

## Oral Glucose Tolerance Testing v2.1

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### 148355.307 Oral Glucose Tolerance Testing

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#### Comments for version 2.1

General Procedure: #3. The last swallow is time zero.

#### Approval and Periodic Review Signatures

Type	Description	Date	Version	Performed By	Notes
Approval	Lab Director	6/10/2022	2.0	Simha Sastry MD Clinical Laboratory Director (M06625)	
Approval	Lab Director	5/23/2022	2.0	Samantha Davenport MD Service Line Chief (M03764)	
Approval	Lab Director	5/18/2022	2.0	Valerie Bush PhD Clinical Laboratory Director (M05512)	
Approval	Lab Director	5/18/2022	2.0	John Fisk MD Clinical Laboratory Director (M08480)	
Approval	Lab Director	5/18/2022	2.0	Ghazala Nathu MD Clinical Laboratory Director (S00134)	
Approval	Lab Director	5/18/2022	2.0	Timothy Chapman MD Clinical Laboratory Director (M11669)	

#### Version History

Version	Status	Type	Date Added	Date Effective	Date Retired
2.1	Approved and Current	Minor revision	2/24/2023	2/24/2023	Indefinite
2.0	Retired	Initial version	5/18/2022	6/10/2022	2/24/2023

## ORAL GLUCOSE TOLERANCE TESTING

### GENERAL POLICY STATEMENT

The following policy outlines performing Oral Glucose Tolerance Testing on patients suspected of having diabetes mellitus. This test is not used to diagnose hypoglycemia. This policy also includes instructions for performing the Growth Hormone Suppression test.

### SCOPE

This policy applies to all areas within Bassett Healthcare where glucose tolerance tests are performed.

### ADMINISTRATION

The Clinical Laboratory Director and Manager, Laboratory Support Services will be responsible for the issuance and coordination of this policy, compliance to the policy, questions regarding the policy, and the altering of the provisions within.

### INTRODUCTION

The National Diabetes Data Group (NDDG) provides classifications for diabetes and glucose impairment. Type 1 (insulin dependent diabetes) comprise ~5-10% of cases. These patients present with sudden onset of polyuria, polydipsia, weight loss and often ketoacidosis. Type II (non-insulin dependent diabetes) represent 90-95% of cases and is characterized by insulin resistance with decreased responsiveness to endogenous and exogenous insulin. This disease typically occurs in patients  $\geq 40$  y.o. and 60-90% are obese. This disease may present at earlier ages in: African-Americans, Native American Indian and Hispanic-American. Diabetes may occur secondary to other diseases, i.e. pancreatic cancer, endocrinopathies, chemical agents or genetic syndromes. Impaired glucose tolerance and gestational diabetes are common clinical entities. The guidelines presented herein include those recommended by American Diabetes Association (ADA), the American College of Obstetricians and Gynecologists (ACOG), and World Health Organization (WHO) for diagnosing diabetes mellitus and gestational diabetes.

### GUIDELINES

According to the ADA, the diagnosis of diabetes should be based on one of the following:

- In a patient with classic symptoms of hyperglycemia (polyuria, polydipsia, weight loss) or hyperglycemic crisis and random glucose  $> 200$  mg/dl;
- Fasting glucose  $\geq 126$  mg/dl on more than one occasion; or
- 2GTT using 75 g glucose load with 2 hour glucose  $\geq 200$  mg/dl.
- Hemoglobin A1c (HBA1c)  $\geq 6.5\%$  using a test certified by the National glycohemoglobin Standardization Program (NGSP) and traceable to the Diabetes Control and Complications Trial (DCCT) reference assay. These are generally laboratory-based methods and not point of care tests. For patients with hemoglobinopathy and normal red cell turnover, an HPLC A1c method should be used. For conditions with abnormal red cell turnover, i.e. hemolytic or iron deficient anemias, the diagnosis of diabetes must employ glucose criteria exclusively. Other factors to consider that may impact hemoglobin glycation independently of glycemia include: age, race/ethnicity, and anemia/hemoglobinopathies.

When there is strong clinical suspicion that diabetes may be present, a glucose tolerance test (GTT) may be ordered to confirm the diagnosis. A GTT should be delayed when acute illness, trauma, burns, pregnancy, endocrinopathies, and various drugs induce hyperglycemia, elevating the fasting glucose value and impairing glucose tolerance. Additionally, physical inactivity and a restricted diet ( $< 150$  g carbohydrate/day) before the GTT may produce abnormal glucose tolerance. Adherence to proper patient preparation is important for meaningful test results.

