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

QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL HERPES SIMPLEX 2 IgM

Code 91025

LOT.NO 232 EXPIRY 2023-11

REAGENTS

CODE	LABEL	DESCRIPTION	LOT No.	EXP	NO
PF93000	007250	MICROPLATE	665	2024-03	1
PF93900/HSV	C4960	NEGATIVE CONTROL	766	2024-04	1
PF92355	007280	POSITIVE CONTROL	199	2024-04	1
PF30056	011560	CONJUGATE	218	2024-01	1
PF91722	007300	ANTIGEN	226	2025-09	6
PF93611	009660	DILUENT 2	225-1	2023-12	1
PF93603	1035	WASHING BUFFER 10x	452	2024-02	1
PF93602	1032/RISK0	STOP SOLUTION	215-1	2024-08	1
PF93619	1034	SUBSTRATE-HS	365-2	2023-11	1
PF30057	011570	CUT-OFF CONTROL	211	2024-04	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.166	< 0,6 CUT-OFF
CUT-OFF CONTROL	0.442	≥ 0.200
POSITIVE CONTROL	2.386	> 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 21.10.2022

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 2 IgM**
 LOT: **232**
 DATE OF TEST: **19/10/2022**

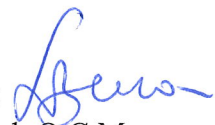
Code 91025
 Code 91187

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE		<i>FOUND</i>	<i>EXPECTED</i>
A) UNIFORMITY BETWEEN PLATES			
1st PLATE	OD450 nm	2.945	
	CV%	4%	<20%
2nd PLATE	OD 450nm	2.964	
>200 PLATES	CV%	12%	<20%
B) UNIFORMITY WITHIN PLATE			
	OD 450nm	2.533	
	CV%	6%	≤15%
2. CONTROL OF COMPLETE KIT			
A) OD 450 nm Substrate Blank		0.065	≤0,100
OD 450 nm Negative Control		0.166	(≤ 0.6xCut-off)
OD 450 nm Cut-off Control		0.442	>0.200
OD 450 nm Positive Control		2.386	(≥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	0.507	
	CV%	5%	≤15%

FINAL RESULT: **ACCEPTED**

Date: **19.10.2022**

Signed: 
 Released: Q.C.Manager

Aggiornamento 05-2012