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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	236	2024-10	2023-09

### REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93000	007250	MICROPLATE	669	2024-10	1
PF93900/HSV	C4960	NEGATIVE CONTROL	797	2025-03	1
PF92355	007280	POSITIVE CONTROL	206	2025-03	1
PF30056	011560	CONJUGATE	225	2024-12	1
PF91722	007300	ANTIGEN	226	2025-09	6
PF93611	009660	DILUENT 2	231	2025-03	1
PF93603	1035	WASHING BUFFER 10x	459	2024-10	1
PF93602	1032/RISK0	STOP SOLUTION	218-3	2025-06	1
PF93619	1034	SUBSTRATE-HS	380	2025-03	1
PF30057	011570	CUT OFF CONTROL	218	2025-03	1

### CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.082	< 0,6 Cut Off
CUT OFF CONTROL	0.347	≥ 0.200
POSITIVE CONTROL	2.055	> 1,5 Cut Off
CV %	8%	≤ 15%

*Evaluation of the method according to the package insert 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: 19/10/23

### 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. 236  
 DATE OF TEST 12/10/2023

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE	FOUND		EXPECTED
A) UNIFORMITY BETWEEN PLATES			
1st PLATE	OD 450 nm	1.566	
	CV%	11%	< 20%
2nd PLATE	OD 450 nm	N/A	
	CV%	N/A	< 20%
B) UNIFORMITY WITHIN PLATE			
	OD 450 nm	1.693	
	CV%	11%	< 15%
2. BULK CONTROL date: 03/10/2023			
A) Average OD of Cut Off Control	OD 450 nm	0.347	≥ 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:12/10/2023			
A) Blank	OD 450 nm	0.038	≤ 0.100
B) Average OD of Negative Control	OD 450 nm	0.082	< 0,6 Cut Off
C) Average OD of Cut Off Control	OD 450 nm	0.347	≥ 0.200
D) Average OD of Positive Control	OD 450 nm	2.055	> 1,5 Cut Off
E) HOMOGENEITY OF CUT OFF			
	No.	6	
	OD 450 nm	0.385	
	CV%	8%	≤ 15%
F) PRECISION OF FILLING PROCESS			

SATISFACTORY

UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date:

Signed:

Released: Q.C.Manager