

CERTIFICATE OF ANALYSIS

PRODUCT NAME: BIALEX LIPASE KINETIC

LOT: 24LK1001

MFGDT: 2024.10.30 to 2024.11.06

EXP. DATE: 2026.09.30

REF. # GQ-LK-60

BATCH QTY: 50 KITS

Physical Inspection:

Labels: Pass

QR Code: Pass

HPDE Bottle: Pass

Vial: Pass

Box: Pass

Performance Characteristics:

Reagent Lipase:

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

Blank @340nm (against water) = 0.013

Reagent Stress: Pass

Control used:

Lyphocheck Bio-Rad (LOT 89740) <https://myeinserts-app.qcnet.com/home>

PassCheck Bialex (LOT 24PCK0814) <https://platinum.bialexlab.com/files>

A study of a reaction's kinetics begins with measuring its reaction rate of lipase, Consider that it is a large chain and the behavior is extreme sensitivity to unstable temperature, and the capacity of instrument to detect the rate, for our release we used the following times in our AA instrument, each instrument could be have a little changes

Read time: 180s // Interval Time: 60 // Lag time 60s

C2 Biorad 105 (107) U/L (n=20)

C1 Biorad 63.7 (61.20) U/L (n=20)

C2 PassCheck: 102 (100) U/L (n=20)

C1 PassCheck: 54 (60) U/L (n=20)

CAL (24CAL0701) = 48UI/L

Conclusion: Released

