

Certificate of Analysis (CoA)



**GOLD
STANDARD
DIAGNOSTICS**



Product: **Entamoeba histolytica IgG**

Prod.No.: **RE58631**

Lot: **ENTG-089**

Expiry: **2027-07-31**

IFU: **Rev. 01**

Component	Number	Lot	Prod. Date	Expiry Date
MTP	1	MG0140-089	2026-01	2027-07-31
CONJ	1	KG0140-089	2026-01	2027-07-31
CONTROL -	1	NG0140-089	2026-01	2027-07-31
CUT OFF	1	CG0140-089	2026-01	2027-07-31
CONTROL +	1	PG0140-089	2026-01	2027-07-31
WASH BUF 20x	1	W-1134	2026-02	2028-02-29
SOLN STOP	1	S-1066	2025-12	2027-12-31
SUB TMB	1	T-079	2025-12	2028-12-10
DIL	1	D-499	2026-01	2028-01-31

Component	OD Value	OD Validation Criteria
CONTROL -	0.014	< 0.200 < Cut-off
CUT OFF	0.608	0.150-1.300
CONTROL +	1.455	> Cut-off

Component	Target Value [NTU]	Target Range [NTU]
CONTROL +	21.70	11.93 - 31.46

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**.

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Approved by: 
 Quality Control

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