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Sede Legale e Amministrazione
Via A. Solari, 19 20144 Milano - Italy

QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL RUBELLA IgG

Code 91030

LOT.NO 280-A EXPIRY 2023-10

REAGENTS

CODE	LABEL	DESCRIPTION	LOT No.	EXP	No
PF93030	006510	MICROPLATE	201	2024-06	1
PF93507	006500	CONJUGATE	237	2023-10	1
PF93910	1036	IgG NEGATIVE CONTROL	173-2	2023-11	1
PF93831	006520	CALIBRATOR 1	197	2024-01	1
PF91830	006540	CALIBRATOR 2	197	2024-01	1
PF93833	006550	CALIBRATOR 3	197	2024-01	1
PF93834	006560	CALIBRATOR 4	197	2024-01	1
PF93835	006530	CALIBRATOR 5	197	2024-01	1
PF93619	1034	SUBSTRATE-HS	364-1	2023-11	1
PF93611	009660	DILUENT 2	224	2023-10	1
PF93603	1035	WASHING BUFFER 10x	450-1	2023-11	1
PF93602	1032/RISK0	STOP SOLUTION	214-4	2024-02	1

CONTROLS

	IU/mL	FOUND RESULTS	EXPECTED RESULTS
IgG NEG CONTROL	0	0.010	≤ 0,6 CUT-OFF
CALIBRATOR 1	5	0.145	< CUT-OFF
CALIBRATOR 2	10 (cut-off)	0.374	≥ 0.200
CALIBRATOR 3	50	1.000	
CALIBRATOR 4	100	1.787	
CALIBRATOR 5	200	2.604	≥ 1.500
CV %		14%	≤ 15%

The test has been carried out in accordance with the package insert

TESTED BY: Simone Baiocchi Simone Baiocchi

APPROVED BY: (RESPONSIBLE HEAD, Quality Control Reagents)

DATE: 25/08/2022

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 FDA approved method 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.

DIESSE

CERTIFICATE OF ANALYSIS

KIT: **RUBELLA IgG** Code 91030
LOT: **280** Code 91176
DATE OF TEST: **10/08/2022**

METHOD: ACCORDING TO THE PACKAGE INSERT

			FOUND	*EXPECTED*
1. SOLID PHASE				
A) UNIFORMITY BETWEEN PLATES				
	1st PLATE	OD450 nm	**2.572**	
		CV%	**5,7%**	≤20%
	2nd PLATE	OD 450nm	**2.715**	
		CV%	**3,7%**	≤20%
B) UNIFORMITY WITHIN PLATE				
		OD 450nm	**2.514**	
		CV%	**4,9%**	≤15%
2. CONTROL OF COMPLETE KIT				
A) Substrate Blank		OD 450 nm	**0.059**	≤0.100
	Calibrator 0 IU/ml	OD 450 nm	**0.010**	≤0,6xCut-off
	Calibrator 5 IU/ml	OD 450 nm	**0.145**	< Cut-off
	Calibrator 10 IU/ml (Cut-off)	OD 450 nm	**0.374**	> 0.200
	Calibrator 50 IU/ml	OD 450 nm	**1.000**	
	Calibrator 100 IU/ml	OD 450 nm	**1.787**	
	Calibrator 200 IU/ml	OD 450 nm	**2.604**	≥1.500
B) PANEL OF HUMAN SERA AND INTERNAL STANDARDS				
	Results of Negative sera		**Accepted**	According to spec.
	Results of Positive sera		**Accepted**	According to spec.
	Results of Internal standards		**Accepted**	According to spec.
C) HOMOGENEITY OF CUT-OFF		No.	**6**	
		OD 450 nm	**0.433**	
		CV%	**14%**	≤15%

D) PRECISION OF FILLING PROCESS

[X] SATISFACTORY [ ] UNSATISFACTORY

FINAL RESULT: **ACCEPTED**

Date: **10/08/2022**

Signed:
Released: Q.C.Manager

Aggiornamento 05.2012