

CERTIFICATE OF ANALYSIS

PRODUCT NAME: Bialex Urea BUN
LOT 25BUN0201 **DATE MANUFACTURER:** 2025-02-18
EXP. DATE: 2026-12-18 **REF. #** GQ-BUN-125

Qty Manufacture: 20L

Physical Inspection:

Labels: Acceptable | QR Code: Acceptable | HPDE Bottle: Acceptable | Box: Acceptable

Performance Characteristics:

Reagent Urea BUN:

Aspect Liquid Translucid, micro-visible particles, with surfactant

Standard:

Include in the kit – Use Standard of Bialex Urea BUN (GQ-BUN-1),

Aspect Translucid

Concentration 20mg/dL

Reagent Urea BUN:

A340 > 1.200 against water - PASS

Reagent

Reagent Urea BUN

Values @ 340nm

(>1.000)

QCNet (Bio-Rad) Lot 89740

Control 1

n=20/ 16 mg/dL

Control 2

n=20 / 43 mg/dL

Comparable method with Abaxis Piccolo.

Results @ 340nm

1.210

Results @ 340nm

18.00 mg/dL

44.90 mg/dL

PassCheck -Lot 25PCK0121 & 24PCK0121

Control 1

13.20 mg/dL

Control 2

43.10 mg/dL

Results:

14.10 mg/dL

43.53 mg/dL

PassCheck CAL-Lot 24CAL0701

Value: 13.97 mg/dL

Time reader for Abs: 1 hours

Pass

Storage 2-8°C

Conclusion: Release for sale

Liable Person:

