GLUCOSE

Enzymatic colorimetric determination of glucose in serum and plasma

TEST SUMMARY

Glucose become oxidize means by Glucose Oxidase creating hydrogen peroxide and Gluconic Acid. The hydrogen peroxide reacts with aminophenazone and phenol creating a red compound. Intensity of colour measures at 510 nm and is proportional to the quantity of Glucose present in the sample.

SAMPLES

Serum, plasma, urine, liquor.
Separated and unhemolysed sample from the corpuscolated part are stable 8 hours at 25°C or 3 days at 2-8°C. Variable stability is observed with longer storage periods.
In non-centrifuged sample glycolysis decreases serum glucose by approximately 5-7% in an hour (5-10 mg/dl) at room temperature. The rate of in vitro glycolysis is higher in presence of leukocytosis or bacterial contamination.
Plasma, if removed from the cells after moderate centrifugation, contains leukocytes that also metabolize glucose , although cell-free sterile plasma has no glycolytic activity.
Glycolysis can be inhibited and glucose stabilized for as long as 3 days at room temperature by adding sodium idoacetate or sodium fluoride to the sample, even if it has no influence in the glycolysis during the first hour from the drawing.
The liquor can be contaminated with bacteria or other cells and may be analyzed immediately. If it's not possible making immediately the analysis the sample have to be centrifuged and stored at 4°C or –20°C.
In 24 hours collection of urine, glucose may be preserved adding 5 ml of acetic acid to the container before starting the collection. The final pH of urine, is usually between 4 and 5 which inhibits bacterial activity. Urine samples may loose as much as 40 % of glucose after 24 hours at room temperature.

REAGENTS

Sole reagent:	Phosphate buffer pH 7.00 200 mM, GOD ≥ 15000 U/l, 4-AAP 1 mM, fenol 10 mM, surfactants.
Standard:	glucose 100 mg/dl.

MATERIALS REQUIRED BUT NOT SUPPLIED

Current laboratory instrumentation. Spectrophotometer UV/VIS with thermostatic cuvette holder. Automatic micropipettes. Glass or high quality polystyrene cuvettes.

PRECAUTIONS

Reagent may contain some non-reactive and preservative components. It is suggested to handle carefully it, avoiding contact with skin and swallow.
Perform the test according to the general "Good Laboratory Practice" (GPL) guidelines.

SAMPLES PREPARATION

Reagents are supplied in liquid form and ready to use.
Reagents are stored at 2-8°C until expiration date on the label, away from light sources or 60 days after first opening.

PROCEDURE

Kind of analysis:	Final point
Reading time:	5 minutes
Wavelength:	510 nm (480-520)
Temperature:	37°C
Lightpath:	1 cm
Zero:	Blank reagent

Reagents	Blank	Standard	Sample
Distilled water	10 µl	--	--
Standard	--	10 µl	--
Sample	--	--	10 µl
Reagent	1 ml	1 ml	1 ml

CALCULATION

Serum/Plasma/ Spontaneous Urine Glucose (mg/dl)

(A Sample / A Standard) x 100

24 hours urine Glucose (mg/24h)

(A Sample / A Standard) x 100 x diuresis (dl)

EXPECTED VALUES

Serum/plasma (fasting patient)	
Adults	70 - 105 mg/dl
Children	70 - 105 mg/dl
Premature neonates	25 - 80 mg/dl
Term neonates	30 - 90 mg/dl
Liquor	70 - 75 mg/dl (60% of plasma value)
Urine (fasting patient)	
Random urine	< 300 mg/dl
24h urine	< 500 mg/24h

Each laboratory should establish appropriate reference intervals related to its population.

NOTES

- If the results are incompatible with clinical presentation, they have to be evaluated within a total clinical study.
- Only for IVD use.

CALIBRATION/QUALITY CONTROL

It is suggested to perform an internal quality control. For this purpose the following control sera on human base are available on request:

QN 0050 CH **10 x 5 ml**
Control Sera normal values

QP 0050 CH **10 x 5 ml**
Control Sera pathological values

TEST PERFORMANCE

Precision

Intra-assay (n = 25)	Mean (mg/dl)	SD (mg/dl)	CV%
Sample 1	87.64	0.8602	0.98
Sample 2	226.6	0.8660	0.38

Inter-assay (n = 25)	Mean (mg/dl)	SD (mg/dl)	CV%
Sample 1	87.64	1.1860	1.35
Sample 2	227.64	1.1503	0.51

Sensibility/limit of detection
The method is able to discriminate until 1 mg/dl.

Methods comparison
A comparison with a commercial available product gave the following results in a comparison on 36 samples of serum:
Glucose LTA = x
Glucose competitor = y
n = 36

y = 0,97801x + 2,41589 r = 0,9756

A comparison with a commercial available product gave the following results in a comparison on 21 samples of urine:
Glucose LTA = x
Glucose competitor = y
n = 21

y = 0,97651x + 0,37795 r = 0,99825

Linearity
The method is able to discriminate until 500 mg/dl.
If the value is exceeded, is suggested to dilute sample 1+9 with saline and to repeat the test, multiplying the results by10.

Interferences
No interference was observed by the presence of:

hemoglobin	≤ 400 mg/dl
bilirubin	≤ 20 mg/dl
lipids	≤ 400 mg/dl

WASTE DISPOSAL

Product is intended for professional laboratories.
Waste products must be handled as per relevant security cards and local regulations.

PACKAGING

CODE CC01900	**(400 TESTS)**	
Sole reagent	4 x 100 ml	(liquid)
Standard	1 x 5 ml	(liquid)

REFERENCES

Trinder P., - J. Clin. Path. 22. 158 (1969).
Tietz Textbook of clinical Chemistry, Second Edition, Burtis – Ashwood (1994).

MANUFACTURER

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SYMBOLS

IVD	Only for IVD use
LOT	Lot of manufacturing
REF	Code number
	Storage temperature interval
	Expiration date (year, month)
	Warning, read enclosed documents
	Read the directions
	Biological risk

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