DIESSE DIAGNOSTICA SENESE SpA 53035 Monteriggioni (SIENA) - Italy - Strada dei Laghi, 39

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QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL CYTOMEGALOVIRUS IgG AVIDITY

Code

91092

LOT.NO 068 **EXPIRY 2024-03**

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93010	007500	MICROPLATE STRIPS	260	2024-04	3
PF93501	007490	CONJUGATE	222	2024-03	1
PF91097	007470	LOW AVIDITY CONTROL	064	2024-06	1
PF91096	007480	HIGH AVIDITY CONTROL	124	2024-06	1
PF91091	007590	AVIDITY BUFFER	127	2024-06	1
PF93619	1034	SUBSTRATE	368	2024-04	1
PF93611	009660	DILUENT 2	226	2024-04	1
PF93603	1035	WASHING BUFFER 10x	453	2024-04	1
PF93602	1032/RISK0	STOP SOLUTION	215-1	2024-08	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
LOW AVIDITY CONTROL	11%	< 35%
HIGH AVIDITY CONTROL	67%	> 50%

The test has been carried out in accordance with the package insert

TESTED BY:

Katia Tanzini

APPROVED BY:

(RESPONSIBLE HEAD, Quality Control Reagents)

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

CYTOMEGALOVIRUS IgG AVIDITY

Code

91092

LOT: DATE OF TEST:

068 09/01/2023

METHOD: ACCORDING TO THE PACKAGE INSERT

		FOUND	EXPECTED
1. C	CONTROL OF COMPLETE KIT		
a)	Low Avidity Control	11%	< 35%
	High Avidity Control	67%	> 50%
b)	Good function Panel of Human Sera and Internal Standards in accordance with		

X SATISI

SATISFACTORY

UNSATISFACTORY

FINAL RESULT:

specifications

ACCEPTED

Date: 09. 01. 623

Released: Q.C.Manager

Signed:

Aggiornamento: 04/99