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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	358	2023-09	2022-06

REAGENTS

CODE	LABEL	DESCRIPTION	LOT No.	EXP	NO
PF91101	007350	MICROPLATE	411	2023-11	2
PF91102	007340	CONJUGATE	361	2023-09	2
V267	007360	NEGATIVE CONTROL	173	2023-11	1
PF93959/N	007370	POSITIVE CONTROL	360	2023-09	1
PF93603	1035	WASHING BUFFER 10x	449-1	2023-11	1
PF93619	1034	SUBSTRATE	364	2023-11	2
PF93602	1032/RISK0	STOP SOLUTION	214-3	2024-02	2

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.125	≤ 0.200
POSITIVE CONTROL	1.516	$\geq 0.600 \leq 2.000$
CUT-OFF (NEG. C. + POS. C.) /3	0.547	

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

TESTED BY: Baiocchi Simone

APPROVED BY: RESPONSIBLE HEAD, Quality Control Reagents

DATE 15/02/2022

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:	SYPHILIS SCREEN RECOMBINANT	Code	91100
LOT:	358		91104
DATE OF TEST:	06/07/2022		91105
			91100-B

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE		FOUND	EXPECTED	
A) UNIFORMITY BETWEEN PLATES				
1st PLATE	OD450 nm	1.020		
	CV%	11%	≤15%	
2nd PLATE	OD 450nm	1.074		
	CV%	7%	≤15%	
B) UNIFORMITY WITHIN PLATE				
	OD 450nm	0.960		
	CV%	9%	≤11%	
2. ALIGNMENT AND GOOD FUNCTION				
A)	Average OD of Negative Calibrator	OD 450 nm	0.127	≤ 0,2
B)	Average OD of Positive Calibrator	OD 450 nm	1.422	≥ 0,800 ≤ 2,000
C)	Sensitivity with secondary standards			
	TPN1 = OD C. Neg. ± 0,050		0.123	0,077-0,177
	TPN2 INDEX		1,0	≥0,7
	TPN3/TPN2		2,2	≥ 1,4
	TPN4 INDEX		4,8	≥1,4
3. CONTROL OF COMPLETE KIT				
A)	Calculation of Cut-off			
	(OD C. Pos. + OD C. Neg.)/3		0.547	
B)	Panel of Human sera			
	Average of 20 Negative sera		0.164	According to spec.
	Average of 8 Positive sera		2.094	According to spec.
C)	Precision of filling:			
	Satisfactory	☒	Unsatisfactory	☐

FINAL RESULT: ACCEPTED

Date: 06/07/2022

Signed: 
Released: Q.C.Manager

Update March,07