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

QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL TREPONEMA IgG

Code	91050		
LOT.NO	144	2025-06	2024-05

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93050	006820	MICROPLATE	420	2025-11	1
PF93505	006810	CONJUGATE	112	2025-08	1
PF93910	1036	NEGATIVE CONTROL	179	2025-06	1
PF92050	005040	POSITIVE CONTROL	095	2025-11	1
PF91850	005060	CUT OFF CONTROL	105	2025-11	1
PF93619	1034	SUBSTRATE-HS	385	2025-08	1
PF93621	006030	DILUENT	166	2025-08	1
PF93603	1035	WASHING BUFFER 10x	475	2025-11	1
PF93602	1032/RISKO	STOP SOLUTION	218-6	2025-06	1

CONTROLS

IU/mL	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL 0	0.000	$\leq 0,6$ CUT-OFF
CUT-OFF CONTROL 0,25	0.346	≥ 0.200
POSITIVE CONTROL 2	1.698	$\geq 1,5$ CUT-OFF
CV %	10%	$\leq 15\%$

*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: 04.06.2024

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. 144
DATE OF TEST 03/06/2024

METHOD: ACCORDING TO THE PACKAGE INSERT

1. MICROPLATE CONTROL	FOUND		EXPECTED
A) UNIFORMITY BETWEEN PLATES			
1st PLATE	OD 450 nm	1.781	
	CV%	6%	<20%
2st PLATE	OD 450 nm	N/A	
	CV%	N/A	<20%
B) UNIFORMITY WITHIN PLATE			
	OD 450nm	1.766	
	CV%	12%	<15%
2. BULK CONTROL date: 29/05/2024			
A) Average OD of Cut Off Control	OD 450nm	0.365	≥ 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: 03/06/2024			
A) Blank	OD 450 nm	0.046	≤ 0.100
B) Average OD of Negative Control	OD 450 nm	0.000	≤ 0.6 Cut Off
C) Average OD of Cut Off Control	OD 450 nm	0.346	≥ 0.200
D) Average OD of Positive Control	OD 450 nm	1.698	≥ 1.5 Cut Off
E) HOMOGENEITY OF CUT-OFF	N° Replicate	6	
	OD 450 nm	0.392	
	CV%	10%	≤ 15%
F) PRECISION OF FILLING PROCESS			

SATISFACTORY

UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 03.06.2024

Signed: 
Released: Q.C.Manager