OBio...
Supporting Care to Cure
A Division of Orchard Medical

Glucose [GOD-POD Method]

IVD

Order Information

Cat. No.	Kit Configuration
OMR1083	Reagent: 4 x 40 mL

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.

Method

"GOD-POD": enzymatic photometric test

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).

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

$$2\,H_2O_2 + \text{4-Aminoantipyrine} + \text{Phenol} \xrightarrow{\text{POD}} \text{Quinoneimine} + 4\,H_2O$$

Reagents Storage Instructions and 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

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!

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

Application sheets for automated systems are available on request.

Wavelength	546 nm (500 – 550 nm)
Optical path	1 cm
Temperature	37°C
Measurement	Against reagent blank

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

Calculation

With standard or calibrator

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

Conversion factor

Glucose [mg/dL] x 0.0555 = Glucose [mmol/L]

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.

Performance Characteristics

Measuring range
The test has been developed to determine glucose concentrations within a measuring range from 10-500 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.

Specificity/Interferences

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

Sensitivity/Limit of Detection

The lower limit of detection is 10 mg/dL.

Linearity

The maximum limit of detection is 500 mg/dL.

Precision

Intra-assay n = 20	Mean [mg/dL]	SD [mg/dL]	CV [%]
Sample 1	205.66	0.55	0.27
Sample 2	86.90	0.57	0.66

Inter-assay n = 20	Mean [mg/dL]	SD [mg/dL]	CV [%]
Sample 1	253.69	1.32	0.52
Sample 2	100.75	0.88	0.87

Method Comparison

A comparison of Nucleus Diagnosys Glucose (y) with a commercially available test (x) using 18 samples gave following results:
$y = 0.973x + 2.392$; $r^2 = 0.998$

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

Each laboratory should check if the references range are transferable to its own patient population and determine own reference ranges if necessary.

Literature

1. **Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p.131-7.**
2. **Sacks DB. Carbohydrates. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B Saunders Company; 1999. p.750–808.**
3. **Barham D, Trinder P. An improved color reagent for the determination of blood glucose by the oxidase system. Analyst1972; 97:142-5.**
4. **Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p.30-1.**
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.**
7. **Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed2007; 45(9):1240–1243.**

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