

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 HERPES SIMPLEX 1 IgM

Code 91028

LOT.NO 237 EXPIRY 2023-11

REAGENTS

CODE	LABEL	DESCRIPTION	LOT No.	EXP	NO
PF93000	007200	MICROPLATE	665	2024-03	1
PF93925	007190	CUT OFF CONTROL	210	2024-03	1
PF93900/HSV	C5020	NEGATIVE CONTROL	764	2024-03	1
PF93923	007220	POSITIVE CONTROL	198	2024-03	1
PF91721	007230	ANTIGEN	220	2025-09	6
PF93611	009660	DILUENT 2	225	2023-12	1
PF93603	1035	WASHING BUFFER 10x	452	2024-02	1
PF93602	1032/RISK0	STOP SOLUTION	215	2024-08	1
PF93619	1034	SUBSTRATE-HS	365-1	2023-11	1
PF30055	007180	CONJUGATE	217	2023-12	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.117	< 0,6 CUT-OFF
CUT-OFF CONTROL	0.433	≥ 0.200
POSITIVE CONTROL	1.868	> 1,5 CUT-OFF
CV %	6%	≤ 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: 06/10/2021

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 IgM** Code 91028
 LOT: **237** Code 91186
 DATE OF TEST: **04/10/2022**

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE		<i>FOUND</i>	<i>EXPECTED</i>
A) UNIFORMITY BETWEEN PLATES			
1st PLATE	OD 450 nm	2.945	
	CV%	4%	<20%
2nd PLATE	OD 450 nm	2.964	
	CV%	12%	<20%
B) UNIFORMITY WITHIN PLATE			
	OD 450 nm	2.533	
	CV%	6%	≤15%
2. CONTROL OF COMPLETE KIT			
A) OD 450 nm Substrate Blank		0.052	≤0,100
OD 450 nm Negative Control		0.117	(≤ 0.6xCut-off)
OD 450 nm Cut-off Control		0.433	>0.200
OD 450 nm Positive Control		1.868	(≥1,5 x Cut-off)
B) PANEL OF HUMAN SERA		accepted	According to specifications
SATISFACTORY	☒	UNSATISFACTORY	☐
C) HOMOGENEITY OF CUT-OFF	No.	8	
	OD 450 nm	0.484	
	CV%	6%	≤15%

FINAL RESULT: **ACCEPTED**

Date:

04.10.2022

Signed:

Released: Q.C.Manager

Aggiornamento 05-2012