*Taddle Creek*

**Family Health Team**

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|---|---|---|---|
| **Title:** | Requisition of Laboratory Investigations for the Management of Diabetes or Prediabetes | **Number:** | TCFHT-MD16 |
| **Activation Date:** | 09-Sep-2014 | **Review Date:** | 12-Jun-2019 |
| **Next Review Date:** | 12-Jun-2020 | | |

Note: Jun 2016 review resulted in a change; ability to order non-fasting lipid profile. Change approved at Jun 14-16 Board Mtg (see minutes) thus negating necessity to get authorizers to re-sign.

**Sponsoring/Contact Person(s)** *(name, position, contact particulars):*

Dr. Mitch Vainberg
790 Bay Street. Suite 300
Toronto, Ontario M5G 1N8
416- 960-1366

Karen Finch, Registered Nurse, Certified Diabetes Educator
790 Bay St. Suite 508
Toronto, Ontario M5G 1N8
416- 204-1256

Sherry Kennedy, Executive Director – skennedy@tcfht.on.ca
790 Bay Street, Suite 306,
Toronto, Ontario M5G 1N8
416-260-1315, x307

**Order and/or Delegated Procedure:**

**Appendix Attached:** __ **No** _X_ **Yes**
**Title:** Appendix C – Performed Controlled Acts and Procedures (CAPs) Implemented Under this Directive

Requisitioning of Laboratory Investigations, by implementers, for patients of the Taddle Creek Family Health Team (TCFHT) Primary Health Care Providers (PCPs) and who meet specific indications described within this directive.

**Recipient Patients:**

**Appendix Attached:** __ **No** _X_ **Yes**
**Title:** Appendix A – Authorizer Approval Form

Recipients must:

- Be active patients of a TCFHT primary care provider who has approved this directive by signing

the Authorizer Approval Form
- Meet the conditions identified in this directive
- Have a diagnosis of Diabetes Mellitus (type 1 or 2) or Prediabetes

**Authorized Implementers:**

**Appendix Attached: ___ No _X_ Yes**
**Title:** Appendix B – Implementer Approval Form

Implementers must be TCFHT employed Regulated Health Care Providers or Physician Assistant (under the supervision of a physician).

Implementers must complete the following preparation and sign the Implementer Approval Form:
- Must be Certified Diabetes Educators (CDEs) who practice according to the most current recommendations for the management of diabetes

**Appendix Attached: ___ No _X_ Yes**
**Title:** Appendix C – Performed Controlled Acts and Procedures (CAPs) implemented under this directive

**Indications:**
- Each action/procedure under this directive will be implemented in the context of the existing PCP-patient relationship and as part of the medical diagnosis and plan of care established by the PCP. These actions/procedures will be implemented without specific prior discussion (but as part of the plan of care) as per the indications and contraindications for each of the directives.
- Specific indications for each laboratory investigation ordered under this medical directive can be found in Appendix C

**Contraindications:**
- Indications described in Appendix C are not met

**Consent:**

**Appendix Attached: _X_ No ___ Yes**
**Title:**

- Patient's consent is implied for implementer to provide lab requisition, as patient has presented seeking support with diabetes management, and is a Family Health Team patient, where interprofessional practice is expected
- Patient informed of purpose of testing, including when results will be available and contact information to review results (if not contacted by PCP)

**Guidelines for Implementing the Order/Procedure:**

**Appendix Attached: ___No _X_ Yes**
**Title:** Appendix C – Performed Controlled Acts and Procedures (CAPs) implemented under this directive
Appendix D – Sample Lab Requisition

1) Identify need for laboratory investigation (blood work) and determine whether indications described in Appendix C are met.
2) Ensure that no recent blood work has been undertaken that would result in duplication of testing.
3) Explain the purpose of the test to the patient
4) Generate a laboratory requisition using the supervising PCP/Authorizers initials.

5) Lab Requisition should be signed as below:
    - Signature
    - Implementer Name/Primary Care Provider Name (Medical Directive TCFHT-MD16)
6) Send a message in Practice Solutions to the PCP indicating that a lab requisition has been provided.
7) PCP will receive completed lab requisitions and forward them to implementers as needed e.g. if earlier follow up with implementer is required
8) Implementer documents that the requisition was provided and follow up plan in the eMR.

