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Sede Legale e Amministrazione
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QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL RUBELLA IgG

Code	91030		
LOT.NO	283	2024-10	2023-09

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93030	006510	MICROPLATE	204	2025-05	1
PF93507	006500	CONJUGATE	242	2024-12	1
PF93910	1036	IgG NEGATIVE CONTROL	177	2025-03	1
PF93831	006520	CALIBRATOR 1	200	2025-03	1
PF91830	006540	CALIBRATOR 2	200	2025-03	1
PF93833	006550	CALIBRATOR 3	200	2025-03	1
PF93834	006560	CALIBRATOR 4	200	2025-03	1
PF93835	006530	CALIBRATOR 5	200	2025-03	1
PF93619	1034	SUBSTRATE-HS	380	2025-03	1
PF93611	009660	DILUENT 2	231	2025-03	1
PF93603	1035	WASHING BUFFER 10x	459	2024-10	1
PF93602	1032/RISK0	STOP SOLUTION	218	2025-06	1

CONTROLS

	IU/ml	FOUND RESULTS	EXPECTED RESULTS
IgG NEG CONTROL	0	0.001	≤ 0,6 CUT-OFF
CALIBRATOR 1	5	0.203	< CUT-OFF
CALIBRATOR 2	10 (Cut Off)	0.429	≥ 0.200
CALIBRATOR 3	50	0.954	
CALIBRATOR 4	100	1.798	
CALIBRATOR 5	200	2.022	≥ 1.500
CV %		7%	≤ 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: 11.10.2023

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 - 010-V



CODE 91030

CODE 91176

QUALITY CONTROL CERTIFICATE

Annex: Method Evaluation

NAME KIT RUBELLA IgG
LOT. 283
DATE OF TEST 03/10/2023

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE	FOUND	EXPECTED
A) UNIFORMITY BETWEEN PLATES		
1st PLATE	OD450 nm 2.237 CV% 2%	< 20%
2nd PLATE	OD 450 nm 1.796 CV% 6%	< 20%
B) UNIFORMITY WITHIN PLATE	OD 450 nm 2.431 CV% 5%	< 15%
2. BULK CONTROL date: 22/09/2023		
A) Average OD of Cut Off Calibrator	OD 450 nm 0.399	≥ 0.200
B) Index of Negative and Positive Sera	accepted	According to specification
C) Sensitivity with working calibrators	accepted	According to specification
3. CONTROL OF COMPLETE KIT date: 03/10/2023		
A) Substrate Blank	OD 450 nm 0.046	≤ 0.100
Calibrator 0 IU/ml	OD 450 nm 0.001	≤ 0,6 Cut-off
Calibrator 5 IU/ml	OD 450 nm 0.203	< Cut-off
Calibrator 10 IU/ml (Cut-off)	OD 450 nm 0.429	≥ 0.200
Calibrator 50 IU/ml	OD 450 nm 0.954	
Calibrator 100 IU/ml	OD 450 nm 1.798	
Calibrator 200 IU/ml	OD 450 nm 2.022	≥ 1.500
B) HOMOGENEITY OF CUT-OFF	No. 6 OD 450 nm 0.474 CV% 7%	≤ 15%
C) PRECISION OF FILLING PROCESS		



SATISFACTORY



UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 03.10.2023

Signed:

Released: Q.C.Manager