

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



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

QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL HERPES SIMPLEX 1 + 2 IgM

Code 91021

LOT.NO 322-A EXPIRY 2023-09

REAGENTS

CODE	LABEL	DESCRIPTION	LOT No.	EXP	No
PF93000	006190	MICROPLATE	663	2023-12	1
PF91520	006180	CONJUGATE	242	2023-09	1
PF93900/HSV	C4940	NEGATIVE CONTROL	750-1	2023-12	1
PF92022	005140	POSITIVE CONTROL	221-1	2023-12	1
PF91821	006150	CUT-OFF CONTROL	233	2023-12	1
PF91621	006170	ANTIGEN	219	2025-03	6
PF93611	009660	DILUENT 2	225	2023-12	1
PF93603	1035	WASHING BUFFER 10x	452-1	2024-02	1
PF93602	1032/RISK0	STOP SOLUTION	215	2024-08	1
PF93619	1034	SUBSTRATE-HS	365-1	2023-11	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.304	< 0,6 CUT-OFF
CUT-OFF CONTROL	0.584	≥ 0.200
POSITIVE CONTROL	2.098	> 1,5 CUT-OFF
CV %	15%	≤ 15%

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

TESTED BY: Silvia Sardelli

APPROVED BY: RESPONSIBLE HEAD, Quality Control Reagents

DATE: 05.10.2022

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 1+2 IgM	Code 91021
LOT:	322	Code 91143
DATE OF TEST:	26/09/2022	Code 91175

METHOD: ACCORDING TO THE PACKAGE INSERT

		<i>FOUND</i>	<i>EXPECTED</i>
1. SOLID PHASE			
A) UNIFORMITY BETWEEN PLATES			
1st PLATE	OD450 nm	1.678	
	CV%	12%	<20%
2nd PLATE	OD 450nm	1.859	
	CV%	8%	<20%
B) UNIFORMITY WITHIN PLATE			
	OD 450nm	1.804	
	CV%	8%	≤15%
2. CONTROL OF COMPLETE KIT			
A) OD 450 nm Substrate Blank			
OD 450 nm Negative Control		0.050	≤0,100
		0.304	(≤0.6xCut-off)
OD 450 nm Cut-off Control		0.584	>0.200
OD 450 nm Positive Control		2.098	(≥1,5 x Cut-off)
B) PANEL OF HUMAN SERA			
Average OD 450nm of Negative Sera		accepted	< Cut-off
Average OD 450nm of Positive Sera		accepted	> Cut-off

D) PRECISION OF FILLING PROCESS

☒ SATISFACTORY☐ UNSATISFACTORYFINAL RESULT: **ACCEPTED**

Date: 27.09.2022

Signed:
Released: Q.C. Manager

Aggiornamento 05.2012