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

QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL SYPHILIS SCREEN RECOMBINANT

Code	91100		
LOT.NO	363-D	2024-09	2023-07

REAGENTS

CODE	LABEL	DESCRIPTION	LOT No.	EXP	NO
PF91101	007350	MICROPLATE	417	2024-12	2
PF91102	007340	CONJUGATE	366-1	2024-10	2
V267	007360	NEGATIVE CONTROL	177-1	2024-09	1
PF93959/N	007370	POSITIVE CONTROL	364-1	2024-10	1
PF93603	1035	WASHING BUFFER 10x	468	2025-06	1
PF93619	1034	SUBSTRATE	381	2025-04	2
PF93602	1032/RISK0	STOP SOLUTION	218-6	2025-06	2

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.128	≤ 0.200
POSITIVE CONTROL	1.213	$\geq 0.600 \leq 2.000$
CUT-OFF (NEG. C. + POS. C.) /3	0.447	

The test has been carried out in accordance with the package insert

TESTED BY: Silvia Sardelli

APPROVED BY: RESPONSIBLE HEAD, Quality Control Reagents

DATE 15.12.2023

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:	SYPHILIS SCREEN RECOMBINANT	Code	91100
LOT:	363		91104
DATE OF TEST:	25/07/2023		91105
			91100-B

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE		<i>FOUND</i>	<i>EXPECTED</i>
A) UNIFORMITY BETWEEN PLATES			
1st PLATE	OD450 nm	1.576	
	CV%	5%	≤15%
2nd PLATE	OD 450nm	1.543	
	CV%	4%	≤15%
B) UNIFORMITY WITHIN PLATE			
	OD 450nm	1.346	
	CV%	7%	≤11%
2. ALIGNMENT AND GOOD FUNCTION			
A) Average OD of Negative Calibrator	OD 450 nm	0.101	≤ 0,2
B) Average OD of Positive Calibrator	OD 450 nm	1.205	≥ 0,800 ≤ 2,000
C) Sensitivity with secondary standards			
TPN1 = OD C. Neg. ± 0,050		0.092	0.051-0.151
TPN2 INDEX		0,9	≥0,7
TPN3/TPN2		2,0	≥ 1,4
TPN4 INDEX		3,9	≥1,4
3. CONTROL OF COMPLETE KIT			
A) Calculation of Cut-off (OD C. Pos. + OD C. Neg.)/3		0.473	
B) Panel of Human sera			
Average of 20 Negative sera		0.146	According to spec.
Average of 8 Positive sera		0.959	According to spec.
C) Precision of filling:			
	Satisfactory <input checked="" type="checkbox"/>	Unsatisfactory <input type="checkbox"/>	

FINAL RESULT: **ACCEPTED**

Date: **25.07.2023**

Signed: 
Released: Q.C.Manager

Update **March,07**