









The Fresh Test™


Specifications for the 50-gram, 75-gram, 100-gram
Diagnostic Glucose Beverages



	Manufacturer		Lot Identification
	Unique Device Identification		Use by date (YYYY-MM-DD)
	Instructions For Use		Catalog Number
	Storage Conditions		Do not use if package is damaged.

DESCRIPTION: The Fresh Test™ is a diagnostic glucose beverage intended for patients who need to be screened for Diabetes Mellitus or Gestational Diabetes Mellitus. Use as directed by a physician. For use in the anhydrous 50-gram, 75-gram or 100-gram glucose load test/oral glucose tolerance test; oral consumption only.


INDICATIONS & USAGE: For use in the detection of (or screening for) glucose intolerance in the evaluation of diabetes mellitus and gestational diabetes mellitus.




 **WARNING:** Before use, inspect the product to ensure it has not been compromised. The patient should confirm that the correct amount of glucose (50-gram, 75-gram or 100-gram) is being used for their glucose tolerance test.

ADVERSE REACTIONS: Patients may experience some or all of the following: nausea, diarrhea, or fainting. For patients previously diagnosed with diabetes, do not consume unless directed by a physician.

Products manufactured by Fresh Test, LLC are manufactured in accordance with Class 2 Medical Device standards; labeled per title 21 CFR Part 820. All Fresh Test LLC products are protected with a USPTO provisional patent.

UNSPSC 41116206 Diagnostic beverage for laboratory testing; 85415101 Accessory to the glucose tolerance test. FDA 3017544399. FDA Regulation Code 862.1345. The Fresh Test™ 50-gram, 75-gram and 100-gram products are proprietary and have undergone studies to confirm that The Fresh Test™ glucose products perform according to the stated intended use.

 50g Glucose Powder 27102055; 50g Glucose Beverage 27102050.
75g Glucose Powder 27102056; 75g Glucose Beverage 27102058.
100g Glucose Powder 27102057; 100g Glucose Beverage 27102059.

 Consult the Instructions For Use printed on the individual units of The Fresh Test™. To request a Certificate of Analysis please reference the  Number or  Unique Device Identification.

INSTRUCTIONS FOR USE & INGREDIENT LIST

50-gram
Glucose Powder
P/N 27102055

Reconstitute
with water.

INSTRUCTIONS FOR USE: Consult a physician for screening protocols. Failure to follow the screening protocol can lead to inaccurate results. Mix the contents of this packet with 10 ounces of water. Mix for three minutes or until dissolved. Consume the 50-gram glucose beverage within 5 minutes. Failure to consume the entire beverage within 5 minutes can lead to inaccurate results. Per your provider and laboratory instruction, a plasma glucose measurement will be taken after 1-hour.

INGREDIENT LIST: Organic Dextrose (source: tapioca or corn), Crystallized Lemon (citric acid, lemon oil, lemon juice), Organic Peppermint Leaf.

50-gram
Glucose Beverage
P/N 27102050

INSTRUCTIONS FOR USE: Consult a physician for screening protocols. Failure to follow the screening protocol can lead to inaccurate results. Shake the beverage to ensure the product is well-mixed. For an enjoyable patient experience, have the product refrigerated. Consume this 50-gram glucose beverage within 5 minutes. Failure to consume the entire beverage within 5 minutes can lead to inaccurate results. Per your provider and laboratory instruction, a plasma glucose measurement will be taken after 1-hour.

INGREDIENT LIST: USP Purified Water, Organic Dextrose (source: tapioca or corn), Crystallized Lemon (citric acid, lemon oil, lemon juice), Organic Peppermint Extract.

75-gram
Glucose Powder
P/N 27102056

Reconstitute
with water.

INSTRUCTIONS FOR USE: Consult a physician for screening protocols. Per the American Diabetes Association, a 75-gram oral glucose tolerance test is to be administered while fasting. Failure to follow the screening protocol can lead to inaccurate results. Mix the contents of this packet with 10 ounces of water. Mix for three minutes or until dissolved. After a fasting plasma glucose measurement is performed, consume the 75-gram glucose beverage within 5 minutes. Failure to consume the entire beverage within 5 minutes can lead to inaccurate results. Per your provider and laboratory instruction, subsequent plasma glucose measurements will be taken at 1-hour and 2-hour.

INGREDIENT LIST: Organic Dextrose (source: tapioca or corn), Crystallized Lemon (citric acid, lemon oil, lemon juice), Organic Peppermint Leaf.

