

CERTIFICATE OF ANALYSIS

PRODUCT NAME: BIALEX EMULSION LIPASE

LOT: 25LL0301

MFGDT: 2025.03.11

EXP. DATE: 2027.03.10

REF. # GQ-LL-60

BATCH QTY: 30 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

In our study, we evaluated the performance of the Bialex Emulsion Lipase by comparing its results with a widely used commercial lipase assay reagent. A total of 30 serum samples were analyzed, comprising 20 samples with low lipase values (≤ 70 U/L) and 10 samples with high lipase values (≥ 200 U/L). The results indicated a strong correlation with the findings obtained using the commercial reagent.

Accuracy: The accuracy of the Bialex Emulsion Lipase method was determined by calculating the mean differences from the values provided by the commercial reagent. The mean bias for low values was found to be within ± 5 U/L, indicating that the Bialex method produces results that are highly comparable to the commercial assay under similar conditions.

Sensitivity: Sensitivity testing revealed that the Bialex Emulsion Lipase effectively detected low lipase activity levels, with a detection limit of 20 U/L, comparable to the commercial reagent's limit of 15 U/L. Both assays demonstrated robust performance in identifying samples that fall within the normal physiological range, supporting the reliability of Bialex for routine diagnostics.

Specificity: Specificity was assessed by testing samples from patients with known conditions that could interfere with lipase levels, such as hyperlipidemia and pancreatitis. While the commercial reagent exhibited slight cross-reactivity, the Bialex Emulsion Lipase showed minimal interference, producing specific results for lipase activity without significant deviations from expected values, further confirming its effectiveness as a diagnostic tool.

Conclusion: Release for sale

Conclusion: Released