**Documentation and Communication:**

**Appendix Attached: __ No __ Yes**
**Title:**

- Documentation in the patient's eMR needs to include: name and number of the directive and name of the implementer (including credential)
- Information regarding implementation of the procedure, the patient's response and follow up plan should be documented in the patient's eMR, in accordance with standard documentation practices (College of Nurses, 2008).

**Review and Quality Monitoring Guidelines:**

**Appendix Attached: __ No __ Yes**
**Title:**

- Review will occur annually on the anniversary of the activation date. Review will involve a collaboration between the authorizing primary care providers and the approved implementers.
- If new information becomes available between routine reviews, such as the publishing of new clinical practice guidelines, and particularly if this new information has implications for unexpected outcomes, the directive will be reviewed by an authorizing primary care provider and a mimimum of one implementer.
- At any such time that issues related to the use of this directive are identified, TCFHT must act upon the concerns and immediately undertake a review of the directive by the authorizing primary care providers and the authorized implementers.
- This medical directive can be placed on hold if routine review processes are not completed, or if indicated for an ad hoc review. During the hold, implementers cannot perform the procedures under authority of the directive and must obtain direct, patient-specific orders for the procedure until it is renewed.

**References**

Diabetes Canada. (2018). Clinical Practice Guidelines for the Prevention and Management of Diabetes in Canada.

College of Nurses of Ontario. (2008). *Practice Standard: Documentation.* Retrieved from http://www.cno.org/Global/docs/prac/41001_documentation.pdf

Anderson et al. (2016). 2016 Canadian Cardiovascular Society Guidelines for the Management of Dyslipidemia for the Prevention of Cardiovascular Disease in the Adult. *Canadian Journal of Cardiology* 32(11), 1263-1282.

Goldenberg, R.M., Cheng A.Y.Y, Punthakee, Z., et al. 2011. Use of glycated hemoglobin (A1C) in the diagnoses of type 2 diabetes in adults. *Canadian Journal of Diabetes*; 35: 247-248.

(Merck Sante. Product Monograph: Glucophage. http://www.sanofi.ca/products/en/glucophage.pdf 2014 Oct. Version 4.2

B12 Deficiency – Investigation and management of Vitamin B12 and Folate Deficiency. 2006 Dec.

House et al. Effect of B-Vitamin Therapy on Progression of Diabetic Nephropathy A Randomized Controlled Trial. JAMA. 2010 Apr 28;303(16):1603-9. doi: 10.1001/jama.2010.490.

**Note: This medical directive is for the routine monitoring of laboratory investigations for the management of diabetes or prediabetes and does not include other laboratory investigations (ALT, AST, CK or CPK, CBC etc.), which are recommended for starting or monitoring the effects of medications e.g. oral antihyperglycemic medications, statin medications etc.**

# Appendix A:

## Authorizer Approval Form

| Name | Signature | Date |
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## Appendix B:

## Implementer Approval Form

To be signed when the implementer has completed the required preparation, and feel they have the knowledge, skill, and judgement to competently carry out the actions outlined in this directive.

| Name | Signature | Date |
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# Appendix C

