

Established Name: Oral Glucose Tolerance Drink

Intended Use: Accessory to an In Vitro Diagnostic Oral Glucose Tolerance Test (OGTT) in the evaluation of diabetes mellitus and related disease conditions. Oral Glucose Tolerance Drinks provide a premeasured glucose load of either 50 grams, 75 grams or 100 grams. After the glucose load is consumed, measurements of blood glucose are drawn at specific time intervals to determine potential defects in insulin secretion and/or insulin action. Insulin is the hormone produced by the pancreas that moves glucose from the bloodstream into cells. 50 gram glucose loads are typically administered for the initial screening of gestational diabetes. 75 gram glucose loads are typically administered for the diagnosis of diabetes mellitus. 100 gram glucose loads are typically administered for the diagnosis of gestational diabetes.

Summary and Explanation of the Test: Oral Glucose Tolerance Drinks have been used for over thirty years to help diagnose Diabetes (Type 2), Gestational Diabetes and Impaired Glucose Tolerance (IGT). Clinical studies have led to the establishment of generally accepted criteria for diagnosis of diabetes. In the absence of unequivocal hyperglycemia with acute metabolic decompensation, the use of an OGTT should be confirmed on a different day by a second OGTT, the measurement of Fasting Plasma Glucose (FPG) or casual plasma glucose measurement as outlined by the WHO or the American Diabetes Association Expert Committee on Diagnosis and Classification of Diabetes Mellitus. [1,2,3,10]

Specimen Collection: The Oral Glucose Tolerance Drink (10 fluid ounce bottle) should be consumed within a 2-5 minute time period. When administering the beverage for the diagnosis of Gestational Diabetes or Diabetes Mellitus, the test should be done after an overnight fast of between 8 and 14 hours, during which water may be consumed and after at least three days of unrestricted diet (≥ 150 g carbohydrate per day) and unlimited physical activity. Consult test administrator for any restrictions before the consumption of Oral Glucose Tolerance Drink (50 g) when initially screening for gestational diabetes. Individuals should refrain from smoking, eating or strenuous activity during the test period. Healthcare providers can provide specific preparations required for individuals under the age of 18. Blood samples shall be drawn at specific time intervals based upon the test being performed. For children, the test load should be 1.75 grams of glucose per kg of body weight up to a total of 75 grams of glucose. [2,3,4,5,11]

Interfering Factors, Substances: The following conditions should be communicated to the healthcare provider since they may influence the accuracy of an OGTT. [2,6,7,8]

Acute stress	Nausea
Recent illness	Caffeine
Vigorous exercise	Smoking

Known Drugs that may cause glucose intolerance include:

Thiazide diuretics (e.g., hydrochlorothiazide)	Steroids
Beta-blockers (e.g., propranolol)	Phenytoin
Oral contraceptives	Oestrogens
Corticosteroids (e.g., prednisone)	Thyroxine
Some psychiatric medications	

Beverage Storage: Oral Glucose Test Drink should be stored at room temperature and may be chilled before administering. Beverage should be kept out of direct sunlight and high heat and humidity areas. Excessive exposure to high heat and humidity or direct sunlight may affect the taste and product stability. If product is frozen during shipping or storage the product must be thoroughly thawed before use. Product should be discarded if cap is missing or not properly sealed. Product should be free from precipitate. Contact distributor if product contents do not match label color. Product certification is available upon request. Please provide product lot number when requesting certification. Lot number and expiration date are printed on individual bottles.

Expected Test Values:

Gestational Diabetes (GDM): Women not at high risk for GDM typically undergo OGTT screening at 24-28 weeks of gestation. The initial screening is performed by measuring the plasma or serum glucose concentration 1 hour after a 50 gram glucose load. The diagnosis of GDM is based upon the administering of 100 gram glucose load. The initial screen with a threshold value > 140 mg/dl (7.8 mmol/l) identifies approximately 80% of women with GDM. The yield is increased to 90% by using a cutoff of > 130 mg/dl (7.2 mmol/l). The most accepted cutoff values for the diagnosis of GDM after administering the 100 gram glucose load are 1 hour 180 mg/dl (10.0 mmol/l), 2 hour 155 mg/dl (8.6 mmol/l) and 3 hour 140 mg/dl (7.8 mmol/l). Diabetes Mellitus (DM) and Impaired Glucose Tolerance (IGT): Accepted values for the diagnosis of DM and IGT are based upon the administering of a 75 gram glucose load.

2-h postload glucose < 140 mg/dl (7.8 mmol/l) = normal glucose tolerance
2-h postload glucose ≥ 140 mg/dl (7.8 mmol/l) and < 200 mg/dl (11.1 mmol/l) = IGT
2-h postload glucose ≥ 200 mg/dl (11.1 mmol/l) = provisional diagnosis of diabetes* (diagnosis must be confirmed on a different day as previously described) [3,4,5,9]

Performance Characteristics: Sensitivity and Specificity of OGTT screening

2-h OGTT venous glucose test with a cutoff point of 11.1 mmol/l has a sensitivity of 90-93% and specificity of 100%.
2-h OGTT capillary glucose test with a cutoff point of 11.1 mmol/l has a sensitivity of 69% and a specificity of 93%. [4]

Adverse Reactions and Warnings: Glucose load may cause nausea, vomiting, diarrhea or fainting. Product should be consumed under the direct supervision of a trained medical professional. Healthcare professionals should be contacted for further information regarding procedures and test results. Ingredients are listed on individual bottles.

Bibliography

- [1] National Diabetes Data Group. Classification and Diagnosis of Diabetes Mellitus. Diabetes 28, 1039-57, 1979
- [2] WHO Definition, Diagnosis and Classification of Diabetes Mellitus and its Complications. World Health Organization, Geneva. 1999
- [3] Gavin JR, et al: Report of the Expert Committee on the Diagnosis and Classification of Diabetes Mellitus. *Diabetes Care* 26:S5-S20, 2003
- [4] Engelgau MM, Vankat Narayan KM, Herman WH: Screening for Type 2 Diabetes. *Diabetes Care* 23:1563-1580, 2000
- [5] Coustan DR: Gestational Diabetes. National Institute of Health, 703-717
- [6] Netina S: Diabetes Mellitus. The Lippincott Manual of Nursing Practice. 6th ed. Lippincott-Raven, 1996, p. 736-737
- [7] Diagnostic Tests Handbook, Springhouse, 1987, p. 114-117
- [8] Brown TT: Glucose Tolerance Test. Medline Medical Encyclopedia 2002
- [9] Harris, MI: Classification, Diagnostic Criteria, and Screening for Diabetes. National Institute of Health, 15-36
- [10] Lebovitz: Diagnosis and Classification of Diabetes Mellitus and Related Disorders. 1999 p. 6-7
- [11] Jeffeat, L: Diabetes for Nurses. The Diagnosis and Classification of Diabetes Mellitus. 1999 p. 4-7

Product Distributor: Azer Scientific, 189 Twin County Road, Morgantown, PA 19543 610.524.5810
01/2/08

