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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 080-A

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
PF97094	007550	CONTROL	138	2025-07	1
PF91091	007590	AVIDITY BUFFER	150	2025-07	1
PF93619	1034	SUBSTRATE	383	2025-05	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%

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: 15 02 2024

WARNING: POTENTIAL BIOHAZARDOUS MATERIALI

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

Code 91095

LOT:

080

DATE OF TEST:

17/01/2024

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. d. 624

Signed:

Released: Q.C.Manager