Bialex®

CERTIFICATE OF ANALYSIS

- **PRODUCT NAME:** BIALEX LIPASE KINETIC
- **LOT:** 26LK0701
- **MFGDT:** 2026-06-17 to 2026-06-25
- **BATCH EXPIRATION DATE:** 2028-02-10
- **REF:** GQ-LK-60 / GQ-LK-30
- **BATCH QTY:** 5L

Physical Inspections:

- **Label:** Pass
- **QR Code:** Pass
- **HPDE Bottle:** Pass
- **Package:** Pass
- **Organoleptic Inspection:** Pass

Performance Characteristics:

Monoliquid reagent slightly cloudy, wo particles with surfactant, Abs 0.683 – Pass (against water)
Instrumental QC: Jenway UV, Runner Instrumentation: Biolis 24i – Chemsense3000 (IL-100)

- **Parameters assay in some semi-automatic instrumentations:** 180s reader, lag time: 60s - Rate Mehod, Calibration parameters: One Point Linear, (GQ-CAL-5)
- **Parameter assay in some semi-automatic instrumentations:** 180s reader, lag time: 60s - Two Point Method, Calibration parameters: 2 Point Linear, Cal 1: 0 (use DI Water), Cal 2: Multicalibrator PassCheck (GQ-CAL-5)

QC Results with Bio Rad Lyphocheck Lot 89740

- **C1:** 56.8 (60.0 U/L) n=20
- **C2:** 102.0 (97.0 U/L) n=20

QC Results with Bialex Multicontrol PassCheck Lot 26PCK170

- **C1:** 55.0 n=20
- **C2:** 92.0 n=20

Cal Value for this lot assigned: 55 in Lot 26CAL0101

- **Final decision:** Release for sale
- **Date:** 2026-06-25

BIALEX LAB QC DATE QUALITY ASSURANCE

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