

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

QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL RUBELLA IgM

Code	91031		
LOT.NO	289-D	2024-06	2023-03

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93031	006450	MICROPLATE	728	2024-09	1
PF91530	006440	CONJUGATE	202-2	2024-06	1
PF93900/RVM	C5060	NEGATIVE CONTROL	787-2	2024-09	1
PF92032	005430	POSITIVE CONTROL	191-2	2024-09	1
PF91831	005440	CUT OFF CONTROL	192-2	2024-09	1
PF91631	006460	ANTIGEN	195	2026-03	6
PF93611	009660	DILUENT 2	229	2024-09	1
PF93603	1035	WASHING BUFFER 10x	458	2024-09	1
PF93602	1032/RISKO	STOP SOLUTION	218	2025-06	1
PF93619	1034	SUBSTRATE-HS	376-1	2024-10	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.152	< 0,6 Cut Off
CUT OFF CONTROL	0.417	≥ 0.200
POSITIVE CONTROL	1.686	> 1,5 Cut Off
CV %	7%	≤ 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: 25.08.2023

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

	FOUND	EXPECTED
1. MICROPLATE CONTROL		
A) UNIFORMITY BETWEEN PLATES		
1st PLATE	OD 450 nm 1.941 CV% 4%	< 20%
2nd PLATE	OD 450 nm 1.755 CV% 3%	< 20%
B) UNIFORMITY WITHIN PLATE		
	OD 450 nm 1.759 CV% 3%	<15%
2. BULK CONTROL date: 20/03/2023		
A) Average OD of Cut Off Control	OD 450 nm 0.450	≥ 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: 16/05/2023		
A) Blank	OD 450 nm 0.060	≤ 0.100
B) Average OD of Negative Control	OD 450 nm 0.179	< 0,6 Cut Off
C) Average OD of Cut Off Control	OD 450 nm 0.550	≥ 0.200
D) Average OD of Positive Control	OD 450 nm 2.287	> 1,5 Cut Off
E) HOMOGENEITY OF CUT-OFF	N° Replicate 6 OD 450 nm 0.610 CV% 4%	≤ 15%
F) PRECISION OF FILLING PROCESS		

SATISFACTORY

UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 16.05.2023

Signed: 
Released: Q.C. Manager