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Document History:

Title:	Gestational Diabetes Mellitus (GDM) - 50g and 75g Oral Glucose Testing	Site(s):	Shared Health Diagnostic Services – Provincial

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Research & Development:	**Yes √ No ☐ N/A ☐**	**LIS Code:**	**GT50, GTTP**
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#	Details of Revisions:	Approval:	Date:
1	New document		
2	Revised		
3	Revised		
4	Added Appendix II for laboratories capable of promptly reporting venous blood. Comment for limitations of glucometer testing: do NOT use venous blood; Delphic LIS comments; Corrections to LIS comments	C. Oleschuk	2 April 2009 27 May 2009 8 June 2009
5	General revision with 2013 CDA Criteria	A. Sokoro	3 Dec 2013
6	General revisions according to 2018 CDA Guidelines. POCT testing removed prior to OGTT	E. Petryayeva	21 Nov 2022
6.1	Delay in centrifugation vs analysis clarification (ps. 4/5)	E Petryayeva	4 Jan 2023
7	Clarified definition of ‘time zero’ (p. 4).	N Landry	14 May 2024

1.0 PURPOSE AND SCOPE

To provide a procedure for provincial standardization of oral glucose tolerance testing for screening and diagnosis of gestational diabetes mellitus (GDM) at 24-28 weeks of gestation following *preferred* approach according to 2018 Diabetes Canada Clinical Practice Guidelines.

2.0 RELATED DOCUMENTS

SOP Number	Title
110-10-17	75g Oral Glucose Tolerance Test (OGTT) for Diagnosis of Prediabetes and Diabetes
100-10-79	Phlebotomy Collection Manual
JA110-10-18	Job Aid for 50g Gestational Diabetes Glucose Challenge Testing (GCT)
JA110-10-17	Job Aid for 75g Oral Glucose Tolerance Testing (T2DM and GDM)
F110-10-17A	Oral Glucose Tolerance Testing (OGTT) Record Form
PB110-10-17	Oral Glucose Tolerance Testing - Patient Brochure
110-20-06	Fasting Protocols

3.0 BACKGROUND

Gestational diabetes mellitus (GDM) is defined as hyperglycemia with onset or first recognition during pregnancy. The global prevalence of hyperglycemia during pregnancy has been estimated at 16.9% using WHO criteria. Between 3% to 20% of pregnant women develop gestational diabetes, depending on their risk factors.

Table 1. Risk factors for GDM include.

Being:	• 35 years of age or older • From a high-risk group (African, Arab, Asian, Hispanic, Indigenous, or South Asian)
Using:	• Corticosteroid medication
Having:	• Obesity (BMI ≥30 kg/m2) • Prediabetes • GDM in previous pregnancy • Given birth to a baby that weighted more than 4 kg • A parent, brother, or sister with type 2 diabetes • PCOS or acanthosis nigricans

Untreated GDM carries short-term and long-term health risks for both mother and baby, while treatment reduces these adverse outcomes. Some common complications of GDM are summarized in Table 2.

Table 2. Adverse outcomes associated with GDM.

	Maternal Complications	Fetal Complications
Short-term	Hypertensive disorders of pregnancy Preeclampsia Pre-term delivery Caesarean section Spontaneous miscarriage Postpartum hemorrhage	Macrosomia / LGA Preterm delivery, ICU admissions Perinatal death, stillbirth Shoulder dystocia and nerve injury Metabolic (hypoglycemia, hypocalcemia) Hematological (polycythemia, low iron stores) Hyperbilirubinemia/jaundice
Long-term	Weight gain/Obesity GDM in subsequent pregnancy Type 2 diabetes, metabolic syndrome Cardiovascular disease (CVD)	Obesity Metabolic syndrome Type 1 diabetes Type 2 diabetes

All pregnant women without known pre-existing diabetes should be screened for GDM at 24 – 28 weeks of gestation. Diagnostic criteria for GDM remain controversial; however, 2018 Diabetes Canada Clinical Practice Guidelines identify *"preferred"* and *"alternative"* screening approach.

