

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

QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL HELICOBACTER PYLORI IgG

Code 91060

LOT.NO 166-A



2025-04



2024-01

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93060	006040	MICROPLATE	270	2026-01	1
PF93504	006100	CONJUGATE	152	2025-04	1
PF93861	006050	CALIBRATOR 1	119	2025-07	1
PF93862	006060	CALIBRATOR 2	119	2025-07	1
PF93863	006070	CALIBRATOR 3	119	2025-07	1
PF93864	006080	CALIBRATOR 4	119	2025-07	1
PF93865	006090	CALIBRATOR 5	119	2025-07	1
PF93619	1034	SUBSTRATE-HS	383	2025-05	1
PF93611	009660	DILUENT 2	232	2025-05	1
PF93603	1035	WASHING BUFFER 10x	468	2025-06	1
PF93602	1032/RISK0	STOP SOLUTION	218-6	2025-06	1

CONTROLS

AU/ml	FOUND RESULTS	EXPECTED RESULTS
CALIBRATOR 1 5	0.178	
CALIBRATOR 2 10	0.247	
CALIBRATOR 3 15	0.434	≥ 0.250
CALIBRATOR 4 50	1.457	
CALIBRATOR 5 100	2.131	≥ 1.400
CV %	6%	≤ 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: 07.02.2024

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.

IO 09 - 017-V



CODE 91060

QUALITY CONTROL CERTIFICATE

Annex: Method Evaluation

NAME KIT H. PYLORI IgG
LOT. 166
DATE OF TEST 07/02/2024

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE	FOUND	EXPECTED
A) UNIFORMITY BETWEEN PLATES		
1st PLATE	OD 450 nm 2.198 CV% 5%	< 20%
2nd PLATE	OD 450 nm 2.243 CV% 7%	< 20%
B) UNIFORMITY WITHIN PLATE	OD 450 nm 1.952 CV% 9%	< 15%
2. BULK CONTROL date: 30/01/2024		
A) Average OD of Cut Off Calibrator	OD 450 nm 0.492	≥ 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: 06/02/2024		
A) Substrate Blank	OD 450 nm 0.049	≤ 0.100
Calibrator 5 AU/ml	OD 450 nm 0.178	
Calibrator 10 AU/ml	OD 450 nm 0.247	
Calibrator 15 AU/ml (Cut Off)	OD 450 nm 0.434	≥ 0.250
Calibrator 50 AU/ml	OD 450 nm 1.457	
Calibrator 100 AU/ml	OD 450 nm 2.131	≥ 1.400
B) HOMOGENEITY OF CUT OFF	No. 6 OD 450 nm 0.482 CV% 6%	≤ 15%
C) PRECISION OF FILLING PROCESS		



SATISFACTORY



UNSATISFACTORY

FINAL RESULT: **ACCEPTED**

Date: 07.02.2024

Signed:

Released: Q.C.Manager