GENESIS

Instructions For Use

Glucose (GOD/PAP Method)

Cat no.	size
1105 101	2*100
1105 102	4*100
1105 103	2*250
1105 104	4*250

Symbols in Product Labeling

EC REP	Authorized Representative		Expiration date
IVD	For in-vitro diagnostic use		CAUTION, consult instructions for use
REF	Catalogue number		
LOT	Lot number		Manufactured by

INTENDED USE

The Glucose Reagent is intended for Quantitative diagnostic determination of Glucose in human serum and plasma

DIAGNOSTIC CHARACTERISTICS

Measurement of glucose concentration in serum or plasma is mainly used in diagnosis and monitoring of treatment in diabetes mellitus. Other applications are the detection of neonatal hypoglycemia, the exclusion of pancreatic islet cell carcinoma as well as the evaluation of carbohydrate metabolism in various diseases.

PRINCIPLE OF THE METHOD

Determination of glucose after enzymatic oxidation by glucose oxidase. The colorimetric indicator is quinoneimine, which is generated from 4-aminoantipyrine and phenol by hydrogen peroxide under the catalytic action of peroxidase (Trinder's reaction).

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

$$2H_2O_2 + \text{4-aminoantipyrine} + \text{Phenol} \xrightarrow{\text{POD}} \text{Quinoneimine}$$

COMPOSITION

Reagent(R)	
Phosphate buffer (pH 7.2)	250 mmol/L
Phenol	5 mmol/L
4-Aminoantipyrine	0.5 mmol/L
Glucose oxidase	≥ 15 kU/L
Peroxidase	≥ 1 kU/L
Standard(S)	100 mg/dL

STORAGE.

Store at 2-8ºC.

Reagent and Standard are stable until the expiry date shown on the Vial label when stored tightly closed and if contaminations are prevented during their use.

REAGENT PREPARATION

Reagent and Standard are provided ready to use.

ADDITIONAL EQUIPMENT

− Thermostatic water bath at 37ºC

− Analyzer, spectrophotometer able to read at 546 nm

SPECIMEN

1-Serum, heparin plasma or Flouride free of hemolysis.

2-Separate at the latest 1h after blood collection from cellular contents.

3-Stability after addition of a glycolytic inhibitor (NaF, KF):

1 Day at 20-25 °C

7 Days at 4 – 8 °C

4-Discard contaminated specimens.

Precautions and Warnings

Do not ingest or inhalate. In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.

PROCEDURE

1. Bring the Reagent to room temperature.
2. Pipette into labeled test tubes:

	Blank	Standard	Sample
Reagent (R)	1.0 mL	1.0 mL	1.0 mL
Standard (S)	-	10 µL	-
Sample	-	-	10 µL

3. Mix thoroughly and incubate the tubes for **20 minutes** at room temperature (16-25ºC) or for **10 minutes** at 37ºC.
4. Measure the absorbance (A) of the Standard and Sample at 546nm against the Blank. The color is stable for 1 hour.

CALCULATIONS

The Glucose concentration in the sample is calculated using the following general formula:

$$\frac{\text{A Sample}}{\text{A Standard}} \times \begin{matrix} 100 \\ 0.05551 \end{matrix} = \begin{matrix} \text{mg/dL Glucose} \\ \text{mmol/L Glucose} \end{matrix}$$

REFERENCE VALUES

Serum/plasma (Fasting)	70-110 mg/dl
Serum/plasma (Post prandial)	70-140 mg/dl
CSF	40-70 mg/dl

QUALITY CONTROL

It is recommended to use The Control Serum level I and II to verify the performance of the measurement procedure.

Each laboratory should establish its own internal Quality Control .

METROLOGICAL CHARACTERISTICS

Detection limit 1.0 mg/dL

Linearity limit: 500 mg/dL.

For higher values dilute sample **1/2** with physiological saline and repeat measurement.

Precision

− Repeatability (within run):

Inter-assay precision n = 20	Mean [mg/dl]	SD [mg/dl]	CV [%]
Sample 1	92.5	1.10	1.19
Sample 2	121	1.02	0.84
Sample 3	292	2.01	0.69

− Reproducibility (run to run):

Intra-assay precision n = 20	Mean [mg/dl]	SD [mg/dl]	CV [%]
Sample 1	94.2	1.12	1.74
Sample 2	122	1.57	1.28
Sample 3	296	4.41	1.49

INTERFERENCES

Ascorbic acid up to 15 mg/dl, bilirubin up to 40 mg/dl, hemoglobin up to 200 mg/dl and Lipemia up to 2000 mg/dl triglycerides observed no interference.

BIBLIOGRAPHY

1.Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, 4th ed. Burtis CA, Ashwood ER, Bruns DE. WB Saunders Co, 2005.

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CE

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