- The *preferred* approach includes a 50g glucose challenge test (GCT) administered in non-fasting state and plasma glucose measured one hour later.
    - If GCT screen is positive (PG 7.8-11.0 mmol/L), a 75g oral glucose tolerance test (OGTT) should be performed for diagnosis. See **Figure 1** for details.
    - PG 11.1 mmol/L is diagnostic of GDM and does not require OGTT for confirmation.
- The *alternative* approach is a 1-step approach of a 75g OGTT, using different cut-off values than the non-gestational 75g OGTT or cut-offs used in *preferred* approach.

The summary table comparing different oral glucose tolerance tests identified in 2018 Diabetes Canada Clinical Practice Guidelines for screening and diagnosis of GDM and Type 2 Diabetes Mellitus (T2DM) is provided in Appendix 1.

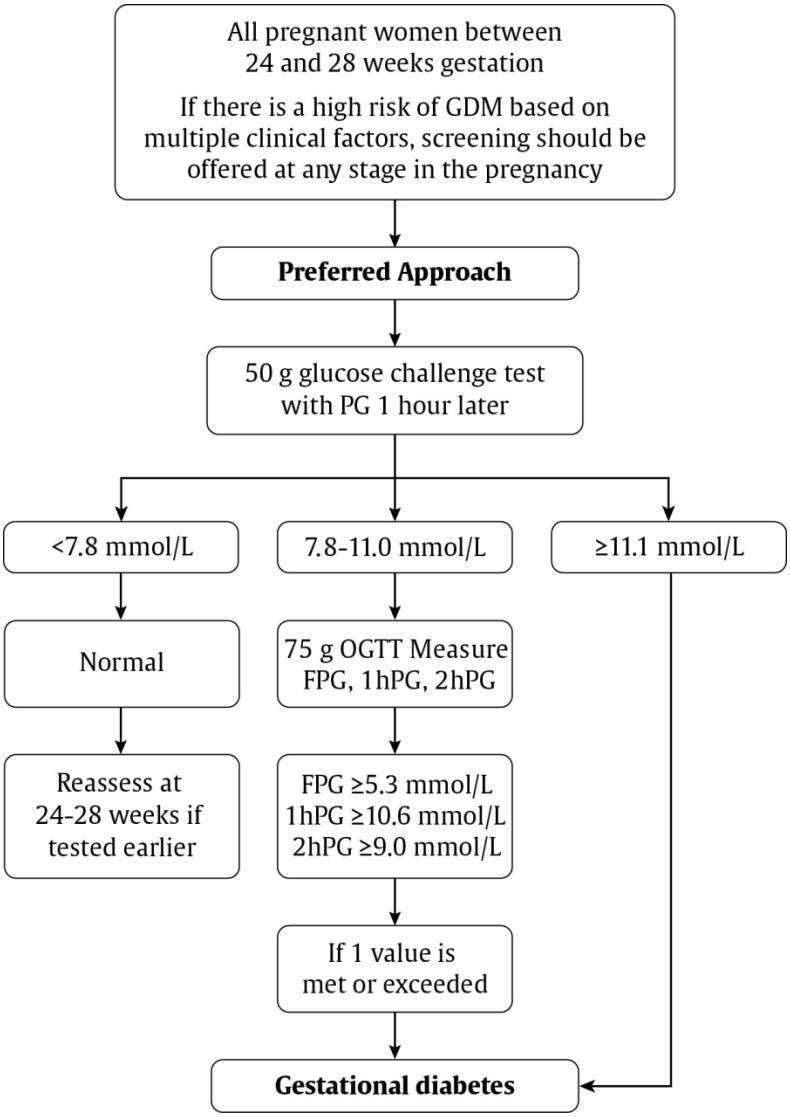

Figure 1. Preferred approach for the screening and diagnosis of gestational diabetes. *1hPG*, 1-hour plasma glucose; *2hPG*, 2-hour plasma glucose; *FPG*, fasting plasma glucose; *GDM*, gestational diabetes mellitus; *OGTT*, oral glucose tolerance test; *PG*, plasma glucose

