DIESSE DIAGNOSTICA SENESE SpA

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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-B

EXPIRY 2023-10

REAGENTS

CODE	LABEL	DESCRIPTION	LOT No.	EXP	No
PF93030	007580	MICROPLATE strips	200	2024-01	3
V140	007570	CONJUGATE	236-1	2023-10	1
PF91094	007550	CONTROL	129-1	2024-01	1
PF91091	007590	AVIDITY BUFFER	135-1	2024-01	1
PF93619	1034	SUBSTRATE	364-2	2023-11	1
PF93611	009660	DILUENT 2	224-1	2023-10	1
PF93603	1035	WASHING BUFFER 10x	450-1	2023-11	1
PF93602	1032/RISK0	STOP SOLUTION	214-4	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: 14,09,612

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

Code 91095

LOT:

077

DATE OF TEST:

21/07/2022

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: 21.07.621

Signed:

Released: Q.C.Manager