

Intended Use

Intended for use as an cholesterol standard for standardization or calibration of enzymatic, endpoint cholesterol assays used with HDL Cholesterol procedures

Summary and Explanation

The HDL Cholesterol standard is prepared from cholesterol dissolved in alcohol and an aqueous solution. The standard provides a concentration level of cholesterol within the linearity range of the enzymatic, endpoint cholesterol procedure. Stabilizers and preservatives added.

Principle

The standard should be used to calibrate the determination of unknown specimens using enzymatic, endpoint cholesterol reagents used with HDL Cholesterol procedures. Controls should be included to validate the calibration of the assay.

Ingredients

Reactive ingredients: Cholesterol solution prepared from cholesterol dissolved in alcohol and a aqueous solution. Preservatives added. Consult vial label for assigned concentration for the standard.

Precautions: For *in vitro* diagnostic use. Handle with the same precautions used for human samples.

Storage and stability

Store at room temperature, 15-30°C. Stable until expiration date if sealed tightly and stored at 15-30°C.

Preparation

Standard is provided as a ready to use liquid.

Procedure

The standard should be used to standardize instrument or assay following the directions that accompany the instrument and reagent kit used.

Materials provided: Aqueous HDL Cholesterol standard 50 mg/dl.










Materials not provided: Pointe Scientific enzymatic, endpoint cholesterol assay used with HDL Cholesterol procedures, HDL precipitating reagent and controls.

Limitations: Among factors that might cause inaccurate results are improper pipetting, inadequate mixing.

Standard Value

The value is 50 mg/dl when used with the Pointe Scientific enzymatic, endpoint cholesterol assays used with HDL Cholesterol procedure.

Symbol Key

 Use by (YYYY-MM)	 Lot and batch code
 Catalog number	 Manufacturer
 <i>In vitro</i> diagnostic medical device	 Temperature limitation
 Consult instructions for use	 CE mark
 Authorized representative in the European Community	



Manufactured by Pointe Scientific, Inc.
5449 Research Drive, Canton, MI 48188



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

Rev. 1/15

P803-H7512-05