOD: ACCORDING TO THE PACKAGE INSERT

1. MICROPLATE CONTROL	FOUND		EXPECTED
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: 28/09/2023			
A) Average OD of Cut Off Control	OD 450 nm	0.457	≥ 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: 09/10/2023			
A) Blank	OD 450 nm	0.048	≤ 0.100
B) Average OD of Negative Control	OD 450 nm	0.273	< 0,6 Cut Off
C) Average OD of Cut Off Control	OD 450 nm	0.511	≥ 0.200
D) Average OD of Positive Control	OD 450 nm	1.899	> 1,5 Cut Off
E) HOMOGENEITY OF CUT-OFF	N° Replicate	6	
	OD 450 nm	0.559	
	CV%	4%	≤ 15%
F) PRECISION OF FILLING PROCESS			



SATISFACTORY



UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 09.10.2023

Signed: 

Released: Q.C. Manager