

CERTIFICATE OF ANALYSIS

PRODUCT NAME: BIALEX LIPASE KINETIC

LOT: 26LK0601 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 Method, 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

