

CERTIFICATE OF ANALYSIS

PRODUCT NAME: Bialex Urea BUN
LOT 25BUN0902 **DATE MANUFACTURER:** 2025-08-27 to 2025-09-05
EXP. DATE: 2027-08-20 (YYYY-MM-DD) **REF. #** GQ-BUN-125

Qty Manufacture: 600KITS

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 ñ 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

Reagent Total Protein

Control 1

Control 2

Comparable method with ROCHE HITACHI COBAS C SYSTEMS (CONTIDUED).

Values @ 340nm

(>1.000)

QCNet (Bio-Rad) Lot 89740

n=20/ 15.1 mg/dL

n=20 /43.60 mg/dL

Results @ 340nm

1.509

Results @ 340nm

15.20 mg/dL

44.70 mg/dL

PassCheck -Lot 25PCK0141 & 24PCK0142

Control 1

12.00 mg/dL

13.17 mg/dL

Control 2

41.00 mg/dL

42.44 mg/dL

Results:

PassCheck CAL-Lot 24CAL0701

Value: 11.49 mg/dL (Using 90s reader time and 20 lag time)

Time reader for Abs: 1 hours

Pass

Storage: 2-8°C

Conclusion: Release for sale

Liable Person:

