

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	178-B		2023-08		2022-07

REAGENTS

CODE	LABEL	DESCRIPTION	LOT No.	EXP	NO
PF93020	006660	MICROPLATE	133	2023-08	1
PF93502	006640	CONJUGATE	153	2023-10	1
PF93910	1036	NEGATIVE CONTROL	174	2024-02	1
PF91629	006680	POSITIVE CONTROL	136	2024-01	1
PF91628	006650	CUT-OFF CONTROL	128	2024-01	1
PF93619	1034	SUBSTRATE-HS	365-1	2023-11	1
PF93611	009660	DILUENT 2	224-1	2023-10	1
PF93603	1035	WASHING BUFFER 10x	451-2	2024-01	1
PF93602	1032/RISK0	STOP SOLUTION	215	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	0.391	≥ 0.200
POSITIVE CONTROL	1.618	$\geq 1,5$ CUT-OFF
CV %	14%	$\leq 15\%$

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

TESTED BY: Katia Tanzini

APPROVED BY: (RESPONSIBLE HEAD, Quality Control Reagents)

DATE: 29.09.2022

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: **HERPES SIMPLEX 2 IgG**
LOT: 178
DATE OF TEST: 24/08/2022

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	1.508	
	CV%	3%	$\leq 20\%$
2. CONTROL OF COMPLETE KIT			
A) OD 450 nm Substrate Blank		0.048	≤ 0.100
OD 450 nm Negative Control		0.004	$(\leq 0.6 \times \text{Cut-off})$
OD 450 nm Cut-off Control		0.391	≥ 0.200
OD 450 nm Positive Control		1.618	$(\geq 1,5 \times \text{Cut-off})$
B) PANEL OF HUMAN SERA		accepted	According to specifications
C) HOMOGENEITY OF CUT-OFF	No.	8	
	OD 450 nm	0.439	
	CV%	14%	$\leq 15\%$

FINAL RESULT: **ACCEPTED**

Date: **24.08.2022**

Aggiornamento 05.2012

Signed: 
Released: Q.C.Manager