

Certificate of Analysis (CoA)



**GOLD
STANDARD
DIAGNOSTICS**



Product: **Entamoeba histolytica IgG**

Prod.No.: **RE58631**

Lot: **ENTG-090**

Expiry: **2027-11-30**

IFU: **Rev. 01**

Component	Number	Lot	Prod. Date	Expiry Date
MTP	1	MG0140-090	2026-05	2027-11-30
CONJ	1	KG0140-090	2026-05	2027-11-30
CONTROL -	1	NG0140-090	2026-05	2027-11-30
CUT OFF	1	CG0140-090	2026-05	2027-11-30
CONTROL +	1	PG0140-090	2026-05	2027-11-30
WASH BUF 20x	1	W-1143	2026-05	2028-05-31
SOLN STOP	1	S-1074	2026-04	2028-04-30
SUB TMB	1	T-080	2026-02	2029-02-23
DIL	1	D-501	2026-03	2028-03-31

Component	OD Value	OD Validation Criteria
CONTROL -	0.021	< 0.200 < Cut-off
CUT OFF	0.648	0.150-1.300
CONTROL +	1.370	> Cut-off

Component	Target Value [NTU]	Target Range [NTU]
CONTROL +	22.44	12.34 - 32.54

The target value and target range of **CONTROL +** may be used optionally.

The positive control is valid if the absorbance value of **CONTROL +** > **CUT OFF**.

Final Report issued: 2026-06-11

Approved by: _____

Quality Control

Approved on: 2026-06-11



Gold Standard Diagnostics Frankfurt GmbH
Waldstrasse 23 A6
63128 Dietzenbach, Germany



IBL International GmbH
Flughafenstrasse 52a, 22335 Hamburg
Germany