Glucose – Instructions for use (IFU)

Distributed by: ISE S.r.l. CUSTOMISED SOLUTIONS FOR YOUR LABORATORY

IVD CE

6 x 50 mL • REF A-R0100000601

3 x 18,5 mL • REF R3330000003

INTENDED USE

Product for use in the quantitative determination in vitro of the concentration of the Glucose in human serum or plasma. The results of the test must always be interpreted in conjunction with the clinical context. For professional use only.

CLINICAL SIGNIFICANCE

Glucose is the result of the chemical decomposition of carbohydrates introduced in the diet and is the primary source of energy for the human organism. When the energetic intake is greater than the energy used, the glucose in excess is converted into fat and glycogen which will be deposited in the form of energy reserves, in the adipose tissue, in the liver and muscles. The glucose concentration in human blood is regulated, within a narrow range, by the action of regulatory hormones such as insulin, glucagon or epinephrine. The most widespread disorder of carbohydrate metabolism is diabetes mellitus, which is evidenced by high blood glucose levels.

PRINCIPLE

In accordance with Trinder's reaction, glucose oxidase (GOD) oxidates glucose to gluconic acid with the formation of hydrogen peroxide, which in the presence of peroxidase (POD), 4-aminophenazone and phenol gives rise to a coloured compound, the intensity of which is directly proportional to the glucose concentration in the sample.

$$\text{Glucose} + O_2 \xrightarrow{\text{GOD}} \text{Gluconic Acid} + H_2O_2$$

$$2H_2O_2 + 4-\text{Aminophenazone} + \text{Phenol} \xrightarrow{\text{POD}} \text{CouloredCompoud}$$

REAGENTS

A-R0100000601 - 6 x 50 mL

Reagent: n° 6 vials x 50.0 mL ready for use

R3330000003 - 3 x 18.5 mL

Reagent: n° 3 vials x 14.0 mL ready for use

Concentrations

Reagents:		
	Conc.	**U.M.**
Phosphate Buffer pH 7.4	200	mmol/L
Phenol	10.0	mmol/L
4-Aminophenazone	0.28	mmol/L
Glucose Oxidase (GOD)	20.000	U/L
Peroxidase (POD)	5.000	U/L
Sodium Azide	14.6	mmol/L

Precautions

Kit for professional laboratory use, used only by qualified and properly trained technical personnel, under the supervision of a doctor in charge of the laboratory. In addition to risk indications related to the active components, reagents may contain inactive components such as preservatives and detergents. The total concentration of these components is lower than the limits reported in the EC 1272/2008 Regulation and subsequent amendments and additions. However, it is recommended to handle reagents according to the standards of good laboratory practice

Reports of serious incidents

In the event of a serious incident in relation to the use of the device, please inform the manufacturer (via your distributor) and the competent authority of the European Union member state where the incident occurred. For other jurisdictions, reporting must be made in accordance with regulatory requirements. Reporting serious incidents helps provide more information about the safety of the diagnostic medical device.

Storage and stability

Store at 2 - 8°C and protect from direct light. When correctly stored, the reagents are stable up the expiry date reported on the label. A slight variation in the composition of the reagent may occur between batches, but this has no effect on the test results.
After opening, the vial R1 and R2 are stable 30 days if recapped immediately and protected from contamination, evaporation, direct light and stored at correct temperature.

Reagent Preparation

Liquid reagent ready for use. After opening the reagent is stable for 30 days if closed, stored at 2 - 8°C, and protect from direct light. Do not mix different baches.

SAMPLE COLLECTION

Type of sample and storage

Serum or EDTA-plasma samples should be used. Once the sample has been centrifuged it must be separated from the erythrocytes, thus avoiding the effect of glycolysis. If the sample is not separated or tested immediately, it is advisable to use a glycolysis inhibitor. Do not use haemolyzed samples. Samples prepared as described above can be stored for 8 hours at 25°C or 3 days at 4°C (1).

Precaution

All human samples must be handled and disposed of as potentially infectious materials.

PROCEDURE

Quality control

Control sera with known glucose concentration are commercially available for quality control, including certificates of analysis showing values and confidence limits. Normal and pathological control sera are available as "Normal control serum" cod. R0400000006 and "Pathological control serum" code R0400000106. The values obtained must be contained within the acceptability range. In case of incorrect results check the following points:

- Cleanliness of glassware.
- Wavelength setting.
- Expiration date of reagents.

