



INSTRUCTION BOOKLET

ATTENTION READ ALL
INSTRUCTIONS BEFORE USING
THIS KIT

A Complete 3 Minute Whole Blood Screening Test for Identification of BLOOD CHOLESTEROL LEVELS

IVD

CONTENTS

The following items are included:

- 2 CHEMCARD™ Cholesterol Tests (in individual sealed foil packages)
- 2 sterile lancets for pricking your finger
- 1 Instruction Booklet

INTENDED USE

The CHEMCARD™ Cholesterol Test is a self-test *in vitro* diagnostic device used to monitor blood cholesterol (also referred to as serum cholesterol) levels. The CHEMCARD™ Test measures your blood cholesterol level using a drop of blood from your finger. Fasting prior to performing the test is **not** required. The CHEMCARD™ Cholesterol Test is a single use and cannot be reused. It is therefore very important that you read and understand all instructions before you begin the test. **Follow all instructions exactly.**

PRINCIPLE OF METHOD

A drop of whole blood from a fingerstick is deposited on the test area of the CHEMCARD™ Cholesterol Test. The plasma is physically separated from the rest of the blood sample. The plasma then reacts with a chemically treated pad and a color change occurs. The resulting depth and shade of the color corresponds to the amount of cholesterol in the blood sample.

LIMITS OF THE TEST

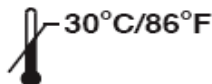
- The results of this test should not be used for instituting drug treatment in individuals with elevated cholesterol levels or altering drug treatment in individuals whose cholesterol levels are being monitored.
- Certain rare medical conditions, such as your blood bilirubin or hematocrit levels being outside normal levels may cause your CHEMCARD™ results to be less accurate. Hematocrit will cause results to be biased high. Elevated bilirubin may be responsible for low results. If you are unsure whether this applies to you, ask your family doctor. Cholesterol oxidase may exhibit some activity for certain steroids such as epiandrosterone, dehydroepiandrosterone, campesterol and sitosterol. However, the plasma concentration of these substances is negligible compared to plasma total cholesterol. Hemoglobin, uric acid, glucose, ascorbic acid, and creatinine do not interfere when fresh capillary blood is used; No interference was found in lipemic samples.
- Interferences from blood lowering cholesterol drugs are unknown.
- Exercise, posture and recent illness can all affect cholesterol levels. Cholesterol assessment should be delayed for three months following major illness (e.g. myocardial infarction or major surgery) and for three weeks minor illness (e.g. influenza or diarrhea) and should be delayed until after pregnancy. If in doubt consult your family doctor.

PRECAUTIONS

- For *in vitro* diagnostic use only.
- Do not use internally
- Keep out of reach of children.
- Do not use tests after the expiration date printed on the foil packaging.
- If any of the listed contents are missing, **do not** continue, instead put everything back into the box and return it to your retailer for replacement.
- If the seal of the foil package is compromised upon opening the kit, **do not** use. Contact the manufacturer for further instructions.
- Do not re-use test.
- Do not take or alter your medication due to the reading of the CHEMCARD™.
- Always consult your doctor on medical matters.

STORAGE

Store at room temperature - below 86°F/ 30°C
Refrigeration is NOT required
The test should be used prior to the expiration date printed on the foil package.



WORKING RANGE

150 - 300 mg/dL or 3.9- 7.8 mmol
Concentrations of less than 125 mg/dL (3.3 mg/mmol) may provide a negative result (no color change).

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 Quality Control standards during manufacturing.

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.

HOW DO I KNOW THE TEST IS WORKING?

Each test card employs two design features which allow the user to verify that the test has worked properly.

- “CONTROL SPOT” changes color allowing the user to verify a sufficient blood volume (>20 µL) has been applied to the test area. Make sure CONTROL SPOT changes to red in 15 seconds after the blood is applied. If this does not happen, apply another drop of blood. CONTROL SPOT must change color to red to ensure that enough blood was added. See STEP 5.

