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## QUALITY CONTROL CERTIFICATE

**KIT NAME** ENZYWELL HERPES SIMPLEX 1 IgG

**Code** 91027

**LOT.NO**

224



2025-05



2024-04

### REAGENTS

| CODE      | LABEL      | DESCRIPTION        | LOT   | EXP     | NO |
|-----------|------------|--------------------|-------|---------|----|
| PF93121   | 007320     | MICROPLATE         | 238   | 2025-09 | 1  |
| PF93499   | 005400     | CONJUGATE          | 267   | 2025-06 | 1  |
| PF93910   | 1036       | NEGATIVE CONTROL   | 178-1 | 2025-05 | 1  |
| PF91999   | 007760     | POSITIVE CONTROL   | 244   | 2025-09 | 1  |
| PF91819   | 007310     | CUT OFF CONTROL    | 241   | 2025-09 | 1  |
| PF93619   | 1034       | SUBSTRATE-HS       | 383   | 2025-05 | 1  |
| PF93611   | 009660     | DILUENT 2          | 233   | 2025-07 | 1  |
| PF93603   | 1035       | WASHING BUFFER 10x | 468   | 2025-06 | 1  |
| PF93602   | 1032/RISK0 | STOP SOLUTION      | 218-6 | 2025-06 | 1  |
| PF91082/G | 007740     | SORBENT 2          | 129   | 2026-01 | 6  |

### CONTROLS

|                  | FOUND RESULTS | EXPECTED RESULTS   |
|------------------|---------------|--------------------|
| NEGATIVE CONTROL | 0.000         | $\leq 0,6$ Cut Off |
| CUT OFF CONTROL  | 0.389         | $\geq 0.200$       |
| POSITIVE CONTROL | 1.511         | $\geq 1,5$ Cut Off |
| CV %             | 9%            | $\leq 15\%$        |

*Evaluatin of the method according to the package inset in the attached document  
This batch has been manufactured and checked according to quality requirements.  
Hereby, it is released to distribution.*

APPROVED BY: RESPONSIBLE HEAD, Quality Control Reagents

DATE:

09.04.2024

### 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 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.

IO 09- 003-V



CODE 91027

CODE 91184

## QUALITY CONTROL CERTIFICATE

Annex: Method Evaluation

NAME KIT HERPES SIMPLEX 1 IgG

LOT. 224

DATE OF TEST 08/04/2024

### METHOD: ACCORDING TO THE PACKAGE INSERT

| 1. SOLID PHASE                          | FOUND     |          | EXPECTED                   |
|-----------------------------------------|-----------|----------|----------------------------|
| A) UNIFORMITY BETWEEN PLATES            |           |          |                            |
| 1st PLATE                               | OD 450 nm | 1.540    |                            |
|                                         | CV%       | 5%       | < 20%                      |
| 2nd PLATE                               | OD 450 nm | N/A      |                            |
|                                         | CV%       | N/A      | < 20%                      |
| B) UNIFORMITY WITHIN PLATE              |           |          |                            |
|                                         | OD 450 nm | 1.515    |                            |
|                                         | CV%       | 5%       | < 15%                      |
| 2. BULK CONTROL date: 03/04/2024        |           |          |                            |
| A) Average OD of Cut Off Control        | OD 450 nm | 0.466    | ≥ 0.200                    |
| B) Index of Negative and Positive Sera  |           | accepted | According to specification |
| C) Sensitivity with working calibrators |           | accepted | According to specification |
| 3. FINAL CONTROL date: 08/04/2024       |           |          |                            |
| A) Blank                                | OD 450 nm | 0.053    | ≤ 0.100                    |
| B) Average OD of Negative Control       | OD 450 nm | 0.000    | ≤ 0,6 Cut Off              |
| C) Average OD of Cut Off Control        | OD 450 nm | 0.389    | ≥ 0.200                    |
| D) Average OD of Positive Control       | OD 450 nm | 1.511    | ≥ 1,5 Cut Off              |
| E) HOMOGENEITY OF CUT OFF               |           |          |                            |
|                                         | No.       | 6        |                            |
|                                         | OD 450 nm | 0.442    |                            |
|                                         | CV%       | 9%       | ≤ 15%                      |
| F) PRECISION OF FILLING PROCESS         |           |          |                            |

☒ SATISFACTORY

☐ UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 08/04/2024

Signed:

Released: Q.C. Manager