## Table 1: Controlled Acts and Procedures (CAPs) Implemented Under this Directive

| Laboratory Investigation | Indications |
|---|---|
| Fasting Blood Glucose (FBG) & Glycated Hemoglobin (HbA1C) | Every 3 months when glycemic targets are not being met and/or when diabetes therapy is being adjusted.<br><br>Every 6 months should be performed in adults during periods of treatment and lifestyle stability when glycemic targets have been consistently achieved.<br><br>Every 6-12 months is recommended for people with prediabetes.<br><br>FBG should be obtained after an 8-12hr fast.<br><br>A Random Blood Glucose (RBG) along with an HbA1C should be considered for patients at high risk for hypoglycemia e.g. those taking insulin, frail elderly etc.<br><br>An HbA1C may be misleading in some people with various hemoglobinopathies, iron deficiency, hemolytic anemias, and severe hepatic and renal disease. A fructosamine test can be used in these cases for a cost of approximately $25. The RN or RD to consult with the PCP and can obtain a verbal order for this test if indicated. |
| Lipid Panel (total cholesterol, triglycerides, HDL – cholesterol, LDL-cholesterol, total cholesterol: HDL-C ratio) | A fasting lipid profile (TC, HDL-C, TG, and calculated LDL-C) should be measured at the time of diagnosis of diabetes. If lipid-lowering treatment is not initiated, repeat testing is recommended yearly. More frequent testing (every 3-6 months) should be performed after treatment for dyslipidemia is initiated (lifestyle and/or medications).<br><br>A non-fasting lipid profile should be considered for some patients to improve adherence and to lower the risk for hypoglycaemia. New evidence indicates minimal differences exist between fasting and non-fasting HDL, LDL, and total cholesterol levels. The differences that occur are less than the within-person variability from repeat lipid testing. Tests of non-fasting HDL and non-HDL levels correlate with future CVD events. Although triglycerides are most susceptible to change without fasting, triglycerides contribute minimally to total cholesterol levels, and triglyceride levels are not consistently associated with CVD.<br><br>People with diabetes >40years old, or diabetes >15 years duration and age >30 years, or with established macrovascular or microvascular disease are considered at high risk for cardiac disease (Framingham Risk Score >20%) |

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| | People with prediabetes and diabetes (who do not meet the criteria above) should be screened following the recommendations outlined in Table 2: Approach on Who and How to Screen for Dyslipidemia.<br><br>Dyslipidemia treatment recommendations are outlined in Table 3: Pharmacological Treatment Recommendations and Targets<br><br>The primary treatment goal for people with diabetes is LDL-C ≤2.0 mmol/L, which is generally achievable with statin monotherapy.<br><br>A lipoprotein profile should be obtained after a 10hr-12hr fast, preferably with the subject refraining from alcohol for 24h-48h .<br><br>An ApoB test can be used if unable to calculate LDL-C (usually when triglycerides are elevated) at a cost of $25. RN or RD to consult with the PCP and can obtain a verbal order for ApoB if indicated. |
| Urine Albumin-to-Creatinine Ratio (ACR) & Serum Creatinine (eGFR) | At diagnosis of type 2 diabetes or 5 years after diagnosis of type 1 diabetes and yearly thereafter<br><br>As the ACR can be elevated with recent major exercise, fever, urinary tract infection, congestive heart failure, menstruation or acute severe elevations of blood pressure (BP) or blood glucose (BG), screening for albuminuria should be delayed in the presence of these conditions.<br><br>Intravascular volume contraction e.g. dehydration or any acute illness can transiently lower kidney function, and GFR estimation for screening purposes should be delayed until such conditions resolve.<br><br>If ACR >20.0 mg/mmol (macroalbuminuria) this is indicative of chronic kidney disease (CKD). RN or RD should refer to the PCP.<br><br>If eGFR $\leq$ 60 ml/min OR ACR $\geq$ 2.0 mg/mmol (microalbuminuria) and there is no established diagnosis of CKD order serum creatinine for eGFR in 3 months AND 2 repeat random urine ACRs performed over the next 3 months. If eGFR $\leq$ 60mL/min or 2 or 3 ACRs $\geq$ 2.0 mg/mmol (indicative of chronic kidney disease) refer to PCP.<br><br>If ACR and/or eGFR is indicative of CKD. It is recommended that a urine dipstick test be performed (by the PCP), either in the laboratory or at point of care, as a screen for renal disease other than diabetic nephropathy.<br><br>People with diabetes and CKD should have a random urine ACR and a serum creatinine converted into an eGFR |

