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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 139 EXPIRY 2023-08

REAGENTS

CODE	LABEL	DESCRIPTION	LOT No.	EXP	NO
PF93050	006820	MICROPLATE	410	2023-11	1
PF93505	006810	CONJUGATE	107	2023-09	1
PF93910	1036	NEGATIVE CONTROL	172-3	2023-08	1
PF92050	005040	POSITIVE CONTROL	090	2023-12	1
PF91850	005060	CUT-OFF CONTROL	100	2023-12	1
PF93619	1034	SUBSTRATE-HS	362-1	2023-09	1
PF93621	006030	DILUENT	160	2023-08	1
PF93603	1035	WASHING BUFFER 10x	449-1	2023-11	1
PF93602	1032/RISK0	STOP SOLUTION	214-3	2024-02	1

CONTROLS

IU/mL	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL 0	0.000	$\leq 0,6$ CUT-OFF
CUT-OFF CONTROL 0,25	0.424	≥ 0.200
POSITIVE CONTROL 2	2.431	$\geq 1,5$ CUT-OFF
CV %	7%	$\leq 15\%$

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: Katia Tanzini

APPROVED BY: (RESPONSIBLE HEAD, Quality Control Reagents)

DATE: 27.06.2022

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: **139**
 DATE OF TEST: **24/06/2022**

METHOD: ACCORDING TO THE PACKAGE INSERT

1. MICROPLATE CONTROL		FOUND	EXPECTED
A) UNIFORMITY BETWEEN PLATES			
1st PLATE	OD 450 nm	2.510	
	CV%	7%	$\leq 20\%$
B) UNIFORMITY WITHIN PLATE			
	OD 450nm	2.572	
	CV%	6%	$\leq 15\%$
2. BULK CONTROL date: 16/06/2022			
A) Average OD of Cut Off Control	OD 450nm	0.422	≥ 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: 24/06/2022			
A) Blank	OD 450 nm	0.060	≤ 0.100
B) Average OD of Negative Control	OD 450 nm	0.000	$< 0.6 \times \text{Cut Off}$
C) Average OD of Cut Off Control	OD 450 nm	0.424	≥ 0.200
D) Average OD of Positive Control	OD 450 nm	2.431	$> 1.5 \times \text{Cut Off}$
E) HOMOGENEITY OF CUT-OFF	N° Replicate	6	
	OD 450 nm	0.484	
	CV%	7%	$\leq 15\%$
F) PRECISION OF FILLING PROCESS			

SATISFACTORY ☒

UNSATISFACTORY ☐

FINAL RESULT: **ACCEPTED**

Date: *24.6.22*

Signed: *[Signature]*
 Released: Q.C.Manager

Aggiornamento 08.2012