Guidelines for Lipid Testing

CLP-017 (rev. 05/04)

1. Background
The OAML's Guidelines for Lipid Testing have been revised, consistent with the Revised Recommendations of the Canadian Working Group on Hypercholesterolemia and Other Dyslipidemias, 2003.

2. Limitations
To test for dyslipidemia, determine total cholesterol (TC), high density lipoprotein cholesterol (HDL-C), triglycerides (TG), low density lipoprotein cholesterol (LDL-C) and TC:HDL-C ratios. Blood samples for these tests are drawn after the patient has been fasting for 12 – 14 hours.

3. Risk Assessment
Patients of any age may be assessed at the discretion of the practitioner. Special consideration should be given to the following groups:

- men over age 40
- women who are post-menopausal or over age 50
- patients with diabetes mellitus
- patients with risk factors such as hypertension, smoking and abdominal obesity
- patients with a strong family history of premature cardiovascular disease (CVD); the risk for first-degree relatives is increased by a factor of 1.7 to 2.0.
- patients with physical manifestations of hyperlipidemia (such as the presence of xanthelasma, xanthoma, *arcus corneae*)
- patients with evidence of symptomatic or asymptomatic atherosclerosis
- patients for whom lifestyle changes are indicated

4. Factors Influencing Risk Assessment
Metabolic Syndrome: The clustering of cardiovascular risk factors is recognized as a major health issue. The metabolic syndrome is defined in qualitative terms and encompasses abdominal obesity, insulin resistance, elevated plasma triglyceride levels, low HDL-C levels and high blood pressure. The criteria for assessment of metabolic syndrome are 3 or more of the risk determinants in the next column:

Risk Factor	Defining Level
Abdominal Obesity Men Women	Waist circumference > 102 cm > 88 cm
Triglycerides	≥ 1.70 mmol/L
HDL Cholesterol Men Women	 < 1.00 mmol/L < 1.30 mmol/L
Blood pressure	≥ 130/85 mmHg
Fasting glucose	6.2-7.0 mmol/L

Apolipoprotein (Apo B): Serum levels of Apo B may be of use in determining CVD risk and adequacy of treatment in patients with the metabolic syndrome. An optimal level of Apo B in a high risk patient is < 0.9g/L.

Lipoprotein (a) [Lp(a)]: An Lp(a) concentration > 30 mg/dL in an individual with a TC:HDL-C ratio > 5.5 or other major risk factors may indicate a need for earlier and more intensive LDL-C lowering.

Homocysteine: There is insufficient evidence to warrant broad screening of homocysteine levels until the results of ongoing clinical trials show that vitamin supplementation to lower homocysteine levels decreases cardiovascular risk.

High sensitivity C-reactive protein (hs-CRP): hs-CRP may be clinically useful in identifying individuals who are at a higher risk than that predicted by a global risk assessment, particularly those with a calculated 10 year risk between 10 and 20%.

Hormone replacement therapy (HRT): Oral HRT does not reduce and may increase the risk of CVD.

Serum triglyceride: Risk-related targets for triglycerides are not included in the 2003 revisions to the Working Group guidelines. Epidemiological studies suggest that triglyceride levels of ≥ 1.70 mmol/L are clinically significant.

5. Risk Categories and Target Lipid Levels

Risk	10-year risk of CVD	LDL-C Target Level	TC:HDL-C Target Level
High [a]	≥ 20%, diabetes, atherosclerotic disease, renal failure	< 2.50 **and**	< 4.0
Moderate	≥ 11% - 19%	< 3.50 **and**	< 5.0
Low [b]	≤ 10%	< 4.50 **and**	< 6.0

a. Apolipoprotein B can be used as an alternative measurement, particularly for follow up of patients treated with statins. An optimal level of Apo B in a high risk patient is < 0.90 g/L, in a moderate risk patient, 1.05 g/L and in a low risk patient < 1.20 g/L.
b. In the "very low" risk stratum, treatment may be deferred if the 10 year risk estimate of CVD is < 5% and the LDL-C is < 5.00 mmol/L.

