

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



Sede Legale e Amministrazione
Via A. Solari, 19 20144 Milano - Italy

QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL RUBELLA IgG AVIDITY

Code 91095

LOT.NO 077 EXPIRY 2023-10

REAGENTS

CODE	LABEL	DESCRIPTION	LOT No.	EXP	No
PF93030	007580	MICROPLATE strips	200	2024-01	3
V140	007570	CONJUGATE	236	2023-10	1
PF91094	007550	CONTROL	129	2024-01	1
PF91091	007590	AVIDITY BUFFER	135	2024-01	1
PF93619	1034	SUBSTRATE	364	2023-11	1
PF93611	009660	DILUENT 2	224	2023-10	1
PF93603	1035	WASHING BUFFER 10x	449-1	2023-11	1
PF93602	1032/RISK0	STOP SOLUTION	214-3	2024-02	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
CONTROL	66%	> 45%

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

TESTED BY: Katia Tanzini

APPROVED BY: (RESPONSIBLE HEAD, Quality Control Reagents)

DATE: 25.01.2024

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 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 IgG AVIDITY
LOT: 077
DATE OF TEST: 21/07/2022

Code 91095

METHOD: ACCORDING TO THE PACKAGE INSERT

FOUND

EXPECTED

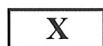
1. CONTROL OF COMPLETE KIT

High Avidity Control

66%

> 45%

Good function with high and low avidity
sera and Internal Standards, in
accordance with specifications



SATISFACTORY



UNSATISFACTORY

FINAL RESULT: **ACCEPTED**

Date: 21.07.2022

Signed:

Released: Q.C.Manager