



## PASSCHECK CONTROL 1/ CALIBRATOR HDL/LDL

REF: GQ-PC1-1

Use: IVD

**Intended of Use:** PassCheck Lipid control 1 / Calibrator was designed for use as control 1 and calibrator for HDL, LDL, Cholesterol, Triglycerides,

**Preparation** Add 5mL of DI Water with follow parameters: pH 7.0 +/-0.2 to each vial using a precision volumetric pipette. Let for 30 minutes or more, and from time to time stir gently. After opened it is stable for 7 days.

**Values:** Updates will be available at [www.platinum.bialexlab.com/files](http://www.platinum.bialexlab.com/files) Precaution All specimens using in the PassCheck Control should be handled in accordance with good laboratory practices using appropriate precautions as described in the CDC/NIH Manual, "Biosafety in Microbiological and Biomedical Laboratories 2nd edition, 1988 HHS Publication No (CDC)88-8395. DBA Bialex and/or third party, certifies all individual human plasma donor units used to manufacture this lot were tested by FDA approved methods and found to non-reactive for HBsAg, HIV-1, HIV -2 and HCV. Please see the chart:

| Serum Analytical | Average | Level 1      | Concentration Factor | Units |
|------------------|---------|--------------|----------------------|-------|
| Cholesterol      | 118.00  | 94.40-141.60 | 132                  | mg/dL |
| Triglycerides    | 110.00  | 85.00-135    | 106                  | mg/dL |
| HDL              | 56.00   | 40.00-72.00  | 58                   | mg/dL |
| LDL              | 58.00   | 49.00-67.00  | 59                   | mg/dL |

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The overall concentration **could require** a correction factor validated by quality controls