

CERTIFICATE OF ANALYSIS

PRODUCT NAME: Bialex Dyazo Direct Bilirrubin

LOT 25BD0702 DATE MANUFACTURER: 2025-07-03

EXP. DATE: 2027-07-01 (YYYY-MM-DD) REF. # GQ-BD-100, GQ-BD-125

LOT QTY: 100L

Physical Inspection:

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

Performance Characteristics:

Reagent Direct Dyazo Bilirrubin

Aspect Liquid Translucid, nonvisible particles, with surfactant

Reagent Nitrite:

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

D.Bilirrubin	QCNet (Bio-Rad) Lot 89740	Results @ 550nm
Control 1	n=20 / 0.379 mg/dL	0.372 (+/- 0.1%)
Control 2	n=20 / 1.680 mg/dL	1.680 (+/- 0.0%)
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
(0.52 mg/dL)	(4.71mg/dL)

Pediatric Control - Biorad Liquichek Lot 74940	Values Siemens Dimension Serie C1:3.17 (3.15) / C2:6.57 (6.60)
Time reader for Abs:	5 minutes
	8 minutes

FACTOR: 11.00

Liabile Person:

PassCheck CAL Lot: 24CAL0701 (Ref: GQ-CAL-5) - Value: 0.56 mg/dL

Storage: 2-25°C

