BIALEX®

CERTIFICATE OF ANALYSIS

Property Name: BIALEX K

Lot: 26K1001

Reference: GQ-K-100

Batch: 60 Kits

Date MNFG: 2026.10.14

Use: IN VITRO DIAGNOSTIC

Expiration Date: 2028-10-09 (YYYY-MM-DD)

SPECIFICATIONS & CHARACTERISTICS

Characteristics: REAGENT AND STANDARD BETWEEN RANGE CHARACTERISTIC
Units: mEq/L

Parameter / Control	Reference Range / Value	Result
Standard Value	4 mEq/L	-
CONTROL 1	4.5 mEq/L	LEVEL 1: 4.30 mEq/L
CONTROL 2	6.5 mEq/L	LEVEL 2: 6.10 mEq/L
PassCheck Calibrator (Lot: 26CAL0201)	3.7 mEq/L	Passed

NOTES & STORAGE CONDITIONS

Note: Storage at 2 to 8°C may induce crystal formation. This process is reversible; for precipitate redissolution, allow the reagent to reach room temperature or use a water bath (25-32°C) until complete homogenization is achieved.

REGULATORY & COMPLIANCE STATEMENTS

Vector Statement: Vector must not be considered pathogenic for livestock or avian species; the kit does not contain genes or express antigens of livestock or poultry disease agents. The kit does not contain any animal derived additives, such as albumin or serum.

Conclusion: Release for sale

Quality Assurance / QC Release

J.Tanaka
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BIALEK LAB QUALITY ASSURANCE

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