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**ACTIMED LABORATORIES, INC.
ENA·C·T™ Total Cholesterol Test**

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

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Name of Device and Name/Address of Sponsor

ENA·C·T™ Total Cholesterol Test

ActiMed Laboratories, Inc.
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Burlington, NJ 08016

Classification Name

Cholesterol (total) test system

Predicate Device

ChemTrak, Inc. AccuMeter® Cholesterol Test (K905405)

Intended Use and Indications for Use

The ActiMed *ENA-C-T*TM Total Cholesterol Test is a non-instrumented, enzymatic assay intended for the *in vitro* quantitative determination of total cholesterol in fingerstick whole blood. It is indicated for professional use in settings such as clinical laboratories and physician office laboratories (POLs) to screen for elevated cholesterol as a risk factor in coronary heart disease (CHD).

Technological Characteristics and Substantial Equivalence

The *ENA-C-T*TM Total Cholesterol Test is based on stable, dry chemistry reagents embedded in a flow device with a factory calibrated scale. The device provides a direct visual read-out of test results. It has built-in controls to indicate that a sufficient volume of whole blood has been added as sample, to verify that the reagents are functioning, and to confirm when the test has been completed. The test device is self-actuating, requiring neither timing nor handling between addition of the sample and reading the result.

The *ENA-C-T*TM Total Cholesterol Test starts when a sufficient amount of whole blood has been introduced into the sample well. A self-actuating siphon, in turn, transfers the blood to an absorbent pad located immediately below the "START" window. The blood saturated pad shows through the clear window as a red indicator, signaling that enough sample has been added and that the analytical process has been initiated. The absorbent pad and a second filter separate red cells from plasma. The plasma 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 plasma to permit completion of the enzymatic reactions. Subsequently, the plasma flows into the measurement zone which acts as a capillary. In

this zone, colorless dyes and the enzyme peroxidase are immobilized on a thin fabric layer.

The hydrogen peroxide converted from cholesterol in the plasma converts the colorless dye layer into a blue color bar, the length of which is proportional to the amount of hydrogen peroxide, and in turn, cholesterol in the sample. The bar extends until a precise amount of plasma has completely filled the measurement zone and "END/QA" draw zone. This draw zone turns green at the end of the procedure when the cholesterol converting enzymes dissolved in the plasma 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. The entire process typically requires 12 to 15 minutes. The color bar formed is stable and may be read at any time within 48 hours.

Each lot of devices is calibrated by using paired fingerstick blood and venous blood samples covering the dynamic range of the test. Fingerstick blood samples are assayed by the *ENA.C.T*TM device, while venous samples are assayed by the Abell-Kendall serum reference method. Calibration coefficients are determined by comparing the fingerstick results to the serum reference method results. These calibration coefficients are used to generate the measurement scales for each lot of devices. Thus, the standardization of the *ENA.C.T*TM Total Cholesterol Test is traceable to the National Reference System for Cholesterol (NRS/CHOL), and results using fingerstick whole blood samples are automatically converted to serum values.

The *ENA.C.T*TM Total Cholesterol Test is substantially equivalent to the AccuMeter® Cholesterol Test in terms of intended use, design, materials, operational features, and performance. Both devices are based upon an enzymatic reaction that occurs when whole blood is added to dry chemistry reagents embedded in a flow device. Both devices are

standardized to the NRS/CHOL. Results from both devices are read visually within approximately 15 minutes of addition of sample to the device.

ENA-C-T™ Total Cholesterol Test results in mg/dL are read directly from a lot-specific, factory-calibrated scale printed on the device, while results for the AccuMeter® Cholesterol Test require conversion of the color peak height to total cholesterol in mg/dL using a lot-specific conversion chart that accompanies the kit. This difference does not raise new questions of safety and effectiveness.

Both the *ENA-C-T™* Total Cholesterol Test and the AccuMeter® Cholesterol Test have built-in controls. The *ENA-C-T™* Total Cholesterol has controls to indicate that a sufficient volume of whole blood has been added as sample, to verify that the reagents are functioning, and to confirm when the test has been completed, while the AccuMeter® Cholesterol Test has controls to indicate that the reagents are functioning and when the test is completed.

Performance characteristics generated during analytical and clinical studies on the *ENA-C-T™* Total Cholesterol Test are comparable to those published for the AccuMeter® Cholesterol Test in its package insert. The linear range of the *ENA-C-T™* Total Cholesterol Test is 120 mg/dL to 360 mg/dL, while the measurement range for the AccuMeter® Cholesterol Test is reported to be 125 to 400 mg/dL.

