

CERTIFICATE OF ANALYSIS

PRODUCT NAME: BIALEX AMYLASE

LOT: 25AMK0901

MFGDT: 2025.08.30

EXP. DATE: 2027.08.30 (YYYY-MM-DD)

REF. # GQ-AMK-2x15, GQ-AMK-2X30, GQ-AMK-60

BATCH QTY: 23L

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) = 0.113

Reagent Stress: Pass

Control Lyphocheck Bio-Rad (LOT 89740)

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

	Result (n=20)
Control 1 (81.15 U/L)	80.10 U/L
Control 2 (415 U/L)	410.00U/L

SD

<1%

Comparable Method with Siemens Advia Chemistry Systems

<1%

Liquichek Unassayed Chemistry Control (LOT 92970)

Control 1 (80 U/L)	81.00 U/L
Control 2 (380 U/L)	376.00U/L

Liquichek Urine Chemistry Control (LOT 97440)

Control 1 (65.10 U/L)	64.70 U/L
Control 2 (200.00 U/L)	201.00 U/L

PassCheck Universal Assayed Serum Chemistry Control (Lot 24PCK0141
& 25PCK0142)

Control 1 (230 U/L)	248.73 U/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 4077.66

Conclusion: Released

