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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 286 **EXPIRY** 2023-11

REAGENTS

CODE	LABEL	DESCRIPTION	LOT No.	EXP	NO
PF93031	006450	MICROPLATE	727	2024-07	1
PF91530	006440	CONJUGATE	199	2023-11	1
PF93900/RVM	C5060	NEGATIVE CONTROL	762	2024-03	1
PF92032	005430	POSITIVE CONTROL	188	2024-02	1
PF91831	005440	CUT-OFF CONTROL	189	2024-02	1
PF91631	006460	ANTIGEN	193	2025-03	6
PF93611	009660	DILUENT 2	225	2023-12	1
PF93603	1035	WASHING BUFFER 10x	451-2	2024-01	1
PF93602	1032/RISK0	STOP SOLUTION	215	2024-08	1
PF93619	1034	SUBSTRATE-HS	365-1	2023-11	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.191	< 0,6 CUT-OFF
CUT-OFF CONTROL	0.385	≥ 0.200
POSITIVE CONTROL	1.890	> 1,5 CUT-OFF
CV %	3%	≤ 15%

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

TESTED BY: Katia Tanzini

APPROVED BY: RESPONSIBLE HEAD, Quality Control Reagents

DATE 26.09.2022

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.



CERTIFICATE OF ANALYSIS

KIT:	RUBELLA IgM	Code	91031
LOT:	286	Code	91177
DATE OF TEST:	21/09/2022		

METHOD: ACCORDING TO THE PACKAGE INSERT

	FOUND	EXPECTED
1. MICROPLATE CONTROL		
A) UNIFORMITY BETWEEN PLATES		
1st PLATE	OD 450 nm	
	CV%	
	0.987	
	4%	≤20%
B) UNIFORMITY WITHIN PLATE		
	OD 450 nm	
	CV%	
	1.052	
	4%	≤15%
2. BULK CONTROL date: 24/08/2022		
A) Average OD of Cut Off Control	OD 450 nm	
B) Average OD of 6 Negative Sera		
C) Average OD of 2 Positive Sera		
D) Sensitivity with working calibrators		
	0.361	≥ 0.200
	accepted	According to specification
	accepted	According to specification
	accepted	According to specification
3. FINAL CONTROL date: 21/09/2022		
A) Blank	OD 450 nm	
B) Average OD of Negative Control	OD 450 nm	
C) Average OD of Cut Off Control	OD 450 nm	
D) Average OD of Positive Control	OD 450 nm	
	0.063	≤ 0.100
	0.191	< 0.6xCut Off
	0.385	≥ 0.200
	1.890	> 1.5 x Cut Off
E) HOMOGENEITY OF CUT-OFF	N° Replicate	
	OD 450 nm	
	CV%	
	6	
	0.448	
	3%	≤ 15%
F) PRECISION OF FILLING PROCESS		

SATISFACTORY ☒

UNSATISFACTORY ☐

FINAL RESULT: **ACCEPTED**

Date: 22.09.2022

Signed: 
Released: Q.C.Manager

Aggiornamento 05.2012