- The presence of a green or blue color in the reagent pad indicates that the detection chemistry is working properly. A reagent pad that is white or cream colored indicates an invalid test result. If no color change is seen in the Test Area perform the test again using a new CHEMCARD™. Follow the instructions exactly. If no color change is observed in the repeated test, your cholesterol may be at or below 125 mg/dL, or there is a problem with the test you are using. For questions regarding test viability, contact the manufacturer. Otherwise contact your doctor for further testing. If you have questions about your test result, call your doctor or call the manufacturer: +001 574 834 2406.

TEST DIRECTIONS BEFORE YOU BEGIN

- Fasting is **not** required before you run the test.
- Read **all** the directions **before** you start the test.
- You need a **timer** and a **tissue** before you start.
- Do not trigger the finger stick device (lancet) until you are ready to draw blood for the test. **Never use a finger stick device that has been used by another person.**
- **Failure to follow instructions may cause inaccurate results.**

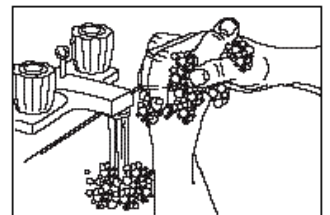
GET READY

- Choose a place indoors, which is well lit, but not in direct sunlight to perform the test. The test should be performed at normal room temperature (below 86°F/30°C). You will need a clean dry table, a timer and a tissue to perform the test.
- Familiarize yourself with the CHEMCARD™ Cholesterol Test.
- When you are ready to perform the test, open the test package. Place the CHEMCARD™ Cholesterol Test card on a table with the test area facing up. Throw away the desiccant (drying) packet.
- The test should be completed within 5 minutes of opening the package.

STEP 1

PREPARE TO DRAW BLOOD

- Wash your hands in warm water for at least **3 minutes**. Dry your hands completely.
- Allow your arm to hang down at your side for 30 seconds to increase blood flow. If you are right handed, it is often best to draw blood from your left hand. The reverse is true if you are left handed.
- Select a finger that is not calloused.



STEP 2

PRICK YOUR FINGER



- Push the lancet cap into the body until it clicks.



- Twist the lancet cap until you feel it separate from the device. Don't pull just twist. Dispose of the cap in a suitable container.



- Position lancet body firmly against the puncture site as illustrated. Hold lancet body between fingers with one finger on the side release button. To activate, press the release button firmly. **DO NOT** pull the lancet away from the puncture site until after activation.
- It is important to get a “good” fingerstick in order to run the test. If you are uneasy about pricking your finger, you might consider having a friend or spouse do this for you.

STEP 3

SQUEEZE YOUR FINGER TO DRAW BLOOD

- Obtain a **large drop** of blood that hangs down from your finger.



STEP 4

PLACE BLOOD ON THE TEST AREA

- Gently touch the drop of blood to the Test Area
- Do not touch the test area with your finger. Only the blood can be allowed to touch the Test Area.
- The Test Area should be completely saturated.
- If you are unsure about the amount of blood, add another drop.



STEP 5

CHECK CONTROL SPOT

- Make sure CONTROL SPOT changes to red in 15 seconds after the blood is applied. If this does not happen, apply another drop of blood.
- CONTROL SPOT must change color to red to ensure that enough blood was added.

STEP 6

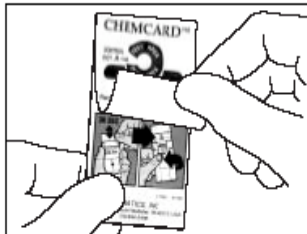
START TIMER

- Set timer for 3 minutes.

STEP 7

AFTER 3 MINUTES, PEEL OFF THE "TAB"

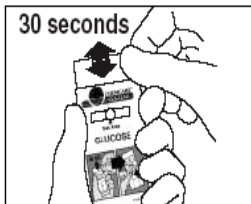
- Grasp the "TAB" near the bottom of the card and SLOWLY peel off the entire top layer.



