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Sede Legale e Amministrazione
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QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL RUBELLA IgM

Code 91031

LOT.NO 287-C

2024-01

2022-10

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93031	006450	MICROPLATE	727	2024-07	1
PF91530	006440	CONJUGATE	200	2024-01	1
PF93900/RVM	C5060	NEGATIVE CONTROL	769	2024-04	1
PF92032	005430	POSITIVE CONTROL	189	2024-04	1
PF91831	005440	CUT OFF CONTROL	190	2024-04	1
PF91631	006460	ANTIGEN	194	2025-09	6
PF93611	009660	DILUENT 2	226	2024-04	1
PF93603	1035	WASHING BUFFER 10x	452	2024-02	1
PF93602	1032/RISK0	STOP SOLUTION	215-1	2024-08	1
PF93619	1034	SUBSTRATE-HS	368	2024-04	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.182	< 0,6 Cut Off
CUT OFF CONTROL	0.411	≥ 0.200
POSITIVE CONTROL	1.878	> 1,5 Cut Off
CV %	5%	≤ 15%

*Evaluation 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: 08.02.2023

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.



CERTIFICATE OF ANALYSIS

KIT:	RUBELLA IgM	Code	91031
LOT:	287	Code	91177
DATE OF TEST:	25/10/2022		

METHOD: ACCORDING TO THE PACKAGE INSERT

		FOUND	EXPECTED
1. MICROPLATE CONTROL			
A) UNIFORMITY BETWEEN PLATES			
1st PLATE	OD 450 nm	0.987	
	CV%	4%	≤20%
B) UNIFORMITY WITHIN PLATE			
	OD 450 nm	1.052	
	CV%	4%	≤15%
2. BULK CONTROL date: 24/10/2022			
A) Average OD of Cut Off Control	OD 450 nm	0.437	≥ 0.200
B) Average OD of 6 Negative Sera		accepted	According to specification
C) Average OD of 2 Positive Sera		accepted	According to specification
D) Sensitivity with working calibrators		accepted	According to specification
3. FINAL CONTROL date: 25/10/2022			
A) Blank	OD 450 nm	0.041	≤ 0.100
B) Average OD of Negative Control	OD 450 nm	0.182	< 0.6x Cut Off
C) Average OD of Cut Off Control	OD 450 nm	0.411	≥ 0.200
D) Average OD of Positive Control	OD 450 nm	1.878	> 1.5 x Cut Off
E) HOMOGENEITY OF CUT-OFF	N° Replicate	5	
	OD 450 nm	0.451	
	CV%	5%	≤ 15%
F) PRECISION OF FILLING PROCESS			

SATISFACTORY ☒

UNSATISFACTORY ☐

FINAL RESULT: **ACCEPTED**

Date:

25/10/2022

Signed:

Released: Q.C. Manager

Aggiornamento 05.2012