

K949458

## SUMMARY OF SAFETY AND EFFECTIVENESS

### ACCUTREND® CHOLESTEROL TEST

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The Accutrend® Cholesterol Test is substantially equivalent to Chemtrak's AccuMeter Cholesterol Self Test. Both systems are used to measure total cholesterol in whole blood. The procedure for both tests entails applying a capillary blood sample to a dry chemistry test strip or cartridge. Both test systems utilize non-wipe technologies. The cholesterol esterase reaction is measured in both tests. Both test systems have lot-specific coding for each lot of test strips or cartridges. Finally, both the Accutrend and AccuMeter systems are cholesterol screening devices which have been cleared specially for home use.

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