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Sede Legale e Amministrazione
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QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL MUMPS IgG

Code 91075

LOT.NO 124



2025-05



2024-02

REAGENTS

| CODE | LABEL | DESCRIPTION | LOT | EXP | NO |
|---------|------------|--------------------|-------|---------|---------|
| PF93210 | 007600 | MICROPLATE STRIPS | 157 | 2025-07 | 48 det. |
| PF93561 | 007610 | CONJUGATE | 116-1 | 2025-05 | 1 |
| PF93910 | 1036 | NEGATIVE CONTROL | 178-1 | 2025-05 | 1 |
| PF92065 | 007630 | POSITIVE CONTROL | 106-1 | 2025-08 | 1 |
| PF91865 | 007620 | CUT OFF CONTROL | 115-1 | 2025-08 | 1 |
| PF93619 | 1034 | SUBSTRATE-HS | 383-1 | 2025-05 | 1 |
| PF93611 | 009660 | DILUENT 2 | 233 | 2025-07 | 1 |
| PF93603 | 1035 | WASHING BUFFER 10x | 473 | 2025-08 | 1 |
| PF93602 | 1032/RISK0 | STOP SOLUTION | 218-6 | 2025-06 | 1 |

CONTROLS

| | FOUND RESULTS | EXPECTED RESULTS |
|------------------|---------------|--------------------|
| NEGATIVE CONTROL | 0.008 | $\leq 0,6$ Cut Off |
| CUT OFF CONTROL | 0.447 | ≥ 0.200 |
| POSITIVE CONTROL | 1.794 | $\geq 1,5$ Cut Off |
| CV % | 6% | $\leq 15\%$ |

*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: 05.06.2024

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 - 304-V



CODE 91075

CODE 91084

QUALITY CONTROL CERTIFICATE

Annex: Method Evaluation

NAME KIT MUMPS IgG
LOT. 124
DATE OF TEST 03/06/2024

METHOD: ACCORDING TO THE PACKAGE INSERT

| 1. SOLID PHASE | FOUND | | EXPECTED |
|---|-----------|----------|----------------------------|
| A) UNIFORMITY BETWEEN PLATES | | | |
| 1st PLATE | OD 450 nm | 1.554 | |
| | CV% | 7% | < 20% |
| 2nd PLATE | OD 450 nm | N/A | |
| | CV% | N/A | < 20% |
| B) UNIFORMITY WITHIN PLATE | | | |
| | OD 450 nm | 1.559 | |
| | CV% | 9% | < 15% |
| 2. BULK CONTROL date: 06/02/2024 | | | |
| A) Average OD of Cut Off Control | OD 450 nm | 0.530 | ≥ 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: 03/06/2024 | | | |
| A) Blank | OD 450 nm | 0.044 | ≤ 0.100 |
| B) Average OD of Negative Control | OD 450 nm | 0.008 | ≤ 0,6 Cut Off |
| C) Average OD of Cut Off Control | OD 450 nm | 0.447 | ≥ 0.200 |
| D) Average OD of Positive Control | OD 450 nm | 1.794 | ≥ 1,5 Cut Off |
| E) HOMOGENEITY OF CUT OFF | No. | 6 | |
| | OD 450 nm | 0.491 | |
| | CV% | 6% | ≤ 15% |
| F) PRECISION OF FILLING PROCESS | | | |



SATISFACTORY



UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 03.06.2024

Signed:

Released: Q.C.Manager