UNDERSTANDING YOUR RESULTS

The National Cholesterol Education Program (NCEP) has divided HDL cholesterol results into three groups: Desirable, Average Risk, and High Risk. Your CholesTrak® HDL reading will place you in one of these groups.

HDL CHOLESTEROL RESULT (NCEP)

HDL	MEN	WOMEN
Desirable	(More) 60	(More) 60
Average Risk	41-59	51-59
High Risk	(Less) 40	(Less) 50

Source:American Heart Associatin and NIH

GROUP SUGGESTED ACTIONS

- **Desirable** - This HDL cholesterol level suggests that you are most likely at low risk for heart disease. Frequency of testing should be done in consultation with your physician.
- **Average Risk** - You may be at an increased risk for heart disease. You should consult with your physician.
- **High Risk** - If your score is 40 or below, you may be at greater risk for heart disease whether or not you have additional risk factors.* You may be in a high risk group that requires medical attention, consult your physician for advice.

  *Additional risk factors include age, obesity, total cholesterol, systolic blood pressure, treatment for hypertension and smoking.
- If you scored in the High Risk category, you should seek advice from your physician.
- You may test again with CholesTrak® HDL. However, frequency of testing should be done in consultation with your physician.

LEARN YOUR HEART DISEASE RISK (CHD)**

TOTAL CHOLESTEROL DIVIDED BY HDL

TC/HDL	MEN	WOMEN
Ideal	(Less) 3.5	(Less) 3.0
Acceptable	(Less) 4.5	(Less) 3.5
High Risk	(More) 5.0	(More) 4.0

**Source:American Heart Association and NIH

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Protected by U.S. patents 4,959,324, 4,973,549, 4,987,085, 4,999,287, 5,132,086, 5,155,025, 5,204,063, 5,260,221, 5,264,180, 5,340,539, 5,409,664, 5,409,780, 5,423,989, and international patents.

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QUESTIONS & ANSWERS

What can I do to make drawing blood easier?

- Wash hands with warm water and dry them.
- Warm hands by rubbing them together.
- Let the arm of your selected finger hang at your side for at least 30 seconds.
- Choose a finger that is warm and callus-free.
- Lay selected hand, palm up, on the table.
- Press the fingerstick device firmly against the side tip of your finger. Do not pull away when triggering the fingerstick device.
- If you would like, someone else can help you prick your finger.

Can both indicators change color without giving me a correct reading?

Yes, both indicators can work, but the result may not be correct if:

- the blood well is not filled with enough blood to cover the black fill circle completely, or
- more than three minutes have elapsed in filling the blood well, or
- you did not wait a full three minutes before pulling the plastic tab, or
- you did not pull the plastic tab out far enough to see the entire arrow, or
- you performed the test in direct sunlight.

How accurate is the CholesTrak® HDL test?

Based on the patient study between lay-user and reference method (A.K. Methods), the observed results from Lay user set at 110 patients with various age, gender, education, socioeconomic backgrounds have been matched to that of the expected result from the reference method. The total accuracy is 97.3% including 2 false negative and 1 false positive samples at a cutoff of 40 mg/dL. The total precision is 96.5% and 96.7% at 40 and 60 mg/dL, respectively. Both accuracy and precision meet National Cholesterol Education Program (NCEP) guideline requirements.

Who do I contact with questions or problems with CholesTrak® HDL test?

Call the CholesTrak® HDL Help Line (1-800-749-9910) Mon. to Fri. 8 a.m. to 4 p.m., Pacific Time Zone.

Do I need to fast before I take the test or perform it at a specific time of day?

No. You can test yourself at any time, so fasting is not necessary. If you repeat the test, try to do so under the same conditions.

Will common foods, alcohol or medications affect my test results?

No, most common foods or alcoholic beverages should not affect your test result. However, some medications may affect your test result. Please see the "Limits of The Test" for more information.

