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Sede Legale e Amministrazione
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QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL HELICOBACTER PYLORI IgA

Code 91062

LOT.NO 113-C



2025-04



2024-01

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93060	007380	MICROPLATE	269	2026-01	1
PF93569	007390	CONJUGATE	109	2025-04	1
PF93910	1036/A	NEGATIVE CONTROL IgA	179-1	2025-06	1
PF92063	007400	POSITIVE CONTROL	103	2025-07	1
PF91863	007410	CUT OFF CONTROL	103	2025-07	1
PF93619	1034	SUBSTRATE-HS	383-1	2025-05	1
PF30267	007430	DILUENT 50x IgA	106	2025-04	1
PF93603	1035	WASHING BUFFER 10x	473	2025-08	1
PF93602	1032/RISKO	STOP SOLUTION	218-6	2025-06	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.011	$\leq 0,6$ Cut-Off
CUT OFF CONTROL	0.376	≥ 0.200
POSITIVE CONTROL	1.855	$\geq 1,5$ 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:

28/05/2024

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.



CERTIFICATE OF ANALYSIS

KIT: **HELICOBACTER PYLORI IgA** Code 91062
 LOT: 113
 DATE OF TEST: 07/02/2023

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE		<i>FOUND</i>	<i>EXPECTED</i>
UNIFORMITY BETWEEN PLATES			
	OD450 nm	2.472	
< 200 PZ.	CV%	8%	<20%
2. CONTROL OF COMPLETE KIT			
A) OD 450 nm Substrate Blank		0.053	<0,1
OD 450 nm Negative Control		0.011	(≤0.6xCut-off)
OD 450 nm Cut-off Control		0.376	>0.200
OD 450 nm Positive Control		1.855	(≥1,5 x Cut-off)
B) PANEL OF HUMAN SERA			
Average OD of Negative Sera		accepted	< Cut-off
Average OD of Positive Sera		accepted	> Cut-off
C) HOMOGENEITY OF CUT-OFF			
	No.	6	
	OD 450 nm	0.428	
	CV%	8%	≤15%

FINAL RESULT: **ACCEPTED**

Date:

07.02.2024

Signed:

Released: Q.C.Manager