



CERTIFICATE OF ANALYSIS

PRODUCT NAME: Bialex Direct HDL

LOT 26HDL0302 **DATE MANUFACTURER:** 2026.03.04 to 2026.03.13

EXP. DATE: 2027.11.20 **REF. #** GQ-HDL-6020

Qty Manufacture: 490 Kits

Physical Inspection:

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

Performance Characteristics:

Reagent 1 & 2 Direct HDL :

Aspect Liquid Translucid clear, non-visible particles, w/o surfactant

Calibrator: No include in the kit

Filter Reader for Manual Use: 550nm Filter Reader for AA Use: 600nm

HDL QCNet (Bio-Rad) Lot 89740 Results @ 600nm

Control 1 81.2 mg/dL 78.00 mg/dL

Control 2 28.6 mg/dL 28.00 mg/dL

Comparable method with Siemens Dimensions Series.

PassCheck (Lot 26PCK0171 & 26PCK0172) Ref. Values: 57 - 122 mg/dL

Result: 56.68 - 124 mg/dL

Lineality: 200 mg/dl Pass

Time reader for Abs: 180 minutes Pass

Storage 2-8°C

PassCheck CAL (GQ-CAL-5): LOT

24CAL0701 = 42.51

LOT 26CAL0101 = 61.00

Liable Person:

Conclusion: Release Approved

Vector must not be considered pathogenic for livestock or avian species; the kit does not contain genes or express antigens of livestock or poultry disease agents. The kit does not contain any animal derived additives, such as albumin or serum. All Rights Reserved by Bialex®