HORIBA Instruments Incorporated
5449 Research Drive, Canton, MI 48188
Phone: 734-487-8300; (800) 445-9853

Pointe Lipid Control Set

Intended Use
The lipid control set is to be used to monitor the accuracy and precision of HDL cholesterol, LDL cholesterol, total cholesterol, and triglycerides determinations. For *in vitro* diagnostic use only. **Rx Only**

Product Description
The lipid control set is a two level, lyophilized, entirely human serum based control, supplied in a 3 x 3ml configuration for each level of the control.

HDL cholesterol values are provided for the following methods: Dextran Sulfate (50,000MW)[1] and PEG precipitation followed by cholesterol determination[2], and the manufacturer's autoHDL™.

LDL cholesterol values have been assigned using the manufacturer's autoLDL cholesterol reagent.

Total Cholesterol values have been assigned using the manufacturer's total cholesterol reagent.[3]

Triglycerides values have been assigned using the manufacturer's Triglycerides GPO reagent.

Warning
All blood donor units comprising the serum pool have been tested and found non-reactive for Hepatitis B surface antigen and HIV antibody when tested by FDA accepted methods.

Potential bio-hazardous material. No known test method can assure that a product derived from human blood does not contain Hepatitis or HIV virus. It is recommended such samples be handled at the Centers for Disease Control's Bio-Safety Level 2.

Storage
1. When stored at 2-8°C, the un-reconstituted material is stable until the expiration date stated on the vial.
2. The reconstituted material is stable for 5 days when stored refrigerated at 2-8°C.
3. Discard the controls if turbid or if there is any evidence of microbial contamination.

Procedure
1. Remove the controls from the refrigerator.
2. Remove stopper and volumetrically add 3.0ml of de-ionized water. Replace the stopper. Gently swirl to dissolve.
3. Allow the controls to stand 15 minutes.
4. Invert gently and swirl to assure homogeneity of the contents. Let the controls stand at least 15 minutes. Swirl gently just prior to use. Avoid foaming.
5. Treat the controls as you would a patient sample and test each level in accordance with the reagent manufacturer's requirement of the test method.
6. Recap the controls and return them to 2-8°C when not in use.

Expected Values
The lipid values were determined by repetitive assays of the listed methods.
Values listed are targets only. Measurements using other reagents and instrument systems may give different results. The ranges listed were obtained from those suggested by the Health Care Finance Administration as acceptable performance criteria for deviation from a target value.[5] Due to method differences and matrix interactions, the values listed may not always be reproduced by other analytical systems. Each laboratory should establish its own precision parameters.

Limitations
The degree of matrix sensitivity for many analytical systems is still unknown. Processed material may exhibit matrix effects which cause them to assay differently from patient specimens on some instruments.[5] Other limitations of the test method are included in the package insert for the reagent kit or instrument being used.
NOTE: Occasionally some turbidity may be observed in the controls. This is characteristic of lyophilized controls and is not lipid related. Therefore the controls, unlike turbid patient samples, should not be diluted. Each control should be run undiluted.

References
1. Warnick, G.R., Benderson, J., Albers, J.J., Ballie, E.E., Sexton, B., et al. Dextran Sulfate Mg^{+2} Precipitation Procedure for Quantification of High Density Lipoprotein Cholesterol Clin. Chem. 1982; 28:1379-88.
2. Lopes-Verella, M.F., Stone, P., Ellis, S., et al., Cholesterol Determination in High Density Lipoprotein Separated by Three different methods. Clin. Chem. 19-70; 23:882-890.
3. Duncan, I.W., Mather, A., Cooper, G.R., The Procedure for the Proposed Cholesterol Reference Method, Centers for Disease Control, Clinical Chemistry Division, 1982:75, Atlanta, Georgia.
4. Clinical Laboratory Improvements Amendments 1988, Federal Register, August 28, 1992.
5. National Reference System for Cholesterol, U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, Atlanta, Georgia.

Assay Data Tables Lot: 319802 Exp. Date: 2025-04-30

Level 1	Beckman AU	Hitachi 717	Mindray BS-200	Mindray BS-480	Pointe 180
autoHDL (mg/dl)	60 ± 21	57 ± 20	62 ± 22	60 ± 21	-
autoLDL (mg/dl)	163 ± 33	144 ± 29	146 ± 29	149 ± 30	-
Cholesterol (mg/dl)	242 ± 36	210 ± 32	246 ± 37	242 ± 36	229 ± 34
Triglyceride (mg/dl)	224 ± 45	221 ± 44	217 ± 43	221 ± 44	251 ± 50

Level 2	Beckman AU	Hitachi 717	Mindray BS-200	Mindray BS-480	Pointe 180
autoHDL (mg/dl)	91 ± 23	87 ± 22	96 ± 24	94 ± 24	-
autoLDL (mg/dl)	329 ± 82	287 ± 72	294 ± 74	307 ± 77	-
Cholesterol (mg/dl)	474 ± 71	420 ± 63	483 ± 72	485 ± 73	449 ± 67
Triglyceride (mg/dl)	446 ± 112	444 ± 111	426 ± 107	439 ± 110	496 ± 124

SymbolKey
Use by (YYYY-MM-DD)	LOT Lot and batch code
REF Catalog number	Manufacturer
IVD *In vitro* diagnostic medical device	Temperature limitation
Consult instructions for use	**Rx Only:** Prescription Use Only
CE mark	EC REP Authorized representative in the European Community

REF L7580-18

Manufactured for
HORIBA Instruments
Inc:- Pointe Brand
5449 Research Drive
Canton, MI 48188

2°C 8°C IVD

Manufactured for HORIBA Instruments Inc- Pointe Brand
5449 Research Drive, Canton, MI 48188

European Authorized Representative:
Obelis s.a.
Boulevard Général Wahis 53
1030 Brussels, BELGIUM
Tel: (32)2.732.59.54 Fax:(32)2.732.60.03 email: mail@obelis.net

Certified to Perform Reagents
The Pointe reagents are certified to be manufactured according to specified parameters. Any Pointe reagent product not meeting specifications through its listed expiration date will be remedied immediately without charge.

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