The recovery of cholesterol in the presence of potentially interfering substances was determined for the *ENA-C-T™* device and compared to the information provided in the AccuMeter® device package insert. For both devices, no interference was found in samples containing up to 1 mg/dL of acetaminophen or up to 200 mg/dL of hemoglobin. No interference was seen with the AccuMeter® device in samples containing up to 1000 mg/dL of triglycerides, while no interference was seen with the *ENA-C-T™* device in samples containing up to 800 mg/dL, the highest concentration tested. No interference was seen with the AccuMeter® device in samples containing up

to 15 mg/dL of bilirubin, while no interference was seen with the *ENA-C-T™* device in samples containing up to 14 mg/dL. Both assays are affected by high concentrations of ascorbic acid.

Precision results for these two visually read tests are comparable, with percent coefficients of variation generally less than 5% for controls at the medical decision points.

In clinical studies at four POL sites, *ENA-C-T™* Total Cholesterol Test, AccuMeter® Cholesterol Test, and Abell-Kendall results were generated on 198 paired fingerstick whole blood and venous samples. Correlations between the *ENA-C-T™* Total Cholesterol Test and the Abell-Kendall method and between the *ENA-C-T™* Total Cholesterol Test and the AccuMeter® Cholesterol Test were acceptable. Thus, the *ENA-C-T™* Total Cholesterol Test is substantially equivalent to the AccuMeter® Cholesterol Test in terms of performance characteristics, as well as intended use, design, materials, and operational features.

Analytical and Clinical Testing

Linear Range

Results from NCCLS Linearity Protocol testing and from testing 40 normal and 40 abnormal clinical samples demonstrated that the linear range of the *ENA-C-T™* Total Cholesterol Test is 120 mg/dL to 360 mg/dL.

Interfering Substances

Studies of the recovery of cholesterol in the presence of potentially interfering substances were carried out. No interference was found in samples containing up to 8 mg/dL of ascorbic acid, 1 mg/dL of acetaminophen, 14 mg/dL of bilirubin, 200 mg/dL of hemoglobin, or 800 mg/dL of triglycerides.

Precision

Precision studies were carried out at the four POLs using two controls near the medical decision points, according to NCCLS EP5-T, User Evaluation of Precision Performance of Clinical Chemistry Devices. Two levels of the *ENA-C-T™* Assayed Total Cholesterol Controls were assayed in duplicate, twice a day for five days at each site. Results were read and recorded by one operator. Within-run CVs were less than 5% for the Level 1 control (range of mean = 178 to 183.75 mg/dL) and less than 4% for the Level 2 control (range of mean = 254 to 261 mg/dL). Total CVs were 5% or less for the Level 1 control and less than 4% for the Level 2 control. These results demonstrate that the visually read *ENA-C-T™* Total Cholesterol Test was reproducible in the hands of potential users in POL settings.

Clinical Studies

A total of 198 paired fingerstick whole blood and venous samples were tested during clinical studies at four POL sites. Fingerstick whole blood samples were assayed at the sites by the *ENA-C-T™* Total Cholesterol Test and the AccuMeter® Cholesterol Test, and venous samples were assayed at a Cholesterol Reference Method Network Laboratory (CRMLN) by the Abell-Kendall serum reference method. For the comparison between the *ENA-C-T™* Total Cholesterol Test and the Abell-Kendall method, the least squares regression equation for all sites was $y = 0.976x + 7.93$, with a correlation coefficient of $r = 0.932$. Bias calculations for the *ENA-C-T™* at 200 mg/dL and at 240 mg/dL were 1.6% and 0.9%, respectively. For the comparison between the *ENA-C-T™* Total Cholesterol Test and the AccuMeter® Cholesterol Test, the least squares regression equation for all sites was $y = 0.917x + 21.3$, with a correlation coefficient of $r = 0.901$.

Bias calculations for the *ENA-C-T™* device, compared to the Abell-Kendall serum reference method were 1.6% at the 200 mg/dL level and 0.9%

at the 240 mg/dL level. These figures were well within the recommendation of the Laboratory Standardization Panel (LSP) on Blood Cholesterol Measurement that bias not exceed 3%. Correlations between the *ENA.C.T*TM device and the Abell-Kendall Method and between the *ENA.C.T*TM device and the AccuMeter® device were within 10%. Thus, the *ENA.C.T*TM Total Cholesterol Test has demonstrated acceptable precision, bias and accuracy, and was shown to be substantially equivalent to the AccuMeter® Cholesterol Test.