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## QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL HERPES SIMPLEX 2 IgM

Code 91025

LOT.NO 234-D



2024-04



2023-01

### REAGENTS

| CODE        | LABEL      | DESCRIPTION        | LOT   | EXP     | NO |
|-------------|------------|--------------------|-------|---------|----|
| PF93000     | 007250     | MICROPLATE         | 666   | 2024-04 | 1  |
| PF93900/HSV | C4960      | NEGATIVE CONTROL   | 782-2 | 2024-07 | 1  |
| PF92355     | 007280     | POSITIVE CONTROL   | 203-2 | 2024-07 | 1  |
| PF30056     | 011560     | CONJUGATE          | 222-2 | 2024-04 | 1  |
| PF91722     | 007300     | ANTIGEN            | 226   | 2025-09 | 6  |
| PF93611     | 009660     | DILUENT 2          | 228   | 2024-07 | 1  |
| PF93603     | 1035       | WASHING BUFFER 10x | 457-1 | 2024-08 | 1  |
| PF93602     | 1032/RISK0 | STOP SOLUTION      | 215-5 | 2024-08 | 1  |
| PF93619     | 1034       | SUBSTRATE-HS       | 375   | 2024-09 | 1  |
| PF30057     | 011570     | CUT OFF CONTROL    | 215-2 | 2024-07 | 1  |

### CONTROLS

|                  | FOUND RESULTS | EXPECTED RESULTS |
|------------------|---------------|------------------|
| NEGATIVE CONTROL | 0.085         | < 0,6 Cut Off    |
| CUT OFF CONTROL  | 0.342         | ≥ 0.200          |
| POSITIVE CONTROL | 2.221         | > 1,5 Cut Off    |
| CV %             | 13%           | ≤ 15%            |

*Evaluation 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:

22.06.2023

### 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 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- 005-V



CODE 91025

CODE 91187

## QUALITY CONTROL CERTIFICATE

Annex: Method Evaluation

|              |                      |
|--------------|----------------------|
| NAME KIT     | HERPES SIMPLEX 2 IgM |
| LOT.         | 234                  |
| DATE OF TEST | 24/02/2023           |

### METHOD: ACCORDING TO THE PACKAGE INSERT

|                                         | FOUND                               | EXPECTED                   |
|-----------------------------------------|-------------------------------------|----------------------------|
| 1. SOLID PHASE                          |                                     |                            |
| A) UNIFORMITY BETWEEN PLATES            |                                     |                            |
| 1st PLATE                               | OD 450 nm 1.799<br>CV% 4%           | < 20%                      |
| 2nd PLATE                               | OD 450 nm 1.772<br>CV% 6%           | < 20%                      |
| B) UNIFORMITY WITHIN PLATE              | OD 450 nm 1.792<br>CV% 7%           | < 15%                      |
| 2. BULK CONTROL date: 15/02/2023        |                                     |                            |
| A) Average OD of Cut Off Control        | OD 450 nm 0.455                     | ≥ 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: 24/02/2023       |                                     |                            |
| A) Blank                                | OD 450 nm 0.045                     | ≤ 0.100                    |
| B) Average OD of Negative Control       | OD 450 nm 0.085                     | < 0,6 Cut Off              |
| C) Average OD of Cut Off Control        | OD 450 nm 0.342                     | ≥ 0.200                    |
| D) Average OD of Positive Control       | OD 450 nm 2.221                     | > 1,5 Cut Off              |
| E) HOMOGENEITY OF CUT OFF               | No. 6<br>OD 450 nm 0.387<br>CV% 13% | ≤ 15%                      |
| F) PRECISION OF FILLING PROCESS         |                                     |                            |

☒ SATISFACTORY

☐ UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 24.02.2023

Signed:

Released: Q.C.Manager