

**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 076-B

EXPIRY 2023-08

### REAGENTS

CODE	LABEL	DESCRIPTION	LOT No.	EXP	No
PF93030	007580	MICROPLATE strips	200	2024-01	3
PF93607-140	007570	CONJUGATE	235	2023-08	1
PF91094	007550	CONTROL	128	2023-11	1
PF91091	007590	AVIDITY BUFFER	134	2023-11	1
PF93619	1034	SUBSTRATE	362-1	2023-09	1
PF93611	009660	DILUENT 2	223	2023-08	1
PF93603	1035	WASHING BUFFER 10x	449-1	2023-11	1
PF93602	1032/RISK0	STOP SOLUTION	214-2	2024-02	1

### CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
CONTROL	60%	> 45%

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

**TESTED BY:** Katia Tanzini *Katiazini*

**APPROVED BY:** (RESPONSIBLE HEAD, Quality Control Reagents) *Aliauel*

**DATE:** 05/07/2022

### 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: 076  
DATE OF TEST: 08/06/2022

Code 91095

METHOD: ACCORDING TO THE PACKAGE INSERT

---

***FOUND******EXPECTED*****1. CONTROL OF COMPLETE KIT**

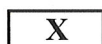
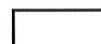
High Avidity Control

60%

> 45%

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

accordance with specifications

**SATISFACTORY****UNSATISFACTORY**

FINAL RESULT: **ACCEPTED**

Date: 09.06.2022

Signed:   
Released: Q.C. Manager