

**DIESSE DIAGNOSTICA SENESE SpA**  
 53035 Monteriggioni (SIENA) – Italy – Strada dei Laghi, 39  
 Tel. +39 0577319554 FAX +39 0577319020



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

### QUALITY CONTROL CERTIFICATE

#### KIT NAME ENZYWELL HERPES SIMPLEX 1 + 2 IgM

Code 91021

LOT.NO 322 EXPIRY 2023-09

#### REAGENTS

| CODE        | LABEL      | DESCRIPTION        | LOT No. | EXP     | No |
|-------------|------------|--------------------|---------|---------|----|
| PF93000     | 006190     | MICROPLATE         | 663     | 2023-12 | 1  |
| PF91520     | 006180     | CONJUGATE          | 242     | 2023-09 | 1  |
| PF93900/HSV | C4940      | NEGATIVE CONTROL   | 750-1   | 2023-12 | 1  |
| PF92022     | 005140     | POSITIVE CONTROL   | 221-1   | 2023-12 | 1  |
| PF91821     | 006150     | CUT-OFF CONTROL    | 233     | 2023-12 | 1  |
| PF91621     | 006170     | ANTIGEN            | 219     | 2025-03 | 6  |
| PF93611     | 009660     | DILUENT 2          | 225     | 2023-12 | 1  |
| PF93603     | 1035       | WASHING BUFFER 10x | 452-1   | 2024-02 | 1  |
| PF93602     | 1032/RISK0 | STOP SOLUTION      | 215     | 2024-08 | 1  |
| PF93619     | 1034       | SUBSTRATE-HS       | 365-1   | 2023-11 | 1  |

#### CONTROLS

|                  | FOUND RESULTS | EXPECTED RESULTS |
|------------------|---------------|------------------|
| NEGATIVE CONTROL | 0.304         | < 0,6 CUT-OFF    |
| CUT-OFF CONTROL  | 0.584         | ≥ 0.200          |
| POSITIVE CONTROL | 2.098         | > 1,5 CUT-OFF    |
| CV %             | 15%           | ≤ 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: 04.10.2022

#### 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: **HERPES SIMPLEX 1+2 IgM** Code 91021  
 LOT: **322** Code 91143  
 DATE OF TEST: **26/09/2022** Code 91175

METHOD: ACCORDING TO THE PACKAGE INSERT

| 1. SOLID PHASE                    |          | <i>FOUND</i>    | <i>EXPECTED</i>  |
|-----------------------------------|----------|-----------------|------------------|
| A) UNIFORMITY BETWEEN PLATES      |          |                 |                  |
| 1st PLATE                         | OD450 nm | <b>1.678</b>    |                  |
|                                   | CV%      | <b>12%</b>      | <20%             |
| 2nd PLATE                         | OD 450nm | <b>1.859</b>    |                  |
|                                   | CV%      | <b>8%</b>       | <20%             |
| B) UNIFORMITY WITHIN PLATE        |          |                 |                  |
|                                   | OD 450nm | <b>1.804</b>    |                  |
|                                   | CV%      | <b>8%</b>       | ≤15%             |
| 2. CONTROL OF COMPLETE KIT        |          |                 |                  |
| A) OD 450 nm Substrate Blank      |          | <b>0.050</b>    | ≤0,100           |
| OD 450 nm Negative Control        |          | <b>0.304</b>    | (≤0.6xCut-off)   |
| OD 450 nm Cut-off Control         |          | <b>0.584</b>    | >0.200           |
| OD 450 nm Positive Control        |          | <b>2.098</b>    | (≥1,5 x Cut-off) |
| B) PANEL OF HUMAN SERA            |          |                 |                  |
| Average OD 450nm of Negative Sera |          | <b>accepted</b> | < Cut-off        |
| Average OD 450nm of Positive Sera |          | <b>accepted</b> | > Cut-off        |

## D) PRECISION OF FILLING PROCESS

☒ SATISFACTORY

☐ UNSATISFACTORY

FINAL RESULT: **ACCEPTED**

Date: **27.09.2022**

Signed:   
 Released: Q.C.Manager

Aggiornamento 05.2012