Glucose GOD FS*

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

Order Information

Cat. No.	Kit size			
1 2550 99 10 021	R 5 x	25 mL	+ 1 x	3 mL Standard
1 2550 99 10 026	R 6 x	100 mL		
1 2550 99 10 023	R 1 x	1000 mL		
1 2500 99 10 030	6 x	3 mL	Standard	

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

Reagent:		
Phosphate buffer	pH 7.5	250 mmol/L
Phenol		5 mmol/L
4-Aminoantipyrine		0.5 mmol/L
Glucose oxidase	(GOD)	≥ 15 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℃, protected from 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 patient's 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℃
7 days	at	4 – 8℃
1 day	at	–20℃

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

8 h	at	25℃
72 h	at	4℃

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℃/37℃
Measurement	Against reagent blank

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

Mix, incubate 10 min. at 20 – 25 ℃ or 5 min. at 37 ℃. Read absorbance against the blank within 60 min.

Calculation

With standard or calibrator

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

Conversion factor

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

Calibrators and Controls

For calibration of automated photometric systems, DiaSys TruCal U 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). DiaSys TruLab N and P controls should be assayed for internal quality control. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
TruCal U	5 9100 99 10 063	20 x 3 mL
	5 9100 99 10 064	6 x 3 mL
TruLab N	5 9000 99 10 062	20 x 5 mL
	5 9000 99 10 061	6 x 5 mL
TruLab P	5 9050 99 10 062	20 x 5 mL
	5 9050 99 10 061	6 x 5 mL

* fluid stable

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 (0,06 mmol/L).

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 DiaSys Glucose FS (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):		
Serum/plasma	70 – 115	3.9 – 6.4

Each laboratory should check if the 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.

Manufacturer

IVD CE

DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim Germany