## ORDERING INFORMATION

1. There must be a doctor's order for the test and a diagnosis.
2. Glucose dose may be administered by an RN, LPN, or trained LST, phlebotomist or technologist.
3. Follow the Unity codes in the table below for the appropriate test. Laboratory Test Request Form #8 can be used during downtime or for non-Bassett providers.
4. Order only the test indicated by the provider.
5. Bassett providers not on the Bassett Medical Center campus should contact a Bassett Medical Center Diabetes Educator (607-547-3649) for consultation and evaluation of testing.

## GENERAL PATIENT PREPARATION

1. Patient should be on an unrestricted high carbohydrate diet (at least 150g/day) for 3 days prior to the test.
2. Patient should not discontinue medications unless instructed by their provider.
3. Fasting is defined as no caloric intake for at least 8 hours. Patient must be NPO (nothing to eat or drink) after midnight the night prior to the test and through the completion of the test. Fasting includes abstinence from tobacco, coffee, tea, juice, alcohol, food, mints, gum, etc.; only water to drink.
4. Glucola is available in 50g, 75g and 100g bottles. Verify the proper dose for the appropriate tolerance test before administering. If 100g bottles are not available, two 50g bottles may be used.
5. The only FDA cleared alternative to glucola is 'The Fresh Test' is available in 50 g and 75 g dose packets of D-glucose (same as glucola). This product must be reconstituted appropriately to ensure the proper dose. Two 50 g packets may be used to obtain a 100 g dose. Follow manufacturer's instructions for reconstitution. Once reconstituted, use as glucola.
6. Other alternatives should not be used as these contain other sugars that may be absorbed and metabolized at different rates compared to glucose. The tolerance tests are validated against known doses of D-glucose.
7. Patient should sit upright and quietly during the test. Each timed collection should be done within 5 minutes of either 60 or 120 minutes from completing the dose.

## GLUCOSE CHALLENGE AND TOLERANCE TESTS FOR PREGNANT OR POSTPARTUM WOMEN

The ADA and ACOG recommend that all pregnant women be screened for diabetes between 24-28 weeks of pregnancy, or earlier if risk factors exist with a 75 g oral glucose tolerance test. Diagnostic cut points have been defined for glucose measurement at each time point (fasting, 1 hr, 2 hr). Alternative screening may be performed using a 1 hr glucose following a 50 g dose of glucola; no fasting is required. Refer to ordering information and interpretations below.

**Table 1: OGTT in Antepartum or Postpartum Women**

UNITY CODE	GLUCOSE TESTING PERFORMED	USAGE
1GCT LAB 3583	1 HR	Screen (50 G) used AS Gestational Diabetes Challenge
OBGTT LAB 3000	FASTING, 1 HR, 2 HR GLUCOSE	Standard OGTT (75g). Used for gestational
2GTT LAB 169	FASTING AND 2 HR GLUCOSE	Standard OGTT (75g). Used 6 weeks postpartum
3OBGTT LAB 3545	FASTING, 1 HR, 2 HR, 3 HR GLUCOSE	Follow-up testing from failed 1GCT (100g)

### Notes:

- A. Perform glucose tolerance test on pregnant patients regardless of fasting glucose. No fasting specimen is required for the 1 hr glucose challenge or antepartum screen (1GCT).
- B. Perform on ambulatory patients only. Do not perform on hospitalized patients or patients with an acute or chronic illness that can affect the test. Delay test 2 weeks after illness.

- C. Patient should not discontinue medications unless instructed by their provider.
- D. Have the patient eat a carbohydrate intake of at least 150 g/day for 3 days before the test.

**GENERAL PROCEDURE**

1. Verify the patient has fasted for 8 - 12 hours. Fasting includes abstinence from tobacco, coffee, tea, juice, alcohol, food, mints, gum, etc., only water to drink.
2. Draw fasting glucose and send to lab for analysis. A fingerstick glucose may NOT be used as this is considered off-label use of the glucometer. Tolerance tests will proceed regardless of the fasting or other timed glucose values. If any glucose is a critical value, this will be called to the provider and proceeding with the tolerance test should be questioned.
3. Give appropriate dose of glucose (see table above). Allow up to 15 minutes for ingestion. The last swallow is time zero. Nausea, dizziness and vomiting are rare. Should vomiting occur the test should be terminated. Notify the laboratory and provider if the test is terminated.
4. Patient should sit upright and quietly during the test. Slow walking is permitted, but vigorous exercise should be avoided. The patient should abstain from eating or drinking, although water may be allowed during the test.
5. Collect venous blood samples (gold, red, green or gray top tube) at the appropriate time intervals for the test ordered. The same tube type should be used for all collections from a single patient. Label each specimen with patient's name, medical record number or date of birth, date and time of collection and test interval (e.g., 1 hr). The clinical laboratory recommends the use of venous samples because whole blood capillary glucose concentrations can be 15% higher than plasma levels.
6. Send each specimen to the Clinical Laboratory within 2 hours of collection for analysis. If gray top tubes are collected, all specimens can be sent to the laboratory after completion of the tolerance test. The laboratory will use a method specific for glucose.
7. The test should be interpreted using ADA or ACOG criteria as described below.

