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

## QUALITY CONTROL CERTIFICATE

**KIT NAME ENZYWELL TREPONEMA IgM**

Code 91051

LOT 171 EXPIRY 2024-02

### REAGENTS

| CODE        | LABEL      | DESCRIPTION        | LOT No. | EXP     | NO |
|-------------|------------|--------------------|---------|---------|----|
| PF93031     | 006820     | MICROPLATE         | 728     | 2024-09 | 1  |
| PF93522     | 006810     | CONJUGATE          | 154     | 2024-02 | 1  |
| PF93900/TPM | C5140      | NEGATIVE CONTROL   | 772     | 2024-05 | 1  |
| PF92053     | 005000     | POSITIVE CONTROL   | 131     | 2024-05 | 1  |
| PF91851     | 005020     | CUT-OFF CONTROL    | 136     | 2024-05 | 1  |
| PF93619     | 1034       | SUBSTRATE-HS       | 368     | 2024-04 | 1  |
| PF93621     | 006030     | DILUENT 10         | 162     | 2024-04 | 1  |
| PF93603     | 1035       | WASHING BUFFER 10x | 452     | 2024-02 | 1  |
| PF93602     | 1032/RISK0 | STOP SOLUTION      | 215-1   | 2024-08 | 1  |

### CONTROLS

|                  | FOUND RESULTS | EXPECTED RESULTS |
|------------------|---------------|------------------|
| NEGATIVE CONTROL | 0.071         | <0,6 CUT-OFF     |
| CUT-OFF CONTROL  | 0.369         | ≥ 0.200          |
| POSITIVE CONTROL | 1.812         | >1,5 CUT-OFF     |
| CV %             | 6%            | ≤ 15%            |

The test has been carried out in accordance with the package insert

TESTED BY: Katia Tanzini

APPROVED BY: RESPONSIBLE HEAD, Quality Control Reagents

DATE 10.01.2023

### 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.

1122406



### CERTIFICATE OF ANALYSIS

KIT: **TREPONEMA IgM**  
 LOT: **171**  
 DATE OF TEST: **29/12/2022**

Code 91051

METHOD: ACCORDING TO THE PACKAGE INSERT

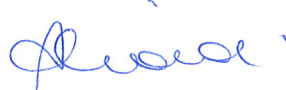
| 1. SOLID PHASE                          |           | FOUND           | EXPECTED                   |
|-----------------------------------------|-----------|-----------------|----------------------------|
| A) UNIFORMITY BETWEEN PLATES            |           |                 |                            |
| 1st PLATE                               | OD450 nm  | <b>1.941</b>    |                            |
|                                         | CV%       | <b>4%</b>       | <20%                       |
| 2nd PLATE                               | OD 450nm  | <b>1.755</b>    |                            |
|                                         | CV%       | <b>3%</b>       | <20%                       |
| B) UNIFORMITY WITHIN PLATE              |           |                 |                            |
|                                         | OD 450nm  | <b>1.759</b>    |                            |
|                                         | CV%       | <b>3%</b>       | ≤15%                       |
| 2. BULK CONTROL date: 01/12/2022        |           |                 |                            |
| A) Average OD of Cut Off Control        | OD 450 nm | <b>0.395</b>    | ≥ 0.200                    |
| B) Index of Negative and Positive Sera  |           | <b>accepted</b> | According to specification |
| C) Sensitivity with working calibrators |           | <b>accepted</b> | According to specification |
| 3. FINAL CONTROL date: 29/12/2022       |           |                 |                            |
| A) Blank                                | OD 450 nm | <b>0.066</b>    | ≤ 0.100                    |
| B) Average OD of Negative Control       | OD 450 nm | <b>0.071</b>    | < 0,6 Cut Off              |
| C) Average OD of Cut Off Control        | OD 450 nm | <b>0.369</b>    | ≥ 0.200                    |
| D) Average OD of Positive Control       | OD 450 nm | <b>1.812</b>    | > 1,5 Cut Off              |
| E) HOMOGENEITY OF CUT-OFF               |           |                 |                            |
|                                         | No.       | <b>6</b>        |                            |
|                                         | OD 450 nm | <b>0.435</b>    |                            |
|                                         | CV%       | <b>6%</b>       | ≤15%                       |

#### F) PRECISION OF FILLING PROCESS

☒ SATISFACTORY ☐ UNSATISFACTORY

FINAL RESULT: **ACCEPTED**

Date: **23/12/2022**

Signed:   
 Released: Q.C.Manager