

CERTIFICATE OF ANALYSIS

PRODUCT NAME: Bialex Dyazo Direct Bilirrubin

LOT 25BD1101 DATE MANUFACTURER: 2025-10-30
EXP. DATE: 2027-11-01 (YYYY-MM-DD) REF. # GQ-BD-100, GQ-BD-125
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)	0.200 (after 8 hours)

D.Bilirrubin	QCNet (Bio-Rad) Lot 89740	Results @ 548nm
Control 1	n=20 / 0.379 mg/dL	0.360 (+/- 1.0%)
Control 2	n=20 / 1.680 mg/dL	1.700 (+/- 1.0%)
Comparable result with Beckman Coulter Au Systems		

GQ-PC-1 PassCheck Control Lot 25PCK0161 & 25PCK0162

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

Pediatric Control - Biorad Liquichek Lot 74940 Siemens Dimensions C1:2.76 (2.56) / C2:6.70 (6.56)	
Time reader for Abs: 5 minutes	8 minutes

Newborn request dilution 1:10

Cal Value (LOT 24CAL07010):0.43

FACTOR: 10.50

Liabe Person:

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

Storage: 2-25°C