ORAL GLUCOSE TOLERANCE TEST
Document Number: CHEM-213.004

PURPOSE:

Hyperglycemia is the hallmark of diabetes mellitus. The common underlying defect is a deficiency of insulin secretion or action, which leads to the development of hyperglycemia. Hyperglycemic disorders can be classified as:

1) Type 1 Diabetes: Characterized by beta cell destruction, usually leading to absolute insulin deficiency. It has two forms: *Immune-Mediated Diabetes Mellitus* which results from a cellular mediated autoimmune destruction of the beta cells of the pancreas; and *Idiopathic Diabetes Mellitus* which refers to forms of the disease that have no known etiologies.
2) Type 2 diabetes: The most common form of diabetes mellitus (90-95% of patients). Most individuals with Type 2 DM have plasma insulin concentrations that are higher than normal but not sufficient to maintain a normal blood glucose concentration - relative deficiency of insulin activity.
3) Impaired glucose tolerance (IGT): These individuals have a slightly abnormal glucose tolerance but not sufficiently abnormal to be diagnostic of diabetes mellitus. They have a greater than normal risk for developing diabetes mellitus.
4) Gestational diabetes mellitus (GDM): Gestational diabetes is diagnosed when an abnormal glucose concentration is found for the first time during pregnancy. Early diagnosis is important so that the patient can be monitored and treatment can be instituted when necessary.

In the oral glucose tolerance test measurements of plasma or serum glucose are made before and after glucose is given orally. This test is most helpful in the following situations:

1) Diagnosis of gestational diabetes mellitus
2) Further evaluation of an individual with a borderline elevation of fasting or postprandial plasma glucose.

PATIENT PREPARATION:

The test should be performed in the AM after 3 days of unrestricted diet and activity and after a 10-16 hour fast. Water is permitted during the fasting period but coffee and smoking are not allowed.

For three days prior to the test omit medications known to affect glucose tolerance (e.g. thiazides, diphenylhydantoin, propranolol, corticosteroids, estrogens, salicylates and diuretics). Oral contraceptives should be omitted for one complete cycle prior to the test.

The presence of anorexia or any other condition precluding adequate food intake automatically invalidates the test.

Inactivity, such as bed rest, has been reported to reduce glucose tolerance. A glucose tolerance test thus should not be performed in non-ambulatory patients.

The test should not be done if the patient has had an illness during the prior two weeks.

SPECIMEN:

Blood should be drawn for glucose levels at each of the prescribed times. 0.5 ml serum or heparinized plasma accepted, store refrigerated. Minimum sample volume is 100 ul plasma or serum.

Urine samples do not need to be collected. Insulin levels may be requested by the physician. Serum for insulin assays should then be drawn along with each glucose sample.

REAGENTS AND EQUIPMENT:

SP Brand Orange 75 and 100 gm Glucose Tolerance Beverage: Contains 75 or 100 g dextrose (D-Glucose)(Source of Dextrose: Corn), citric acid, flavoring, 0.05% sodium benzoate and 0.01% propylparahydroxybenzoate as preservative. Do not freeze. Store at room temperature. Stable until expiration date on bottle.

75-g 2 HOUR ORAL GLUCOSE TOLLERANCE PROCEDURE (NON-PREGNANT):

1. Collect a fasting blood sample. Determine the fasting glucose. If the fasting glucose is within the range 75-125 mg/dl, proceed with the test. If the fasting glucose is >125 mg/dL, NPL should call the ordering physician and obtain their decision whether to proceed with the test or cancel it. NOTE: If the ordering physician is not available, contact a pathologist before proceeding with the test.

2. For an adult, give 75 grams of glucose tolerance beverage.

3. For a child, give 1.75 grams of glucose per kg body weight.* Convert the child's weight from lbs to kg by dividing the number of pounds by 2.2. Multiply this value by 1.75 grams to determine the dosage in grams of glucose. To convert dosage in grams to dosage in ml apply the following formula:

$$\text{Dosage in ml (see note)} = \frac{296 \text{ ml}}{100 \text{ gm}} \times \text{Dosage in grams}$$

NOTE: this formula applies to the 100 gm size of glucose beverage

*This calculation should be used if the child is less than 94 pounds. If they are 94 pounds or more, give the adult dose (75 grams).

4. Administer the glucose tolerance beverage in a single dose over 5 minutes. Begin timing the tolerance as soon as the patient has finished drinking.

