PROCEDURES

The procedures below describe four glucose tolerance tests offered at the University of Chicago Medical Center Laboratories to screen for and diagnose diabetes and impaired glucose homeostasis.

A. GESTATIONAL DIABETES SCREEN (GDS)

Purpose/Principle

The GDS test is a screening test for possible diabetes in *pregnant patients*. Without regard to prior food intake, venous plasma glucose is measured, usually between 24 and 28 weeks of pregnancy, at an interval of one hour following an oral dose of 50 mg of glucose.

Equipment/Materials

- 1. Glucocrush® 50 gram glucose tolerance beverage or equivalent
- 2. Standard venipuncture equipment.
- 3. Gray-top Na-fluoride, BD Vacutainer tube or equivalent.

Procedure

To be followed in order as listed below:

- 1. Glucose beverage ingestion
 - a. Patient drinks the entire bottle of refrigerator-temperature Glucocrush® 50 solution from a paper cup within 5 minutes. The patient may pour the Glucocrush® 50 over ice if so desired.
 - b. Timing begins the moment the patient starts drinking.
 - c. Patient is to remain seated as much of the time as possible and is **not** to chew gum, smoke, drink or eat during the test.

2. Prepare for Blood Draw

- a. Patient will return for blood draw no more than 55 minutes after the ingestion of the Glucocrush® 50 solution.
- b. If the patient feels ill, or if she regurgitates, the phlebotomy staff should be notified immediately in order to contact the patient's physician for further instructions. If the physician instructs to have the test completed, this will be noted on the chemistry requisition.

3. Draw/Tube/Transport

- a. Sample is drawn using a Gray Top Tube, exactly 60 minutes after the patient started drinking the Glucocrush® 50.
- b. Sample tube is labeled "1 hr GDS" and sent immediately to Laboratory Service Center.

4. <u>Interpretation of Results</u>

Any result equal to or greater than **140 mg/dL**, is considered abnormal. This level is recommended as a threshold to indicate the need for a full diagnostic glucose tolerance test, e.g. the Gestational Glucose Tolerance Test (GGTT). The GDS should identify the majority of women with gestational diabetes mellitus (GDM), although some false negative may occur, especially in patients who are not fasting. (see references below.)

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B. GESTATIONAL GLUCOSE TOLERANCE TEST (GGTT)

Purpose/Principle

The <u>GGTT</u> is a diagnostic test for diabetes in <u>pregnant patients</u>, usually between 24 and 28 weeks of pregnancy. Venous plasma glucose is measured in a fasting patient before and at 1, 2, and 3 hour intervals after an oral dose of 100 gm of glucose.

Equipment/Materials

- 1. Glucocrush® 100 gram glucose tolerance beverage or equivalent
- 2. Standard venipuncture equipment.
- 3. Gray-top Na-fluoride, BD Vacutainer tube or equivalent.

Procedure

To be followed in order as listed below.

1. Patient Fasting

The patient is to eat no food after midnight prior to the test (fasting 8-14 hours before test).

2. Fasting Draw

- a. A fasting blood sample should be drawn into a gray top Vacutainer tube before Glucocrush® 100 ingestion.
- b. Sample is labeled GGTT Fasting or GGTT-Fast.

3. Glucose Beverage Ingestion

- a. Patient drinks the entire bottle of refrigerator-temperature Glucocrush® 100 solution from a paper cup within 5 minutes. The patient may pour the Glucocrush® 100 over ice if so desired.
- b. Timing begins the moment the patient starts drinking.
- c. Patient is to remain seated as much of the time as possible and is **not** to chew gum, smoke, drink or eat during the test. Ingestion of small amounts of water is acceptable.

