

DIESE 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 IgG

Code	91030		
LOT.NO	286-A	2025-07	2024-05

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93030	006510	MICROPLATE	207	2026-04	1
PF93507	006500	CONJUGATE	246	2025-08	1
PF93910	1036	IgG NEGATIVE CONTROL	180	2025-11	1
PF93831	006520	CALIBRATOR 1	203	2025-11	1
PF91830	006540	CALIBRATOR 2	203	2025-11	1
PF93833	006550	CALIBRATOR 3	203	2025-11	1
PF93834	006560	CALIBRATOR 4	203	2025-11	1
PF93835	006530	CALIBRATOR 5	203	2025-11	1
PF93619	1034	SUBSTRATE-HS	385	2025-08	1
PF93611	009660	DILUENT 2	233	2025-07	1
PF93603	1035	WASHING BUFFER 10x	473	2025-08	1
PF93602	1032/RISKO	STOP SOLUTION	220	2026-03	1

CONTROLS

	IU/ml	FOUND RESULTS	EXPECTED RESULTS
IgG NEG CONTROL	0	0.003	≤ 0,6 CUT-OFF
CALIBRATOR 1	5	0.268	< CUT-OFF
CALIBRATOR 2	10 (Cut Off)	0.555	≥ 0.200
CALIBRATOR 3	50	1.126	
CALIBRATOR 4	100	1.710	
CALIBRATOR 5	200	2.456	≥ 1.500
CV %		12%	≤ 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: 21.05.2024

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 - 010-V



CODE 91030
CODE 91176

QUALITY CONTROL CERTIFICATE

Annex: Method Evaluation

NAME KIT RUBELLA IgG
LOT. 286
DATE OF TEST 17/05/2024

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE	FOUND	EXPECTED
A) UNIFORMITY BETWEEN PLATES		
1st PLATE	OD450 nm 2.483 CV% 5%	< 20%
2nd PLATE	OD 450 nm 2.613 CV% 6%	< 20%
B) UNIFORMITY WITHIN PLATE		
	OD 450 nm 2.548 CV% 6%	< 15%
2. BULK CONTROL date: 14/05/2024		
A) Average OD of Cut Off Calibrator	OD 450 nm 0.582	≥ 0.200
B) Index of Negative and Positive Sera	accepted	According to specification
C) Sensitivity with working calibrators	accepted	According to specification
3. CONTROL OF COMPLETE KIT date: 17/05/2024		
A) Substrate Blank	OD 450 nm 0.046	≤ 0.100
Calibrator 0 IU/ml	OD 450 nm 0.003	≤ 0,6 Cut-off
Calibrator 5 IU/ml	OD 450 nm 0.268	< Cut-off
Calibrator 10 IU/ml (Cut-off)	OD 450 nm 0.555	≥ 0.200
Calibrator 50 IU/ml	OD 450 nm 1.126	
Calibrator 100 IU/ml	OD 450 nm 1.710	
Calibrator 200 IU/ml	OD 450 nm 2.456	≥ 1.500
B) HOMOGENEITY OF CUT-OFF	No. 6 OD 450 nm 0.602 CV% 12%	≤ 15%
C) PRECISION OF FILLING PROCESS		

SATISFACTORY

UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 20.05.2024

Signed: 
Released: Q.C.Manager