4.0 50g ORAL GLUCOSE CHALLENGE TEST (GCT) – LIS code: GT50

4.1 Materials

Reagents	• 50 g glucose drink (50g in 300 mL) *Alternative:* 200 mL from 75g/300mL bottle
Equipment	• Core lab chemistry analyzer • Do not use POCT devices to measure glucose

4.2 Patient preparation

- Pregnant patients between 24-28 weeks of gestation
- Testing may be done at any time of the day and patient does not need to fast
- The patient should not be dehydrated prior to test
- Some laboratories may only perform this test by appointments (see Appendix 2)

4.3 Testing Procedure

- Confirm patient identity as per Phlebotomy Collection Manual 100-10-79
- Provide patient a copy of patient brochure for OGTT testing SOP PB110-10-17
- Order test ***GT50*** in Delphic
    - Create separate lab ID# from any other blood work.

- Add entry to "Glucose Tolerance Testing Record Form" F110-10-17A
- Administer 50 g glucose.

- **Time zero (t = 0) is when the patient has finished consuming the drink. The entire drink must be consumed within 5 minutes**.

    - Notify physician/nursing staff if patient is unable to drink entire contents or should they become sick.
    - Discontinue test if patient becomes sick. Do not proceed to collect blood sample. Cancel the test using ***REJS*** and add comment:

"Patient got sick, test is cancelled."

- Update Record Form F110-10-17A with time zero and scheduled 1 hour time.
- Inform the patient about the time for 1 hour collection.
    - Clearly state that it must be within 10 minutes or test will be cancelled.
    - Woman must remain seated throughout the test. No exercise or walking. No smoking, food, or caffeinated drinks are not permitted during the test.

- Collect a plasma blood sample 1 h post the start of consuming of the drink. Label tube as 1 hour.
    - If *Collected* sample time exceeds *Scheduled* time by more than 10 minutes, cancel the test using ***REJS*** and add comment:

"Specimen collected outside of acceptable time window (10 min) for timed collection."

    - Forward samples to the laboratory immediately. On the GTT format, report the 1 hour glucose.

Note: All collected plasma samples must be sent to the lab immediately to be centrifuged and analyzed. Delay (>30 minutes) causes decrease in glucose levels and potentially missed diagnosis of GDM.

4.4 Interpretation or 50g GCT for screening and diagnosis of GDM

Plasma glucose is measured 1 hour post challenge:

Plasma glucose, mmol/L	Interpretation
<7.8	Normal.
≥11.1	Diagnosis of GDM. Confirmation with 75g OGTT is not required.
7.8-11.0	Screen for GDM is positive, follow-up with confirmatory 75g OGTT. See Section 5.0

5.0 75g ORAL GLUCOSE TOLERANCE TEST (OGTT) – LIS code: GTTP

In *Preferred Approach* to diagnose GDM, this test is only performed when 50 g GCT is positive with 1 h glucose within 7.8-11.0 mmol/L.

5.1 Materials

Reagents	• 75 g glucose drink (75g/300mL bottle; 0.25 g/mL)
Equipment	• Core lab chemistry analyzer • Do not use POCT devices to measure glucose

5.2 Patient preparation

- Pregnant patients between 24-28 weeks of gestation
- The patient should fast for 8-14 h (only water permitted) prior to test
- The patient woman should not be dehydrated
- Pregnant patients should not be on any medication affecting glucose levels for at least 3 days: atypical antipsychotics, beta-adrenergic agonists, diazoxide, glucocorticoids, interferon alpha, nicotinic acid, pentamidine, phenytoin, protease inhibitors, thiazide diuretics
- This test should be performed after three days of unrestricted diet and physical activity
- Some laboratories may only perform this test by appointments (see Appendix 2)

5.3 Testing Procedure

- Confirm patient identity as per Phlebotomy Collection Manual 100-10-79
- Provide patient a copy of patient brochure for OGTT testing SOP PB110-10-17

- Order test ***GTTP*** in Delphic
  - Create separate lab ID# from any other blood work on the same requisition.

