

Indications for Use

510(k) Number: **K 072523**
 Device Name: **Diazyme LDL-Cholesterol Reagent**

Indications for Use: The Diazyme LDL-Cholesterol Assay is intended for the in vitro quantitative determination of Low Density Lipoprotein Cholesterol in human serum or plasma. The reagents can assist in the diagnosis and treatment of patients at risk of developing coronary heart disease. Elevated LDL cholesterol is the primary target of cholesterol-lowering therapy.

Calibrator: For calibration of the Diazyme LDL-Cholesterol Reagent Assay in serum or plasma.
 For In Vitro Diagnostic Use

Controls: To monitor the performance of Diazyme LDL-Cholesterol Reagent.
 For In Vitro Diagnostic Use

Prescription Use X
 (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
 (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Court C. Benson
 Division Sign-Off Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

510(k) Summary

Office of In Vitro Diagnostic Device
 Evaluation and Safety