Glucose GOD FS*

Order Information

Cat. No.	Kit size	
1 2500 99 10 021	6 x	25 mL
1 2500 99 10 026	6 x	100 mL
1 2500 99 10 023	1 x	1000 mL
1 2500 99 10 704	8 x	50 mL
1 2500 99 10 717	6 x	100 mL
1 2500 99 10 917	10 x	60 mL

Kits for use in conjunction with DiaSys CE applications.

Intended Use

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

Summary

Glucose is a monosaccharide and one of the most important carbohydrates for the human organism, as it is a metabolic substrate and a source of energy. The glucose concentration in blood is kept constant by several regulatory mechanisms. The main regulation occurs via secretion of insulin and glucagon. Primarily for the organism, the coverage of the steady glucose demand of the central nervous system with only minimal glucose reserves and the demand of erythrocytes is of major importance [1]. Glucose concentration in blood depends on nutritional status of an individual. Three conditions can be distinguished: Fasting status (8-10 h after the last nutritional intake), postprandial status (2-3 h after beginning of food intake) and postabsorptive status (6-12 h after beginning of food intake) [2]. Glucose measurement is recommended, whenever hypo- or hyperglycemia is suspected. Altered glucose can be the cause of many medical conditions. The main diseases causing elevated blood glucose levels are the different types of diabetes mellitus (DM). The primary purpose of glucose measurement is to diagnose DM respectively to define and monitor therapeutic interventions [2].

Method

"GOD-PAP": enzymatic photometric test

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

Storage and Stability

Reagent is stable up to the date of expiry indicated on the kit, if stored at 2 - 8°C and contamination is avoided. Do not freeze and protect from light.

The open-vial stability of the reagent is 18 months until expiry date.

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. The reagent contains material of biological origin. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice.
3. In very rare cases, samples of patients with gammopathy might give falsified results [4].
4. N-acetylcysteine (NAC), acetaminophen and metamizole medication leads to falsely low results in patient samples.
5. In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
6. Any serious incident related to the product must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is located.
7. Please refer to the safety data sheets (SDS) 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.
8. For professional use only.

Waste Management

Refer to local legal requirements for chemical disposal regulations as stated in the relevant SDS to determine the safe disposal.

Warning: Handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Reagent Preparation

The reagent is ready to use.

Materials Required

General laboratory equipment

Specimen

Human serum or heparin plasma

Only use suitable tubes or collection containers for specimen collection and preparation.

When using primary tubes, follow the manufacturer's instructions.

Separate at the latest 1h after blood collection from cellular contents.

Stability in serum/plasma after addition of a glycolytic inhibitor (fluoride, monoiodacetate, mannose) [5]:

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

Only freeze once. Discard contaminated specimens.

Stability in serum (separated from cellular contents, hemolysis free) without adding a glycolytic inhibitor [6,7]:

8 h	at	25°C
72 h	at	4°C

Discard contaminated specimens.

Assay Procedure

Basic settings for respons®910

Wavelength	508/700 nm
Temperature	37°C
Measurement	Endpoint
Sample/Calibrator	2.0 µL
Reagent	180 µL
Addition reagent	04:24 min
Absorbance 1	-00:12 min
Absorbance 2	09:48 min
Calibration	Linear

Calculation

With Calibrator

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

Conversion Factor

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

Calibrators and Controls

DiaSys TruCal U is recommended for calibration. Calibrator values have been made traceable to the reference method gas chromatography – isotope dilution mass spectrometry (GC-IDMS). Glucose Standard FS may be used alternatively for calibration. Use DiaSys TruLab N and P for internal quality control. Quality control must be performed after calibration. Control intervals and limits have to be adapted to the individual requirements of each laboratory. Results must be within the defined ranges. Follow the relevant legal requirements and guidelines. 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
Glucose Standard FS	1 2500 99 10 030	6	x	3 mL

Performance Characteristics

Data evaluated on respons®910

Measuring range from 0.43 mg/dL up to 500 mg/dL, linearity is given within ± 5%.
In case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.

Limit of detection**	0.43 mg/dL
Limit of quantitation**	0.43 mg/dL

Interference by	Interferences ≤ 10% up to	Analyte concentration [mg/dL]
Ascorbic acid	18 mg/dL	183
Bilirubin (conjugated)	15 mg/dL	75.8
	20 mg/dL	115
Bilirubin (unconjugated)	30 mg/dL	82.1
	30 mg/dL	131
Hemolysis	200 mg/dL	87.4
	200 mg/dL	119
Lipemia (triglycerides)	1500 mg/dL	42.1
	1500 mg/dL	126

For further information on interfering substances, refer to the literature [8-10].

Precision			
Repeatability (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	44.1	97.5	280
CV [%]	2.53	2.14	2.02
Between day (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	45.7	99.5	280
CV [%]	1.58	2.61	2.32

Method comparison (n=142)	
Test x	DiaSys Glucose GOD FS (Hitachi 917)
Test y	DiaSys Glucose GOD FS (respons®910)
Slope	1.01
Intercept	-0.394 mg/dL
Coefficient of correlation	0.999

** according to CLSI document EP17-A, Vol. 24, No. 34

Reference Range [2]

	[mg/dL]	[mmol/L]
Newborns		
Cord blood	63 – 158	3.5 – 8.8
1 h	36 – 99	2.0 – 5.5
2 h	39 – 89	2.2 – 4.9
5 – 14 h	34 – 77	1.9 – 4.3
20 – 28 h	46 – 81	2.6 – 4.5
44 – 52 h	48 – 79	2.7 – 4.4
Children (fasting)	60 – 99	3.3 – 5.5
Adults (fasting)	60 – 95	3.3 – 5.3

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

Literature

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Additions and/or changes in the document are highlighted in grey. Deletions are communicated via customer info by stating the edition no. of the package insert/instruction for use.

IVD CE

DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim
Germany
www.diasys-diagnostics.com

* Fluid Stable