5. Draw a blood sample for glucose at 2 hours.

6. If nausea, fainting, sweating or other autonomic nervous system over-activity occurs, draw a specimen for glucose immediately, discontinue the procedure and notify a pathologist.

7. The glucose tolerance test may be extended to 3, 4 or 5 hours if specifically requested by the physician. Each additional glucose must be test-requested in the LIS as an individual glucose with a comment added stating the number of hours post dose (e.g. "3 hours post-dose".)

NOTE:

1) Occasionally a patient may have symptoms of nausea, pallor, sweating, faintness, headache, etc. Take them into a drawing room, let them lie down, and observe them. Contact the provider if the symptoms worsen or the patient starts to vomit. If the patent vomits, the remaining draws must be discontinued.

REPORTING RESULTS:

The test code for a glucose tolerance test is GTOL.

Enter all glucose results into the computer.

Classification of Glucose Results (2023 ADA classifications)[6]

Patients may be classified into 3 categories based on the 2-hour post load glucose:

Age	Fasting Glucose	Patient Category
**See Glucose CHEM-178 for fasting glucose reference ranges		
Age	2-hr Post-load Glucose	Patient Category
<125 years	<140 mg/dl	Normal glucose tolerance
	≥140 mg/dl or <200 mg/dl	Impaired glucose tolerance
	≥200 mg/dl	Provisional diabetes mellitus
Critical Values: Refer to Critical values LAB148		

NOTE: The ADA has defined 3 criteria for the diagnosis of diabetes:[6]

- Symptoms of hyperglycemia or hyperglycemic crisis, and a random plasma glucose ≥200 mg/dl
- Fasting plasma glucose of ≥126 mg/dl (fasting is defined as no caloric intake for at least 8 hours)
- Oral glucose tolerance test value of ≥200 mg/dl at 2 hours after an appropriate glucose dose (e.g. 75 gm glucose in adults)

Unless there is a clear clinical diagnosis (e.g. patient in a hyperglycemic crisis or with a classic symptoms of hyperglycemia and a random plasma glucose ≥200 mg/dL), diagnosis requires two abnormal screening test results, either from the same sample, or in two separate test samples. If using two separate test samples, it is recommended that the second test, which may either be a repeat of the initial test, or a different test, be performed without delay.[6]

SCREEN FOR GESTATIONAL DIABETES

PRINCIPLE:

If individuals are not screened prior to pregnancy, universal early screening at <15 weeks of gestation for undiagnosed diabetes may be considered, particularly in populations with high prevalence of risk factors and undiagnosed diabetes in people of child bearing age. Standard diagnostic criteria for identify undiagnosed diabetes in early pregnancy are the same as those used in the non-pregnant population (see CHEM-178 Glucose).[6]

If early screening is negative, individuals should be rescreened for gestational diabetes between 24-28 weeks of gestation. Gestational diabetes can be diagnosed between 24-28 weeks gestations using either the one-step out two-step approach outlined below. NPL utilizes the two-step approach.[6]

1. One-step 75-g oral glucose tolerance test derived from the International Association of the Diabetes and Pregnancy Study Groups (IADPSG).
2. Two-step approach with a 50-g (non-fasting) screen followed by a 100-g oral glucose tolerance test for those who screen positive.

PATIENT PREPARATION:

Fasting is not required. During the one hour testing period the patient may drink water, but should not eat or drink anything else.

SPECIMEN:

Draw blood one hour following administration of the glucose challenge. Heparinized plasma or serum accepted, 0.5 ml refrigerated. Urine samples are not required.

REAGENTS AND EQUIPMENT:

SP Brand Orange 100 gm Glucose Tolerance Beverage: Contains 100 g dextrose (D-Glucose)(Source of Dextrose: Corn), citric acid, flavoring, 0.05% sodium benzoate and

0.01% propylparahydroxybenzoate as preservative. Do not freeze. Store at room temperature. Stable until expiration date on bottle.

50-g NON-FASTING ORAL GLUCOSE TOLERANCE TEST PROCEDURE:

1. Administer an oral 50 gm glucose load to the patient (148 ml of the 100 gram glucose tolerance beverage).

2. One hour later draw a blood sample for glucose.

REPORTING RESULTS:

The test code is GLUP1.

The following interpretive comment will be appended to the result:[6] "A glucose threshold value >140 mg/dl identifies approximately 82% of women with GDM. The yield is further increased to 93% by using a cutoff of >130 mg/dl. If ≥130 mg/dL, ADA recommends proceeding with a 100-g oral glucose tolerance test."

