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Sede Legale e Amministrazione
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QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL RUBELLA IgG AVIDITY

Code 91095

LOT.NO 080



2025-04



2024-01

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93030	007580	MICROPLATE strips	205	2025-10	3
V140	007570	CONJUGATE	245	2025-04	1
PF91094	007550	CONTROL	138	2025-07	1
PF91091	007590	AVIDITY BUFFER	150	2025-07	1
PF93619	1034	SUBSTRATE	381	2025-04	1
PF93611	009660	DILUENT 2	232	2025-05	1
PF93603	1035	WASHING BUFFER 10x	468	2025-06	1
PF93602	1032/RISK0	STOP SOLUTION	218-6	2025-06	1

CONTROLS

FOUND RESULTS		EXPECTED RESULTS	
CONTROL	56%	> 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:

19.01.2024

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 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: 080
DATE OF TEST: 17/01/2024

Code 91095

METHOD: ACCORDING TO THE PACKAGE INSERT

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

High Avidity Control

56%

> 45%

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

☒

SATISFACTORY



UNSATISFACTORY

FINAL RESULT: **ACCEPTED**

Date:

17.1.2024

Signed:

A handwritten signature in blue ink, appearing to be "Bruno".

Released: Q.C.Manager