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Sede Legale e Amministrazione
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QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL RUBELLA IgG

Code 91030

LOT.NO 285-D



2025-03



2023-12

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93030	006510	MICROPLATE	205	2025-10	1
PF93507	006500	CONJUGATE	244-1	2025-03	1
PF93910	1036	IgG NEGATIVE CONTROL	178	2025-05	1
PF93831	006520	CALIBRATOR 1	202-1	2025-06	1
PF91830	006540	CALIBRATOR 2	202-1	2025-06	1
PF93833	006550	CALIBRATOR 3	202-1	2025-06	1
PF93834	006560	CALIBRATOR 4	202-1	2025-06	1
PF93835	006530	CALIBRATOR 5	202-1	2025-06	1
PF93619	1034	SUBSTRATE-HS	383	2025-05	1
PF93611	009660	DILUENT 2	232	2025-05	1
PF93603	1035	WASHING BUFFER 10x	468	2025-06	1
PF93602	1032/RISKO	STOP SOLUTION	218-6	2025-06	1

CONTROLS

IU/ml	FOUND RESULTS	EXPECTED RESULTS
IgG NEG CONTROL 0	0.002	≤ 0,6 CUT-OFF
CALIBRATOR 1 5	0.219	< CUT-OFF
CALIBRATOR 2 10 (Cut Off)	0.446	≥ 0.200
CALIBRATOR 3 50	1.190	
CALIBRATOR 4 100	2.109	
CALIBRATOR 5 200	2.650	≥ 1.500
CV %	15%	≤ 15%

*Evaluation of the method according to the package insert 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: 07.03.2024

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 - 010-V



CODE 91030

CODE 91176

QUALITY CONTROL CERTIFICATE

Annex: Method Evaluation

NAME KIT RUBELLA IgG
LOT. 285
DATE OF TEST 03/01/2024

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE	FOUND		EXPECTED
A) UNIFORMITY BETWEEN PLATES			
1st PLATE	OD450 nm	2.496	
	CV%	7%	< 20%
2nd PLATE	OD 450 nm	2.641	
	CV%	4%	< 20%
B) UNIFORMITY WITHIN PLATE			
	OD 450 nm	2.434	
	CV%	5%	< 15%
2. BULK CONTROL date: 19/12/2023			
A) Average OD of Cut Off Calibrator	OD 450 nm	0.524	≥ 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: 03/01/2024			
A) Substrate Blank	OD 450 nm	0.048	≤ 0.100
Calibrator 0 IU/ml	OD 450 nm	0.004	≤ 0,6 Cut-off
Calibrator 5 IU/ml	OD 450 nm	0.265	< Cut-off
Calibrator 10 IU/ml (Cut-off)	OD 450 nm	0.581	≥ 0.200
Calibrator 50 IU/ml	OD 450 nm	1.348	
Calibrator 100 IU/ml	OD 450 nm	2.293	
Calibrator 200 IU/ml	OD 450 nm	2.901	≥ 1.500
B) HOMOGENEITY OF CUT-OFF	No.	6	
	OD 450 nm	0.629	
	CV%	7%	≤ 15%
C) PRECISION OF FILLING PROCESS			

☒ SATISFACTORY

☐ UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 03.01.2024

Signed:

Released: Q.C.Manager