INSTRUCTIONS FOR USE & INGREDIENT LIST

75-gram
Glucose Beverage
P/N 27102058

INSTRUCTIONS FOR USE: Consult a physician for screening protocols. Per the American Diabetes Association, a 75-gram oral glucose tolerance test is to be administered while fasting. Failure to follow the screening protocol can lead to inaccurate results. Shake the beverage to ensure the product is well-mixed. For an enjoyable patient experience, have the product refrigerated. After a fasting plasma glucose measurement is performed, consume this 75-gram glucose beverage within 5 minutes. Failure to consume the entire beverage within 5 minutes can lead to inaccurate results. Per your provider and laboratory instruction, subsequent plasma glucose measurements will be taken at 1-hour and 2-hour.

INGREDIENT LIST: USP Purified Water, Organic Dextrose (source: tapioca or corn), Crystallized Lemon (citric acid, lemon oil, lemon juice), Organic Peppermint Extract.

100-gram
Glucose Powder
P/N 27102057
Reconstitute
with water.

INSTRUCTIONS FOR USE: Consult a physician for screening protocols. Per the American Diabetes Association, a 100-gram oral glucose tolerance test is to be administered while fasting. Failure to follow the screening protocol can lead to inaccurate results. Mix the contents of this packet with 10 ounces of water. Mix for three minutes or until dissolved. After a fasting plasma glucose measurement is performed, consume the 100-gram glucose beverage within 5 minutes. Failure to consume the entire beverage within 5 minutes can lead to inaccurate results. Per your provider and laboratory instruction, subsequent plasma glucose measurements will be taken at 1-hour, 2-hour and 3-hour.

INGREDIENT LIST: Organic Dextrose (source: tapioca or corn), Crystallized Lemon (citric acid, lemon oil, lemon juice), Organic Peppermint Leaf.

100-gram
Glucose Beverage
P/N 27102059

INSTRUCTIONS FOR USE: Consult a physician for screening protocols. Per the American Diabetes Association, a 100-gram oral glucose tolerance test is to be administered while fasting. Failure to follow the screening protocol can lead to inaccurate results. Shake the beverage to ensure the product is well-mixed. For an enjoyable patient experience, have the product refrigerated. After a fasting plasma glucose measurement is performed, consume this 100-gram glucose beverage within 5 minutes. Failure to consume the entire beverage within 5 minutes can lead to inaccurate results. Per your provider and laboratory instruction, subsequent plasma glucose measurements will be taken at 1-hour, 2-hour and 3-hour.

INGREDIENT LIST: USP Purified Water, Organic Dextrose (source: tapioca or corn), Crystallized Lemon (citric acid, lemon oil, lemon juice), Organic Peppermint Extract.

SPECIFICATIONS



Storage Requirements: Store at Room Temperature; between 2° - 30°C.



Shelf Life: Glucose Powder Line; 24 months.
Glucose Beverage Line; 16 months.

Flavor: Mint Lemonade

Allergens: Gluten, Dairy and Latex Free

Physical Appearance: White Crystalline Powder or Clear Translucent Beverage
*Color variation may occur due to the lemon and mint natural ingredients.

Void of the following potential irritants: BPA, BVO, GMOS, Artificial flavoring, Artificial dyes.

Dosage: The Fresh Test™ glucose products are manufactured in 50-gram, 75-gram and 100-gram dosages. Please confirm the amount of glucose prior to consumption.

ISO 17025 laboratory reports and Certificates of Analysis are available upon request. Please reference the Unique Device Identifier (UDI).

SAFETY DATA SHEET

Please be advised that The Fresh Test™ glucose tolerance beverage, all flavors and concentrations, do not require a Safety Data Sheet. The products are FDA Registered Class 2 Medical Devices and are therefore exempt from the OSHA Standard for Chemical Labeling. It is the responsibility of the user to determine the appropriateness and applicability to their situation.

HAZARD(S) IDENTIFICATION

Classification: This product is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200). The Fresh Test™ Glucose Beverages are FDA Registered Class 2 Medical Devices and are exempt from the OSHA standard for chemical labeling.

WARRANTY

Please visit thefreshtest.com for the return policy. Fresh Test, LLC should be notified immediately of any defective units.

MANUFACTURER



Fresh Test, LLC
Los Angeles CA 90066
www.thefreshtest.com

Phone 1-424-353-7889
Fax 1-310-943-2181

Serious incidents that occur with device use should be reported to Fresh Test, LLC and the competent authority of the Member State.
Made in the USA.

Product Code & Device Type ID: MRV 619.

UDI Identification Code: G219

For more information or technical support, please contact info@thefreshtest.com or visit www.thefreshtest.com.

REFERENCE

American Diabetes Association.
Classification and Diagnosis of Diabetes: Standards of Medical Care in Diabetes. Diabetes Care. 2021;44 (Supplement 1):S15. doi: 10.2337/dc21-5002.