

CERTIFICATE OF ANALYSIS

PRODUCT NAME: Bialex Glucose Oxidase

LOT 25GO0902 DATE MANUFACTURER: 2025-08-30 to 2025-09-09

EXP. DATE: 2027.09.03 (YYYY-MM-DD) REF. GQ-GO-100, GQ-GO-125

BATCH QTY: 600 Kits

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

Performance Characteristics:

Reagent Glucose:

Aspect Liquid clear pale yellowish to pink, non-visible particles, with surfactant

Standard:

Aspect Liquid Translucid, nonvisible particles, w/o surfactant, concentration 100mg/dL

Reagent	Values @ 505nm	Results @ 505nm
Reagent Glucose	(0.010-0.300)	0.027

Glucose	QCNet (Bio-Rad) Lot 89740	Results @ 510nm
Control 1	74 mg/dL n=20	75.00 (+/- 0.1%)
Control 2	273 mg/dL n=20	274.00 (+/- 0.1%)

Comparable Method with Abbott Alinity c Analyzer PassCheck Control,
GQ-PC-1 PassCheck Multicontrol LOT 25PCK0141 & 25PCK0142

Control 1	Control 2
96.00 mg/dL	272.00 mg/dL

MultiCalibrator PassCheck Lot 24CAL0701 REF: GQ-CAL-5

Value: 92.52 mg/dL

Linearity: up 600 mg/dL

Time reader for Abs: 5 minutes Pass

Reader after 20 minutes: 3% of variation, recommend read between 5 to 10 minutes

Liabile Person: Jean Tanaka

