

DIESSSE 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	165	2025-01	2023-11		

REAGENTS 2023-11

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93060	006040	MICROPLATE	266	2025-09	1
PF93504	006100	CONJUGATE	151	2025-01	1
PF93861	006050	CALIBRATOR 1	118	2025-04	1
PF93862	006060	CALIBRATOR 2	118	2025-04	1
PF93863	006070	CALIBRATOR 3	118	2025-04	1
PF93864	006080	CALIBRATOR 4	118	2025-04	1
PF93865	006090	CALIBRATOR 5	118	2025-04	1
PF93619	1034	SUBSTRATE-HS	380	2025-03	1
PF93611	009660	DILUENT 2	231	2025-03	1
PF93603	1035	WASHING BUFFER 10x	466	2025-04	1
PF93602	1032/RISK0	STOP SOLUTION	218-5	2025-06	1

CONTROLS

AU/ml	FOUND RESULTS	EXPECTED RESULTS
CALIBRATOR 1 5	0.193	
CALIBRATOR 2 10	0.310	
CALIBRATOR 3 15	0.571	≥ 0.250
CALIBRATOR 4 50	1.769	
CALIBRATOR 5 100	2.391	≥ 1.400
CV %	10%	≤ 15%

*Evaluation of the method according to the package insert 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: 20.11.2023

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. 165
DATE OF TEST 17/11/2023

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE	FOUND	EXPECTED
A) UNIFORMITY BETWEEN PLATES		
1st PLATE	OD 450 nm 2.190 CV% 6%	< 20%
2nd PLATE	OD 450 nm 2.178 CV% 6%	< 20%
B) UNIFORMITY WITHIN PLATE	OD 450 nm 2.365 CV% 8%	< 15%
2. BULK CONTROL date: 09/11/2023		
A) Average OD of Cut Off Calibrator	OD 450 nm 0.478	≥ 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: 17/11/2023		
A) Substrate Blank	OD 450 nm 0.060	≤ 0.100
Calibrator 5 AU/ml	OD 450 nm 0.193	
Calibrator 10 AU/ml	OD 450 nm 0.310	
Calibrator 15 AU/ml (Cut Off)	OD 450 nm 0.571	≥ 0.250
Calibrator 50 AU/ml	OD 450 nm 1.769	
Calibrator 100 AU/ml	OD 450 nm 2.391	≥ 1.400
B) HOMOGENEITY OF CUT OFF	No. 6 OD 450 nm 0.631 CV% 10%	≤ 15%
C) PRECISION OF FILLING PROCESS		

SATISFACTORY

UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 17.11.2023

Signed: 
Released: Q.C.Manager