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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-A EXPIRY 2024-09

#### REAGENTS

| CODE    | LABEL      | DESCRIPTION        | LOT No. | EXP     | NO |
|---------|------------|--------------------|---------|---------|----|
| PF93050 | 006820     | MICROPLATE         | 416     | 2024-09 | 1  |
| PF93505 | 006810     | CONJUGATE          | 110-1   | 2025-02 | 1  |
| PF93910 | 1036       | NEGATIVE CONTROL   | 177-2   | 2025-03 | 1  |
| PF92050 | 005040     | POSITIVE CONTROL   | 093-1   | 2025-05 | 1  |
| PF91850 | 005060     | CUT-OFF CONTROL    | 103-1   | 2025-05 | 1  |
| PF93619 | 1034       | SUBSTRATE-HS       | 383     | 2025-05 | 1  |
| PF93621 | 006030     | DILUENT            | 165     | 2025-05 | 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   | 0.009         | ≤ 0,6 CUT-OFF    |
| CUT-OFF CONTROL 0,25 | 0.408         | ≥ 0.200          |
| POSITIVE CONTROL 2   | 1.789         | ≥ 1,5 CUT-OFF    |
| CV %                 | 8%            | ≤ 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: 25.06.2024

#### 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 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