respons®920

Glucose GOD FS*

Diagnostic reagent for quantitative in vitro determination of glucose in serum or plasma on DiaSys respons®920

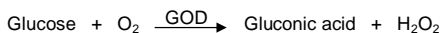## Order Information

Cat. No. 1 2500 99 10 923
4 containers for 200 determinations 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].

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

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

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 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

1. The reagent contains sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
2. To avoid carryover interference, please take care of efficient washing especially after use of interfering reagents. Please refer to the DiaSys respons®920 Carryover Pair Table. Carryover pairs and automated washing steps with the recommended cleaning solution can be specified in the system software. Please refer to the user manual.
3. In very rare cases, samples of patients with gammopathy might give falsified results [7].
4. N-acetylcysteine (NAC), acetaminophen and metamizole medication leads to falsely low results in patient samples.
5. 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.
6. For professional use only!

Waste Management

Please refer to local legal requirements.

Reagent Preparation

The reagent is ready to use. Place bottles 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

DiaSys TruCal U calibrator is recommended for calibration. 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
TruLab P	5 9050 99 10 062	20	x	5 mL
	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 with NaCl solution (9 g/L) or use rerun function).	
Limit of detection**	1 mg/dL glucose
On-board stability	4 weeks
Calibration stability	4 weeks

Interferences < 10% by	
Ascorbate up to 18 mg/dL	
Hemoglobin up to 700 mg/dL	
Bilirubin up to 24 mg/dL	
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]	53.4	97.7	307
Coefficient of variation [%]	0.84	0.93	0.72
Between run (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	53.5	93.0	296
Coefficient of variation [%]	1.74	2.25	1.23

Method comparison (n=110)	
Test x	DiaSys Glucose GOD FS (Hitachi 917)
Test y	DiaSys Glucose GOD FS (respons®920)
Slope	0.994
Intercept	0.129 mg/dL
Coefficient of correlation	0.998

** lowest measurable concentration which can be distinguished from zero mean + 3 SD (n=20) of an analyte free specimen

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

1. Barham D, Trinder P. An improved color reagent for the determination of blood glucose by the oxidase system. Analyst 1972; 97: 142-5.
2. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 30-1.
3. 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.
4. 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.
5. 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.
6. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 131-7.
7. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240–1243.

Manufacturer

IVD CE

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respons®920

Glucose GOD FS

Application for serum and plasma

Test Details		Test Volumes		Reference Ranges	
Test	: GLUC			Auto Rerun	☐
Report Name	: Glucose			Online Calibration	☐
Unit	: mg/dL	Decimal Places	: 1	Cuvette Wash	☐
Wavelength-Primary	: 505	Secondary	: 700	Total Reagents	: 1
Assay Type	: 1-Point	Curve Type	: Linear	Reagent R1	: GLUC R1
M1 Start	: 0	M1 End	: 0	Reagent R2	:
M2 Start	: 33	M2 End	: 33		
Sample Replicates	: 1	Standard Replicates	: 3	Consumables/Calibrators:	
Control Replicates	: 1	Control Interval	: 0	Blank/Level 0	0
Reaction Direction	: Increasing	React. Abs. Limit	: 0.00	Calibrator 1	*
Prozone Limit %	: 0	Prozone Check	: Lower		
Linearity Limit %	: 0	Delta Abs./Min.	: 0.00		
Technical Minimum	: 1.00	Technical Maximum	: 400.00		
Y = aX + b a=	: 1.00	b=	: 0.00		

* Enter calibrator value.

Test Details		Test Volumes	Reference Ranges
Test	: GLUC		
Sample Type	: Serum		

Sample Volumes

Normal	: 2.00 µL	Dilution Ratio	: 1	X
Increase	: 4.00 µL	Dilution Ratio	: 1	X
Decrease	: 2.00 µL	Dilution Ratio	: 2	X
Standard Volume	: 2.00 µL			

Reagent Volumes and Stirrer Speed

RGT-1 Volume	: 180 µL	R1 Stirrer Speed	: High
RGT-2 Volume	: µL	R2 Stirrer Speed	:

Sample Types
☑ Serum
☐ Urine
☐ CSF
☑ Plasma
☐ Whole Blood
☐ Other

Test Details		Test Volumes	Reference Ranges
Test	: GLUC		
Sample Type	: Serum		
Reference Range	: DEFAULT		
Category	: Male		

Reference Range

	Lower Limit (mg/dL)	Upper Limit (mg/dL)
Normal	: 70.00	115.00
Panic	: 0.00	0.00

Sample Types
☑ Serum
☐ Urine
☐ CSF
☑ Plasma
☐ Whole Blood
☐ Other