

DIESSA DIAGNOSTICA SENESE SpA
53035 Monteriggioni (SI), Italy, Strada dei Laghi 39
Tel. +39 0577319554 FAX +39 0577319020



Sede Legale e Amministrazione
20144 Milano (Italy) Via A. Solari 19 sc. 6

QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL TREPONEMA IgM

Code	91051		
LOT.NO	175	2025-07	2024-05

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93031	006820	MICROPLATE	729	2025-07	1
PF93522	006810	CONJUGATE	158	2025-08	1
PF93900/TPM	C5140	NEGATIVE CONTROL	823	2025-11	1
PF92053	005000	POSITIVE CONTROL	135	2025-11	1
PF91851	005020	CUT OFF CONTROL	140	2025-11	1
PF93619	1034	SUBSTRATE-HS	385	2025-08	1
PF93621	006030	DILUENT 10	166	2025-08	1
PF93603	1035	WASHING BUFFER 10x	473	2025-08	1
PF93602	1032/RISK0	STOP SOLUTION	220	2026-03	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL 0	0.154	<0,6 CUT OFF
CUT-OFF CONTROL 0,25	0.413	≥ 0.200
POSITIVE CONTROL 2	1.731	>1,5 CUT-OFF
CV %	13%	≤ 15%

*Evaluatin of the method according to the package inset 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: 27.05.2024

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 09-019-V



CODE 91051

QUALITY CONTROL CERTIFICATE

Annex: Method Evaluation

NAME KIT TREPONEMA IgM
LOT. 175
DATE OF TEST 23/05/2024

METHOD ACCORDING TO THE PACKAGE INSERT

1. SOLIDE PHASE	FOUND		EXPECTED
A) UNIFORMITY BETWEEN PLATES			
1st PLATE	OD 450nm	2.017	
	CV%	2%	<20%
2nd PLATE	OD 450nm	2.012	
	CV%	4%	<20%
B) UNIFORMITY WITHIN PLATE			
	OD450nm	1.896	
	CV%	4%	<15%
2. BULK CONTROL date: 16/05/2024			
A) Average OD of Cut Off Control	OD 450 nm	0.426	≥ 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: 23/05/2024			
A) Blank	OD 450 nm	0.060	≤ 0.100
B) Average OD of Negative Control	OD 450 nm	0.154	< 0,6 Cut Off
C) Average OD of Cut Off Control	OD 450 nm	0.413	≥ 0.200
D) Average OD of Positive Control	OD 450 nm	1.731	> 1,5 Cut Off
E) HOMOGENEITY OF CUT-OFF	No.	6	
	OD 450 nm	0.473	
	CV%	13%	≤15%
F) PRECISION OF FILLING PROCESS			



SATISFACTORY



UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 23/05/2024

Signed: 
Released: Q.C.Manager