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Sede Legale e Amministrazione  
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## QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL MEASLES IgG

Code 91072

LOT.NO 126

2024-05

2023-02

### REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93220	007440	MICROPLATE STRIPS	117	2024-10	48 det.
PF93562	007450	CONJUGATE	117	2024-05	1
PF93910	1036	NEGATIVE CONTROL	175-2	2024-06	1
PF92075	008070	POSITIVE CONTROL	107	2024-08	1
PF91875	008050	CUT OFF CONTROL	117	2024-08	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	0.006	$\leq 0,6$ Cut Off
CUT OFF CONTROL	0.472	$\geq 0.200$
POSITIVE CONTROL	2.346	$\geq 1,5$ Cut Off
CV%	8%	$\leq 15\%$

Evaluation of the method according to the package insert 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.

IO 09 - 307-V



CODE 91072

CODE 91080

## QUALITY CONTROL CERTIFICATE

Annex: Method Evaluation

NAME KIT MEASLES IgG  
LOT. 126  
DATE OF TEST 16/03/2023

### METHOD: ACCORDING TO THE PACKAGE INSERT

#### 1. SOLID PHASE

##### A) UNIFORMITY BETWEEN PLATES

1st PLATE

#### FOUND

OD 450 nm 2.729

CV% 6%

#### EXPECTED

< 20%

2nd PLATE

OD 450 nm 2.633

CV% 8%

< 20%

##### B) UNIFORMITY WITHIN PLATE

OD 450 nm 2.668

CV% 6%

< 15%

#### 2. BULK CONTROL date: 21/02/2023

A) Average OD of Cut Off Control

OD 450 nm 0.472

≥ 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: 16/03/2023

A) Blank

OD 450 nm 0.047

≤ 0.100

B) Average OD of Negative Control

OD 450 nm 0.006

≤ 0,6 Cut Off

C) Average OD of Cut Off Control

OD 450 nm 0.472

≥ 0.200

D) Average OD of Positive Control

OD 450 nm 2.346

≥ 1,5 Cut Off

##### E) HOMOGENEITY OF CUT OFF

No. 6

OD 450 nm 0.518

≤ 15%

CV% 8%

##### F) PRECISION OF FILLING PROCESS



SATISFACTORY



UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 16/03/2023

Signed:

Released: Q.C.Manager