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Sede Legale e Amministrazione
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QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL RUBELLA IgM

Code 91031

LOT.NO

291



2025-03



2024-01

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93031	006450	MICROPLATE	729	2025-03	1
PF91530	006440	CONJUGATE	204	2025-04	1
PF93900/RVM	C5060	NEGATIVE CONTROL	814	2025-07	1
PF92032	005430	POSITIVE CONTROL	193	2025-07	1
PF91831	005440	CUT OFF CONTROL	194	2025-07	1
PF91631	006460	ANTIGEN	195	2026-03	6
PF93611	009660	DILUENT 2	232	2025-05	1
PF93603	1035	WASHING BUFFER 10x	468	2025-06	1
PF93602	1032/RISKO	STOP SOLUTION	218-6	2025-06	1
PF93619	1034	SUBSTRATE-HS	383	2025-05	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.168	< 0,6 Cut Off
CUT OFF CONTROL	0.428	≥ 0.200
POSITIVE CONTROL	2.034	> 1,5 Cut Off
CV %	14%	≤ 15%

*Evaluatin 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:

01/02/2024

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 - 011-V



CODE 91031

CODE 91177

QUALITY CONTROL CERTIFICATE

Annex: Method Evaluation

NAME KIT RUBELLA IgM

LOT. 291

DATE OF TEST 30/01/2024

METHOD: ACCORDING TO THE PACKAGE INSERT

1. MICROPLATE CONTROL

A) UNIFORMITY BETWEEN PLATES

1st PLATE

OD 450 nm 2.017
CV% 2%

< 20%

2nd PLATE

OD 450 nm 2.012
CV% 4%

< 20%

B) UNIFORMITY WITHIN PLATE

OD 450 nm 1.896
CV% 4%

<15%

2. BULK CONTROL date:25/01/2024

A) Average OD of Cut Off Control

OD 450 nm 0.393

≥ 0.200

B) Index of Negative and Positive Sera

accepted

According to specification

C) Sensitivity with working calibrators

accepted

According to specification

3. FINAL CONTROL date: 30/01/2024

A) Blank

OD 450 nm 0.051

≤ 0.100

B) Average OD of Negative Control

OD 450 nm 0.168

< 0,6 Cut Off

C) Average OD of Cut Off Control

OD 450 nm 0.428

≥ 0.200

D) Average OD of Positive Control

OD 450 nm 2.034

> 1,5 Cut Off

E) HOMOGENEITY OF CUT-OFF

N° Replicate 6

OD 450 nm 0.480

≤ 15%

CV%

F) PRECISION OF FILLING PROCESS



SATISFACTORY



UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 30.01.2024

Signed:

Released: Q.C. Manager