Glucose GOD FS
Glucose Reagent Test Kit

Intended Use
Diagnostic reagent for in vitro quantitative determination of Glucose in human serum or plasma on photometric analyzers.

Reagent Kits

Item Code	Pack Size
125009934840	R: 4 x 60 mL

Summary
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).

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

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

Reagents

Components and Concentrations

Phospate buffer	100mmol/L
Glucose oxidase	>8 U/L
4-Amino Antipyrine	0.16mmol/L
D-Glucose	1 g/L
Peroxidase	0.6 U/L
Preservatives & Stabilizers	q.s.

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!

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 505 nm.

Waste Management
Please refer to local legal requirements.

Reagent Preparation
Reagent is ready to use.

Traceability
The assigned values of this calibrator have been made traceable to the reference method gas chromatography – isotope dilution mass spectrometry (GC-IDMS).

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):

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	492/505 nm
Optical path	1 cm
Temperature	20 – 25°C/37°C
Measurement	Against reagent blank

	Blank	Sample or Calibrator
Sample or Calibrator	-	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

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

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

Calibrators and Controls
For the 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). For internal quality control, DiaSys TruLab N and P controls should be assayed. Each laboratory should establish corrective action in case of deviations in control recovery.

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):		
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.

Clinical Interpretation
A blood glucose test is a blood test that screens for diabetes by measuring the level of glucose (sugar) in a person's blood. Normal blood glucose level (while fasting) range within 70 to 115 mg/dL

(3.9 to 6.4 mmol/L). Higher ranges could indicate pre-diabetes or diabetes.

Performance Characteristics

Measuring range

The test has been developed to determine glucose concentrations within a measuring range from 2 – 500 mg/dL (0.11 – 27.7 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.

Sensitivity/Limit of Detection

The lower limit of detection is 2 mg/dL.

Precision (at 37°C)

Intra-assay precision n = 20	Mean [mg/dL]	SD [mg/dL]	CV [%]
Sample 1	82.2	1.70	2.06
Sample 2	89.0	1.74	1.95
Sample 3	272.1	4.47	1.64

Inter-assay precision n = 20	Mean [mg/dL]	SD [mg/dL]	CV [%]
Sample 1	84.8	0.50	0.59
Sample 2	87.2	1.12	1.29
Sample 3	276	1.89	0.69

Method Comparison

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

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.
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!

Limitations

Hemolysis: No significant interference up to an H index of 200 mg/dL.
Icterus: No significant interference up to an I index of 40 mg/dL.
Lipemia: No significant interference up to an L index of 2000. There is poor correlation between the L index (corresponds to turbidity) and triglycerides concentration. See package insert for additional interference and cross-reactivity studies. The results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

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.

Notes on Symbols and Marks

	Consult instruction for use
	Use-by date
LOT	Batch code
REF	Catalogue number
	Caution
	Manufacturer
IVD	In vitro diagnostic medical device
	Temperature limit
	Do not reuse
CONT.	The pack contains
	Recycle
	Date of manufacture

ISO 9001, ISO 13485 and ICMED 13485 Certified Company

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Revision No. :01
Mar. 2022