DEXTROSE SOLUTION

IVD CE

PRODUCT CODE	DESCRIPTION
GP032	Dextrose Solution ORANGE 75 G
GP033	Dextrose Solution ORANGE 100 G
GP034	Dextrose Solution ORANGE 50 G

PRINCIPLE

The action mechanism of dextrose solutions for the glucose metabolism diagnosis is based on the normal physiological and biochemical processes of the organism. This dextrose solution intake causes a glucose overload in the blood from which the physiological capability of the organisms to regulate this glycaemia is evaluated. The Dextrose Solution has been carefully designed to offer a safe and a practical product to standardize glucose metabolization tests. They have been formulated to be pleasant for ingestion and to avoid the frequent nausea caused by these types of preparations. They are products with natural citrus flavorings and do not contain artificial colorings. The additives contained in the product do not have any contraindication according to the current food regulations in the European Union. They are presented in three different concentrations, 50, 75 and 100 g in order to adjust the exact glucose intake according to diagnosis to be cried out and the patient characteristics. Usually, the 50g is used for screening gestational diabetes; the one of 75g for the diagnosis of Diabetes mellitus and the one of 100g for the diagnosis of gestational diabetes.

DIAGNOSTIC USE

Glucose solution for oral use, intended for the performance of diagnostic tests related to glucose metabolism, for glucose tolerance test in the evaluation of diabetes mellitus and related diseases. Single test result cannot be used to make a clinical diagnosis. It should integrate clinical and laboratory data. It must be administered by a healthcare professional and under proper supervision.

REAGENT COMPOSITION DEXTROSE

DEXTROSE SOLUTION ORANGE 100 g

Citric acid anhydrous (E-330) 0.25 %
Preservative (E-202) 0.1 %
D- Glucose 50 %
Orange flavor 0.1 %

DEXTROSE SOLUTION ORANGE 75 g

Citric acid anhydrous (E-330) 0.25 %
Preservative (E-202) 0.1 %
D- Glucose 37.5 %
Orange flavor 0.1 %

All solutions have been prepared from conventional corn dextrose that does not contain wheat gluten, there is no risk of cross contamination with gluten residues or products that could contain them in the manufacturing process. Dextrose solution may contain traces of fructose (<0.2%).

METHOD OF ADMINISTRATION AND APPLICATIONS

The solutions are single-use only and ready to use. The method of use depends on the type of test to be performed, whether it is a glucose tolerance test, an O'Sullivan test or a Glucose Stimulation test. Each laboratory will determine how to perform these tests and how the dextrose solution should be used. The dose to be administered may vary depending on the age of the patient. These parameters will be indicated by the medical professional. As an example, for O'Sullivan test, orally administer a 200mL bottle of Dextrose Solution 50 (orange or lemon); Determine serum glucose at 60 minutes.

CONSERVATION AND STABILITY

Dextrose solutions are stable until the expiration date indicated on the label, when kept at room temperature.

Indications of reagent alteration: These solutions are transparent and free of suspended particles. If the bottle presents turbidity must be discarded.

SYMBOL ON LABELS

Symbols	Signify	Symbols	Signify
REF	Catalogue Number	SIZE	Pack Size
	Expiry Date	VOL	Volume
	Storage Condition	LOT	Lot Number
	Instruction for Use	IVD	In Vitro Diagnostics
	Manufacturing Date		Manufacturer
	Number of Tests	2	For Single Use Only
EC REP	EC Representative	CE	European conformity

REFERENCES

Defi nition, Diagnosis and Classifi cation of Diabetis Mellitus and its Complications. World Health Organization (1999). Screening for type 2 Diabetes. Clinical Daibetes vol.18 NO. 2 Spring (2000). Tiezt, NW., Textbook of Clinical Chemistry 5th Edition, W.B. Saunders, Philadelphia (2012). Young, D.S.; Eff ects of drugs on Clinical Laboratory Tests. 4th Ed. AACC Press. 2000.

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