

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 TREPONEMA IgM

Code 91051

LOT 171-A EXPIRY 2024-02

REAGENTS

CODE	LABEL	DESCRIPTION	LOT No.	EXP	NO
PF93031	006820	MICROPLATE	728	2024-09	1
PF93522	006810	CONJUGATE	154-2	2024-02	1
PF93900/TPM	C5140	NEGATIVE CONTROL	772-2	2024-05	1
PF92053	005000	POSITIVE CONTROL	131-2	2024-05	1
PF91851	005020	CUT-OFF CONTROL	136-2	2024-05	1
PF93619	1034	SUBSTRATE-HS	371	2024-06	1
PF93621	006030	DILUENT 10	162	2024-04	1
PF93603	1035	WASHING BUFFER 10x	452	2024-02	1
PF93602	1032/RISK0	STOP SOLUTION	215-1	2024-08	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.071	<0,6 CUT-OFF
CUT-OFF CONTROL	0.369	≥ 0.200
POSITIVE CONTROL	1.812	>1,5 CUT-OFF
CV %	6%	≤ 15%

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

TESTED BY: Katia Tanzini

APPROVED BY: RESPONSIBLE HEAD, Quality Control Reagents

DATE 06.03.2023

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: **TREPONEMA IgM**
 LOT: **171**
 DATE OF TEST: **29/12/2022**

Code 91051

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE		FOUND	EXPECTED
A) UNIFORMITY BETWEEN PLATES			
1st PLATE	OD450 nm	1.941	
	CV%	4%	<20%
2nd PLATE	OD 450nm	1.755	
	CV%	3%	<20%
B) UNIFORMITY WITHIN PLATE			
	OD 450nm	1.759	
	CV%	3%	≤15%
2. BULK CONTROL date: 01/12/2022			
A) Average OD of Cut Off Control	OD 450 nm	0.395	≥ 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: 29/12/2022			
A) Blank	OD 450 nm	0.066	≤ 0.100
B) Average OD of Negative Control	OD 450 nm	0.071	< 0,6 Cut Off
C) Average OD of Cut Off Control	OD 450 nm	0.369	≥ 0.200
D) Average OD of Positive Control	OD 450 nm	1.812	> 1,5 Cut Off
E) HOMOGENEITY OF CUT-OFF			
	No.	6	
	OD 450 nm	0.435	
	CV%	6%	≤15%

F) PRECISION OF FILLING PROCESS

☒ SATISFACTORY ☐ UNSATISFACTORY

FINAL RESULT: **ACCEPTED**

Date: 23/12/2022

Signed:
 Released: Q.C. Manager