

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



Sede Legale e Amministrazione  
20144 Milano (Italy) Via A. Solari 19 sc. 6

Pag 1/1

## QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL EPSTEIN BARR VCA IgM

Code 91056

LOT.NO 130-B



2024-02



2022-11

### REAGENTS

| CODE    | LABEL      | DESCRIPTION        | LOT   | EXP     | NO |
|---------|------------|--------------------|-------|---------|----|
| PF93054 | 007000     | MICROPLATE         | 028   | 2024-04 | 1  |
| PF93571 | 006990     | CONJUGATE          | 125   | 2024-02 | 1  |
| PF93910 | 1036       | NEGATIVE CONTROL   | 174-2 | 2024-02 | 1  |
| PF91871 | 016590     | CALIBRATOR 1       | 111   | 2024-05 | 1  |
| PF30077 | 016600     | CALIBRATOR 2       | 111   | 2024-05 | 1  |
| PF92072 | 016610     | CALIBRATOR 3       | 111   | 2024-05 | 1  |
| PF93619 | 1034       | SUBSTRATE-HS       | 368   | 2024-04 | 1  |
| 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  |
| PF30253 | B5160      | SAMPLE SORBENT 10  | 014   | 2024-05 | 1  |

### CONTROLS

|                          | FOUND RESULTS | EXPECTED RESULTS |
|--------------------------|---------------|------------------|
| NEGATIVE CONTROL (CAL 0) | 0.008         | < 0,6 CUT OFF    |
| CUT OFF CONTROL (CAL 1)  | 0.460         | ≥ 0.200          |
| POSITIVE CONTROL (CAL 3) | 1.909         | ≥ 1.000          |
| CALIBRATOR 2             | 1.203         | ≥ 0.500          |
| CV %                     | 4%            | ≤ 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: 25.01.2023

### 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 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: EPSTEIN BARR VCA IgM Code 91056  
 LOT: 130  
 DATE OF TEST: 28/11/2022

METHOD: ACCORDING TO THE PACKAGE INSERT

| 1. SOLID PHASE                          |           | <b>FOUND</b>    | <b>EXPECTED</b>            |
|-----------------------------------------|-----------|-----------------|----------------------------|
| A) UNIFORMITY BETWEEN PLATES            |           |                 |                            |
|                                         | OD450 nm  | <b>2.204</b>    |                            |
|                                         | CV%       | <b>4%</b>       | <20%                       |
| B) UNIFORMITY WITHIN PLATE              |           |                 |                            |
|                                         | OD 450nm  | <b>1.993</b>    |                            |
|                                         | CV%       | <b>5%</b>       | <15%                       |
| 2. BULK CONTROL date: 22/11/2022        |           |                 |                            |
| A) Average OD of Cut Off Calibrator     | OD 450 nm | <b>0.551</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: 28/11/2022       |           |                 |                            |
| A) Blank                                | OD 450 nm | <b>0.060</b>    | ≤ 0.100                    |
| B) Negative Control                     | OD 450 nm | <b>0.008</b>    | < 0,6Cut Off               |
| C) Calibrator 1 (Cut-off)               | OD 450 nm | <b>0.460</b>    | ≥ 0.200                    |
| D) Calibrator 2                         | OD 450 nm | <b>1.203</b>    | ≥ 0.500                    |
| E) Calibrator 3                         | OD 450 nm | <b>1.909</b>    | ≥ 1.000                    |
| F) HOMOGENEITY OF CUT OFF               | No.       | <b>6</b>        |                            |
|                                         | OD 450 nm | <b>0.521</b>    |                            |
|                                         | CV%       | <b>4%</b>       | ≤15%                       |

G) PRECISION OF FILLING PROCESS

☒ X SATISFACTORY ☐ UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 28/11/2022

Signed:  
Released: Q.C.Manager