

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



Sede Legale e Amministrazione
20144 Milano (Italy) Via A. Solari 19 sc. 6

QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL HERPES SIMPLEX 2 IgG

Code	91026				
LOT.NO	179-B	2024-02	2022-11		

REAGENTS

CODE	LABEL	DESCRIPTION	LOT No.	EXP	NO
PF93020	006660	MICROPLATE	134	2024-04	1
PF93502	006640	CONJUGATE	154	2024-02	1
PF93910	1036	NEGATIVE CONTROL	174-2	2024-02	1
PF91629	006680	POSITIVE CONTROL	137	2024-05	1
PF91628	006650	CUT-OFF CONTROL	129	2024-05	1
PF93619	1034	SUBSTRATE-HS	368	2024-04	1
PF93611	009660	DILUENT 2	226	2024-04	1
PF93603	1035	WASHING BUFFER 10x	452	2024-02	1
PF93602	1032/RISK0	STOP SOLUTION	215-1	2024-08	1
PF91081/G	006670	SORBENT 1	142	2025-07	6

CONTROLS

FOUND RESULTS		EXPECTED RESULTS
NEGATIVE CONTROL	0.004	$\leq 0,6$ CUT-OFF
CUT-OFF CONTROL	0.437	$\geq 0,200$
POSITIVE CONTROL	1.601	$\geq 1,5$ CUT-OFF
CV %	4%	$\leq 15\%$

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

TESTED BY: Katia Tanzini

APPROVED BY: (RESPONSIBLE HEAD, Quality Control Reagents)

DATE: 11.01.2023

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.

1122406

**CERTIFICATE OF ANALYSIS**

KIT: **HERPES SIMPLEX 2 IgG**
LOT: **179**
DATE OF TEST: **21/11/2022**

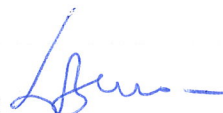
Code **91026**
Code **91185**

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE		<i>FOUND</i>	<i>EXPECTED</i>
UNIFORMITY BETWEEN PLATES			
	OD 450 nm	1.490	
	CV%	4%	$\leq 20\%$
2. CONTROL OF COMPLETE KIT			
A) OD 450 nm Substrate Blank		0.050	≤ 0.100
OD 450 nm Negative Control		0.004	$(\leq 0.6 \times \text{Cut-off})$
OD 450 nm Cut-off Control		0.437	≥ 0.200
OD 450 nm Positive Control		1.601	$(\geq 1,5 \times \text{Cut-off})$
B) PANEL OF HUMAN SERA		accepted	According to specifications
C) HOMOGENEITY OF CUT-OFF	No.	6	
	OD 450 nm	0.487	
	CV%	4%	$\leq 15\%$

FINAL RESULT: **ACCEPTED**

Date: **21/11/2022**

Signed: 

Released: Q.C.Manager

Aggiornamento 05.2012