STEP 8

MATCH COLORS

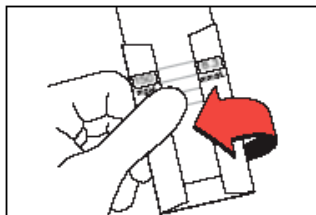
- Slide the color chart up and down to bring different colors into the windows on either side of the Test Area.
- Compare the color of the Test Area with that appearing in the windows.
- Choose the color that most closely matches the Test Area.
- Check all six colors before you make your choice.
- If the Test Area is unevenly colored simply match the overall color area on the test pad against the sliding color chart or perform the test again using a new CHEMCARD™. Follow the instructions exactly.
- Color matching must be completed within 30 seconds; after that the colors begin to fade and color matching should not be attempted.
- If no color change is seen in the Test Area perform the test again using a new CHEMCARD™. Follow the instructions exactly.
- If no color change is observed in the repeated test, your cholesterol may be at or below 125 mg/dL, or there is a problem with the test you are using. For questions regarding test viability, contact the manufacturer. Otherwise contact your doctor for further testing.
- If you have questions about your test result, call your doctor or call the manufacturer: +001 574 834 2406



STEP 9

READ THE NUMBERS ON THE BACK OF THE TEST

- Your cholesterol level is shown in the windows on the back of the card. The windows on the left show your result in mg/dL and the window on the right shows your result in mmol/L.



STEP 10

DISPOSAL

- After you get your results, place the contents of the kit back into the original box and dispose of with your normal household waste products.

WHAT DO MY RESULTS MEAN?

The purpose of the test is to give you an indication of your CHOLESTEROL LEVEL, to determine if you are in the categories of "DESIRABLE", "BORDERLINE - HIGH" or "HIGH". The numbers in the windows are a close numeric indication of your cholesterol level in two internationally accepted formats.

DESIRABLE: Below 200 mg/dL (5.2 mmol/L): This is the area of LOW RISK. You should maintain a healthy diet, exercise regularly and monitor your cholesterol periodically.

BORDERLINE - HIGH: 200 - 250 mg/dL (5.2 - 6.5 mmol/L): This is a MODERATE RISK area. You should not become unnecessarily alarmed as there are other factors, such as your general state of health, smoking habits, age, weight, etc., that have to be taken into consideration. Test yourself again in 1 - 8 weeks. If the result is again in the Borderline - High area, see your doctor for a more accurate assessment and advice.

HIGH: 250 mg/dL+ (6.5 mmol/L+): This is a HIGH RISK area. You should contact your doctor for further tests and advice, if you are not already under a doctor's care for high cholesterol.

FREQUENTLY ASKED QUESTIONS

Q: What Is Cholesterol?

A: Your liver makes a fatty, wax-like substance, which travels in the blood, called blood cholesterol or serum cholesterol. Cholesterol performs many essential body functions and is vital for your good health.

Too much cholesterol in your blood contributes to the build-up of a material which can partially or completely block the arteries in different parts of the body and lead to serious health problems. A blocked artery in the heart results in a heart attack; such a blockage in the head or neck can cause a stroke.

Cholesterol is also present in all foods of animal origin, such as meats, egg yolks and dairy products. The cholesterol you eat is called dietary cholesterol. In most people, eating large amounts of dietary cholesterol tends to raise blood cholesterol levels. Your body makes all the cholesterol it needs.

Q: What is the difference between "good" and "bad" cholesterol?

A: Cholesterol travels in the blood in "packages" of fat and protein called lipoproteins. Two main types are HDL and LDL.

HDL (High Density Lipoprotein) - often called "good" cholesterol because it appears to clear excess cholesterol from the arteries.

LDL (Low Density Lipoprotein) - often called "bad" cholesterol, because it tends to build up on artery walls.

Q: Why Do Cholesterol Test?

