

CERTIFICATE OF ANALYSIS

PRODUCT NAME: Bialex Glucose Oxidase

LOT 24GO1102 DATE MANUFACTURER: 2024-11-05
EXP. DATE: 2026-11-10 REF. GQ-GO-100, **BATCH:** 70L

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

Performance Characteristics:

Reagent Glucose:

Aspect Liquid Translucid pale yellowish, non-visible particles, with surfactant

Standard:

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

Reagent	Values @ 510nm	Results @ 505nm
Reagent Glucose	(0.010-0.300)	0.028

Glucose	QCNet (Bio-Rad) Lot 89730	Results @ 505nm
Control 1	74 mg/dL n=20	76.10
Control 2	273 mg/dL n=20	276.00

Comparable Method with Abbott Alinity c Analyzer PassCheck Control,

GQ-PC-1 PassCheck Multicontrol LOT 24PCK0814 (24PCK0401)

Control 1

Control 2

90 mg/dL (97mg/dL)

275 mg/dL (265mg/dL)

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

Value: 87.23 mg/dL

Time reader for Abs:

5 minutes

Pass

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

Liabile Person:

