FOR PROFESSIONAL USE ONLY

INTENDED USE
This test can be used to identify elevated blood cholesterol levels associated with increased risk of coronary artery disease.

The CHEMCARD™ Cholesterol Test provides a preliminary semi-quantitative analytical test result. All results indicating elevated blood cholesterol levels should be verified by a quantitative cholesterol method. Clinical considerations and professional judgment should be applied to the interpretation of results by this test.

SUMMARY
Studies have been conducted that show the incidence of Coronary Artery Disease (CAD) rises linearly with blood cholesterol. Individuals with elevated blood cholesterol levels of 200 mg/dL or greater are considered at increased risk for the development of Coronary Artery Disease. The CHEMCARD™ Cholesterol Test is intended to identify those individuals with elevated blood cholesterol levels associated with increased risk of CAD by providing the physician with fast, accurate results and the opportunity for further testing.

PRINCIPLE
The CHEMCARD™ Cholesterol Test is a solid phase chemistry which employs the same principle as the enzymatic wet chemistry which is presently being used in many hospital laboratories. This enzymatic reaction makes use of a highly sensitive chromagen, tetramethylbenzidine, which allows for a visual determination of blood cholesterol. The CHEMCARD™ Cholesterol Test incorporates a unique cell separator as an integral part of the device. This separation device allows the use of whole blood as a specimen.

Cholesterol ester $\rightarrow$ ESTERASE $\rightarrow$ Cholesterol + Fatty Acid

Cholesterol

Oxygen $\rightarrow$ CHOLESTEROL OXIDASE $\rightarrow$ 4-Cholesterolene Hydrogen peroxide

Hydrogen peroxide $\rightarrow$ PEROXIDASE $\rightarrow$ Dye + Water

COMPOSITION
- Buffer
- Tetramethylbenzidine
- Cholesterol esterase EC 3.1.1.13
- Cholesterol oxidase EC 1.1.3.6
- Sodium chlorate
- Peroxidase ES 1.11.1.7
- Other materials, required for stability and system compatibility.

FOR IN-VITRO DIAGNOSTIC USE ONLY

STORAGE and STABILITY
CHEMCARD™ Cholesterol Tests are to be stored at room temperature, not to exceed 88°F (30°C). Refrigeration is not required. The test cards may be used until the expiration date stamped on package. Any sealed packages that appear to have a broken seal should not be used for testing. Return the package to Chematics, Inc. for replacement.

SPECIMEN
The CHEMCARD™ is intended for use with fresh whole capillary blood collected from a fingertip.

Fingerstick samples must be obtained from free flowing capillary blood. Excessive squeezing or milking can produce somewhat lower results.

MATERIALS PROVIDED
- Test Card

MATERIALS NEEDED BUT NOT PROVIDED
- Alcohol or Alcohol Swab
- Clean Dry Tissue
- Watch or Other Timing System
- Sterile Lancet

PROCEDURE

1. Clean fingertip with alcohol and let dry.


3. Squeeze finger to obtain a large hanging drop of blood.

4. Gently bring the hanging drop into contact with the test area.

5. After 3 minutes, remove entire TAB area from CHEMCARD™ and discard.

6. Compare the color of the Test Area with color in window on either side by sliding inner card up and down. Find closest matching color in 30 SECONDS. Note: the reactive pad will begin to fade within 3–5 minutes.

7. Turn the card over. The cholesterol level appears in the clear windows in both mg/dL and mmol/L.

RESULTS
Results are obtained by visually comparing the developed color of the Test Area with those of the sliding color standard appearing in the windows at the side of the Test Area. After a visual match is made, the card is turned over and the total cholesterol concentration value appears in the window on the back side of the card. A Test Area that appears lighter than the 150 color block should be interpreted as a cholesterol result of less than 150 mg/dL. A Test Area that appears darker than the 300+ color block should be interpreted as greater than 300 mg/dL.

CALIBRATION
Calibration of the CHEMCARD™ Cholesterol Test is not required. The color development for each lot of test cards is calibrated by use of precise standards during manufacturing.

QUALITY CONTROL
It is recommended that quality control material be analyzed at regular intervals. Upon request, a control is available from Chematics, Inc. to verify the integrity of the test cards in each new shipment and for use in routine testing. It is also recommended for use in training new test operators.

Other manufacturer control materials are not recommended for use with CHEMCARD™ Cholesterol. As an alternate control material, a fresh capillary blood sample from an individual with a known cholesterol level may be used to verify the integrity of the test.

For technical assistance, Chematics, Inc. Technical Service may be contacted by dialing 1-574-834-2406.
LIMITATIONS OF PROCEDURE
The results of this test should not be used for instituting drug treatment in individuals with elevated cholesterol levels or altering drug treatment in individuals whose cholesterol levels are being monitored.

CHEMATIC™ Cholesterol allows the specific, enzymatic determination of cholesterol and cholesterol esters. Hemacrit will cause a bias in inverse relationship. For this reason plasma and serum will read high and are not recommended for use with this test.

The plasma oxidase may exhibit some activity for certain steroids such as epianandrosterone, dehydroepianandrosterone, campesterol and sitosterol. However, the plasma concentration of these substances is negligible compared to plasma total cholesterol. Hemoglobin, uric acid, and creatinine do not interfere when fresh capillary blood is used; however if elevated, bilirubin may be responsible for low results.

When stored in the original package and in the temperature range specified, the cards are stable up to the expiration date shown on the package label.

If the values obtained are unusually high or low, repeat the test using a fresh sample on a new unused test card.

EXPECTED RESULTS
The National Heart, Lung and Blood Institute's National Cholesterol Education Program at the National Institutes of Health released in October, 1987, a report on the detection, evaluation, and treatment of high blood cholesterol in adults. The report simplified the previous guidelines published in 1985. The new report eliminates the age and sex categories for risk levels and classifies total cholesterol levels as follows:

Total cholesterol levels:
- Less than 200 mg/dL — Desirable Blood Cholesterol
- 200 to 239 mg/dL — Borderline High Blood Cholesterol
- 240 mg/dL and above — High Blood Cholesterol

All results of 200 mg/dL or greater should be repeated by a quantitative laboratory method before a diagnosis of hypercholesterolemia is made.

In addition, if an individual's blood cholesterol level does fall into a borderline high or high cholesterol category, it is recommended that a lipid profile be completed to determine the extent of the risk for CAD, taking into account other risk factors such as hypertension, cigarette smoking and family history.

PERFORMANCE CHARACTERISTICS
MEASURING RANGE
150–300 mg/dL or 3.9–7.8 mmol/L

ACCURACY
The following data were calculated from the testing of a total of 158 patients at three different sites.

Results by CHEMATIC™ Cholesterol were compared to results by the Liebermann-Burchard method and by an enzymatic method. The comparison data are presented in the following graphs:

N = 158
Range X = 109–348 mg/dL
Range Y = 150–500 mg/dL

In the following table only, the Liebermann-Burchard and enzymatic laboratory assay results were rounded to the nearest estimated color block. Each color in the following table represents the distribution of observed CHEMATIC™ Cholesterol results with respect to the expected results. The percent of CHEMATIC™ Cholesterol results within +1 color block of the laboratory assay result is represented in the last row in the following table.

CHEMATIC™ LIEBERMANN-BURCHARD (mg/dL)

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