4. Patient Instructions

- a. A copy of the draw schedule will be provided to the patient and she will be instructed to return for blood draws 5 minutes prior to the designated specimen collection times.
- b. If the patient feels ill, or if she regurgitates, the staff will be notified immediately in order to contact the patient's physician for further instructions. If the physician instructs to complete the test, this will be noted on the requisition

5. Additional Draws/Time Intervals

The remaining blood samples are also collected in gray top tubes and labeled as follows (in minutes after glucose ingestion began):

- At 1 hour (60 min. after glucose ingestion) label GGTT60
- At 2 hours (120 min. after glucose ingestion) label GGTT120
- At 3 hours (180 min. after glucose ingestion) label GGTT180

6. Storage/Transport

All blood samples are kept at room temperature until the test is completed. Then all the samples are sent together, immediately to Laboratory Service Center.

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7. Interpretation of Results

Any two results reaching or exceeding the following limits for a 100 gram oral glucose load are generally considered definitive for the diagnosis of gestational diabetes mellitus (GDM); however, exceptions can occur (see references below).:

- Fasting level 95 mg/dL
- 1 hour level of 180 mg/dL
- 2 hour level of 155 mg/dL
- 3 hour level of 140 mg/dL

C. TWO HOUR POST-PRANDIAL GLUCOSE SCREEN (PPG)

Purpose/Principle

This is a screening test for possible diabetes mellitus. The test is so named because it was common long ago to screen for diabetes mellitus by measuring blood glucose two hours following a meal. The test involves measuring plasma glucose from samples taken before and two hours after a 75 gram oral dose of glucose. Alternatively, some physicians prescribe a specified meal in place of the oral glucose.

Doses for children are based on patient weight (1.75 g/kg ideal body weight, not to exceed 75 gram). However, GTTs on children are ordinarily performed by the Department of Pediatrics in the University of Chicago Children's Hospital.

Equipment/Materials

- 1. Glucocrush® 75 gram glucose tolerance beverage or equivalent
- 2. Standard venipuncture equipment.
- 3. Gray-top Na-fluoride, BD Vacutainer tube or equivalent.

Procedure

To be followed in order as listed below.

1. Patient Fasting

The patient is to eat no food after midnight prior to the test (fasting 8-14 hours before test).

2. Fasting Draw

A fasting glucose sample is collected from the patient in a gray top (fluoride) Vacutainer tube prior to Glucocrush® 75 ingestion. The sample is labeled <u>Fasting</u> or PPG-Fast, with indication of collection time.

3. Glucose Beverage Ingestion

- a. Patient drinks the entire bottle of refrigerator-temperature Glucocrush® 100 solution from a paper cup within 5 minutes. The patient may pour the Glucocrush® 75 over ice if so desired.
- b. Timing begins the moment the patient starts drinking.
- c. In the case of regurgitation, the test is discontinued unless the ordering physician can be contacted and decides to have the test continued. In this case, a note should be made on the requisition that the test has been performed in spite of the patient's regurgitation, per doctor's instruction.
- d. **No** smoking, gum-chewing, drinking, or eating during test. The patient may imbibe small volumes of water. The patient should remain seated as much of the time as possible.

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4. Glucose Beverage Alternative

In some cases, the ordering physician will ask the patient to have a fasting sample drawn and then to ingest a specified meal and return for the 2-hour sample collection.

5. Blood Draw

- a. A non-fasting sample is drawn into a gray vacutainer tube 2 hours after finishing Dextol ingestion.
- b. Sample is labeled non-fasting or PPG-NONFAST, with indication of collection time.

6. Interpretation of Results

In a position statement of the American Diabetes Association (ADA) on the Diagnosis and Classification of Diabetes Mellitus in 2010 [Ref. 2], criteria for the provisional diagnosis of diabetes mellitus may be made when:

- a. Fasting plasma glucose level of $\geq 126 \text{ mg/dL}$ OR
- b. A 2 hour post load glucose level of ≥ 200 mg/dL during an oral glucose tolerance test (using a 75 gram glucose load) OR
 c. Any casual (random) glucose level of ≥ 200 mg/dL with symptoms of
- c. Any casual (random) glucose level of ≥ 200 mg/dL with symptoms of hyperglycemia or hyperglycemic crisis.

