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

### QUALITY CONTROL CERTIFICATE

**KIT NAME** ENZYWELL MEASLES IgG

Code	91072		
LOT.NO	133-A	2025-06	2024-04

### REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93220	007440	MICROPLATE STRIPS	123	2026-02	48 det.
PF93562	007450	CONJUGATE	124-1	2025-07	1
PF93910	1036	NEGATIVE CONTROL	179	2025-06	1
PF92075	008070	POSITIVE CONTROL	114-1	2025-10	1
PF91875	008050	CUT OFF CONTROL	124-1	2025-10	1
PF93619	1034	SUBSTRATE-HS	385	2025-08	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	0.002	$\leq 0,6$ Cut Off
CUT OFF CONTROL	0.506	$\geq 0.200$
POSITIVE CONTROL	1.893	$\geq 1,5$ Cut Off
CV%	8%	$\leq 15\%$

*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 - 307-V



CODE 91072  
CODE 91080

### QUALITY CONTROL CERTIFICATE

Annex: Method Evaluation

NAME KIT MEASLES IgG  
LOT. 133  
DATE OF TEST 02/05/2024

#### METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE	FOUND	EXPECTED
A) UNIFORMITY BETWEEN PLATES		
1st PLATE	OD 450 nm	2.241
	CV%	5% < 20%
2nd PLATE	OD 450 nm	N/A
	CV%	N/A < 20%
B) UNIFORMITY WITHIN PLATE		
	OD 450 nm	2.062
	CV%	8% < 15%
2. BULK CONTROL date: 24/04/2024		
A) Average OD of Cut Off Control	OD 450 nm	0.394 ≥ 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: 02/05/2024		
A) Blank	OD 450 nm	0.050 ≤ 0.100
B) Average OD of Negative Control	OD 450 nm	0.001 ≤ 0,6 Cut Off
C) Average OD of Cut Off Control	OD 450 nm	0.424 ≥ 0.200
D) Average OD of Positive Control	OD 450 nm	1.643 ≥ 1,5 Cut Off
E) HOMOGENEITY OF CUT OFF	No.	6
	OD 450 nm	0.473
	CV%	5% ≤ 15%
F) PRECISION OF FILLING PROCESS		



SATISFACTORY



UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 02/05/2024

Signed:   
Released: Q.C.Manager