GLUCOSE

GOD-PAP

Intended use:
Enzyme in vitro test for the quantitative determination of glucose in human serum, plasma.

Summary:
Glucose is the central energy source of the cells in the organism. The most common supply follows hydrolytic cleavage of polymeric carbohydrates, in general starch. Glucose is a monosaccharide with an postprandial concentration of 5 mmol/l in the blood and serves as an indispensable energy-supply for cellular functions. The glucose catabolism takes place via the glycolysis as the first step, followed by the citric acid cycle and oxidative phosphorylation.
Glucose regulations become executed the diagnosis and course control of carbohydrate metabolism illnesses like the diabetes mellitus, neonatal hypoglycemia, idiopathic hypoglycemia and with insulinoma.
The test bases on the coupling of the enzymatic oxidation of glucose by glucose oxidase resulting in hydrogen peroxide, which is subsequently used for the generation of a coloured product by peroxidase. In the Trinder method the carcinogenic ortho-dianisidine used in earlier formulations has been replaced by phenole and 4-amino-antipyrine.

Test principle:
Enzymatic colorimetric test on basis of Trinder – Reaction:

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

$$2H_2O_2 + \text{Phenol} + \text{4–Aminoantipyrine} \xrightarrow{\text{Peroxidase}} \text{Red Quinoneimine} + 4H_2O$$

Reagent concentration and stability:
R1:

Phosphate buffer, pH 7.5	0,5 mol/l
Phenol	7,5 mmol/l
GOD	12000 U/l
POD	660 U/l
4-amino-antipyrine	0,40 mmol/l

Preparation and stability:
R1: Ready for use opening:
until expiry date at +2°C to +8°C
3 weeks at +20°C to +25°C
Coloration of the reagent (reagent blank at 546 nm, 1 cm > 0.2) indicates a contamination or damage by storage at higher temperatures.
Onboard Stability: 28 days (2°C -8°C)

Specimen:
Capillary blood*, serum, Heparin-or EDTA-plasma.
The separation of the cells of the blood test should take place to not later than one half an hour after the decline. Non-hemolyzed serum or plasma can be stored refrigerated for up to 12 hours before the determination. Centrifuge samples containing precipitate before performing the assay. *Capillary blood has to be liberated from protein (deproteinization)

Limitations - interference:
Criterion: Recovery within ±10% of initial value.
Icterus: No significant interference up to an index I of 55 (approximate conjugated bilirubin: 55 mg/dl)
Hemolysis: No significant interference up to an index H of 450 (approximate haemoglobin concentration: 450 mg/dl).
Lipemia (Intralipid): No significant interference up to an index L of 2000 (approximate triglycerides concentration: 2000 mg/dl). There is poor correlation between turbidity and triglycerides concentration.

Analytical sensitivity (lower detection limit):
Detection limit: 20 mg/dl
The lower detection limit represents the lowest measurable glucose concentration that can be distinguished from zero.

Measuring /reportable range:
The endpoint method is linear up to 400 mg /dl
At higher concentrations, dilute the sample 1 + 1 with 0.9 % NaCl. Multiply the result by factor 2.

Testing procedure:
Applications for automated systems are available on request.
Materials provided
Working solutions as described above Additional materials required
Calibrators and controls as indicated below
0.9% NaCl

Manual procedure for endpoint:	
Wavelength:	Hg 546 nm (492 – 550 nm)
Temperature:	+37°C
Cuvette:	1 cm light path
Zero adjustment:	against reagent blank
	Sample / Calibrator
R1	1000 µl
Cal/sample	10 ul
Mix, and incubate 5 minutes at 37°	
Within 60 minutes read absorbance of sample and standard against reagent blank.	
Calculation:	
Acalibrator	x Calibrator conc. = Glucose conc.(mg/dL)

Imprecision:
Reproducibility was determined using controls between day. The following results were obtained:

	Within run		
Sample	Mean mg/dl	SD mg/dl	CV (%)
Sample1	92,5	1,74	1,88
Sample2	221	3,94	1,78
Sample3	483	7,04	1,46

	Betwen day		
Sample	Mean mg/dl	SD mg/dl	CV (%)
Sample1	95,7	0,43	0,45
Sample2	235	1,26	0,55
Sample3	501	3,34	0,67

Expected values:
Serum, Plasma: 70 – 105 mg/dl
Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference range. For diagnostic purposes, the glucose results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

Method comparison:
A comparison of the BIOANALYTIC Glucose GOD-PAP (y) with a commercial obtainable assay (x) gave the following result (mg/dl):
y = 0.990 x – 1.001; r =0.999

Quality Control:
Control Serum:

BIOCON N	5 x 5 ml	#B10814
BIOCON P	5 x 5 ml	#B10817

The control intervals and limits must be adapted to the individual laboratory and country-specific requirements. Values obtained should fall within established limits. Each laboratory should establish corrective measures to be taken if values fall outside the limits.

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Calibration:
S1: 0.9% NaCl
S2: BIOCAL H 5 x 3 ml #B11895

Calibration frequency:
A two-point-calibration is recommended in case of:
1-change of lot
2- quality control requirements

Literature:
1. Glick MR, Ryder KW, Jackson SA. Graphical Comparisons of Interferences in Clinical Chemistry Instrumentation. Clin Chem 1986; 24:863-869.
2. Greiling H, Gressner AM (Hrsg.) Lehrbuch der Klinischen Chemie und Pathobiochemie, 3 Auflage, Stuttgart / New York; Schattauer Verlag: 1995.
3. Krieg M et al. Vergleichende quantitative Analytik klinisch-chemischer Kenngrößen im 24 Stunden- Urin und Morgenurin. J Clin Chem Clin Biochem 1985;24:863-869.
4. Peterson Jl, Young DS. Anal Biochemistry 1985:23:301.
5. Schmidt FH, Klein Wschr 1961:39:1244
6. Thomas L (Hrsg). Labor und Diagnose, 4. Auflage. Marburg: Die Medizinische Verlagsgesellschaft, 1992.
7. Tietz NW (Hrsg). Clinical Guide to Laboratory Tests, 3. Auflage. Philadelphia. PA: WB Saunders Company: 1995:266-273.

Order information (Cat No.) :

CC415	AB415	B25165	B30165	B34165	B80166
SH415	BGLU250	B25166	B30166	B35165	
CR415	B21165	B27165	B31165	B36165	
OL415	B21166	B27166	B32165	B37165	
KL415	B22165	B28165	B33165	B42165	
BGLU500	B24165	B28166	B33166	B80165	

Manufacturer
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SYMBOLS

IVD	for in vitro diagnostic use only
LOT	lot of manufacturing
REF	code number
	storage at temperature interval
	expiration date (year/month)
	warning, read enclosed documents
	Read the directions