

CERTIFICATE OF ANALYSIS

PRODUCT NAME: Bialex Urea BUN
LOT 26BUN0301 **DATE MANUFACTURER:** 2026-02-05 to 2026-02-13
EXP. DATE: 2028-02-10 (YYYY-MM-DD) **REF. #** GQ-BUN-125

Qty Manufacture: 435 KITS

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 > 1.840 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

1.900

Results @ 340nm

14.00 mg/dL

41.00 mg/dL

PassCheck -Lot 26PCK0171 & 26PCK0172

Control 1

12.00 mg/dL

12.92 mg/dL

Control 2

41.00 mg/dL

39.97 mg/dL

PassCheck CAL-Lot 26CAL0101

Value: 14.40 mg/dL (Using 90s reader time and 10 lag time)

Time reader for Abs: 1 hours

Pass

Storage: 2-8°C

Conclusion: Release for sale

Liable Person:





Clarification Note for the Certificate of Analysis (CoA)

Please be informed that the internal vial lot corresponding to this main Lot: 25BUN1101, FV: 2027-10-10 is **25LDH1101**. However, it is important to note that the lot **25LDH1101** matches the lot of another product in our records.

This clarification is provided to maintain traceability and accuracy in the documentation, ensuring that the internal lot mentioned corresponds exactly to the delivered product with Lot 25BUN1101.

We appreciate your understanding and are available for any further questions.

