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Sede Legale e Amministrazione
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QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL HELICOBACTER PYLORI IgG

Code 91060

LOT.NO 163-A



2024-07



2023-05

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93060	006040	MICROPLATE	261	2025-04	1
PF93504	006100	CONJUGATE	149	2024-08	1
PF93861	006050	CALIBRATOR 1	116	2024-11	1
PF93862	006060	CALIBRATOR 2	116	2024-11	1
PF93863	006070	CALIBRATOR 3	116	2024-11	1
PF93864	006080	CALIBRATOR 4	116	2024-11	1
PF93865	006090	CALIBRATOR 5	116	2024-11	1
PF93619	1034	SUBSTRATE-HS	375	2024-09	1
PF93611	009660	DILUENT 2	228	2024-07	1
PF93603	1035	WASHING BUFFER 10x	457-1	2024-08	1
PF93602	1032/RISK0	STOP SOLUTION	215-5	2024-08	1

CONTROLS

AU/ml	FOUND RESULTS	EXPECTED RESULTS
CALIBRATOR 1 5	0.121	
CALIBRATOR 2 10	0.333	
CALIBRATOR 3 15	0.738	≥ 0.250
CALIBRATOR 4 50	2.168	
CALIBRATOR 5 100	3.424	≥ 1.400
CV %	4%	≤ 15%

*Evaluation 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:

06.06.2023

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 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 - 017-V



CODE 91060

QUALITY CONTROL CERTIFICATE

Annex: Method Evaluation

NAME KIT H. PYLORI IgG
LOT. 163
DATE OF TEST 31/05/2023

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE		FOUND		EXPECTED
A) UNIFORMITY BETWEEN PLATES				
1st PLATE	OD 450 nm	1.539		
	CV%	15%		< 20%
2nd PLATE	OD 450 nm	1.708		
	CV%	7%		< 20%
B) UNIFORMITY WITHIN PLATE				
	OD 450 nm	1.760		
	CV%	10%		< 15%
2. BULK CONTROL date: 19/05/2023				
A) Average OD of Cut Off Calibrator	OD 450 nm	0.690		≥ 0.250
B) Index of Negative and Positive Sera		accepted		According to specification
C) Sensitivity with working calibrators		accepted		According to specification
3. CONTROL OF COMPLETE KIT date: 31/05/2023				
A)	Substrate Blank	OD 450 nm	0.045	≤ 0.100
	Calibrator 5 AU/ml	OD 450 nm	0.121	
	Calibrator 10 AU/ml	OD 450 nm	0.333	
	Calibrator 15 AU/ml (Cut Off)	OD 450 nm	0.738	≥ 0.250
	Calibrator 50 AU/ml	OD 450 nm	2.168	
	Calibrator 100 AU/ml	OD 450 nm	3.424	≥1.400
B)	HOMOGENEITY OF CUT OFF	No.	6	
		OD 450 nm	0.783	
		CV%	4%	≤15%
C)	PRECISION OF FILLING PROCESS			

☒ SATISFACTORY

☐ UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 05.06.2023

Signed:

Released: Q.C. Manager