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

QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL SYPHILIS SCREEN RECOMBINANT

| | | | |
|---------------|-------|---------|---------|
| Code | 91100 | | |
| LOT.NO | 364 | 2024-12 | 2023-12 |

REAGENTS

| CODE | LABEL | DESCRIPTION | LOT No. | EXP | NO |
|-----------|------------|--------------------|---------|---------|----|
| PF91101 | 007350 | MICROPLATE | 417 | 2024-12 | 2 |
| PF91102 | 007340 | CONJUGATE | 367 | 2025-03 | 2 |
| V267 | 007360 | NEGATIVE CONTROL | 178 | 2025-05 | 1 |
| PF93959/N | 007370 | POSITIVE CONTROL | 365 | 2025-03 | 1 |
| PF93603 | 1035 | WASHING BUFFER 10x | 468 | 2025-06 | 1 |
| PF93619 | 1034 | SUBSTRATE | 381-1 | 2025-04 | 2 |
| PF93602 | 1032/RISK0 | STOP SOLUTION | 218-6 | 2025-06 | 2 |

CONTROLS

| | FOUND RESULTS | EXPECTED RESULTS |
|--------------------------------|---------------|------------------|
| NEGATIVE CONTROL | 0.108 | ≤ 0.200 |
| POSITIVE CONTROL | 1.196 | ≥ 0.600 ≤ 2.000 |
| CUT-OFF (NEG. C. + POS. C.) /3 | 0.435 | |

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

TESTED BY: Silvia Sardelli

APPROVED BY: RESPONSIBLE HEAD, Quality Control Reagents

DATE 22.02.24

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: | SYPHILIS SCREEN RECOMBINANT | Code | 91100 |
| LOT: | 364 | | 91104 |
| DATE OF TEST: | 19/01/2024 | | 91105 |
| | | | 91100-B |

METHOD: ACCORDING TO THE PACKAGE INSERT

| 1. SOLID PHASE | | <i>FOUND</i> | <i>EXPECTED</i> |
|--|--|---|--------------------|
| A) UNIFORMITY BETWEEN PLATES | | | |
| 1st PLATE | OD450 nm | 1.576 | |
| | CV% | 5% | ≤15% |
| 2nd PLATE | OD 450nm | 1.543 | |
| | CV% | 4% | ≤15% |
| B) UNIFORMITY WITHIN PLATE | | | |
| | OD 450nm | 1.346 | |
| | CV% | 7% | ≤11% |
| 2. ALIGNMENT AND GOOD FUNCTION | | | |
| A) Average OD of Negative Calibrator | OD 450 nm | 0.132 | ≤ 0,2 |
| B) Average OD of Positive Calibrator | OD 450 nm | 1.401 | ≥ 0,800 ≤ 2,000 |
| C) Sensitivity with secondary standards | | | |
| TPN1 = OD C. Neg. ± 0,050 | | 0.106 | 0,082- 0,182 |
| TPN2 INDEX | | 1.2 | ≥0,7 |
| TPN3/TPN2 | | 2.3 | ≥ 1,4 |
| TPN4 INDEX | | 5.2 | ≥1,4 |
| 3. CONTROL OF COMPLETE KIT | | | |
| A) Calculation of Cut-off (OD C. Pos. + OD C. Neg.)/3 | | 0.435 | |
| B) Panel of Human sera | | | |
| Average of 20 Negative sera | | 0.158 | According to spec. |
| Average of 8 Positive sera | | 1.390 | According to spec. |
| C) Precision of filling: | | | |
| | Satisfactory <input checked="" type="checkbox"/> | Unsatisfactory <input type="checkbox"/> | |

FINAL RESULT: **ACCEPTED**

Date: *19.01.2024*

Signed: 
Released: Q.C. Manager

Update March,07