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

QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL RUBELLA IgG

Code 91030

LOT.NO 285-A

 2025-03

 2023-12

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93030	006510	MICROPLATE	205	2025-10	1
PF93507	006500	CONJUGATE	244	2025-03	1
PF93910	1036	IgG NEGATIVE CONTROL	178-1	2025-05	1
PF93831	006520	CALIBRATOR 1	202	2025-06	1
PF91830	006540	CALIBRATOR 2	202	2025-06	1
PF93833	006550	CALIBRATOR 3	202	2025-06	1
PF93834	006560	CALIBRATOR 4	202	2025-06	1
PF93835	006530	CALIBRATOR 5	202	2025-06	1
PF93619	1034	SUBSTRATE-HS	381-1	2025-04	1
PF93611	009660	DILUENT 2	232	2025-05	1
PF93603	1035	WASHING BUFFER 10x	468	2025-06	1
PF93602	1032/RISK0	STOP SOLUTION	218-6	2025-06	1

CONTROLS

IU/ml	FOUND RESULTS	EXPECTED RESULTS
IgG NEG CONTROL 0	0.004	$\leq 0,6$ CUT-OFF
CALIBRATOR 1 5	0.265	< CUT-OFF
CALIBRATOR 2 10 (Cut Off)	0.581	≥ 0.200
CALIBRATOR 3 50	1.348	
CALIBRATOR 4 100	2.293	
CALIBRATOR 5 200	2.901	≥ 1.500
CV %	7%	$\leq 15\%$

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: 15.02.2024

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