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Sede Legale e Amministrazione  
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## QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL MEASLES IgG

Code 91072

LOT.NO 125-B

 2024-02

 2022-11

### REAGENTS

| CODE    | LABEL      | DESCRIPTION        | LOT   | EXP     | NO      |
|---------|------------|--------------------|-------|---------|---------|
| PF93220 | 007440     | MICROPLATE STRIPS  | 117   | 2024-10 | 48 det. |
| PF93562 | 007450     | CONJUGATE          | 116-1 | 2024-02 | 1       |
| PF93910 | 1036       | NEGATIVE CONTROL   | 175-2 | 2024-06 | 1       |
| PF92075 | 008070     | POSITIVE CONTROL   | 106-1 | 2024-05 | 1       |
| PF91875 | 008050     | CUT OFF CONTROL    | 116-1 | 2024-05 | 1       |
| PF93619 | 1034       | SUBSTRATE-HS       | 371   | 2024-06 | 1       |
| PF93611 | 009660     | DILUENT 2          | 228-1 | 2024-07 | 1       |
| PF93603 | 1035       | WASHING BUFFER 10x | 457   | 2024-08 | 1       |
| PF93602 | 1032/RISK0 | STOP SOLUTION      | 215-3 | 2024-08 | 1       |

### CONTROLS

|                  | FOUND RESULTS | EXPECTED RESULTS   |
|------------------|---------------|--------------------|
| NEGATIVE CONTROL | 0.002         | $\leq 0,6$ Cut Off |
| CUT OFF CONTROL  | 0.432         | $\geq 0,200$       |
| POSITIVE CONTROL | 2.541         | $\geq 1,5$ Cut Off |
| CV%              | 15%           | $\leq 15\%$        |

Evaluation 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: 19.04.2023

### 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: MEASLES IgG Code 91072  
 LOT: 125 91080  
 DATE OF TEST: 17/12/2022

METHOD: ACCORDING TO THE PACKAGE INSERT

|                              | <i>FOUND</i> | <i>EXPECTED</i>                    |
|------------------------------|--------------|------------------------------------|
| 1. CONTROL OF COMPLETE KIT   |              |                                    |
| A) OD 450 nm Substrate Blank | 0.053        | $\leq 0.100$                       |
| OD 450 nm Negative Control   | 0.002        | $(\leq 0.6 \times \text{Cut-off})$ |
| OD 450 nm Cut-off Control    | 0.432        | $> 0.200$                          |
| OD 450 nm Positive Control   | 2.541        | $(\geq 1,5 \times \text{Cut-off})$ |
| B) PANEL OF HUMAN SERA       |              |                                    |
| Average OD of Negative Sera  | accepted     | $< \text{Cut-off}$                 |
| Average OD of Positive Sera  | accepted     | $> \text{Cut-off}$                 |
| C) HOMOGENEITY OF CUT-OFF    |              |                                    |
| No.                          | 6            |                                    |
| OD 450 nm                    | 0.485        |                                    |
| CV%                          | 15%          | $\leq 15\%$                        |

FINAL RESULT: **ACCEPTED**

Date: 27/12/2022

Signed:   
 Released: Q.C.Manager

Aggiornamento 11.2008