Glucose

Reagent for quantitative In-vitro-determination of glucose in blood and serum / plasma

GLU 142

Order No. **GLU 142**
Content: 40 tests

Method
GOD-PAP method, modified

Sample material
Capillary or venous blood which has been treated with di-potassium-EDTA to prevent coagulation, serum, heparinized or EDTA plasma.
Blood should be pipetted immediately into buffer solution. Blood will be completely and immediately haemolyzed by the haemolyzing reagent.
Stability of glucose in the haemolyzing reagent solution:
at +2°C to +8°C: 8 hours
at +15°C to +25°C: 4 hours
Stability of glucose in serum or plasma which has been prepared within 30 minutes: at +2°C to +8°C: 24 hours

Reagent
Contents / concentrations:
1. Starter reagent (caps in PE-bottle)
   Glucose oxidase (GOD) >120 kU/L, Peroxidase (POD) >2.5 kU/L
2. Buffer solution (pre-portioned in round cuvettes)
   Mutarotase > 1.0 kU/L, 2.4-Dichlorophenol 0.6 mmol/L, 4-Amino-phenazone 0.25 mmol/L, Sodium azide < 0.1 %, Triton X-100 < 1%, Phosphate buffer 0.1 mol/L, pH 7.8

Safety information
The buffer solution (round cuvette) contains sodium azide (< 0.1%) as preserving agent and Triton X-100. Do not swallow and avoid contact with skin and mucous membranes.
If desired a safety data sheet will be provided.[1)]

Storage and shelf life
The test reagents can be kept at a temperature between +2°C and +8°C until the expiry date indicated on the packaging.

Measurement conditions

Measurement device:	Diaglobal Photometer
Meas. wavelength:	520nm, 546nm
Temperature:	Room temperature

The algorithms to compute the glucose concentration are coded in the above-named photometers. Diaglobal Photometers are plasma-calibrated up to version V5.9

Measurement range
Serum/plasma: 20 - 600 mg/dL (1.11 - 33.3 mmol/L)
Blood: 30 - 600 mg/dL (1.67 - 33.3 mmol/L)

Working instructions

Pipette into round cuvette:	
	Analysis
Blood or serum/plasma	10 µL
Mix thoroughly.	

Diaglobal Photometer
- Select the <**GLU**> test
- Insert analysis cuvette (blank value)
- Screw the cap from PE-bottle onto the cuvette, dissolve the starter reagent by inverting several times.
- Press [ON/ENTER]
- Insert analysis cuvette again
- Wait 2 min. for result

Dr. Lange Photometer
- Select the <**Gluc**> test
- Screw the cap from PE-bottle onto cuvette, do not mix
- Insert cuvette, press key <**Gluc**> and [*] respectively Take the cuvette from the Photometer at display <4>
- Display <5-4-3-2-1-0>, invert cuvette at <2-1-0> at each signal
- Insert analysis cuvette again
- Wait 2 min. for result

Quality assurance
For quality assurance we recommend our glucose control solution GLU QS.

Reference values[2)]

Fasting	mg/dL	mmol/L
Blood	55 - 100	3.05 - 5.55
Serum/plasma	55 - 115	3.05 - 6.38

Bibliography

1. http://www.diaglobal.de/de/service/downloads/index.html
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3. Neumann G, Pfützner A, Hottenrott K. Alles unter Kontrolle. 6th edition. Aachen: Meyer und Meyer Verlag 2000: 158
4. Barhan D, Trinder P. An improved colour reagent for the determination of blood glucose by the oxidase system.
5. Ziegenhorn J. In: Bergmeyer HU. Grundlagen der enzymatischen Analyse. Weinheim:Verlag Chemie, 1977:83
6. Sonntag O. Arzneimittelinterferenzen. Stuttgart, New York: Thieme Verlag, 1985:37
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Summary

Glucose is the pivotal substance of the carbohydrate metabolism. It is storaged as glycogen both in the muscle and liver. The glucose concentration in the blood is regulated hormonally and is kept constant in narrow limits if the person is healthy. Disorders are expressed in form of the diabetes mellitus.

Indications / diagnostic significance[2)]
-Recognition of a diabetic metabolism disorder
-Therapeutic control of the diabetes mellitus as well as monitoring the patient's self-control by the physician
In the sports area, the determination of glucose provides valuable indication of the adequate nutrition during the training and tournament[3)].

In order to quantify the glucose concentration in the blood enzymatical methods are applied exclusively nowadays.[2)] Besides the hexokinase UV method, particularly the glucose oxidase (GOD) methods have gained prevalence. When using these methods glucose becomes oxidised in gluconic acid by means of GOD. Here, H_2O_2 is generated which is determined either amperometrically or photometrically and reflecto-metrically respectively after conversion with a chromogen.

Measurement principle
The GLU 142 test uses the PAP indicator system.[4)] Furthermore the reagent contains mutarotase, an enzyme which accelerates the adjustment of the balance between α- and β-D-Glucose.

$$\alpha\text{-D-Glucose} \xrightleftharpoons{\text{Mutarotase}} \beta\text{-D-Glucose}$$

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

$$H_2O_2 + \text{4-Aminophenazone} + \text{2.4-Dichlorophenol} \xrightarrow{\text{POD}} \text{Quinonimine dye (red)}$$

The concentration of the quinonimine dye is a measure for the glucose concentration in the blood and is measured at 520 nm or 546 nm (depending on device). The final value, which appears after approximately 6 to 10 minutes, is calculated from several measuring points by means of a common functional correlation so that the result is available already after 2 minutes.[5)]

Performance parameters

Specificity / interferences
Neither uric acid, ascorbic acid, glutathione in physiological concentrations nor bilirubin (up to 12 mg/dL), lipaemie (triglycerides up tp 2000 mg/dL) as well as high and low haemoglobin levels will interfere with the determination. Pharmaceutical interferences: low values due to Methyldopa (>7mg/L), Novaminsulfon (>200 mg/L), and Tetracycline (>20 mg/L in concentrations above the therapeutic field. [6)]

Inaccuracy
The reproducibility was checked using human and control samples.

In series [n = 20]	Average [mg/dL]	Standard deviation [mg/dL]	VK [%]
EDTA blood 1	95.3	1.9	2.0
EDTA blood 2	243	4.1	1.7
Serum 1	134	2.0	1.3
From day to day [n = 20]	**Average [mg/dL]**	**Standard dev.[mg/dL]**	**VK [%]**
Serum 2	97.3	1.8	1.8
Serum 3	242	3.4	1.4

Analytic sensitiveness
Lower detection limit:
20 mg/dL (serum/plasma)
30 mg/dL (blood)

Comparison of methods
A comparison of the Diaglobal test GLU 142 (y) and a commercially available test (x) based on the hexokinase method resulted in the following correlation according to the Passing/Bablok[7)] process:

a) Blood	b) Serum
y = 1.033x - 1.74	y = 0.980x + 1.69
r = 0.995	r = 0.999
n = 78	n = 38

Concentration range: 40 - 600 mg/dL

A comparison of values between blood (y) and plasma (x) of only one proband resulted for the plasma-calibrated Diaglobal Gyn Photometer in the following correlation:
y = 1,007x - 2,42
r = 0,998
n = 51

Concentration range: 40 - 600 mg/dL

Information on disposal
Waste code number 180106:
Vials with reagent are considered hazardous waste. Do not allow reagent to reach surface water or sewage system.
Dispose of in accordance with official regulations.
Non-contaminated and completely empty packaging can be recycled.
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