How often should I test my HDL cholesterol?

Although there are no official guidelines, we believe that if you fall between Average and High Risk, you should consult with your physician for frequency of cholesterol testing.

LIMITS OF THE TEST

- Please do not perform the test if you take 500 mg or more of vitamin C, standard dose of Acetaminophen (e.g., Tylenol) Naproxen (e.g., Aleve) or L-dopa (e.g., DopaBean).
- You must perform all the steps correctly to get an accurate reading.
- The use of this product is intended for those 18 years of age and older.
- Recent illness, pregnancy, birth control pills and other conditions may change your cholesterol level. If you are concerned, talk to your doctor.
- If you use these tests in direct sunlight, your result may not be correct.
- This test is for in-vitro diagnostic use only. Do not use any part of this kit internally.
- This test provides information about your HDL level. Your doctor may request other tests.

WARNINGS

- Not for use by hemophiliacs or those taking medicines that thin blood (anticoagulants).
- Do not use within one month of recovering from an acute illness.
- Keep test device at room temperature (below 86 °F or 30 °C).
- DO NOT use test beyond the expiration date on the package.
- This is a single use disposable test.
- Use only with fingerstick blood drops.
- Not for use with any other bodily fluids or food.
- Do not perform the test in direct sunlight.
- Keep out of reach of children.
- Never use a fingerstick that has been used by another person.
- Do not use in the presence of hydrogen peroxide.
- Never adjust your medication based on CholesTrak® HDL results.

DISCARDING THE KIT

After your result is known, put all contents back in the original box and dispose with your daily household waste products.

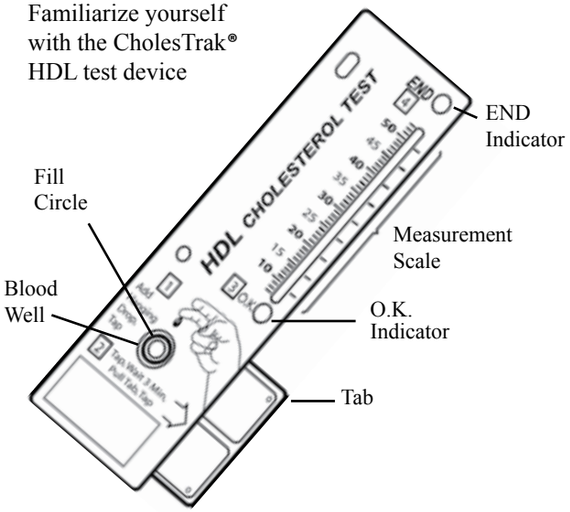
CHOLESTRAK®

HDL

CHOLESTEROL HOME TEST

Directions

Familiarize yourself with the CholesTrak® HDL test device



WHY TEST YOUR HDL CHOLESTEROL

Low levels of HDL "good cholesterol" may put you at a higher risk for heart attack and stroke. This test will identify your HDL level, so you can take steps for improvement if necessary.

STEP 1

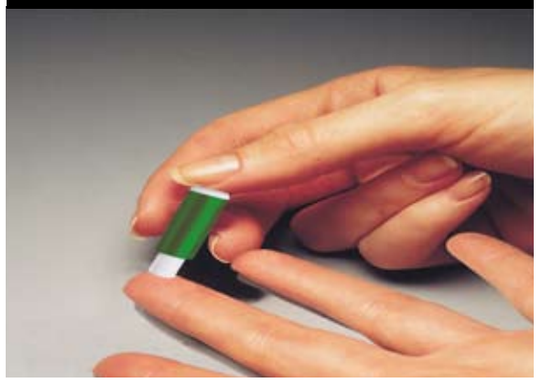
BEFORE TESTING

- **Read all directions before starting this test.**
- This is a single use disposable test.
- Do not open foil pouch until ready to start.
- **Do not pull the tab until Step 4.**
- Do not perform the test within four hours of taking 500 mg or more of Vitamin C or a standard dose of Acetaminophen (e.g. Tylenol). These medications may cause a low reading.
- Do not use if you are a hemophiliac or taking medicines that thin blood (anticoagulants).
- Do not use the fingerstick device (lancet) until you are ready to draw blood. The fingerstick device is one time use only.
- You will need a clock or timer.