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| | performed at least every 6 months |
| Cobalamin (Vitamin $B_{12}$) | At least every one to two years in **patients on long-term treatment with Metformin[1]**. If treating $B_{12}$ deficiency, re-test 2-3 months after initiating treatment[2].<br><br>The conventional reference interval for serum $B_{12}$ is 150-600pmol/L. Using this reference interval, the following interpretation is recommended[2]:<br><br><75pmol/L (102pg/mL) – high probability of deficiency<br>75-150pmol/L (102-203pg/mL) – moderate probability of deficiency*<br>150-220pmol/L (203-298pg/mL) – low probability of deficiency*<br>>220pmol/L (>298pg/mL) – rare probability of deficiency<br>***Clinically significant $B_{12}$ deficiency may occur with vitamin $B_{12}$ levels in normal range particularly in elderly patients.***<br><br>Recommended treatment is 1,000 mcg B12 PO OD. Patients with significant neurological symptoms should however receive initial IM injections of 1000mcg $B_{12}$[2].<br><br>A $B_{12}$ supplementation may be associated with a decrease in eGFR in people with CKD; caution using supplementation in this population unless deficiency confirmed[3]. |

Table 2: Approach on Who and How to Screen for Dyslipidemia

## WHO TO SCREEN

**Men ≥40 years of age; women ≥40 years of age (or postmenopausal)**

Consider earlier in ethnic groups at increased risk such as South Asian or First Nations individuals

**All patients with the following conditions regardless of age:**

- Clinical evidence of atherosclerosis
- Abdominal aortic aneurysm
- Diabetes
- Arterial hypertension
- Current cigarette smoking
- Stigmata of dyslipidemia (arcus cornea, xanthelasma or xanthoma)
- Family history of premature CVD*
- Family history of dyslipidemia
- Chronic kidney disease
- Obesity (BMI ≥30 kg/m$^2$)
- Inflammatory bowel disease
- HIV infection
- Erectile dysfuntion
- Chronic obstructive pulmonary disease
- Hypertensive diseases of pregnancy

## HOW TO SCREEN

**For all:**

- History and physical examination
- Standard lipid panel (TC, LDL-C, HDL-C, TG)
- Non-HDL-C (will be calculated from profile)
- Glucose
- eGFR

**Optional:**

- ApoB
- Urine albumin:creatinine ratio (if eGFR <60 mL/min/1.73m$^2$, hypertension or diabetes)

**NON-FASTING LIPID TESTING IS ACCEPTABLE**

# Table 3: Pharmacological Treatment Indications and Targets

Pharmacological treatment indications and targets

| Category | Consider initiating pharmacotherapy if | Target | NNT |
|---|---|---|---|
| Primary prevention | High FRS (≥ 20%)<br>All | LDL-C < 2.0 mmol/L or > 50% ↓<br>Or | 35 |
| | Intermediate FRS (10%-19%)<br>LDL-C ≥ 3.5 mmol/L<br>or non-HDL-C ≥ 4.3 mmol/L<br>or ApoB ≥ 1.2 g/L<br>or men ≥ 50 and women ≥ 60 years and 1 additional CVD RF | ApoB < 0.8 g/L<br>Or<br>non-HDL-C < 2.6 mmol/L | 40 |
| Statin-indicated conditions* | Clinical atherosclerosis† | | 20 |
| | Abdominal aortic aneurysm | | |
| | Diabetes mellitus<br>Age ≥ 40 years<br>15-Year duration for age ≥ 30 years (DM 1) | | |
| | Microvascular disease | | |
| | Chronic kidney disease (age ≥ 50 years)<br>eGFR < 60 mL/min/1.73 $m^2$ or ACR > 3 mg/mmol | | |
| | LDL-C ≥ 5.0 mmol/L | > 50% ↓ in LDL-C | |

# Appendix D:

## Sample Lab Requisition

Ontario Ministry of Health and Long-Term Care

**Laboratory Requisition**
Requisitioning Clinician / Practitioner

Name
Pauline Pariser

Address
790 Bay Street, Suite 300, PO Box 5,
Toronto, ON,
M5G 1N8

**Laboratory Use Only**

Clinician/Practitioner's Contact Number for Urgent Results
( 416 ) 960-1366 Ext.