**INTERPRETATIONS**

Normal Fasting Glucose: See B-Net Laboratory Manual

- A. Diagnostic Criteria in Gestational Diabetes using the Antepartum Screening Test (1GCT); If the 1 hour glucose > 135 mg/dL, the patient is referred for a 3OBGTT: See Online Laboratory Manual for normal 1HR venous glucose range
- B. Diagnostic Criteria in Gestational Diabetes using the Standard Screening Test (OBGTT); One or more of the values after a 75 g oral glucose challenge: See Online Laboratory Manual for normal Fasting, 1 HR, or 2 HR venous glucose ranges.
  - a. If the 1 hour glucose is >300 mg/dL, the 2 hour may be deferred and the patient may be referred to Endocrinology.
- C. Diagnostic Criteria for Postpartum 2GTT following a 75g oral glucose challenge: See Online Laboratory Manual for Fasting and 2HR Diagnostic Criteria.
- D. Diagnostic Criteria in Gestational Diabetes using the 3 HR OBGTT; Two or more values after a 100 g oral glucose challenge must be equaled or exceeded for a diagnosis: See Online Laboratory Manual for Fasting, 1HR, 2HR, 3HR Diagnostic Criteria.

**Table 2: Glucose Tolerance Tests for Non-pregnant Adults and Pediatrics**

UNITY CODE	GLUCOSE TESTING PERFORMED	USAGE
2GTT - LAB 169	FASTING, 2 HR GLUCOSE	Standard OGTT (75g)
3GTTL - LAB 164	FASTING, 1, 2, 3 HR GLUCOSE	ADA Obsolete Screen (100g)
5GTT - LAB 167	FASTING, 1, 2, 3, 4, 5 HR GLUCOSES	Screen for reactive hypoglycemia. Performed under provider supervision. Provider can stop the test at any time. (75g)

**Notes:**

- A. Perform on ambulatory patients only. Do not perform on hospitalized patients or patients with an acute or chronic illness or on medications that can affect the test. Delay test 2 weeks after illness.
- B. Have the patient eat a carbohydrate intake of at least 150 g/day for 3 days before the test.
- C. If fasting glucose value exceeds 126 mg/dL on more than one occasion, or HBA1C is  $\geq 6.5\%$  GTT is not necessary to make a diagnosis of diabetes mellitus. The most common method is a combination of symptoms (e.g., polydypsia, polyuria, weight loss) and a random glucose  $\square$  200 mg/dL.

**GENERAL PROCEDURE**

- 1. Verify the patient has fasted for 8-12 hours. Fasting includes abstinence from tobacco, coffee, tea, juice, alcohol, food, mints, gum, etc., only water to drink.
- 2. Draw fasting glucose prior to administering glucose load. A fingerstick glucose may NOT be used as this is considered off-label use of the glucometer.  
**Note:** Assure the proper dose before administering. For pediatric patients the glucose load is 1.75 g/kg (maximum of 100 g) after a 12 hour fast. *Weight is based on ideal body weight.* Typically, a 2GTT is performed.
- 3. Give appropriate dose of glucose for the test ordered (see table above). Allow up to 15 minutes for ingestion. The first swallow is time zero. Nausea, dizziness and vomiting are rare, but should vomiting occur the test should be terminated. Notify the laboratory and provider if the test is terminated.
- 4. Patients should sit upright and quietly during the test. Slow walking is permitted, but vigorous exercise should be avoided. The patient should abstain from eating or drinking, although water may be allowed, during the test.
- 5. Collect venous blood samples (gold, red, green or grey top tube) at the appropriate time intervals ( $\pm 5$  mins) for the test ordered. The same tube type should be used for all collections from a single patient. Label each specimen with patient's name, medical record number or date of birth, date and time of collection and test interval (e.g., 1 hr). The clinical laboratory recommends the use of venous samples as whole blood capillary glucose concentrations can be 15% higher than plasma levels. Proceed with testing regardless of fasting glucose or other values during the test. Proper patient preparation before and during the test are important for patient safety and meaningful results. However, if the fasting glucose is a critical value, this will be called to the provider and proceeding with the tolerance test should be questioned.
- 6. Send each specimen to the Clinical Laboratory within 2 hours of collection for analysis. If gray top tubes are collected, all specimens can be sent to the laboratory after completion of the tolerance test. The laboratory will use a method specific for glucose.
- 7. The test should be interpreted using ADA criteria (see below).

