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

QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL TREPONEMA IgM

| | | | |
|--------|-------|---------|---------|
| Code | 91051 | | |
| LOT.NO | 176 | 2025-07 | 2024-06 |

REAGENTS

| CODE | LABEL | DESCRIPTION | LOT | EXP | NO |
|-------------|------------|--------------------|-----|---------|----|
| PF93031 | 006820 | MICROPLATE | 729 | 2025-07 | 1 |
| PF93522 | 006810 | CONJUGATE | 159 | 2025-09 | 1 |
| PF93900/TPM | C5140 | NEGATIVE CONTROL | 825 | 2025-12 | 1 |
| PF92053 | 005000 | POSITIVE CONTROL | 136 | 2025-12 | 1 |
| PF91851 | 005020 | CUT OFF CONTROL | 141 | 2025-12 | 1 |
| PF93619 | 1034 | SUBSTRATE-HS | 387 | 2025-09 | 1 |
| PF93621 | 006030 | DILUENT 10 | 166 | 2025-08 | 1 |
| PF93603 | 1035 | WASHING BUFFER 10x | 475 | 2025-11 | 1 |
| PF93602 | 1032/RISKO | STOP SOLUTION | 220 | 2026-03 | 1 |

CONTROLS

| | FOUND RESULTS | EXPECTED RESULTS |
|----------------------|---------------|------------------|
| NEGATIVE CONTROL 0 | 0.105 | <0,6 CUT OFF |
| CUT-OFF CONTROL 0,25 | 0.406 | ≥ 0.200 |
| POSITIVE CONTROL 2 | 1.737 | >1,5 CUT-OFF |
| 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: 13/06/24

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 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 09-019-V



CODE 91051

QUALITY CONTROL CERTIFICATE

Annex: Method Evaluation

NAME KIT TREPONEMA Igm
LOT. 176
DATE OF TEST 11/06/2024

METHOD: ACCORDING TO THE PACKAGE INSERT

| 1. SOLIDE PHASE | FOUND | EXPECTED |
|---|-----------|-------------------------------------|
| A) UNIFORMITY BETWEEN PLATES | | |
| 1st PLATE | OD 450nm | 2.017 |
| | CV% | 2% <20% |
| 2nd PLATE | OD 450nm | 2.012 |
| | CV% | 4% <20% |
| B) UNIFORMITY WITHIN PLATE | | |
| | OD450nm | 1.896 |
| | CV% | 4% <15% |
| 2. BULK CONTROL date:06/06/2024 | | |
| A) Average OD of Cut Off Control | OD 450 nm | 0.383 ≥ 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: 11/06/2024 | | |
| A) Blank | OD 450 nm | 0.051 ≤ 0.100 |
| B) Average OD of Negative Control | OD 450 nm | 0.105 < 0,6 Cut Off |
| C) Average OD of Cut Off Control | OD 450 nm | 0.406 ≥ 0.200 |
| D) Average OD of Positive Control | OD 450 nm | 1.737 > 1,5 Cut Off |
| E) HOMOGENEITY OF CUT-OFF | No. | 6 |
| | OD 450 nm | 0.456 |
| | CV% | 4% ≤15% |
| F) PRECISION OF FILLING PROCESS | | |

SATISFACTORY

UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 11.06.2024

Signed:

Released: Q.C.Manager