

CERTIFICATE OF ANALYSIS

PRODUCT NAME: Bialex Dyazo Direct Bilirrubin

LOT 26BD0401 DATE MANUFACTURER: 2026-04-03

EXP. DATE: 2028-04-10 (YYYY-MM-DD) REF. # GQ-BD-100, GQ-BD-125

LOT QTY: 40L

Physical Inspection:

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

Performance Characteristics:

Reagent Direct Dyazo Bilirrubin

Aspect Liquid Translucid, nonvisible particles

Reagent Nitrite:

Aspect Liquid Translucid, nonvisible particles

Reagent	Values @ 548nm	Results @ 548nm
Abs Work Reagent	(0.038-0.200)	0.210 (after 8 hours)

D.Bilirrubin	QCNet (Bio-Rad) Lot 89740	Results @ 550nm
Control 1	n=20 / 0.379 mg/dL	0.360 (+/- 1.0%)
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 26PCK0171 & 26PCK0172

Control 1	Control 2
0.495 mg/dL	4.67 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: 11.00

Liabe Person:

PassCheck CAL Lot: 26CAL0101 (Ref: GQ-CAL-5) - Value: 0.49 mg/dL

Storage: 2-25°C