

CERTIFICATE OF ANALYSIS

PRODUCT NAME: Bialex Dyazo Direct Bilirubin

LOT 26BD0601 DATE MANUFACTURER: 2026-06-04
EXP. DATE: 2028-06-01 (YYYY-MM-DD) REF. # GQ-BD-100, GQ-BD-125
LOT QTY: 60L

Physical Inspection:

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

Performance Characteristics:

Reagent Direct Dyazo Bilirubin
Aspect Liquid Translucid, nonvisible particles
Reagent Nitrite:
Aspect Liquid Translucid, nonvisible particles

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

D. Bilirubin	QCNet (Bio-Rad) Lot 89740	Results @ 550nm
Control 1	n=20 / 0.379 mg/dL	0.370 (+/- 0.5%)
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 26PCK0171 & 26PCK0172

Control 1	Control 2
0.57 mg/dL	4.77 mg/dL
(0.50 mg/dL)	(4.70mg/dL)
Pediatric Control - Biorad Liquichek Lot 74940 Comparable with Siemens ADVIA C1:4.10 (4.70) / C2:9.40 (9.71)	
Time reader for Abs: 5 minutes	8 minutes

FACTOR: 9.70

Liabe Person:

PassCheck CAL Lot: 26CAL0101 (Ref: GQ-CAL-5) - Value: 0.57 mg/dL

Storage: 2-25°C