

DIESSE DIAGNOSTICA SENESE SpA
53035 Monteriggioni (SI), Italy, Strada dei Laghi 39
Tel. +39 0577319554 FAX +39 0577319020



Sede Legale e Amministrazione
20144 Milano (Italy) Via A. Solari 19 sc. 6

Pag 1/1

QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL RUBELLA IgM

Code 91031

LOT.NO

289



2024-06



2023-03

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93031	006450	MICROPLATE	728	2024-09	1
PF91530	006440	CONJUGATE	202	2024-06	1
PF93900/RVM	C5060	NEGATIVE CONTROL	787	2024-09	1
PF92032	005430	POSITIVE CONTROL	191	2024-09	1
PF91831	005440	CUT OFF CONTROL	192	2024-09	1
PF91631	006460	ANTIGEN	195	2026-03	6
PF93611	009660	DILUENT 2	229	2024-09	1
PF93603	1035	WASHING BUFFER 10x	457	2024-08	1
PF93602	1032/RISKO	STOP SOLUTION	215-5	2024-08	1
PF93619	1034	SUBSTRATE-HS	375	2024-09	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.179	< 0,6 Cut Off
CUT OFF CONTROL	0.550	≥ 0.200
POSITIVE CONTROL	2.287	> 1,5 Cut Off
CV %	4%	≤ 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:

19/05/2023

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.

IO 09 - 011-V



CODE 91031
CODE 91177

QUALITY CONTROL CERTIFICATE

Annex: Method Evaluation

NAME KIT	RUBELLA IgM
LOT.	289
DATE OF TEST	16/05/2023

METHOD: ACCORDING TO THE PACKAGE INSERT

1. MICROPLATE CONTROL

A) UNIFORMITY BETWEEN PLATES

1st PLATE

2nd PLATE

B) UNIFORMITY WITHIN PLATE

2. BULK CONTROL date: 20/03/2023

- A) Average OD of Cut Off Control
- B) Index of Negative and Positive Sera
- C) Sensitivity with working calibrators

3. FINAL CONTROL date: 16/05/2023

- A) Blank
- B) Average OD of Negative Control
- C) Average OD of Cut Off Control
- D) Average OD of Positive Control

E) HOMOGENEITY OF CUT-OFF

F) PRECISION OF FILLING PROCESS

FOUND

OD 450 nm 1.941

CV% 4%

OD 450 nm 1.755

CV% 3%

OD 450 nm 1.759

CV% 3%

OD 450 nm 0.450

accepted

accepted

OD 450 nm 0.060

OD 450 nm 0.179

OD 450 nm 0.550

OD 450 nm 2.287

N° Replicate 6

OD 450 nm 0.610

CV% 4%

EXPECTED

< 20%

< 20%

<15%

≥ 0.200

According to specification

According to specification

≤ 0.100

< 0,6 Cut Off

≥ 0.200

> 1,5 Cut Off

≤ 15%



SATISFACTORY



UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 16.05.2023

Signed:

Released: Q.C.Manager