

DIESSE DIAGNOSTICA SENESE SpA53035 Monteriggioni (SIENA) – Italy – Strada dei Laghi, 39
Tel. +39 0577319554 FAX +39 0577319020Sede Legale e Amministrazione
Via Solari, 19 20144 Milano - Italy**QUALITY CONTROL CERTIFICATE****KIT NAME ENZYWELL HERPES SIMPLEX 1 IgM**

Code 91028

LOT.NO 235-C

EXPIRY 2023-07

REAGENTS

CODE	LABEL	DESCRIPTION	LOT No.	EXP	NO
PF93000	007200	MICROPLATE	661	2023-08	1
PF93925	007190	CUT OFF CONTROL	206	2023-10	1
PF93900/HSV	C5020	NEGATIVE CONTROL	744	2023-10	1
PF93923	007220	POSITIVE CONTROL	194	2023-10	1
PF91721	007230	ANTIGEN	219	2024-11	6
PF93611	009660	DILUENT 2	224	2023-10	1
PF93603	1035	WASHING BUFFER 10x	449-1	2023-11	1
PF93602	1032/RISK0	STOP SOLUTION	214-3	2024-02	1
PF93619	1034	SUBSTRATE-HS	362-1	2023-09	1
PF30055	007180	CONJUGATE	213	2023-07	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.127	< 0,6 CUT-OFF
CUT-OFF CONTROL	0.376	≥ 0.200
POSITIVE CONTROL	1.698	> 1,5 CUT-OFF
CV %	5%	≤ 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:** 24.06.2022**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 IgM** Code 91028
 LOT: 235 Code 91186
 DATE OF TEST: **12/05/2022**

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE		<i>FOUND</i>	<i>EXPECTED</i>
A) UNIFORMITY BETWEEN PLATES			
1st PLATE	OD 450 nm	1.875	
	CV%	4%	<20%
2nd PLATE	OD 450 nm	1.723	
	CV%	3%	<20%
B) UNIFORMITY WITHIN PLATE			
	OD 450 nm	1.901	
	CV%	7%	≤15%
2. CONTROL OF COMPLETE KIT			
A) OD 450 nm Substrate Blank		0.047	≤0,100
OD 450 nm Negative Control		0.127	(≤ 0.6xCut-off)
OD 450 nm Cut-off Control		0.376	>0.200
OD 450 nm Positive Control		1.698	(≥1,5 x Cut-off)
B) PANEL OF HUMAN SERA			According to specifications
SATISFACTORY	☒	UNSATISFACTORY	☐
C) HOMOGENEITY OF CUT-OFF	No.	6	
	OD 450 nm	0.423	
	CV%	5%	≤15%

FINAL RESULT: **ACCEPTED**

Date: **12.05.2022**

Signed: 
 Released: Q.C.Manager

Aggiornamento 05-2012