Automation

Although this device has been developed and manufactured to be used by manual method and instrumental systems, it can also be used in combination with other instrumental devices that are able to meet the requirements indicated in the paragraph "Reaction conditions / Technique".
All applications that are not explicitly approved cannot be guaranteed in terms of performance and will therefore have to be evaluated by the user.

Calibration

For calibration use the kit "Multicalibrator" code R0300000006. For ISE srl instruments, calibration is recommended every 10 days.

Traceability:

The glucose value is visible in the insert of the calibration serum package.

Reaction conditions

Wavelenght (primary):	510 nm
Wavelength (secondary):	620 nm
Temperature:	37°C

Technique – Procedure with Reagent B as starter

Bring the reagents to the reaction temperature.

	U.M.	**Calib. Serum**	**Sample**	**Blanck**
Reagent	µL	1000	1000	1000
Calib. Serum	µL	10	-	-
Sample	µL	-	10	-
Blank	µL	-	-	10

Mix gently then incubate at 37°C for 10 minutes.
Read the absorbances of the sample and the calibrator, subtracting the absorbance of the reagent white.
The reaction volumes can be varied proportionally while the calculation remains unchanged.

Results

The concentration of glucose is obtained through the following:

$$\frac{\text{D.O. Sample}}{\text{D.O. Calib.Serum}} \times \text{Concentration Calibr.} = \text{Glucose mg/dL}$$

Materials included in the kit

Reagent as described.

Necessary materials not included in the kit

Controls and calibrators.

NORMAL VALUES

Serum or plasma:
70 - 110 mg/dL (3.88 – 6.10 mmol/L)
Urine:
< 0.5 g/24 h (< 2.8 mmol/L/24 h)
Each laboratory should calculate its own normal values on the basis of its local population.

ANALYTICAL CHARACTERISTICS / PERFORMANCE

Linearity

The method is linear up to 600 mg/dL of Glucose. If the value in the sample exceeds the linearity limit of the method, dilute the sample with physiological saline and multiply the result by the dilution factor.

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Accuracy-Recovery
Glucose added to a serum matrix containing known amounts of glucose gave an average recovery of 90.4%.

Interference
The high dilution of the sample with the reagent reduces to a minimum possible interference by lipids. In the case that these are present, the concentration must not exceed 300 mg/dL of Triglycerides. Bilirubin below 20 mg/dL does not interfere in the reaction. Haemoglobin influences the reaction at concentrations over 12.0 g/L. For other interfering substances, make reference to the bibliography reported below (5).

Precision of the method

Within-run precision					
Range	U.M.	Mean	S.D.	C.V. (%)	No.
Low	mg/dL	61.6	1.03	1.68	18
High	mg/dL	358	7.00	1.96	18
Between-run precision					
Range	U.M.	Mean	S.D.	C.V. (%)	No.
Low	mg/dL	61.6	1.78	2.89	18
High	mg/dL	358	10.04	2.80	18

Sensitivity
At λ 505 nm a concentration of about 2.0 mg/dL of Glucose.

Comparative method
The Glucose method was compared with a similar commercial method. Samples tested = No. 50; Y = 1.003x + 3.3; Correlation Coefficient r = 0.995.

Disposal of reagent
Disposal of reagents must be performed in accordance with the EC regulations regarding waste, or the local national or regional legislation.

Manufacturer:
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Symbols used in IFU and Packaging	
IVD In vitro diagnostic medical device vitro	Manufacturer
REF Catalogue Number	Instruction for use
LOT Lot Number	Temperature limitation
Expiration date	

References

1. Trinder P. Determination of Glucose in blood using glucose oxidase with an alternative oxygen acceptor. Ann. Clin. Biochem. 6: 24 (1969).
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3. Thomas L. (ed.), Clinical laboratory Results, 1st Edition, TH-Books Verlag Gesellaschaft mBH, Frankfurt/Main, Germany, 1998, pp. 131139.
4. Guder WG, Narayanan S., Wisser H., Zavata B. List of analytes; preanalytical variables. Brochure in: Samples from patient to the laboratory. Git Verlag GmbH, Darmstad, 1996.
5. Young D, Effects of drugs on clinical laboratory tests. 5st Edition, AACC Press, Washington, DC, 3-349 – 3-367, 2000.

REVISION	DATE	CHANGE
Rev.A	12/2022	New Issue for IVDR Regulation (UE) 2017/746 compliance