ORAL GLUCOSE TOLERANCE TEST FOR GESTATIONAL DIABETES MELLITUS

PATIENT PREPARATION:

This test should be performed in the morning after the patient has had 3 days of unrestricted diet and activity and after a 10-16 hour fast.
All medications known to affect glucose tolerance should be omitted.
This test may be ordered by the physician if the gestational screen is abnormal.

SPECIMEN:

Blood specimens should be drawn at the times specified in the procedure. 0.5 mL serum or heparinized plasma is acceptable. Store refrigerated. Minimum sample volume is 100 ul plasma or serum.

REAGENT:

SP Brand Orange 100 gm Glucose Tolerance Beverage: Contains 100g dextrose (D-Glucose)(Source of Dextrose: Corn), citric acid, flavoring, 0.05% sodium benzoate and

0.01% propylparahydroxybenzoate as preservative. Do not freeze. Store at room temperature. Stable until expiration date on bottle.

SP Brand Orange 75 gm Glucose Tolerance Beverage: Contains 75g dextrose (D-Glucose)(Source of Dextrose: Corn), citric acid, flavoring, 0.05% sodium benzoate and 0.01% propylparahydroxybenzoate as preservative. Do not freeze. Store at room temperature. Stable until expiration date on bottle.

100g 3 HOUR ORAL GLUCOSE TOLLERANCE PROCEDURE (GTOLP/GTOLR):

1. Draw a fasting blood glucose. See NOTES

2. Administer 100 gm of the glucose tolerance beverage to the patient (296 ml of the 100 gram glucose tolerance beverage). Have the patient finish the drink within 5 minutes. Note the time the patient starts to drink.

3. Draw blood for glucose determinations at 1 hour, 2 hours and 3 hours.

NOTES:

1. The 3-hour glucose tolerance for Gestational Diabetes should only be ordered if results of a previous 1-hour, 50-gram glucose challenge (GLUP1) were abnormal.

2. If the result of the previous GLUP1 for the patient was <200 mg/dL, it is not necessary to wait for the fasting glucose result before administering the glucola.

3. If the result of the previous GLUP1 for the patient was ≥200 mg/dL, do not administer the glucose tolerance beverage until the fasting glucose is complete. If the fasting result is <200 mg/dL, proceed with the test. If the fasting glucose is ≥200, the 100-gram tolerance test should be cancelled.

4. The patient is to remain at the lab for the duration of the test, unless the patient has been given approval from their provider. The patient may have small amounts of water only. They cannot smoke, chew gum, or consume any other liquids. Physical activity must be kept to a minimum.

5. Occasionally a patient may have symptoms of nausea, pallor, sweating, faintness, headache, etc. Take them into a drawing room, let them lie down, and observe them. Contact the provider if the symptoms worsen or the patient starts to vomit. If the patent vomits, the remaining draws must be discontinued.

REPORTING RESULTS:

The test code for this test is GTOLP/GTOLR.

The 2023 ADA criteria for diagnosis of gestational diabetes mellitus are:[6]

If any two of the four plasma glucose levels (fasting, 1, 2 and 3 hr) are elevated above the levels in the following table, a diagnosis of gestational diabetes may be made.

Age	Collection	Reference Range
< 125 years	Fasting	75 - 95 mg/dl
	1 hour	75 - 180 mg/dl
	2 hour	75 - 155 mg/dl
	3 hour	75 - 140 mg/dl
Critical Values: Refer to Critical values LAB148		

REFERENCES:

1. Henry, J.B., Ed., Clinical Diagnosis and Management by Laboratory Methods, 17th Ed., W. B. Saunders Co., Philadelphia, pp. 172-174, 1984.

2. Tietz, N.W., Ed., Fundamentals of Clinical Chemistry, 3rd Ed., W. B. Saunders Co., Philadelphia, pp. 431-435, 1987.

3. Diagnostic Criteria for Diabetes Mellitus. Report of the Expert Committee on the Diagnosis and Classification of Diabetes Mellitus. Diabetes Care 22:s5-s17, 1999.

4. Gestational Diabetes Mellitus, Diabetes Care Supplement, Volume 21 Supplement 1, American Diabetes Association: Clinical Practice Recommendations 1998.

5. Diagnosis and Classification of Diabetes Mellitus, Diabetes Care Supplement, Volume 30 Supplement 1, American Diabetes Association, Jan 2007.

6. ElSayed, Nuha A et al. “2. Classification and Diagnosis of Diabetes: Standards of Care in Diabetes-2023.” Diabetes care 46.Suppl 1 (2023): S111–S127.