**INTERPRETATION**

Normal Fasting Glucose: See B-Net Laboratory Manual

- A. Diagnostic Criteria for 2 HR GTT (2GTT) following 75 gram dose for adults: Diagnosis requires elevations to be documented on more than one occasion. See B-Net Laboratory Manual for Result Interpretation.
- B. Diagnostic Criteria for 3 HR GTT (3GTTL) following 100 gram dose for adults; See B-Net Laboratory Manual for Result Interpretation.
- C. Diagnostic Criteria for 5 HR GTT (5GTT) following 100 gram dose for adults; Used for reactive hypoglycemia. See B-Net Laboratory Manual for Result Interpretation.

**GROWTH HORMONE SUPPRESSION TEST**

**Note:** This test is performed by Endocrinology only.

This test is performed when there is a suspicion of acromegaly. Acromegaly is caused by excessive growth hormone (GH) secretion. Over production of GH may be due to a functioning pituitary tumor, or to ectopic secretion of GH Releasing Hormone. Over production of GH results in growth of bone and soft tissue and the syndrome acromegaly.

Normal subjects will show suppression of GH after oral administration of glucose. It is usually less than 5 ng/mL at 1-2 hours post dose. Most patients with acromegaly fail to show this degree of suppression and may show a paradoxical increase, regardless of the basal level after a 100g dose. The basal GH level does not correlate with the severity of clinical manifestations. In children, if the second blood sample is taken after the second hour, there may be increased levels from a rebound phenomenon due to the occurrence of reactive hypoglycemia.

UNITY CODE	GLUCOSE TESTING PERFORMED	USAGE
GTGH - LAB 24228	FASTING, ½, 1, 1½, 2 GLUCOSES AND GH	Growth Hormone Suppression Test (100g)

**GENERAL PROCEDURE**

1. Patient should be NPO after midnight the night before the test.
2. Medications should not be discontinued unless specified by the provider.
3. Verify the patient has fasted for 8-12 hours. Fasting includes abstinence from tobacco, coffee, tea, juice, alcohol, food, mints, gum, etc., only water to drink.
4. Administer 100 g PO dose of glucose. Allow up to 15 minutes for ingestion. The first swallow is time zero. Document the time the glucose dose was administered as a comment. Nausea, dizziness and vomiting are rare, but should vomiting occur the test should be terminated. Notify the laboratory and the provider if the test is terminated.
5. Patient should be supine for blood collections. Insert a 21G butterfly needle for blood collections.
6. Collect glucose and GH at baseline (before glucose dose), 30, 60, 90, 120 minutes post glucose dose. Glucose is collected in either a gold, red, green or grey top tube; GH is collected in a gold or red top tube.

**Note:** Both tests can be performed from the same tube if it is filled to capacity. Send each specimen to the Clinical Laboratory within 2 hours of collection for analysis. The laboratory will use a method specific for glucose.

Diagnostic criteria: See B-Net Online Laboratory Manual

Reference Ranges for Growth Hormone Suppression Test (GTGH) following 100 gram dose for adults:  
See b-Net Online Laboratory Manual.

## IMPLEMENTATION

It shall be the responsibility of the Clinical Laboratory Director and Manager, Laboratory Support Services to implement and ensure compliance to the policy. This will be done through staff education including:

1. Providing formal training to all new staff required to comply with the policy.
2. Communicating policy to all current provider, management and staff performing testing.
3. Ensuring placement of the policy in the Nursing Procedure Manual.
4. Overseeing, follow-up to ensure compliance of the policy within the individual clinical departments.

## ENFORCEMENT

The Clinical Laboratory Director and the Manager, Laboratory Support Services will be responsible for enforcement.

## DISTRIBUTION

It will be placed in The Laboratory General Procedure Manual, and as part of the Laboratory Manual on the Bassett Intranet.

## REVISION

It shall be the responsibility of the Clinical Laboratory Director and the Department of Endocrinology and/or Department of OB/GYN to revise this policy as warranted.

## REFERENCES

1. 2022 ADA Clinical Practice Recommendations. *Diabetes Care* 2022; 45 (Suppl 1).
2. ADA Standards of Medical Care in Diabetes -2022; *Clinical Diabetes* 2022; 40 (Suppl 1).
3. Definition and diagnosis of diabetes mellitus and intermediate hyperglycemia: Report of a WHO/IDF consultation. WHO Press. 2021.
4. American College of Obstetrics and Gynecology. Screening and diagnosis of gestational diabetes. Committee Opinion 190, February, 2018.