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

## QUALITY CONTROL CERTIFICATE

**KIT NAME** ENZYWELL RUBELLA IgG AVIDITY

Code 91095

LOT.NO 081



2025-07



2024-06

### REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93030	007580	MICROPLATE strips	205	2025-10	3
V140	007570	CONJUGATE	248	2025-09	1
PF91094	007550	CONTROL	141	2025-12	1
PF91091	007590	AVIDITY BUFFER	154	2025-12	1
PF93619	1034	SUBSTRATE	387	2025-09	1
PF93611	009660	DILUENT 2	233	2025-07	1
PF93603	1035	WASHING BUFFER 10x	475	2025-11	1
PF93602	1032/RISK0	STOP SOLUTION	220	2026-03	1

### CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
CONTROL	63%	> 45%

*Evaluation 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: 17.06.2024

### 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.

**CERTIFICATE OF ANALYSIS**

KIT: RUBELLA IgG AVIDITY  
LOT: 081  
DATE OF TEST: 14/06/2024

Code 91095

METHOD: ACCORDING TO THE PACKAGE INSERT

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

High Avidity Control

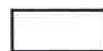
**63%**

**> 45%**

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



SATISFACTORY



UNSATISFACTORY

FINAL RESULT: **ACCEPTED**

Date: 14/06/2024

Signed:

Released: Q.C.Manager

A handwritten signature in blue ink, appearing to be "Al", followed by a comma.