

DIESSE DIAGNOSTICA SENESE SpA
53035 Monteriggioni (SI), Italy, Strada dei Laghi 39
Tel. +39 0577319554 FAX +39 0577319020



Sede Legale e Amministrazione
20144 Milano (Italy) Via A. Solari 19 sc. 6

Pag 1/1

QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL HELICOBACTER PYLORI IgG

Code 91060

LOT.NO 162-A



2024-06



2023-03

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93060	006040	MICROPLATE	260	2025-02	1
PF93504	006100	CONJUGATE	148	2024-06	1
PF93861	006050	CALIBRATOR 1	115	2024-09	1
PF93862	006060	CALIBRATOR 2	115	2024-09	1
PF93863	006070	CALIBRATOR 3	115	2024-09	1
PF93864	006080	CALIBRATOR 4	115	2024-09	1
PF93865	006090	CALIBRATOR 5	115	2024-09	1
PF93619	1034	SUBSTRATE-HS	372	2024-07	1
PF93611	009660	DILUENT 2	229	2024-09	1
PF93603	1035	WASHING BUFFER 10x	457	2024-08	1
PF93602	1032/RISK0	STOP SOLUTION	215-3	2024-08	1

CONTROLS

AU/ml	FOUND RESULTS	EXPECTED RESULTS
CALIBRATOR 1 5	0.178	
CALIBRATOR 2 10	0.469	
CALIBRATOR 3 15	0.777	≥ 0.250
CALIBRATOR 4 50	1.922	
CALIBRATOR 5 100	2.550	≥ 1,400
CV %	11%	≤ 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:

28.06.2023

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.	162
DATE OF TEST	14/04/2023

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE	FOUND	EXPECTED
A) UNIFORMITY BETWEEN PLATES		
1st PLATE	OD 450 nm 1.449	
	CV% 16%	< 20%
2nd PLATE	OD 450 nm N/A	
	CV% N/A	< 20%
B) UNIFORMITY WITHIN PLATE		
	OD 450 nm 1.474	
	CV% 13%	< 15%
2. BULK CONTROL date: 29/03/2023		
A) Average OD of Cut Off Calibrator	OD 450 nm 0.572	≥ 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: 14/04/2023		
A) Substrate Blank	OD 450 nm 0.048	≤ 0.100
Calibrator 5 AU/ml	OD 450 nm 0.178	
Calibrator 10 AU/ml	OD 450 nm 0.469	
Calibrator 15 AU/ml (Cut Off)	OD 450 nm 0.777	≥ 0.250
Calibrator 50 AU/ml	OD 450 nm 1.922	
Calibrator 100 AU/ml	OD 450 nm 2.550	≥ 1.400
B) HOMOGENEITY OF CUT OFF	No. 6	
	OD 450 nm 0.825	
	CV% 11%	≤ 15%
C) PRECISION OF FILLING PROCESS		



SATISFACTORY



UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 14.04.2023

Signed:

Released: Q.C. Manager