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

QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL HERPES SIMPLEX 1 IgM

Code 91028

LOT.NO 235 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	223	2023-08	1
PF93603	1035	WASHING BUFFER 10x	448-1	2023-10	1
PF93602	1032/RISK0	STOP SOLUTION	214-1	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: 30.05.2022

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: **12.05.22**

Signed: 
 Released: Q.C.Manager

Aggiornamento 05-2012