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

QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL RUBELLA IgM

Code 91031

LOT.NO 287

EXPIRY 2023-11

REAGENTS

CODE	LABEL	DESCRIPTION	LOT No.	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	365-2	2023-11	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%

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

TESTED BY: Silvia Sardelli

APPROVED BY: RESPONSIBLE HEAD, Quality Control Reagents

DATE 26.10.22

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.



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%	$\leq 20\%$
B) UNIFORMITY WITHIN PLATE			
	OD 450 nm	1.052	
	CV%	4%	$\leq 15\%$
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	$< 0.6 \times \text{Cut Off}$
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	$> 1.5 \times \text{Cut Off}$
E) HOMOGENEITY OF CUT-OFF	N° Replicate	5	
	OD 450 nm	0.451	
	CV%	5%	$\leq 15\%$
F) PRECISION OF FILLING PROCESS			

SATISFACTORY ☒

UNSATISFACTORY ☐

FINAL RESULT: **ACCEPTED**

Date: 25/10/2022

Signed: 
Released: Q.C.Manager

Aggiornamento 05.2012