- Add entry to “Glucose Tolerance Testing Record Form” F110-10-17A
- Collect fasting glucose sample. Indicate on the tube label “fasting”.
- Administer 75 g glucose drink.

- **Time zero (t = 0) is when the patient has finished consuming the drink. The entire drink must be consumed within 5 minutes.**

  - Notify physician/nursing staff if patient is unable to drink entire contents or should they become sick.
  - Discontinue test if patient becomes sick. Do not proceed to collect next blood sample. Report glucose results collected prior to patient vomiting and cancel other(s) with comment:

“Patient got sick, test is cancelled.”

- Update Record Form F110-10-17A with time zero and scheduled 1-hour and 2-hour time.

- Inform the patient about the time for 1-hour and 2-hour collections.
  - Clearly state that it must be within 10 minutes or test will be cancelled.
  - The patient must remain seated throughout the test. No exercise or walking. Food and drinks are not permitted, except water

- Collect a plasma blood sample 1 and 2 h post the start of consuming of the drink. Indicate on the labels of the tube, "1 hour" and "2 hour", respectively
  - If *Collected* sample time exceeds *Scheduled* time by more than 10 minutes, cancel the test using ***REJS*** and add comment:

    "Specimen collected outside of acceptable time window (10 min) for timed collection."

  - Forward samples to the laboratory. On the GTT format, report the fasting, 1-hour and 2-hour glucose.

Note: All collected plasma samples must be sent to the lab immediately to be centrifuged and analyzed. Delay in separating from cells (>30 min) causes decrease in glucose levels and potentially missed diagnosis of GDM.

5.4 Interpretation of 75g OGTT for diagnosis of GDM

GDM is diagnosed using one or more of the following criteria:

Sample	Criteria
Fasting PG	≥5.3 mmol/L
1 h PG	≥10.6 mmol/L
2 h PG	≥9.0 mmol/L

Appendix 1: Oral Glucose Tolerance Testing for GDM and T2DM

	Gestational Diabetes (GDM) (24-28 weeks of gestation)			Type 2 Diabetes Mellitus (T2DM)		
	Preferred Approach		Alternative Approach			
Test	50g glucose challenge test (GCT) *Pregnant* *1st tier test*	75g OGTT for GDM *Pregnant* *2nd tier test*	75g OGTT for GDM *pregnant*	75g OGTT for T2DM *non-pregnant*		
LIS code	GT50	GTTP	Not available	GTT2		
Preparation	Non-fasting	Fasting	Fasting	Fasting		
Drink	75g in 300 mL, give 200 mL only 50g in 300 mL	75g in 300 mL	75g in 300 mL	75g in 300 mL (adult) 1.75g/kg weight (child <18y.o ***and*** <42 kg)		
Sample(s) collected	1 hour	Fasting plasma 1 hour 2 hours	Fasting plasma 1 hour 2 hours	Fasting plasma 2 hours		
Interpretation	PG<7.8 mmol/L → normal • *repeat at 24-28 weeks of gestation if done earlier* PG≥11.1 mmol/L → GDM • *No further testing needed* PG 7.8-11.0 mmol/L • *Perform 75g OGTT for GDM (code:GTTP)*	If ≥1 value is met → GDM: ▪ FPG ≥ 5.3 mmol/L ▪ 1h ≥ 10.6 mmol/L ▪ 2h ≥ 9.0 mmol/L	If ≥1 value is met → GDM: ▪ FPG ≥ 5.1 mmol/L ▪ 1h ≥ 10.0 mmol/L ▪ 2h ≥ 8.5 mmol/L		**Prediabetes**	**Diabetes**
				FPG	6.1-6.9 mmol/L	≥ 7.0 mmol/L
				2h PG	7.8-11.0 mmol/L	≥ 11.1 mmol/L

PG, plasma glucose; *FPG*, fasting plasma glucose

References:

Diabetes Canada Clinical Practice Guidelines Expert Committee. *Diabetes Canada 2018 Clinical Practice Guidelines for the Prevention and Management of Diabetes in Canada*. Can J Diabetes. 2018;42(Suppl 1):S1-S325.