

CERTIFICATE OF ANALYSIS

PRODUCT NAME: BIALEX AMYLASE

LOT: 25AMK0902

MFGDT: 2025.09.25

EXP. DATE: 2027.09.10 (YYYY-MM-DD)

REF.: GQ-AMK-60 BATCH QTY: 200KITS

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 w/o surfactant

Standard: No required

Blank @405nm (against water) = 0.102

Reagent Stress: Pass

Control Lyphocheck Bio-Rad (LOT 89740)

<https://myeinserts-app.qcnet.com/home>

	Result (n=20)
Control 1 (81.15 U/L)	81.0 U/L
Control 2 (415 U/L)	417.00U/L

SD
<1%
<1%

Comparable Method with Siemens Advia Chemistry Systems

Liquichek Unassayed Chemistry Control (LOT 92970)

Control 1 (80 U/L)	81.00 U/L
Control 2 (380 U/L)	379.00U/L

Liquichek Urine Chemistry Control (LOT 97440)

Control 1 (65.10 U/L)	64.20 U/L
Control 2 (200.00 U/L)	199.00 U/L

PassCheck Universal Assayed Serum Chemistry Control (Lot 24PCK0151
& 25PCK0152)

Control 1 (210 U/L)	210.27 U/L
Control 2 (420 U/L)	421.76 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 3954

Cal Value (Lot 24CAL0701): 212.76

Conclusion: Released

