

CERTIFICATE OF ANALYSIS

PRODUCT NAME: Bialex Dyazo Direct Bilirrubin

LOT 25BD0401 DATE MANUFACTURER: 2025-04-14
EXP. DATE: 2027-04-10 (YYYY-MM-DD) REF. # GQ-BD-100
LOT QTY: 10L

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)	0.190 (after 8 hours)

D.Bilirrubin	QCNet (Bio-Rad) Lot 89740	Results @ 550nm
Control 1	n=20 / 0.379 mg/dL	0.369 (+/- 0.1%)
Control 2	n=20 / 1.680 mg/dL	1.690 (+/- 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
(0.52 mg/dL)	(4.71mg/dL)

Pediatric Control - Biorad Liquichek Lot 74940	Values Siemens Dimension Serie C1:3.17 (3.15) / C2:6.57 (6.65)	
Time reader for Abs:	5 minutes	8 minutes

FACTOR: 11.60

Liabile Person:

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

Storage: 2-25°C

