Unassayed Lipoprotein (LP) Quality Control Material

REF LPQC-L (LP QC Low) REF LPQC-H (LP QC High)

INTENDED USE:
LP QC Quality Control Material from Sun Diagnostics is intended for *in vitro* diagnostic use as unassayed quality control material for HDL_3 cholesterol (HDL_3-C) and small dense LDL cholesterol (sdLDL-C).

SUMMARY:
The routine use of quality control materials is a well-established way for clinical laboratories to monitor the performance (accuracy and precision) of their analytical systems. LP QC is provided at two levels to assist in the monitoring of these systems.

REAGENTS:
LP QC is human-serum based and contains purified human lipoproteins, as well as preservatives and stabilizers to maintain product integrity.

PRECAUTIONS AND WARNINGS

WARNING: Potentially Bio-hazardous
Human source material is considered potentially bio-hazardous. This material was tested for communicable diseases (HIV, Hepatitis B and Hepatitis C) with kits approved by the FDA (where available) and found to be negative (non-reactive). Because no test method can offer complete assurance that infectious agents are absent, these specimens should be handled and treated as potentially infectious.

Dispose of all waste material in accordance with requirements of your local waste management authorities.

STORAGE AND STABILITY;
LP QC is stable until the expiration date on the vial when stored at -10°C to -20°C. Once thawed, the material is stable for up to 72 hours when stored at 2-8°C.

PREPARATION AND PROCEDURE:
Prior to use, remove the LP QC material from storage and bring to room temperature (18°C – 25°C). Gently mix the contents of the vial.

LP QC Materials should be treated in the same manner as patient samples and run according to the instructions for the assay and test system(s).

LIMITATIONS

- LP QC is NOT intended for use as an assayed quality control material, a calibrator or standard.
- If there is evidence of microbial contamination discard the vial.
- As part of good laboratory practice, each laboratory should establish its own acceptable range for quality control materials for its test methods.
- Variations, which can occur over time and between laboratories, may be due to differences in analytical systems, laboratory technique, reagent lot, and other systematic errors, including random error.

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Symbols Used:

LOT	Lot Number		Consult Package Insert
	Expiration		Manufacturer
2°C 8°C	Storage Temp	REF	Reorder Number
IVD	**For in vitro diagnostic use only**		**Biohazard**