

CERTIFICATE OF ANALYSIS

PRODUCT NAME: BIALEX AMYLASE

LOT: 26AMK0401

MFGDT: 2026.04.13

EXP. DATE: 2028.04.01 (YYYY-MM-DD)

REF. # GQ-AMK-60

BATCH QTY: 5L

Physical Inspection:

Labels: Pass

QR Code: Pass

HPDE Bottle: Pass

Vial: Pass

Box: Pass

Performance Characteristics:

Reagent Amylase:

Aspect: Liquid Yellow Translucid, non visible particles with surfactant

Standard: No required

Blank @405nm (against water) = 0.040

Reagent Stress: Pass

Control Lyphocheck Bio-Rad (LOT 89740)

<https://myeinserts-app.qcnet.com/home>
Result (n=20)

Control 1 (81.15 U/L) 80.10 U/L

Control 2 (415 U/L) 412.00U/L

SD

<1%

<1%

Comparable Method with Siemens Advia Chemistry Systems

Liquichek Urine Chemistry Control (LOT 1007110)

Control 1 (Pending U/L) Pending

Control 2 (Pending U/L) Pending

PassCheck Universal Assayed Serum Chemistry Control (Lot 26PCK0171 & 26PCK0172)

Control 1 (210 U/L) 208.00U/L

Control 2 (420U/L) 420.00 U/L

Recommended programming: 180s read time, Interval read time: 60s, Lag Time 60s other recommendations: Pre-incubation reagent by 2 min @ 37°C Use factors as following:

Semi-automatic instrument 3714

26CAL0101 (Ref.:GQ-CAL-5): 208.14 U/L

Conclusion: Released

