

CERTIFICATE OF ANALYSIS

PRODUCT NAME: BIALEX EMULSION LIPASE

LOT: 24LL0901

MFGDT: 2024.09.02

EXP. DATE: 2026.09.01

REF. # GQ-LL-60

BATCH QTY: 70 KITS

Physical Inspection:

Labels: Pass

QR Code: Pass

HPDE Bottle: Pass

Vial: Pass

Box: Pass

Performance Characteristics:

Buffer:

Aspect: Liquid Trans-lucid, non visible particles w/o surfactant Standard: No required, CAL: No Required

Blank @340nm (against water) = 0.026

Substrate: Alcohol basis, mfg according protocol

Control used:

Fresh serums valued

Recommendation for using the reagent: Given that this method employs emulsion lipase without colipase, be aware that standard commercial controls may not be suitable. Action Required: You must validate the reagent's performance using known values and serum samples. Additionally, validate your calculated factor by testing both low and high-value controls and comparing the results.

Conclusion: Released

