

DIESSE DIAGNOSTICA SENESE SpA
53035 Monteriggioni (SIENA) – Italy – Strada dei Laghi, 39
Tel. +39 0577319554 FAX +39 0577319020



Sede Legale e Amministrazione
Via Solari, 19 20144 Milano - Italy

QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL EPSTEIN BARR EBNA IgG

Code 91057

LOT.NO 101-D EXPIRY 2023-12

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93071	054800	MICROPLATE	114	2024-02	1
PF93509	005470	CONJUGATE	101	2023-12	1
PF93910	1036	NEGATIVE CONTROL	174-2	2024-02	1
PF92073	005390	POSITIVE CONTROL	093	2024-03	1
PF91873	005450	CUT-OFF CONTROL	093	2024-03	1
PF93619	1034	SUBSTRATE-HS	368	2024-04	1
PF93621	006030	DILUENT 10	162	2024-04	1
PF93603	1035	WASHING BUFFER 10x	452	2024-02	1
PF93602	1032/RISK0	STOP SOLUTION	215-1	2024-08	1
PF91083	006840	SORBENT G	092	2024-04	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.008	$\leq 0,6 \times \text{CUT-OFF}$
CUT-OFF CONTROL	0.412	$\geq 0,200$
POSITIVE CONTROL	2.016	$\geq 1.5 \times \text{Cut-off}$
CV %	5%	$\leq 15\%$

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

TESTED BY: Katia Tanzini

APPROVED BY: RESPONSIBLE HEAD, Quality Control Reagents

DATE: 12-12-2022

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.



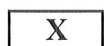
CERTIFICATE OF ANALYSIS

KIT: EPSTEIN BARR EBNA IgG Code 91057
 LOT: 101
 DATE OF TEST: 14/09/2022

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE	FOUND	EXPECTED
UNIFORMITY BETWEEN PLATES		
OD450 nm	1.275	
CV%	4%	≤20%
B) UNIFORMITY WITHIN PLATE		
OD 450nm	1.237	
CV%	6%	≤15%
2. CONTROL OF COMPLETE KIT		
A) OD 450 nm Substrate Blank	0.048	≤0.100
OD 450 nm Negative Control	0.008	(≤0.6xCut-off)
OD 450 nm Cut-off Control	0.412	≥0.200
OD 450 nm Positive Control	2.016	(≥1,5 x Cut-off)
B) PANEL OF HUMAN SERA		
Average OD of Negative Sera	accepted	< Cut-off
Average OD of Positive Sera	accepted	> Cut-off
C) HOMOGENEITY OF CUT-OFF	No. 5	
OD 450nm	0.460	
CV%	5%	≤15%

D) PRECISION OF FILLING PROCESS



SATISFACTORY



UNSATISFACTORY

FINAL RESULT: **ACCEPTED**

Date: 14/09/2022

Signed: 
 Released: Q.C.Manager

Update 07.2012