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

QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL TREPONEMA IgG

Code 91050

LOT.NO 141 EXPIRY 2024-04

REAGENTS

CODE	LABEL	DESCRIPTION	LOT No.	EXP	NO
PF93050	006820	MICROPLATE	414	2024-04	1
PF93505	006810	CONJUGATE	109	2024-04	1
PF93910	1036	NEGATIVE CONTROL	175-2	2024-06	1
PF92050	005040	POSITIVE CONTROL	092	2024-07	1
PF91850	005060	CUT-OFF CONTROL	102	2024-07	1
PF93619	1034	SUBSTRATE-HS	368	2024-04	1
PF93621	006030	DILUENT	163	2024-06	1
PF93603	1035	WASHING BUFFER 10x	454	2024-05	1
PF93602	1032/RISK0	STOP SOLUTION	215-3	2024-08	1

CONTROLS

IU/mL	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL 0	0.009	≤ 0,6 CUT-OFF
CUT-OFF CONTROL 0,25	0.372	≥ 0.200
POSITIVE CONTROL 2	2.228	≥ 1,5 CUT-OFF
CV %	7%	≤ 15%

The test has been carried out in accordance with the package insert
The IU/mL are calculated against the 1st International Standard Preparation 1958.

TESTED BY: Silvia Sardelli

APPROVED BY: (RESPONSIBLE HEAD, Quality Control Reagents)

DATE: 19.06.2023

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 IgG** Code 91050
 LOT: **141**
 DATE OF TEST: **17/02/2023**

METHOD: ACCORDING TO THE PACKAGE INSERT

1. MICROPLATE CONTROL	FOUND	EXPECTED
A) UNIFORMITY BETWEEN PLATES		
1st PLATE	OD 450 nm 1.769	
	CV% 7%	≤20%
B) UNIFORMITY WITHIN PLATE		
	OD 450nm 1.835	
	CV% 9%	≤15%
2. BULK CONTROL date: 13/02/2023		
A) Average OD of Cut Off Control	OD 450nm 0.431	≥ 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: 17/02/2023		
A) Blank	OD 450 nm 0.048	≤ 0.100
B) Average OD of Negative Control	OD 450 nm 0.009	< 0.6xCut Off
C) Average OD of Cut Off Control	OD 450 nm 0.372	≥ 0.200
D) Average OD of Positive Control	OD 450 nm 2.228	> 1.5 x Cut Off
E) HOMOGENEITY OF CUT-OFF	N° Replicate 6	
	OD 450 nm 0.420	
	CV% 7%	≤ 15%
F) PRECISION OF FILLING PROCESS		

SATISFACTORY

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UNSATISFACTORY

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FINAL RESULT: **ACCEPTED**

Date: **17.02.2023**

Signed:

Released: Q.C.Manager

Aggiornamento 08.2012