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Sede Legale e Amministrazione
20144 Milano (Italy) Via A. Solari 19 sc. 6

QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL HERPES SIMPLEX 2 IgM

Code	91025		
LOT.NO	237-B	2025-02	2023-11

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93000	007250	MICROPLATE	673	2025-05	1
PF93900/HSV	C4960	NEGATIVE CONTROL	809-1	2025-05	1
PF92355	007280	POSITIVE CONTROL	208-1	2025-05	1
PF30056	011560	CONJUGATE	227-1	2025-02	1
PF91722	007300	ANTIGEN	227	2026-11	6
PF93611	009660	DILUENT 2	232	2025-05	1
PF93603	1035	WASHING BUFFER 10x	468	2025-06	1
PF93602	1032/RISK0	STOP SOLUTION	218-6	2025-06	1
PF93619	1034	SUBSTRATE-HS	383	2025-05	1
PF30057	011570	CUT OFF CONTROL	220-1	2025-05	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.256	< 0,6 Cut Off
CUT OFF CONTROL	0.505	≥ 0.200
POSITIVE CONTROL	1.667	> 1,5 Cut Off
CV %	15%	≤ 15%

*Evaluatin of the method according to the package inset in the attached document
This batch has been manufactured and checked according to quality requirements.
Hereby, it is released to distribution.*

APPROVED BY: RESPONSIBLE HEAD, Quality Control Reagents

DATE: 13.02.2024

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 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.

IO 09- 005-V



CODE 91025
CODE 91187

QUALITY CONTROL CERTIFICATE
Annex: Method Evaluation

NAME KIT HERPES SIMPLEX 2 IgM
LOT. 237
DATE OF TEST 23/11/2023

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE	FOUND		EXPECTED
A) UNIFORMITY BETWEEN PLATES			
1st PLATE	OD 450 nm	2.715	
	CV%	15%	< 20%
2nd PLATE	OD 450 nm	2.817	
	CV%	8%	< 20%
B) UNIFORMITY WITHIN PLATE			
	OD 450 nm	2.707	
	CV%	7%	< 15%
2. BULK CONTROL date: 17/11/2023			
A) Average OD of Cut Off Control	OD 450 nm	0.417	≥ 0.200
B) Index of Negative and Positive Sera		accepted	According to specification
C) Sensitivity with working calibrators		accepted	According to specification
3. FINAL CONTROL date: 23/11/2023			
A) Blank	OD 450 nm	0.045	≤ 0.100
B) Average OD of Negative Control	OD 450 nm	0.173	< 0,6 Cut Off
C) Average OD of Cut Off Control	OD 450 nm	0.410	≥ 0.200
D) Average OD of Positive Control	OD 450 nm	1.329	> 1,5 Cut Off
E) HOMOGENEITY OF CUT OFF	No.	6	
	OD 450 nm	0.454	
	CV%	11%	≤ 15%
F) PRECISION OF FILLING PROCESS			

SATISFACTORY

UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 23/11/2023

Signed: 
Released: Q.C.Manager