Glucose (GOD)

DiaSystem Scandinavia AB

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

Order Information

Cat. No.	Kit size
01 00095 70 04 0125	R: 5 x 25 mL
01 00095 70 04 0600	R: 6 x 100 mL
01 00095 70 02 0240	R: 4 x 60 mL
01 00095 70 10 0160	R: 4 x 40 mL
CDT-GlucG	R: 4 x 30 mL
06 00108 70 04 0018	Glucose Standard 6x3 mL

Summary [1,2]

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.

Method

"GOD-PAP": 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) [3]

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

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

Reagents

Components and Concentrations

Phosphate buffer	pH 7.5	250 mmol/L
Phenol		5 mmol/L
4-Aminoantipyrine		0.5 mmol/L
Glucose oxidase	(GOD)	≥ 10 kU/L
Peroxidase	(POD)	≥ 1 kU/L
Standard:		100 mg/dL (5.55 mmol/L)

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 fr om light and contamination is avoided. Do not freeze the reagents! Note: It has to be mentioned, that the measurement is not influenced by occasionally occurring color changes, as long as the absorbance of the reagent is < 0.3 at 546 nm.

Warnings and Precautions

1. The reagent contains sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
2. In very rare cases, samples of patients with gammopathy might give falsified results [7].
3. N-acetylcysteine (NAC), acetaminophen and metamizole medication leads to falsely low results in patient samples.
4. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patients' medical history, clinical examinations and other findings.
5. For professional use only!

Waste Management

Please refer to local legal requirements.

Reagent Preparation

Reagent and standard are ready to use.

Materials required but not provided

NaCl solution 9 g/L
General laboratory equipment

Specimen

Serum, heparin plasma or EDTA plasma Separate at the latest 1h after blood collection from cellular contents.

Stability in plasma after addition of a glycolytic inhibitor (Fluoride, monoiodacetate, mannose) [4]:

2 days	at	20 – 25 °C
7 days	at	4 – 8 °C
1 day	at	-20 °C

Stability in serum (separated from cellular contents, hemolysis free) without adding a glycolytic inhibitor [2, 5]:

8 h	at	25 °C
72 h	at	4 °C

Only freeze once! Discard contaminated specimens!

Assay Procedure

Application sheets for automated systems are available on request.

Wavelength	500 nm, Hg 546 nm
Optical path	1 cm
Temperature	20 – 25 °C/37 °C
Measurement	Against reagent blank

	Blank	Sample or standard
Sample or standard	-	10 µL
Dist. water	10 µL	-
Reagent	1000 µL	1000 µL

Mix, incubate 20 min at 20 - 25 °C or 10 min at 37 °C.
Read absorbance against the blank within 60 min.

Calculation

With standard or calibrator

$$Glucose\ [mg/dL] = \frac{A\ Sample}{A\ Std/Cal} \times\ Conc.\ Std/Cal\ [mg/dL]$$

Conversion factor

Glucose [mg/dL] x 0.05551 = Glucose [mmol/L]

Glucose (GOD)

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Calibrators and Controls

For the calibration of automated photometric systems, DiaSystem UniCal CC calibrator is recommended. The assigned values of this calibrator have been made traceable to the reference method gas chromatography – isotope dilution mass spectrometry (GC-IDMS). For internal quality control, DiaSystem UniLab N and DiaSystem UniLab P controls should be assayed. Each laboratory should establish corrective action in case of deviations in control recovery

	Cat. No.	Kit size
UniCal CC	06 00122 70 04 0018	6 x 3 mL
UniLab N	07 00123 70 05 0030	6 x 5 mL
UniLab P	07 00124 70 05 0030	6 x 5 mL
UniLab Urine Level 1	07 00125 70 04 0030	6 x 5 mL
UniLab Urine Level 1	07 00126 70 04 0030	6 x 5 mL

Performance Characteristics

Measuring range

The test has been developed to determine glucose concentrations within a measuring range from 1 - 400 mg/dL (0.06 - 22.2 mmol/L). When values exceed this range samples should be diluted 1 + 4 with NaCl solution (9 g/L) and the result multiplied by 5.

Specificity/Interferences

No interference was observed by 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. For further information on interfering substances refer to Young DS [6].

Sensitivity/Limit of Detection

The lower limit of detection is 1 mg/dL.

Precision (at 37 °C)

Intra-assay precision n = 20	Mean [mg/dL]	SD [mg/dL]	CV [%]
Sample 1	43.9	0.30	0.67
Sample 2	89.5	0.72	0.81
Sample 3	297	2.45	0.82

Inter-assay precision n = 20	Mean [mg/dL]	SD [mg/dL]	CV [%]
Sample 1	45.7	0.40	0.87
Sample 2	92.3	0.79	0.85
Sample 3	301	2.09	0.70

Method Comparison

A comparison of DiaSystem Glucose (GOD) (y) with a commercially available test (x) using 78 samples gave following results: y = 1.00 x + 1.00 mg/dL; r= 0.996.

Reference Range [1]

	[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):		
Venous plasma	70 – 115	3.9 – 6.4

Each laboratory should check if reference ranges 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.
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3. Barham D, Trinder P. An improved color reagent for the determination of blood glucose by the oxidase system. Analyst 1972; 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 Press 2000.
7. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240-1243.

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