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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	159-B	2023-09	2022-06

REAGENTS

CODE	LABEL	DESCRIPTION	LOT No.	EXP	NO
PF93060	006040	MICROPLATE	250	2023-09	1
PF93504	006100	CONJUGATE	145	2023-09	1
PF93861	006050	CALIBRATOR 1	112	2023-12	1
PF93862	006060	CALIBRATOR 2	112	2023-12	1
PF93863	006070	CALIBRATOR 3	112	2023-12	1
PF93864	006080	CALIBRATOR 4	112	2023-12	1
PF93865	006090	CALIBRATOR 5	112	2023-12	1
PF93619	1034	SUBSTRATE-HS	364	2023-11	1
PF93611	009660	DILUENT 2	224	2023-10	1
PF93603	1035	WASHING BUFFER 10x	449-1	2023-11	1
PF93602	1032/RISK0	STOP SOLUTION	214-3	2024-02	1

CONTROLS

	AU/mL	FOUND RESULTS	EXPECTED RESULTS
CALIBRATOR 1	5	0.227	
CALIBRATOR 2	10	0.479	
CALIBRATOR 3	15	0.641	≥ 0.250
CALIBRATOR 4	50	2.128	
CALIBRATOR 5	100	2.566	≥ 1.400
CV %		11%	$\leq 15\%$

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

TESTED BY: Silvia Sardelli

APPROVED BY: RESPONSIBLE HEAD, Quality Control Reagents

DATE 14/07/2022

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: **159**
DATE OF TEST: **30/06/2022**

METHOD: According to the Technical Information sheet.

1. SOLID PHASE **FOUND** **EXPECTED**

a) Uniformity between plates

OD 450nm	1.440	
CV%	11%	≤20%

b) Uniformity in the plates

OD 450nm	1.323	
CV%	10%	≤15%

2. CONTROL OF COMPLETE KIT

a) OD 450nm Calibrator 1	0.227	
OD 450nm Calibrator 2	0.479	
OD 450nm Calibrator 3	0.641	≥ 0.250
OD 450nm Calibrator 4	2.128	
OD 450nm Calibrator 5	2.566	≥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	0.693	
CV%	11%	≤15%

d) Precision of filling:

Satisfactory ☒

Unsatisfactory ☐

FINAL RESULT: **ACCEPTED**

Date:

30.06.2022

Signed:

Released: Q.C.Manager

Aggiornamento 07.2012