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Sede Legale e Amministrazione
Via A. Solari, 19 20144 Milano - Italy

QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL HELICOBACTER PYLORI IgG

Code	91060		
LOT.NO	160-B	2023-12	2022-09

REAGENTS

CODE	LABEL	DESCRIPTION	LOT No.	EXP	NO
PF93060	006040	MICROPLATE	255	2024-07	1
PF93504	006100	CONJUGATE	146	2023-12	1
PF93861	006050	CALIBRATOR 1	113	2024-03	1
PF93862	006060	CALIBRATOR 2	113	2024-03	1
PF93863	006070	CALIBRATOR 3	113	2024-03	1
PF93864	006080	CALIBRATOR 4	113	2024-03	1
PF93865	006090	CALIBRATOR 5	113	2024-03	1
PF93619	1034	SUBSTRATE-HS	368	2024-04	1
PF93611	009660	DILUENT 2	226	2024-04	1
PF93603	1035	WASHING BUFFER 10x	452	2024-02	1
PF93602	1032/RISK0	STOP SOLUTION	215-1	2024-08	1

CONTROLS

	AU/mL	FOUND RESULTS	EXPECTED RESULTS
CALIBRATOR 1	5	0.178	
CALIBRATOR 2	10	0.382	
CALIBRATOR 3	15	0.580	≥ 0.250
CALIBRATOR 4	50	1.870	
CALIBRATOR 5	100	2.488	≥ 1.400
CV %		8%	≤ 15%

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

TESTED BY: Katia Tanzini

APPROVED BY: RESPONSIBLE HEAD, Quality Control Reagents

DATE 11.01.2023

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 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: **H. PYLORI IgG** Code 91060
 LOT: **160**
 DATE OF TEST: **11/10/2022**

METHOD: According to the Technical Information sheet.

1. SOLID PHASE		<i>FOUND</i>	<i>EXPECTED</i>
a) Uniformity between plates			
	OD 450nm	1.852	
	CV%	15%	≤20%
b) Uniformity in the plates			
	OD 450nm	1.886	
	CV%	9%	≤15%
2.CONTROL OF COMPLETE KIT			
a)OD 450nm Calibrator 1		0.178	
OD 450nm Calibrator 2		0.382	
OD 450nm Calibrator 3		0.580	≥ 0.250
OD 450nm Calibrator 4		1.870	
OD 450nm Calibrator 5		2.488	≥1.400
b) Panel of Human Sera			
Average OD 450nm of Negative sera	accepted		According to Spec.
Average OD 450nm of Positive sera	accepted		According to Spec.
c) Homogeneity of Calibrator 3 N°		6	
	OD 450nm	0.628	
	CV%	8%	≤15%
d) Precision of filling:			
Satisfactory	☒		Unsatisfactory ☐

FINAL RESULT: **ACCEPTED**

Date: *11/10/2022*

Signed: *[Signature]*
 Released: Q.C.Manager

Aggiornamento 07.2012