

CERTIFICATE OF ANALYSIS

PRODUCT NAME: Bialex Dyazo Direct Bilirrubin

LOT 25BD1001 DATE MANUFACTURER: 2025-10-30
EXP. DATE: 2027-08-30 (YYYY-MM-DD) REF. # GQ-BD-100
LOT QTY: 20L

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 @ 548nm	Results @ 548nm
Abs Work Reagent	(0.038-0.200)	0.220 (after 8 hours)

D. Bilirrubin	QCNet (Bio-Rad) Lot 89740	Results @ 550nm
Control 1	n=20 / 0.379 mg/dL	0.380 (+/- 1.0%)
Control 2	n=20 / 1.680 mg/dL	1.780 (+/- 1.0%)
Comparable result with Beckman Coulter Au Systems		

GQ-PC-1 PassCheck Control Lot 25PCK0151 & 25PCK0152

Control 1	Control 2
0.50 mg/dL	4.70 mg/dL
(0.50 mg/dL)	(4.70mg/dL)

Pediatric Control - Biorad Liquichek Lot 74940 Comparable with Siemens ADVIA C1:4.60 (4.70) / C2:9.91 (9.91)	
Time reader for Abs: 5 minutes	8 minutes

FACTOR: 9.91

Liabile Person:

PassCheck CAL Lot: 24CAL0701 (Ref: GQ-CAL-5) - Value: 0.495 mg/dL

Storage: 2-25°C