Service Date yyyy mm dd

Clinician/Practitioner Number: 239822
CPSO / Registration No.:
Health Number:
Version:
Sex: ☒ M ☐ F
Date of Birth yyyy mm dd: 1957 04 18

Check (✓) one:
☒ OHIP/Insured ☐ Third Party / Uninsured ☐ WSIB

Province:
Other Provincial Registration Number:
Patient's Telephone Contact Number: 416 204-1256

Additional Clinical Information *(e.g. diagnosis)*

Patient's Last Name *(as per OHIP Card)*: Diabetes

Patient's First & Middle Names *(as per OHIP Card)*: Doug

☐ Copy to: Clinician/Practitioner
Last Name: First Name
Address

Patient's Address *(including Postal Code)*
790 Bay St. Suite 508
Toronto, ON
M5G 1N8

***Note: Separate requisitions are required for cytology, histology / pathology and tests performed by Public Health Laboratory***

| x | Biochemistry |
|---|---|
| ☒ | Glucose ☐ Random ☒ Fasting |
| ☒ | HbA1C |
| ☒ | Creatinine (eGFR) |
| | Uric Acid |
| | Sodium |
| | Potassium |
| | Chloride |
| | CK |
| | ALT |
| | Alk. Phosphatase |
| | Bilirubin |
| | Albumin |
| ☒ | Lipid Assessment (includes Cholesterol, HDL-C, Triglycerides, calculated LDL-C & Chol/HDL-C ratio; individual lipid tests may be ordered in the "Other Tests" section of this form) |
| ☒ | Albumin / Creatinine Ratio, Urine |
| | Urinalysis (Chemical) |
| | Neonatal Bilirubin: |
| | Child's Age: days hours |
| | Clinician/Practitioner's tel. no. |
| | Patient's 24 hr telephone no. |
| | Therapeutic Drug Monitoring: |
| | Name of Drug #1 |
| | Name of Drug #2 |
| | Time Collected #1 hr. #2 hr. |
| | Time of Last Dose #1 hr. #2 hr. |
| | Time of Next Dose #1 hr. #2 hr. |

| x | Hematology |
|---|---|
| | CBC |
| | Prothrombin Time (INR) |
| | **Immunology** |
| | Pregnancy Test (Urine) |
| | Mononucleosis Screen |
| | Rubella |
| | Prenatal: ABO, RhD, Antibody Screen (titre and ident. if positive) |
| | Repeat Prenatal Antibodies |
| | **Microbiology ID & Sensitivities (if warranted)** |
| | Cervical |
| | Vaginal |
| | Vaginal / Rectal – Group B Strep |
| | Chlamydia *(specify source)*: |
| | GC *(specify source)*: |
| | Sputum |
| | Throat |
| | Wound *(specify source)*: |
| | Urine |
| | Stool Culture |
| | Stool Ova & Parasites |
| | Other Swabs / Pus *(specify source)*: |

**Specimen Collection**
Time Date

**Fecal Occult Blood Test (FOBT)** *(check one)*
☐ FOBT (non CCC) ☐ ColonCancerCheck FOBT (CCC) no other test can be ordered on this form

| x | Viral Hepatitis *(check one only)* |
|---|---|
| | Acute Hepatitis |
| | Chronic Hepatitis |
| | Immune Status / Previous Exposure<br>*Specify:* ☐ Hepatitis A ☐ Hepatitis B ☐ Hepatitis C<br>or order individual hepatitis tests in the "Other Tests" section below |

**Prostate Specific Antigen (PSA)**
☐ Total PSA ☐ Free PSA
Specify one below:
☐ Insured – Meets OHIP eligibility criteria
☐ Uninsured – Screening: Patient responsible for payment

**Vitamin D (25-Hydroxy)**
☐ Insured - Meets OHIP eligibility criteria: osteopenia; osteoporosis; rickets; renal disease; malabsorption syndromes; medications affecting vitamin D metabolism
☐ Uninsured - Patient responsible for payment

**Other Tests** - one test per line

*I hereby certify the tests ordered are not for registered in or out patients of a hospital.*

Robert Smith RD CDE
As per medical directive TCFHT-MD16
X 02/09/2014
Clinician/Practitioner Signature Date

**Laboratory Use Only**

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