6. Recommendations
The National Working Group recognized that additional cardiac endpoints and risk factors must be included in an individual patient's risk assessment and has therefore recommended use of the NCEP ATP-III risk algorithm, based on the Framingham Heart Study. The algorithm is available from the OAML website, in printable pdf. form. Visit www.oaml.com. Under our Quick Links click "for practitioners." You can also find an online version of the risk assessment tool at:
http://hin.nhlbi.nih.gov/atpiii/calculator.asp?usertype=prof
or a downloadable version at:
http://hin.nhlbi.nih.gov/atpiii/riskcalc.htm

Monitoring Treatment:
Clinical judgement should be used for patients with one or more risk factors who are outside the target ages. The recommended frequency of test ordering to monitor treatment for dyslipidemia is as follows:

For patients on diet therapy only (testing should include complete lipid profile)

- Initiation: every 3-6 months up to one year
- Maintenance: every 6-12 months

For patients on diet and drug therapy (testing should include complete lipid profile and, for those on statins, ALT and CK)

- Initiation of drug therapy: baseline, at 2-3 months and at 6 months.
- Maintenance: every 6-12 months.
- Enzyme testing should be performed more frequently for patients at higher risk for side effects.

The Ontario Association of Medical Laboratories (OAML) represents the community-based laboratory sector in Ontario. Its mission is to promote excellence in the provision of laboratory services and to contribute to shaping the future of health care in Ontario. The OAML encourages the highest level of professional and ethical integrity and technical excellence among laboratory owners, operators and staff in the provision of services to the benefit of the people of Ontario.

OAML Community Laboratory Practice Guidelines
The OAML, through its Quality Assurance of Clinical Laboratory Practice Program, co-ordinates the development and dissemination, implementation and evaluation of guidelines for practitioners ordering laboratory testing from community laboratories.

A proposed guideline is developed by a working group of the Committee with the participation of outside experts. The proposed guideline is submitted to the Committee as a whole, to laboratory Medical Directors and others for additional comment. The document is revised in light of these comments and submitted to the OAML Board for approval.

Approved guidelines are distributed to Community Laboratories and by them to their client physicians. The comments of end users are essential to the development of guidelines that will encourage adherence. You are strongly encouraged to submit your comments on this or any other OAML Guideline to:

Chair, Quality Assurance of Clinical Laboratory Practice Committee, OAML
5160 Yonge Street, Suite 710,
Toronto, Ontario M2N 6L9
Tel: (416) 250-8555 Fax: (416) 250-8464
E-mail: oaml@oaml.com www.oaml.com

 The OAML is grateful to the Canadian Working Group on Hypercholesterolemia and Other Dyslipidemias for their generosity. This guideline has been reviewed by and comments received from Dr. Stuart Klein, DABIM, FACP, FACC, Assoc. Professor, University of Toronto, Staff North York General Hospital and from Dr. Lawrence Leiter, FACP, FRCPC, Assoc. Professor, University of Toronto, Staff, St. Michael's Hospital. The OAML is solely responsible for the content of this guideline. While generally applicable, OAML guidelines are not a substitute for sound clinical judgement.

Members of the Expert Panel

Sheila Boss, PhD, FCACB,
Laboratory Director,
MDS Inc.,
Toronto, Ontario

Anthony Cheng, MD, FRCP(C),
Internal Medicine, Cardiology,
North York General Hospital,
Toronto, Ontario

G. Jiri Fodor, MD, PhD, FRCPC,
Head, Research & Prevention
Rehabilitation Centre,
University of Ottawa Heart Institute
Professor Emeritus of Medicine, Memorial University,
Canadian Working Group on Hypercholesterolemia & Other Dyslipidemias

Salva Gideon, HBSc, BEd, MD, CCFP
Family Physician,
Toronto, Ontario