

CERTIFICATE OF ANALYSIS

PRODUCT NAME: Bialex Dyazo Direct Bilirubin

LOT 25BD0701 DATE MANUFACTURER: 2025-05-30
EXP. DATE: 2027-05-01 (YYYY-MM-DD) REF. # GQ-BD-100
LOT QTY: 40L

Physical Inspection:

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

Performance Characteristics:

Reagent Direct Dyazo Bilirubin, LOT 25BD0501
Aspect Liquid Translucid, nonvisible particles, with surfactant
Reagent Nitrite:
Aspect Liquid Translucid, nonvisible particles, with surfactant, Lot 25BT0502

Reagent	Values @ 550nm	Results @ 550nm
Abs Work Reagent	(0.038-0.200)	0.190 (after 8 hours)

D.Bilirubin	QCNet (Bio-Rad) Lot 89740	Results @ 550nm
Control 1	n=20 / 0.412 mg/dL	0.456 (+0.2%)
Control 2	n=20 / 1.40 mg/dL	1.44 (+/- 0.1%)

Comparable result with Beckman Coulter Au Systems

GQ-PC-1 PassCheck Control Lot 25PCK0131 & 25PCK0132	Control 1	Control 2
	0.50 mg/dL	4.70 mg/dL
	(0.50 mg/dL)	(4.70mg/dL)

Time reader for Abs:	5 minutes	8 minutes
FACTOR: 10.87		

Liabile Person:

PassCheck CAL Lot: 24CAL0701 (Ref: GQ-CAL-5) - Value: 0.48 mg/dL

Storage: 2-25°C

