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Sede Legale e Amministrazione  
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## QUALITY CONTROL CERTIFICATE

**KIT NAME** ENZYWELL MEASLES IgM

Code 91073

LOT.NO 156

2024-10

2023-10

### REAGENTS

| CODE        | LABEL      | DESCRIPTION        | LOT   | EXP     | NO      |
|-------------|------------|--------------------|-------|---------|---------|
| PF93000     | 008090     | MICROPLATE STRIPS  | 669   | 2024-10 | 48 det. |
| PF91575     | 008100     | CONJUGATE          | 148   | 2025-01 | 1       |
| PF93900/MVM | C5270      | NEGATIVE CONTROL   | 802   | 2025-04 | 1       |
| PF92375     | 008110     | POSITIVE CONTROL   | 132   | 2025-04 | 1       |
| PF91975     | 008120     | CUT OFF CONTROL    | 137   | 2025-04 | 1       |
| PF91675     | 008140     | ANTIGEN            | 118   | 2026-02 | 3       |
| PF93611     | 009660     | DILUENT 2          | 231   | 2025-03 | 1       |
| PF93603     | 1035       | WASHING BUFFER 10x | 459   | 2024-10 | 1       |
| PF93602     | 1032/RISKO | STOP SOLUTION      | 218-3 | 2025-06 | 1       |
| PF93619     | 1034       | SUBSTRATE-HS       | 380   | 2025-03 | 1       |

### CONTROLS

|                  | FOUND RESULTS | EXPECTED RESULTS |
|------------------|---------------|------------------|
| NEGATIVE CONTROL | 0.109         | < 0,6 Cut Off    |
| CUT OFF CONTROL  | 0.396         | ≥ 0.200          |
| POSITIVE CONTROL | 1.496         | > 1,5 Cut Off    |
| CV%              | 12%           | ≤ 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: 26.10.2023

### 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.

IO 09 - 308-V



CODE 91073  
CODE 91081

## QUALITY CONTROL CERTIFICATE

Annex: Method Evaluation

NAME KIT MEASLES IgM  
LOT. 156  
DATE OF TEST 20/10/2023

### METHOD: ACCORDING TO THE PACKAGE INSERT

| 1. SOLID PHASE                          | FOUND     |          | EXPECTED                   |
|-----------------------------------------|-----------|----------|----------------------------|
| A) UNIFORMITY BETWEEN PLATES            |           |          |                            |
| 1st PLATE                               | OD 450 nm | 1.566    |                            |
|                                         | CV%       | 11%      | < 20%                      |
| 2nd PLATE                               | OD 450 nm | N/A      |                            |
|                                         | CV%       | N/A      | < 20%                      |
| B) UNIFORMITY WITHIN PLATE              |           |          |                            |
|                                         | OD 450 nm | 1.693    |                            |
|                                         | CV%       | 11%      | < 15%                      |
| 2. BULK CONTROL date: 13/10/2023        |           |          |                            |
| A) Average OD of Cut Off Control        | OD 450 nm | 0.470    | ≥ 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: 20/10/2023       |           |          |                            |
| A) Blank                                | OD 450 nm | 0.046    | ≤ 0.100                    |
| B) Average OD of Negative Control       | OD 450 nm | 0.109    | < 0,6 Cut Off              |
| C) Average OD of Cut Off Control        | OD 450 nm | 0.396    | ≥ 0.200                    |
| D) Average OD of Positive Control       | OD 450 nm | 1.496    | > 1,5 Cut Off              |
| E) HOMOGENEITY OF CUT OFF               |           |          |                            |
|                                         | No.       | 6        |                            |
|                                         | OD 450 nm | 0.441    |                            |
|                                         | CV%       | 12%      | ≤ 15%                      |
| F) PRECISION OF FILLING PROCESS         |           |          |                            |



SATISFACTORY



UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 20.10.2023

Signed:   
Released: Q.C.Manager