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 076

EXPIRY 2023-08

REAGENTS

CODE	LABEL	DESCRIPTION	LOT No.	EXP	No
PF93030	007580	MICROPLATE strips	200	2024-01	3
PF93507	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	450-1	2023-11	1
PF93602	1032/RISK0	STOP SOLUTION	214-2	2024-02	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS	
	2004		
CONTROL	1 60%	> 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: 14.06.600

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:

DATE OF TEST:

076

08/06/2022

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: 09.06.671

Signed: /

Released: Q.C.Manager