A: High cholesterol can be a major causative factor for hypertension, arteriosclerosis, and heart disease. High cholesterol levels can be treated through diet and exercise. Regular monitoring of your cholesterol level and seeking the advice of your family doctor is recommended.

Q: Should My Results Vary?

A: Cholesterol Readings can vary daily because of many different factors. It would not be unusual for results in some individuals to vary 10-20% over a period of time because of various reasons, such as stress, recent diet, rest/exercise, and other biological factors, etc.

Q: What can I do to make it easier to draw blood?

- Wash your hands in warm water for at least 3 minutes to increase circulation before performing the test.
- Prick the side of your finger, near the tip. It's a less sensitive area and is less likely to be calloused.
- Press the lancet device firmly against your finger. Push the trigger firmly. Try not to pull away when you trigger the lancet.
- It might be easier to have someone else prick your finger.

Q: What can I do to make it easier to match colors?

- Make sure there is plenty of light. Fluorescent light is best for most people.
- Try viewing the test at arms length.
- Make sure you look at all five colors before you decide the best match.
- Try having someone else match the colors for you.

Q: The color on the test pad faded after I performed the test. Is this normal?

A: Yes. The color of the test pad will begin to fade 1 to 5 minutes after removing the TAB. Try to make sure that you match the colors within 30 seconds after the TAB is removed.

Q: How accurate is the CHEMCARD™ Cholesterol Test?

A: In clinical studies, 90.7% of the observed sample results were correctly classified as compared to laboratory results.

MONITORING YOUR OWN CHOLESTEROL

Almost everyone with elevated cholesterol can be helped by self-testing of their cholesterol levels. If you are on a special diet, exercise program, or taking medication prescribed by your doctor, self-testing can be a useful tool to monitor your progress toward lower cholesterol levels. Repeated testing allows you to see the effects of exercise and diet on your cholesterol level. Doctors know that knowledge and participation by the patient are important factors in helping you to exercise, stay on your diet, and to take your medication.

THE ROLE OF OTHER HEALTH FACTORS

Health factors, such as high cholesterol, high blood pressure, diabetes, being overweight (more than 20%), previous heart disease and cigarette smoking, are characteristics which over time, usually without noticeable symptoms, contribute to the development of heart disease. You can make lifestyle changes, such as modifying your diet, stop smoking, or exercising to control the risk factors.

The Centers for Disease and Prevention is an excellent source of information regarding cholesterol and associated risk factors. Contact them at:

Centers for Disease and Prevention

1600 Clifton Road

Atlanta, GA 30333, U.S.A.

Phone # +001 404 639 3311 / Public Inquires: +001 404 639 3534

USA: (404) 639-3311 / Public Inquires: (404) 639-3534 or (800) 311-3435

<http://www.cdc.gov>

PERFORMANCE CHARACTERISTICS

The following data were calculated from the results of self-tests performed by 227 untrained volunteers.

- 90.7 % of test subjects were able to determine their cholesterol level within one color block as compared to laboratory based tests.
- By defining a positive test as a result of 200 or greater then the diagnostic sensitivity and diagnostic specificity of the CHEMCARD™ (using the cholesterol reference result as “truth”) is computed. Diagnostic sensitivity is the estimate of the percent of true positives for the CHEMCARD™ test, that is, the percent of the positive cholesterol reference results which are positive by the CHEMCARD™ test. Diagnostic specificity is the percent of true negatives for the CHEMCARD™ test, that is, the percent of negative cholesterol reference results which are negative by the CHEMCARD™ test.
- The estimate of diagnostic sensitivity for the test subjects’ self-interpreted CHEMCARD™ results when compared to the diagnosis based on a laboratory based reference cholesterol test is 92.4% and the estimate of diagnostic specificity is 81.3%.
- Among the test subjects’ self-interpreted results there were 28 of 227 (12.3%) incorrect diagnoses, 18 false positives and 10 false negatives.



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STERILE - SINGLE USE

Do not use if cap has been
previously removed.



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