

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 2 IgM

Code 91025

LOT.NO 230 EXPIRY 2023-08

REAGENTS

CODE	LABEL	DESCRIPTION	LOT No.	EXP	NO
PF93000	007250	MICROPLATE	662	2023-09	1
PF93900/HSV	C4960	NEGATIVE CONTROL	746	2023-11	1
PF92355	007280	POSITIVE CONTROL	195	2023-11	1
PF30056	011560	CONJUGATE	214	2023-08	1
PF91722	007300	ANTIGEN	224	2025-04	6
PF93611	009660	DILUENT 2	223	2023-08	1
PF93603	1035	WASHING BUFFER 10x	449	2023-11	1
PF93602	1032/RISK0	STOP SOLUTION	214-2	2024-02	1
PF93619	1034	SUBSTRATE-HS	362-1	2023-09	1
PF30057	011570	CUT-OFF CONTROL	207	2023-11	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.185	< 0,6 CUT-OFF
CUT-OFF CONTROL	0.536	≥ 0.200
POSITIVE CONTROL	1.574	> 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

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 IgM**
 LOT: **230**
 DATE OF TEST: **27/05/2022**

Code 91025

Code 91187

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE		<i>FOUND</i>	<i>EXPECTED</i>
A) UNIFORMITY BETWEEN PLATES			
1st PLATE	OD450 nm	1.908	
	CV%	7%	<20%
2nd PLATE	OD 450nm	1.884	
>200 PLATES	CV%	3%	<20%
B) UNIFORMITY WITHIN PLATE			
	OD 450nm	1.915	
	CV%	6%	≤15%
2. CONTROL OF COMPLETE KIT			
A) OD 450 nm Substrate Blank		0.046	≤0,100
OD 450 nm Negative Control		0.185	(≤ 0.6xCut-off)
OD 450 nm Cut-off Control		0.536	>0.200
OD 450 nm Positive Control		1.574	(≥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	0.582	
	CV%	15%	≤15%

FINAL RESULT: **ACCEPTED**

Date:

20.05.2022

Signed:

Released: Q.C.Manager

Aggiornamento 05-2012