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

## QUALITY CONTROL CERTIFICATE

**KIT NAME** ENZYWELL TOXOPLASMA IgM

|          |       |         |         |
|----------|-------|---------|---------|
| Code     | 91041 |         |         |
| LOT. NO. | 315-A | 2023-11 | 2022-09 |

### REAGENTS

| CODE        | LABEL      | DESCRIPTION        | LOT No. | EXP     | NO |
|-------------|------------|--------------------|---------|---------|----|
| PF93000     | 006330     | MICROPLATE         | 664     | 2023-12 | 1  |
| PF91540     | 006320     | CONJUGATE          | 220-1   | 2023-11 | 1  |
| PF93900/TXM | C5100      | NEGATIVE CONTROL   | 761-1   | 2024-02 | 1  |
| PF92042     | 005370     | POSITIVE CONTROL   | 201-1   | 2024-02 | 1  |
| PF91841     | 005120     | CUT-OFF CONTROL    | 200     | 2024-02 | 1  |
| PF91641     | 005130     | ANTIGEN (3,0 mL)   | 204     | 2025-02 | 6  |
| PF93611     | 009660     | DILUENT 2          | 226     | 2024-04 | 1  |
| PF93603     | 1035       | WASHING BUFFER 10x | 452     | 2024-02 | 1  |
| PF93602     | 1032/RISK0 | STOP SOLUTION      | 215-1   | 2024-08 | 1  |
| PF93619     | 1034       | SUBSTRATE-HS       | 366     | 2023-12 | 1  |

### CONTROLS

|                  | FOUND RESULTS | EXPECTED RESULTS |
|------------------|---------------|------------------|
| NEGATIVE CONTROL | 0.109         | < 0,6 CUT-OFF    |
| CUT-OFF CONTROL  | 0.269         | ≥ 0.200          |
| POSITIVE CONTROL | 2.243         | > 1,5 CUT-OFF    |
| CV %             | 7%            | ≤ 15%            |

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

TESTED BY: Silvia Sardelli

APPROVED BY: RESPONSIBLE HEAD, Quality Control Reagents

DATE 18.11.2021

### 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: **TOXOPLASMA IgM** Code 91041  
 LOT: **315** Code 91179  
 DATE OF TEST: **15/11/2022**

METHOD: ACCORDING TO THE PACKAGE INSERT

| 1. SOLID PHASE                          |           | FOUND           | EXPECTED                   |
|-----------------------------------------|-----------|-----------------|----------------------------|
| A) UNIFORMITY BETWEEN PLATES            |           |                 |                            |
| 1st PLATE                               | OD 450 nm | <b>1.521</b>    |                            |
|                                         | CV%       | <b>12%</b>      | < 20%                      |
| 2nd PLATE                               | OD 450 nm | <b>1.529</b>    |                            |
|                                         | CV%       | <b>9%</b>       | < 20%                      |
| B) UNIFORMITY WITHIN PLATE              |           |                 |                            |
|                                         | OD 450 nm | <b>1.763</b>    |                            |
|                                         | CV%       | <b>12%</b>      | < 15%                      |
| 2. BULK CONTROL date: 12/09/2022        |           |                 |                            |
| A) Average OD of Cut Off Control        | OD 450 nm | <b>0.313</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: 15/11/2022       |           |                 |                            |
| A) Blank                                | OD 450 nm | <b>0.051</b>    | ≤ 0.100                    |
| B) Average OD of Negative Control       | OD 450 nm | <b>0.109</b>    | < 0,6Cut Off               |
| C) Average OD of Cut Off Control        | OD 450 nm | <b>0.269</b>    | ≥ 0.200                    |
| D) Average OD of Positive Control       | OD 450 nm | <b>2.243</b>    | > 1,5Cut Off               |
| E) HOMOGENEITY OF CUT OFF               |           |                 |                            |
|                                         | No.       | <b>6</b>        |                            |
|                                         | OD 450 nm | <b>0.320</b>    |                            |
|                                         | CV%       | <b>7%</b>       | ≤ 15%                      |
| F) PRECISION OF FILLING PROCESS         |           |                 |                            |

☒ SATISFACTORY ☐ UNSATISFACTORY

FINAL RESULT: **ACCEPTED**

Date: **17-11-2022**

Signed:   
 Released: Q.C.Manager

Aggiornamento 07.2012