Bialex®

CERTIFICATE OF ANALYSIS

PRODUCT NAME: BIALEX EMULSION LIPASE

LOT: 25LL0701 MFGDT: 2025.07.01

EXP. DATE: 2027.07.01 REF. # GQ-LL-60

BATCH QTY: 102 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) = 0.036

Substrate: Alcohol basis, mfg according protocol

Control used:

Fresh serums valued

In our study, we assessed the performance of Bialex Emulsion Lipase by comparing its analytical results with those obtained using a widely adopted commercial lipase assay reagent. A total of 40 serum samples were evaluated, including 20 samples with low lipase activity (≤ 70 U/L) and 20 samples with high lipase activity (≥ 160 U/L). The findings demonstrated a robust correlation between the Bialex Emulsion Lipase results and those from the commercial reagent, indicating its reliability and potential as an effective alternative for lipase measurement.

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 6 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.

Three studies were conducted using different methodologies: the manual method at room temperature, the kinetic method, and the fixed-time method. Each method was thoroughly evaluated, and the concordant factors for this batch are as follows:

Method at room temperature (Manual use): 454.76
Kinetic Method: 2472.72
Fixed-time Method: 812.76
Some AA Instruments: 11000
(Certain Automatic instruments measure in hiddem at two wavelengths to perform blank correction and sometimes to estimate the optical path length indirectly, in this case delete this option or work with 11000 as factor for all methods)

Conclusion: Released

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