

Glucose (GOD – POD METHOD)

Diagnostic reagent for quantitative in vitro determination of glucose in serum or plasma on photometric systems.

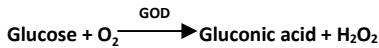
Reagent :

Reagent : Enzyme Solution

Standard: Glucose - 100 mg/dL

Principle

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).



Summary

Estimation of glucose concentration in serum or plasma is basically utilized in diagnosis and observing of treatment in diabetes mellitus. Different applications are the detection of neonatal hypoglycemia, the exclusion of pancreatic islet cell carcinoma and in addition the assessment of carbohydrate metabolism in various diseases.

Storage Instructions and Reagent Stability

Reagent and standard are stable up to the end of the indicated month of expiry, if stored at 2°– 8°C, protected from light and contamination is avoided. Do not freeze the reagents!

Composition

Reagent: Phosphate buffer- 100 mmol/L, GOD - > 8 U/L, POD - > 0.6 U/L, 4-Amino antipyrine - 0.160 gm/L, Phenol - 52 mmol/L, preservative and stabilizer.

Standard: Glucose - 100 mg/dL

Waste Management

Please refer to local legal requirements.

Reagent Preparation

The reagent and the standard are ready to use.

Materials required but not provided

NaCl solution 9 g/L

General laboratory equipment

Specimen

Serum, EDTA- plasma.

Serum or plasma should be separated from cells immediately if possible, else within one hour after collecting the sample. The sample can be stored up to 24 hours at 15° - 25°C after addition of glycolysis inhibitor (NaF ,KF), or up to seven days in closed vessels at 2°-8°C.

Assay Procedure

Wavelength 505 nm
Optical path 1 cm
Temperature 37°C
Measurement Against reagent blank

	Blank	Sample/Standard/ Calibrator
Sample/Standard/ Calibrator	-	10 µL
Distilled water	-	-
Reagent	1000 µL	1000 µL
Mix, incubate for 10 min. at 37°C. Read absorbance against reagent blank.		

Calculation

With standard or calibrator

$$\text{Glucose (mg/dL)} = \frac{\Delta A \text{ Sample}}{\Delta A \text{ Std. /Cal}} \times \text{Conc. of Std. /Cal (mg/dL)}$$

Quality Control

For internal quality normal and abnormal controls should be assayed with each batch of samples.

Each laboratory should establish corrective action in case of deviations in control recovery.

Warnings and Precautions

1. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
2. Take off immediately all contaminated clothing.
3. The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow. Avoid contact with skin and mucous membranes.
4. For professional use only!

Performance Characteristics

Measuring range

The test has been developed to determine glucose concentrations within a measuring range from 2 - 500 mg/dL. When values exceed this range samples should be diluted 1 + 4 with NaCl solution (9 g/L) and the result is multiplied by 5.

Linearity/Limit of Maximum Detection

The maximum limit of detection is 500 mg/dL.

Sensitivity/Limit of Detection

The lower limit of detection is 2 mg/dL.

Specificity/Interferences

No interference was observed by, Bilirubin up to 12 mg/dL and triglycerides up to 2000 mg/dL.

Precision

Intra-assay n = 20	Mean [mg/dL]	SD [mg/dL]	CV [%]
Sample 1	57.28	0.51	0.89
Sample 2	94.22	0.90	0.96
Sample 3	226.82	2.06	0.91

Inter-assay n = 20	Mean [mg/dL]	SD [mg/dL]	CV [%]
Sample 1	53.91	0.44	0.81
Sample 2	115.42	1.16	1.00
Sample 3	203.68	2.00	0.98

Method Comparison

A comparison of Precision Biomed Glucose (y) with a commercially available test (x) using 18 samples gave following results:
 $y = 1.000x - 0.104; r^2 = 0.999$

Reference Range

	[mg/dL]	[mmol/L]
Newborns:		
Cord blood	63 – 158	3.5 – 8.8
1 h	36 – 99	2.0 – 5.5
2 h	36 – 89	2.2 – 4.9
5 – 14 h	34 – 77	1.9 – 4.3
10 – 28 h	46 – 81	2.6 – 4.5
44 – 52 h	48 – 79	2.7 – 4.4

Children (fasting):

1 –6 years	74 – 127	4.1 – 7.0
7 –19 years	70 – 106	3.9 – 5.9

Adults(fasting):

Serum/plasma	70 – 115	3.9 – 6.4
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Note: It is recommended that each laboratory should establish its own reference range based on the patient population.

Quick Reference

Parameter	Glucose
Mode	End point
Wavelength	505(500-540) nm
Path length	10 mm
Temperature	37° C
Reagent volume	1000 µL
Sample volume	10 µL
Blank	Reagent Blank
Standard Conc.	100 mg/dL
Incubation time	10 min
Normal range (mg/dL)	Blood: 70 – 100
	Serum/plasma : 70 – 115
Linearity	500 mg/dL
Sensitivity	2 mg/dL

Literature

1. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p.131-7.
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5. Sacks DB, Bruns DE, Goldstein DE, Mac Laren NK, Mc Donald JM, Parrott M. Guidelines and recommendations for laboratory analysis in the diagnosis and management of diabetes mellitus. *Clin Chem* 2002; 48: 436-72.
6. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press2000.
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Version : GLU/00

Pack Size :

Cat No.	Configuration	Pack
GLU00500	Reagent - 5 x 100mL	500mL
	Standard – 1 x 3mL	



IVD In Vitro Diagnostic Use
See Pack Insert For Procedure
Single Use only
CE

Temperature Limit
Manufacturer's Address
Manufacturing Date
Expiry Date
LOT Lot Number



Manufactured in India by:

Precision Biomed Pvt. Ltd.

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