

QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL TREPONEMA IgG

Code	91050		
LOT.NO	143-A	2025-05	2024-03

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93050	006820	MICROPLATE	419	2025-09	1
PF93505	006810	CONJUGATE	111	2025-06	1
PF93910	1036	NEGATIVE CONTROL	178-1	2025-05	1
PF92050	005040	POSITIVE CONTROL	094	2025-09	1
PF91850	005060	CUT OFF CONTROL	104	2025-09	1
PF93619	1034	SUBSTRATE-HS	383	2025-05	1
PF93621	006030	DILUENT	166	2025-08	1
PF93603	1035	WASHING BUFFER 10x	468	2025-06	1
PF93602	1032/RISK0	STOP SOLUTION	218-6	2025-06	1

CONTROLS

IU/mL	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL 0	0.038	$\leq 0,6$ CUT-OFF
CUT-OFF CONTROL 0,25	0.431	≥ 0.200
POSITIVE CONTROL 2	2.007	$\geq 1,5$ CUT-OFF
CV %	9%	$\leq 15\%$

*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: 23.06.2024

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 09-018-V



CODE 91050

QUALITY CONTROL CERTIFICATE
Annex: Method Evaluation

NAME KIT TREPONEMA IgG
LOT. 143
DATE OF TEST 21/03/2024

METHOD: ACCORDING TO THE PACKAGE INSERT

I. MICROPLATE CONTROL		FOUND	EXPECTED
A) UNIFORMITY BETWEEN PLATES			
1st PLATE		OD 450 nm 1.391	
		CV% 8%	<20%
2st PLATE		OD 450 nm N/A	
		CV% N/A	<20%
B) UNIFORMITY WITHIN PLATE			
		OD 450nm 1.585	
		CV% 7%	<15%
2. BULK CONTROL date: 18/03/2024			
A) Average OD of Cut Off Control		OD 450nm 0.381	≥ 0.200
B) Average OD of 5 Negative Sera		accepted	According to specification
C) Average OD of 3 Positive Sera		accepted	According to specification
D) Sensitivity with working calibrators		accepted	According to specification
3. FINAL CONTROL date: 21/03/2024			
A) Blank		OD 450 nm 0.051	≤ 0.100
B) Average OD of Negative Control		OD 450 nm 0.038	≤ 0.6 Cut Off
C) Average OD of Cut Off Control		OD 450 nm 0.431	≥ 0.200
D) Average OD of Positive Control		OD 450 nm 2.007	≥ 1.5 Cut Off
E) HOMOGENEITY OF CUT-OFF			
		N° Replicate 6	
		OD 450 nm 0.481	
		CV% 9%	≤ 15%
F) PRECISION OF FILLING PROCESS			

SATISFACTORY

UNSATISFACTORY

FINAL RESULT: ACCEPTED
Date: 21.03.2024

Signed:
Released: Q.C.Manager