

Glucose GOD FS*

Diagnostic reagent for quantitative in vitro determination of glucose in serum or plasma on DiaSys respons[®] 910

Order Information

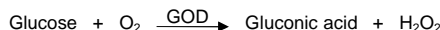
Cat. No. 1 2500 99 10 923
4 containers for 200 tests each

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) [1].



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 Instructions and Reagent Stability

The reagent is stable up to the end of the indicated month of expiry, if stored at 2 – 8 °C, protected from light and contamination is avoided. DiaSys respons containers provide protection from light. Do not freeze the reagent!

Warnings and Precautions

- The reagent contains sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
- In very rare cases, samples of patients with gammopathy might give falsified results.
- 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.

Waste Management

Please refer to local legal requirements.

Reagent Preparation

The reagent is ready to use. The bottles are placed directly into the reagent rotor.

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]:

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 [3,4]:

8 h	at	25 °C
72 h	at	4 °C

Discard contaminated specimens. Freeze only once.

Calibrators and Controls

For the calibration the 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.

	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
	5 9050 99 10 062	20 x 5 mL
TruLab P	5 9050 99 10 061	6 x 5 mL

Performance Characteristics

Measuring range up to 400 mg/dL glucose (in case of higher concentrations re-measure samples after manual dilution or use rerun function)	
Limit of detection**	3 mg/dL glucose
On-board stability	6 weeks
Calibration stability	6 weeks

Interfering substance	Interferences < 10%	Glucose [mg/dL]
Ascorbate	up to 18 mg/dL	183
Hemoglobin	up to 200 mg/dL	87.4
	up to 200 mg/dL	119
Bilirubin, conjugated	up to 15 mg/dL	75.8
	up to 20 mg/dL	115
Bilirubin, unconjugated	up to 30 mg/dL	82.1
	up to 30 mg/dL	131
Lipemia (triglycerides)	up to 1500 mg/dL	42.1
	up to 1500 mg/dL	126

For further information on interfering substances refer to Young DS [5].

Precision

Within run (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	44.1	97.5	280
Coefficient of variation [%]	2.53	2.14	2.02
Between run (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	45.7	99.5	280
Coefficient of variation [%]	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	1.011
Intercept	-0.394 mg/dL
Coefficient of correlation	0.999

** according to NCCLS document EP17-A, vol. 24, no. 34

Conversion factor

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

Reference Range [6]

	[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 year(s)	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 the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Literature

- Barham D, Trinder P. An improved color reagent for the determination of blood glucose by the oxidase system. *Analyst* 1972; 97: 142-5.
- Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 30-1.
- 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.
- 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.
- 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.
- Thomas L. *Clinical Laboratory Diagnostics*. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 131-7.

Manufacturer

DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim Germany



Glucose GOD FS 10'

Application for serum and plasma samples

This application was set up and evaluated by DiaSys. It is based on the standard equipment at that time and does not apply to any equipment modifications undertaken by unqualified personnel

Identification	
This method is usable for analysis:	Yes
Name:	GLUC
Shortcut:	
Reagent barcode reference:	036
Host reference:	

Technic	
Type:	Endpoint
First reagent:[μ L]	180
Blanc correction	Yes
Second reagent:[μ L]	
Blanc correction	
Main wavelength:[nm]	508
Secondary wavelength:[nm]	700
Polychromatic factor:	1.000
1 st reading time [min:sec]	(-00:12)
Last reading time [min:sec]	09:48
Reaction way:	Increasing
Linear Kinetics	
Substrate depletion: absorbance limit	
Linearity: Maximum deviation [%]	
Fixed Time Kinetics	
Substrate depletion: absorbance limit	
Endpoint	
Stability: largest remaining slope	-
Prozone Limit [%]	-

Sample	
Diluent	NaCl
Concentration technical limits-Lower	1
Concentration technical limits-Upper	400
SERUM	
Normal volume [μ L]	2
Normal dilution (factor)	1
Below normal volume [μ L]	4
Below normal dilution (factor)	1
Above normal volume [μ L]	2
Above normal dilution (factor)	6
URIN	
Normal volume [μ L]	2
Normal dilution (factor)	1
Below normal volume [μ L]	4
Below normal dilution (factor)	1
Above normal volume [μ L]	2
Above normal dilution (factor)	6
PLASMA	
Normal volume [μ L]	2
Normal dilution (factor)	1
Below normal volume [μ L]	4
Below normal dilution (factor)	1
Above normal volume [μ L]	2
Above normal dilution (factor)	6
CSF	
Normal volume [μ L]	2
Normal dilution (factor)	1
Below normal volume [μ L]	4
Below normal dilution (factor)	1
Above normal volume [μ L]	2
Above normal dilution (factor)	6

Results	
Decimals	1
Units	mg/dL
Correlation factor-Offset	0.000
Correlation factor-Slope	1.000

Range	
Genre	All
Age	
SERUM	>=70 <=115
URINE	
PLASMA	>=70 <=115
CSF	
Genre	
Age	
SERUM	
URINE	
PLASMA	
CSF	

Contaminants	
Contaminant 1	
Wash with	
Cycle	
Volume [μ L]	
Contaminant 2	
Wash with	
Cycle	
Volume [μ L]	

Calibrators details	
Calibrator list	Concentration
Cal. 1	0
Cal. 2	*
Cal. 3	*
Cal. 4	*
Cal. 5	*
Cal. 6	*
Max delta abs.	
Cal. 1	0.015
Cal. 2	0.040
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	
Drift limit [%]	0.8
Calculations	
Model	X degree
Degree	1

* Enter calibrator value