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Sede Legale e Amministrazione  
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## QUALITY CONTROL CERTIFICATE

**KIT NAME ENZYWELL TREPONEMA IgG**

Code 91050

LOT.NO 142 EXPIRY 2024-09

### REAGENTS

CODE	LABEL	DESCRIPTION	LOT No.	EXP	NO
PF93050	006820	MICROPLATE	416	2024-09	1
PF93505	006810	CONJUGATE	110	2025-02	1
PF93910	1036	NEGATIVE CONTROL	178	2025-05	1
PF92050	005040	POSITIVE CONTROL	093	2025-05	1
PF91850	005060	CUT-OFF CONTROL	103	2025-05	1
PF93619	1034	SUBSTRATE-HS	381	2025-04	1
PF93621	006030	DILUENT	164	2024-12	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	0.028	$\leq 0,6$ CUT-OFF
CUT-OFF CONTROL 0,25	0.422	$\geq 0.200$
POSITIVE CONTROL 2	1.745	$\geq 1,5$ CUT-OFF
CV %	6%	$\leq 15\%$

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: 13.12.2023

#### 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: **142**  
 DATE OF TEST: **12/12/2023**

METHOD: ACCORDING TO THE PACKAGE INSERT

1. MICROPLATE CONTROL	FOUND	EXPECTED
A) UNIFORMITY BETWEEN PLATES		
1st PLATE	OD 450 nm	<b>1.865</b>
	CV%	<b>5%</b> ≤20%
B) UNIFORMITY WITHIN PLATE		
	OD 450nm	<b>1.747</b>
	CV%	<b>10%</b> ≤15%
2. BULK CONTROL date: 06/12/2023		
A) Average OD of Cut Off Control	OD 450nm	<b>0.449</b> ≥ 0.200
B) Average OD of 5 Negative Sera	<b>accepted</b>	According to specification
C) Average OD of 3 Positive Sera	<b>accepted</b>	According to specification
D) Sensitivity with working calibrators	<b>accepted</b>	According to specification
3. FINAL CONTROL date: 12/12/2023		
A) Blank	OD 450 nm	<b>0.050</b> ≤ 0.100
B) Average OD of Negative Control	OD 450 nm	<b>0.028</b> < 0.6xCut Off
C) Average OD of Cut Off Control	OD 450 nm	<b>0.422</b> ≥ 0.200
D) Average OD of Positive Control	OD 450 nm	<b>1.745</b> > 1.5 x Cut Off
E) HOMOGENEITY OF CUT-OFF		
	N° Replicate	<b>6</b>
	OD 450 nm	<b>0.471</b>
	CV%	<b>6%</b> ≤ 15%
F) PRECISION OF FILLING PROCESS		

SATISFACTORY

UNSATISFACTORY

FINAL RESULT: **ACCEPTED**

Date: **12.12.2023**

Signed:   
 Released: Q.C.Manager

Aggiornamento 08.2012