

Indications for Use

510(k) Number: K 072395
 Device Name: Diazyme HDL-Cholesterol Reagent

Indications for Use: The Diazyme HDL-Cholesterol reagent is intended for the *in vitro* quantitative determination of High 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.

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

Controls: To monitor the performance of Diazyme HDL-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)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Caryl J. Benner
 Division Sign-Off

Office of In Vitro Diagnostic Device
 Evaluation and Safety