

Certificate of Analysis (CoA)



**GOLD
STANDARD
DIAGNOSTICS**



Product: **Helicobacter pylori IgG plus**
 Prod.No.: **30114048**
 Lot: **PHELG-141**
 Expiry: **2026-10-31**
 IFU: **Rev. 01**

Component	Number	Lot	Prod. Date	Expiry Date
MTP	1	MG022-141	2025-04	2026-10-31
CONJ	1	KG022-141	2025-04	2026-10-31
CAL A	1	SAG022-141	2025-04	2026-10-31
CAL B	1	SBG022-141	2025-04	2026-10-31
CAL C	1	SCG022-141	2025-04	2026-10-31
CAL D	1	SDG022-141	2025-04	2026-10-31
CONTROL	1	CG022-141	2025-04	2026-10-31
WASH BUF 20x	1	W-1110	2025-03	2027-03-31
SOLN STOP	1	S-1041	2025-02	2027-02-28
SUB TMB	1	T-077	2022-09	2027-03-31
DIL	1	D-491	2025-02	2027-02-28

Component	Concentration	OD Value	OD Validation Criteria
CAL A	0 NTU/mL	0.014	< 0.200
CAL B	15 NTU/mL	0.653	> 0.100 & > Standard A
CAL C	75 NTU/mL	1.255	> 0.400 & > Standard B
CAL D	150 NTU/mL	1.864	> 0.900 & > Standard C

Component	Target Value (NTU/mL)	Target Range (NTU/mL)
CONTROL	81.51	44.83 - 118.19

Final Report issued: 2025-05-14

Approved by: ACr
 Quality Control

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