



**GOLD  
STANDARD  
DIAGNOSTICS**



# Certificate of Analysis (CoA)

Product: **Helicobacter pylori IgG plus**  
 Prod.No.: **30114048**  
 Lot: **PHELG-143**  
 Expiry: **2027-04-30**  
 IFU: **Rev. 01**

Component	Number	Lot	Prod. Date	Expiry Date
<b>MTP</b>	1	MG022-143	2025-10	2027-04-30
<b>CONJ</b>	1	KG022-143	2025-10	2027-04-30
<b>CAL A</b>	1	SAG022-143	2025-10	2027-04-30
<b>CAL B</b>	1	SBG022-143	2025-10	2027-04-30
<b>CAL C</b>	1	SCG022-143	2025-10	2027-04-30
<b>CAL D</b>	1	SDG022-143	2025-10	2027-04-30
<b>CONTROL</b>	1	CG022-143	2025-10	2027-04-30
<b>WASH BUF 20x</b>	1	W-1124	2025-10	2027-10-31
<b>SOLN STOP</b>	1	S-1055	2025-09	2027-09-30
<b>SUB TMB</b>	1	T-078	2025-04	2028-04-28
<b>DIL</b>	1	D-495	2025-09	2027-09-30

Component	Concentration	OD Value	OD Validation Criteria
<b>CAL A</b>	0 NTU/mL	0.008	< 0.200
<b>CAL B</b>	15 NTU/mL	0.225	> 0.100 & > Standard A
<b>CAL C</b>	75 NTU/mL	0.620	> 0.400 & > Standard B
<b>CAL D</b>	150 NTU/mL	1.250	> 0.900 & > Standard C

Component	Target Value (NTU/mL)	Target Range (NTU/mL)
<b>CONTROL</b>	78.63	43.25 - 114.01

Final Report issued: 2025-11-10

Approved by:   
 Quality Control

Approved on: 2025-11-10



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