

CERTIFICATE OF ANALYSIS

PRODUCT NAME: Bialex Urea BUN

LOT 25BUN1101 DATE MANUFACTURER: 2025-10-27 to 2025-11-04

EXP. DATE: 2027-10-10 (YYYY-MM-DD) REF. # GQ-BUN-125

Qty Manufacture: 400 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 > 1.853 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

1.853

Results @ 340nm

15.00 mg/dL

44.00 mg/dL

PassCheck -Lot 25PCK0151 & 24PCK0152

Control 1

12.00 mg/dL

12.80 mg/dL

Control 2

41.00 mg/dL

44.00 mg/dL

PassCheck CAL-Lot 24CAL0701

Value: 13.97 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.

