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510(k) SUMMARY

ACTIMED LABORATORIES, INC.
ENA·C·T™ Assayed Total Cholesterol Controls

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

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Date Prepared: January 25, 1996

Name of Device and Name/Address of Sponsor

ENA·C·T™ Assayed Total Cholesterol Controls

ActiMed Laboratories, Inc.
5 Terri Lane
Burlington, NJ 08016

Classification Name

Quality Control Material

Predicate Device

ChemTrak, Inc. AccuMeter® Cholesterol Controls (K905405)

Intended Use and Indications for Use

ENA·C·T™ Assayed Total Cholesterol Controls are intended for exclusive use with the *ENA*·C·T™ Total Cholesterol Test to monitor the performance of the test at the medical decision points in the determination of elevated cholesterol. The *ENA*·C·T™ Total Cholesterol Test is an instrument-free enzymatic assay for the quantitative determination of cholesterol in fingerstick whole blood for use by physicians to screen for elevated cholesterol as a risk factor in coronary heart disease (CHD).

Technological Characteristics and Substantial Equivalence

The *ENA*·C·T™ Assayed Total Cholesterol Controls are ready to use polymer solutions containing cholesterol from non-human (bovine) plasma. There are two levels of control included with each set: Level I is approximately 200 mg/dL and Level II is approximately 240 mg/dL. Assay range values for the *ENA*·C·T™ Assayed Total Cholesterol Controls are determined by testing the materials on multi-lot *ENA*·C·T™ Total Cholesterol devices which have been calibrated to produce results correlating to the Abell-Kendall reference method and are thus, traceable to the National Reference System for Cholesterol (NRS/CHOL). The controls are intended for exclusive use with the *ENA*·C·T™ Total Cholesterol Test.

The controls are used to ensure proper performance of the *ENA*·C·T™ Total Cholesterol Test and are tested in the same manner as a patient sample. Sufficient volume of the control is added to the *ENA*·C·T™ Total Cholesterol Test device in the sample well. A self-actuating siphon, in turn, transfers the control to an absorbent pad located immediately below the "START" window. The control-saturated pad shows through the clear window as a yellow indicator, signaling that enough volume has been added and that the analytical process has been initiated. The control solution subsequently flows into an enzyme pad containing cholesterol esterase and

cholesterol oxidase which completely convert cholesterol and cholesterol esters into cholestenone and hydrogen peroxide. A flow delay pad restricts passage of the control solution to permit completion of the enzymatic reactions. Subsequently, the control solution flows into the measurement zone where colorless dyes and the enzyme peroxidase are immobilized on a thin fabric layer.

The hydrogen peroxide generated from the cholesterol in the control solution converts the colorless dyes into a blue color bar, the length of which is proportional to the amount of hydrogen peroxide, and in turn, cholesterol in the control. The bar grows until a precise amount of solution has completely filled the measurement zone and "End/Q. A." draw zone. This draw zone turns green at the end of the procedure when the cholesterol converting enzymes dissolved in the solution react with control cholesterol contained in the draw zone. The appearance of a green color signals that the test is complete and that reagents were active. The total cholesterol concentration is directly read from the factory calibrated scale on the device. Results outside the linear measurement range of the *ENA*·C·T™ Total Cholesterol Test cannot be reported since the printed scale on the device only covers the range between 120 and 360 mg/dL. The color formed is stable and may be read at any time within 48 hours.

The *ENA*·C·T™ Assayed Total Cholesterol Controls are substantially equivalent in design and intended use to other products which are used as controls in total cholesterol test systems. Most notably, it is substantially equivalent to the AccuMeter®Cholesterol Controls, manufactured for ChemTrak Incorporated, Sunnyvale, CA.