Intermediate states indicative of impaired glucose homeostasis that do not meet the diagnostic criteria for diabetes mellitus include:

- a. Impaired fasting glucose (IFG), where fasting plasma glucose levels are **100-125** mg/dL.
- b. Impaired glucose tolerance test (IGT), where 2 hour post 75 gram glucose load glucose levels are **140-199** mg/dL during an oral glucose tolerance test

D. GLUCOSE TOLERANCE TEST (GTT) FOR NONPREGNANT ADULTS

Purpose/Principle

This test is used primarily to diagnose diabetes mellitus. The test involves measuring venous plasma glucose in samples taken before and at varying intervals after a 75 gram dose of oral glucose given to an adult patient who is fasted 8-14 hours before the test.

Doses for children are based on patient weight (1.75 g/kg ideal body weight, not to exceed 75 grams). However, GTTs on children are ordinarily performed by the Department of Pediatrics in the University of Chicago Children's Hospital.

Equipment/Materials

- 1. Glucocrush® 75 gram glucose tolerance beverage or equivalent
- 2. Standard venipuncture equipment.
- 3. Gray-top Na-fluoride, BD Vacutainer tube or equivalent.

Procedure

To be followed in order as listed below.

1. Patient Fast

The patient is to eat no food after midnight prior to the test (fasting 8-14 hours before test).

2. <u>Fasting Draw</u>

A fasting blood sample should be drawn into a gray top Vacutainer tube before Glucocrush® 75 ingestion. Sample is labeled Fasting or GTT-FAST.

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3. Glucose Beverage Ingestion

- a. Patient drinks the entire bottle of refrigerator-temperature Glucocrush® 75 solution from a paper cup within 5 minutes. The patient may pour the Glucocrush® 75 over ice if so desired
- b. Timing begins the moment the patient starts drinking.

4. Patient Instructions

- a. A copy of the time schedule will be provided to the patient and any differences in collection times will be noted on the specimen's label.
- b. If patient feels ill, or regurgitates solution, the ordering physician will be notified immediately. In the case of regurgitation, the test is discontinued unless the ordering physician instructs to continue the test. All requisition and patient reports will contain information regarding this occurrence.

5. Additional Draws/Time Intervals

Remaining samples of blood are collected according to the following schedule (in minutes after glucose ingestion began):

- At 1/2 hour (30 min. after glucose ingestion) label GTT30
- At 1 hour (60 min. after glucose ingestion) label GTT60
- At 1-1/2 hours (90 min. after glucose ingestion) label GTT90
- At 2 hours (120 min. after glucose ingestion) label GTT120

[NOTE: If M.D. specifically orders, blood samples may continue to be obtained on an hourly schedule, up to 6 hours (360 minutes). Reactive hypoglycemia may necessitate the 5-6 hour test schedule.]

6. Results Reporting

In a position statement of the American Diabetes Association (ADA) on the Diagnosis and Classification of Diabetes Mellitus [Ref. 2], criteria for the provisional diagnosis of diabetes mellitus may be made when:

- a. Fasting plasma glucose level of ≥ 126 mg/dL <u>OR</u>
- b. A 2 hour post load glucose level of \geq 200 mg/dL during an oral glucose tolerance test (using a 75 gram glucose load) OR
- c. Any casual (random) glucose level of ≥ 200 mg/dL with symptoms of hyperglycemia or hyperglycemic crisis.

Intermediate states indicative of impaired glucose homeostasis that do not meet the diagnostic criteria for diabetes mellitus include:

- a. Impaired fasting glucose (IFG), where fasting plasma glucose levels are **100-125** mg/dL
- b. Impaired glucose tolerance test (IGT), where 2 hour post 75 gram glucose load glucose level are **140-199** mg/dL during an oral glucose tolerance test

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