Intended Use

For in vitro diagnostic use only

The CARESIDE Analyzer™ calculates the total cholesterol/HDL-cholesterol (CHOL/HDLC) ratio from the CARESIDE Total Cholesterol and CARESIDE HDL-Cholesterol measurements from a single patient specimen.

The calculation, in conjunction with other laboratory measures and clinical evaluation, aids in the diagnosis and treatment of patients with disorders of lipid and lipoprotein metabolism. The CHOL/HDLC ratio is provided whenever a CARESIDE CHOL and CARESIDE HDLC are ordered for a patient at the same time.

Test Summary

Cholesterol, a lipid, is associated with the pathogenesis of atherosclerosis and coronary artery disease, and the measurement of cholesterol blood levels is used to classify patients according to coronary heart disease risk, to diagnose and treat various primary or secondary hyperlipidemias, and to monitor changes resulting from treatment. The ratio of total cholesterol to HDL-cholesterol has been suggested as a means of interpreting the significance of HDL-cholesterol levels.

Virtually all human cells and body fluids contain some cholesterol. In blood, cholesterol is contained in the blood lipoproteins. Blood lipoproteins are spherical particles containing varying amounts of cholesterol, triglycerides, phospholipids and proteins. The relative proportion of protein to lipid determines the lipoprotein density, and the lipoproteins are classified into fractions, including: high density lipoprotein (HDL), low density lipoprotein (LDL), and very low density lipoprotein (VLDL). Cholesterol is the major component of the LDL fraction and a minor component of the HDL and VLDL fractions. Total cholesterol in blood comprises all of the cholesterol found in the various lipoproteins.

The HDL, LDL and VLDL fractions vary in their role in the pathogenesis of atherosclerosis and coronary artery disease. Elevated total cholesterol and LDL-cholesterol are directly related to the risk of atherosclerosis. Increased LDL-Cholesterol is associated with an increased risk for coronary artery disease even within the reference interval for total cholesterol, whereas HDL-cholesterol concentration and coronary artery disease risk are inversely related.

Test Explanation

Refer to the CARESIDE Total Cholesterol and CARESIDE HDL-Cholesterol test inserts for relevant operation information.

Test Principle

The CARESIDE Analyzer uses the CHOL and HDLC cartridge test results from a single patient specimen to determine the CHOL/HDLC ratio.

Test Warnings and Precautions

• For in vitro diagnostic use only.
CHOL/HDLC ratio

- For professional laboratory use: not for point of care or physician office laboratory use.
- Do not dilute samples for total cholesterol, HDL-cholesterol, and triglyceride testing prior to analysis or HDLC pre-treatment.
- Dietary and/or drug treatment should not be initiated based on a single assessment.

Test Calibration

No routine user calibration is required. Each cartridge lot is factory calibrated and the calibration information is read automatically by the CARESIDE Analyzer.

Specimen Collection

The calculated CHOL/HDLC ratio uses results from the CARESIDE Total Cholesterol and the CARESIDE HDL-Cholesterol test. In order to determine CHOL/HDLC ratio, obtain from a single patient specimen at least 90 ± 10µL (whole blood, serum or plasma) for total cholesterol testing and 250µl (serum or plasma) for HDLC testing. Refer to the respective CARESIDE cartridge test inserts for test-specific information. Follow specimen collection instructions indicated in the CARESIDE CHOL and CARESIDE HDLC test cartridge test inserts. Collect specimen using standard venipuncture techniques.

Patient Preparation

Fasting for 12-14 hours before specimen collection is desirable but not necessary unless the CHOL/HDLC determination is part of a complete lipid profile.

Interference

Refer to CARESIDE CHOL and CARESIDE HDLC test cartridge test inserts.

Whole blood (for CHOL)

Collect whole blood in blood collection tubes containing sodium heparin or EDTA. Do not use sodium fluoride, citric acid, oxalic acid, or monooiodoacetic acid. Mix anticoagulant according to manufacturer instructions allowing sufficient time for anticoagulation to occur.

Serum (for CHOL, HDLC)

Collect blood in the absence of anti-coagulant. Allow blood to fully clot at room temperature. Centrifuge the clotted blood and separate the serum promptly from the clot.

Plasma (for CHOL, HDLC)

Collect blood using sodium heparin or EDTA. Promptly centrifuge the blood and separate the plasma from the cells.

Specimen Handling and Preparation

All specimens and samples may be stored at room temperature when tested within 4 hours of draw. If necessary, specimens and samples may be refrigerated at 2 to 8°C. If testing is delayed beyond 4 days, serum or plasma samples may be frozen at -20°C or colder for at least 10 days. Thoroughly mix any stored specimens before testing. Do not freeze whole blood.

Do not dilute specimens.

Test Procedures

1. Perform the CARESIDE Total Cholesterol and CARESIDE HDL-Cholesterol tests as indicated in their respective test inserts. Note that for HDLC analysis, specimen pre-treatment is required.

2. Follow the instructions for loading the CARESIDE CHOL and HDLC test cartridges and press “Confirm” (see the CARESIDE Analyzer Operator’s Manual for more information).

Quality Control

Each CARESIDE test cartridge barcode contains all required calibration information. The CARESIDE Analyzer scans the barcode, continuously performs quality control self-checks during operation, and alerts and prevents the user from proceeding if an unacceptable condition exists.

Follow the QC recommendations described in the Total Cholesterol and HDLC test inserts.
Results

Results require no user calculation and appear on the CARESIDE Analyzer screen, as they become available.

CHOL/HDLC

Reporting Units: No units

(Results reported as a ratio)

Reportable Range 1 to 45

Expected Values (Reference Interval)

The ratio of total cholesterol to HDL-cholesterol is used to interpret risk for developing coronary heart disease, and the relative risk is different for men and women. The average relative risk (50% quantile) for developing coronary heart disease corresponds to a CHOL/HDLC ratio of 4.88 for men and 4.23 for women. The lower the ratio, the lower the risk of developing coronary heart disease.

The following table summarizes CHOL/HDLC ratios found in the Framingham Heart Study.

<table>
<thead>
<tr>
<th>Quantile</th>
<th>CHOL/HDLC</th>
<th>Male</th>
<th>Female</th>
</tr>
</thead>
<tbody>
<tr>
<td>5%</td>
<td>2.94</td>
<td>2.57</td>
<td></td>
</tr>
<tr>
<td>10%</td>
<td>3.30</td>
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<tr>
<td>25%</td>
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<tr>
<td>50%</td>
<td>4.88</td>
<td>4.23</td>
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<td>75%</td>
<td>6.09</td>
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<tr>
<td>90%</td>
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</tr>
<tr>
<td>95%</td>
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<td>7.25</td>
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</tr>
</tbody>
</table>

Limitations

An abnormal CHOL/HDLC ratio may be due to an analytical error in the measurement of total cholesterol or HDL-cholesterol (refer to individual test inserts).

Performance Characteristics

CARESIDE Total Cholesterol and CARESIDE HDL-Cholesterol test cartridge performance characteristics are indicated in their respective test inserts.

Bibliography


Technical Assistance

If questions arise concerning the CARESIDE Analyzer or test cartridges, please contact CARESIDE Technical Service:

Telephone: (888) 698-CARE (2273)
(310) 338-6767
Fax: (310) 338-6789

Ordering Information

For product ordering or general information, please contact CARESIDE Customer Service:

Telephone: (888) 698-CARE (2273)
(310) 338-6767
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