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Sede Legale e Amministrazione
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QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL MEASLES IgG

Code 91072

LOT.NO 122 EXPIRY 2023-08

REAGENTS

CODE	LABEL	DESCRIPTION	LOT No.	EXP	NO
PF93220	007440	MICROPLATE STRIPS	116	2024-04	48 det.
PF93562	007450	CONJUGATE	114	2023-08	1
PF93910	1036	NEGATIVE CONTROL	172-3	2023-08	1
PF92075	008070	POSITIVE CONTROL	104	2023-11	1
PF91875	008050	CUT-OFF CONTROL	114	2023-11	1
PF93619	1034	SUBSTRATE-HS	362-1	2023-09	1
PF93611	009660	DILUENT 2	223	2023-08	1
PF93603	1035	WASHING BUFFER 10x	449-1	2023-11	1
PF93602	1032/RISK0	STOP SOLUTION	214-2	2024-02	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.002	$\leq 0,6$ CUT-OFF
CUT-OFF CONTROL	0.453	≥ 0.200
POSITIVE CONTROL	2.419	$\geq 1,5$ CUT-OFF
CV %	8%	$\leq 15\%$

The test has been carried out in accordance with the package insert

TESTED BY: Silvia Sardelli

APPROVED BY: RESPONSIBLE HEAD, Quality Control Reagents

DATE: 13.06.2024

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 FDA approved method 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: 122 91080
 DATE OF TEST: 17/06/2022

METHOD: ACCORDING TO THE PACKAGE INSERT

	<i>FOUND</i>	<i>EXPECTED</i>
1. CONTROL OF COMPLETE KIT		
A) OD 450 nm Substrate Blank	0.045	≤ 0.100
OD 450 nm Negative Control	0.002	$(\leq 0.6 \times \text{Cut-off})$
OD 450 nm Cut-off Control	0.453	> 0.200
OD 450 nm Positive Control	2.419	$(\geq 1,5 \times \text{Cut-off})$
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.	8	
OD 450 nm	0.498	
CV%	8%	$\leq 15\%$

FINAL RESULT: **ACCEPTED**

Date: 21.06.2022

Signed: 
 Released: Q.C.Manager

Aggiornamento 11.2008