PREPARATION FOR TESTING

- If you are unsure about how to prick your finger call the CholesTrak® HDL Help Line.
- Wash hands with warm water and dry them.
- Sit down and rub your hands together vigorously to warm them.
- Open up the pouch and place contents on a table or other flat surface. If any part of the test device content is broken or opened, do not use the kit. Throw away the desiccant (drying) packet.
- Once opened, use within 30 minutes.
- Check that the area within the measurement scale of the test device is off-white. If green or yellow, call the CholesTrak® HDL Help Line.

STEP 2

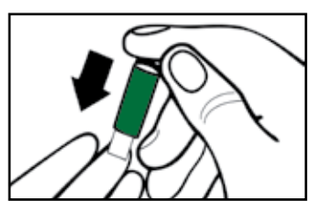


DRAWING BLOOD SAMPLE

- Select your middle or ring finger. The finger should be warm and callus-free.

Twist off green protective stem from the sterile needle.

- Lay selected hand, palm up, on a flat table surface.
- Hold the fingerstick in your other hand as shown below and pierce your finger. Do not pull your finger away, you may not get enough blood.



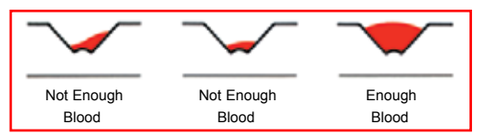
Apply white end (with hole) against side of finger. Press firmly until device clicks.

- Take the gauze pad and wipe away the first sign of blood. Blood may not appear until you squeeze your finger (using a milking action from the base of the finger).
- Let your arm hang at your side for 10 seconds to increase blood flow.

STEP 3

ADDING BLOOD TO THE WELL

YOU MUST ADD ENOUGH BLOOD WITHIN 3 MINUTES OF PRICKING YOUR FINGER TO COVER THE BLACK FILL CIRCLE.



- To form a hanging blood drop, squeeze your finger from the base to the puncture several times with a milking action.
- Point your finger down directly over the blood well and drop blood into the well.
- Do not wipe or scrape blood across the well.
- Do not worry about adding too much blood.
- Fill up the well until the black fill circle is no longer visible.
- Tap the cassette device on a flat table surface 3 times to facilitate the test.
- Once the well is filled, set your clock or timer.

WAIT AT LEAST 3 MINUTES BEFORE PULLING THE TAB

- Apply the bandage to your finger while waiting.
- After waiting 3 minutes, hold the test device firmly in your hand and pull firmly on the clear plastic tab (on the right side of the test). Pull until you can see the entire arrow.(See Step 4)
- Tap test device on a flat table surface 3 times.

STEP 4

PULL TAB - TAP DEVICE - READ RESULT

- The "O.K." indicator turns blue/purple in about 5 minutes.
- The "END" indicator turns green in about 12 minutes. Now the test is finished.
- Be sure to read the test after both indicators have changed color.

- Read the test result within 15 minutes.
- Read the result under bright light. Find the very tip of the blue/purple color bar in the Measurement Scale, even if fuzzy or faint.
- Take your HDL Result Chart. Look under "Test Device Reading" and find the number from your test. The number to the right or under "HDL mg/dL" is your HDL cholesterol level.
- For those with results between 25 to 85 mg/dL refer to "Understanding Your Results" section of these directions to find out whether your HDL level is Desirable, Average Risk, or High Risk. If your test falls outside of this range call our Help Line.
- IMPORTANT: Only use HDL cholesterol result charts included in this kit. Use of a chart from another kit may give inaccurate results.