

DIESSE DIAGNOSTICA SENESE SpA
 53035 Monteriggioni (SIENA) – Italy – Strada dei Laghi, 39
 Tel. +39 0577319554 FAX +39 0577319020



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

QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL SYPHILIS SCREEN RECOMBINANT

Code	91100		
LOT.NO	360-C	2023-11	2022-09

REAGENTS

CODE	LABEL	DESCRIPTION	LOT No.	EXP	NO
PF91101	007350	MICROPLATE	413	2024-02	2
PF91102	007340	CONJUGATE	363	2023-12	2
V267	007360	NEGATIVE CONTROL	174	2023-11	1
PF93959/N	007370	POSITIVE CONTROL	361	2023-12	1
PF93603	1035	WASHING BUFFER 10x	452	2024-02	1
PF93619	1034	SUBSTRATE	368	2024-04	2
PF93602	1032/RISK0	STOP SOLUTION	215-1	2024-08	2

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.108	≤ 0.200
POSITIVE CONTROL	1.502	$\geq 0.600 \leq 2.000$
CUT-OFF (NEG. C. + POS. C.) /3	0.537	

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

TESTED BY: Katia Tanzini

APPROVED BY: RESPONSIBLE HEAD, Quality Control Reagents

DATE 05.12.22

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:	360		91104
DATE OF TEST:	20/09/2022		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	1.037	
	CV%	8%	≤15%
2nd PLATE	OD 450nm	N/A	
	CV%	N/A	≤15%
B) UNIFORMITY WITHIN PLATE			
	OD 450nm	1.189	
	CV%	10%	≤11%
2. ALIGNMENT AND GOOD FUNCTION			
A) Average OD of Negative Calibrator	OD 450 nm	0.096	≤ 0,2
B) Average OD of Positive Calibrator	OD 450 nm	1.684	≥ 0,800 ≤ 2,000
C) Sensitivity with secondary standards			
TPN1 = OD C. Neg. ± 0,050		0.096	0.046 - 0.146
TPN2 INDEX		0,9	≥0,7
TPN3/TPN2		1,9	≥ 1,4
TPN4 INDEX		3,7	≥1,4
3. CONTROL OF COMPLETE KIT			
A) Calculation of Cut-off		0.537	
(OD C. Pos. + OD C. Neg.)/3			
B) Panel of Human sera			
Average of 20 Negative sera		0.154	According to spec.
Average of 8 Positive sera		1.428	According to spec.
C) Precision of filling:			
Satisfactory	☒	Unsatisfactory	☐

FINAL RESULT: ACCEPTED

Date: 21.09.2022

Signed: 
Released: Q.C.Manager

Update: March,07