Spectrum For Diagnostic Industries

Glucose
GOD - PAP

IVD

REF.	Pack size
128 02 125	(2 x 125 ml) 250 tests
128 05 125	(5 x 125 ml) 625 tests
128 04 250	(4 x 250 ml) 1000 tests

Intended Use

Liquizyme glucose reagent is intended for the in-vitro quantitative, diagnostic determination of glucose in human serum, plasma, urine and CSF on both manual and automated systems.

Introduction

Oxidation of glucose present in the peripheral blood represents the major source of cellular energy in the body. Dietary glucose is stored in the liver in the form of glycogen or converted to fatty acids and stored in the adipose tissues. The accurate estimation of glucose is important in the diagnosis and management of hyperglycemia & hypoglycemia. The most frequent cause of hyperglycemia is diabetes mellitus resulting from a deficiency in insulin secretion or action. Hypoglycemia may be the result of an insulinoma, insuline administration, inborn error of carbohydrate metabolism or fasting. The concentration of glucose in the blood is controlled within narrow limits by many hormones, the most important of which are produced by the pancreas.
Glucose measurement in urine is used as diabetes screening procedure and to aid in the evaluation of glucosuria to detect renal tubular defect and in the management of diabetes mellitus.
Glucose measurement in cerebrospinal fluid (CSF) is used for evaluation of meningitis, neoplastic involvement of meninges and other neurological disorders.

Method

GOD-PAP enzymtic colorimetric method.

Principle

Glucose is determined after enzymatic oxidation in the presence of glucose oxidase. The formed hydrogen peroxide reacts under catalysis of peroxidase (PAP) with phenol and 4-aminoantipyrine to form a red violet quinoneimine dye as indicator.

1- Glucose + $2\,H_2O + O_2$ —*GOD*→ Gluconic acid + H_2O_2

2- $2\,H_2O_2$ + Phenol + 4-amino-antipyrine —*PAP*→ $4H_2O$ + Quinoneimine

Reagents

Reagent	
Phosphate Buffer	100 mmol/L
Phenol	4.0 mmol/L
4-amino-antipyrine	1.0 mmol/L
Glucose oxidase	> 2 KU/L
Peroxidase	> 2.0 KU/L
Sodium Azide	8 mmol/L
Standard	100 mg/dL
	5.55 mmol/L

Reagents preparation, storage and stability

Glucose reagents are supplied ready-to-use and stable up till the expiration date labeled on the bottles when properly stored refrigerated at 2 – 8 °C.Once opened the reagent and the standard are stable for 3 months at the specified temperature.

Deterioration

The reagent is normally clear or pale pink. Do not use Glucose reagent if it is turbid or if the absorbance is greater than 0.2 at 546 nm.

Precautions and Warnings

Do not ingest or inhalate. In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.
Reagent (R) contains sodium azide which may react with copper or lead plumbing.

Specimen collection and preservation

Serum or Plasma
Heparin, EDTA, and flouride are the only accepted anticoagulants The stability of glucose in specimen is affected by storage temperature, bacterial contamination and glycolysis. Serum or plasma should be separated within 30 minutes. When blood is drawn and permitted to clot and to stand uncentrifuged at room temperature. Unhemolyzed serum glucose is stable up to 8 hours at 25°C or up to 72 hours at 4°C.
Urine
Urine samples are stable 1 day at 4°C . In case of delay due to transportation or for 24 hour urine collection, it is recommended to add either merthiolate (0.23 mmol/L) or 5 ml glacial acetic acid to the container before collection. Unpreserved urine samples may lose up to 40% of their glucose after 24 hour storage at room temperature; therefore, keep samples on ice during collection.
CSF
Sample should be analyzed for glucose immediately to avoid contamination with bacteria. If a delay in measurement is unavoidable, the sample should be centrifuged and stored at 4°C.

Procedure

Wavelength	546 nm (492 – 550 nm)
Optical path	1 cm
Assay type	End-point
Direction	Increase
Sample : Reagent Ratio	1 : 100
Temperature	37 °C or 20 – 25 °C
Incubation time	20 minutes at 20 – 25 °C or 10 minutes at 37 °C
Zero adjustment	Reagent Blank
Reagent Blank Limits	Low 0.00 AU High 0.2 AU

	Reagent blank	Standard	Specimen
Reagent	1.0 ml	1.0 ml	1.0 ml
Standard	____	10 µl	____
Specimen	____	____	10 µl

Mix and incubate for 10 minutes at 37 °C or 20 minutes at 15 -25°C. Measure absorbance of specimen ($A_{specimen}$) and standard ($A_{standard}$) against reagent blank within 30 minutes.

Calculation

$$\text{Glucose concentration (mg/dL)} = \frac{(A_{specimen})}{(A_{standard})} \times 100$$

Quality control

Normal and abnormal control serum of known concentration should be analyzed with each run.

Interference

Haemolysis
No significant interference from haemoglobin up to 500 mg/dL.

Icterus
No significant interference from free and conjugated bilirubin up to levels of 15 mg/dL (257 µmol/L).

lipemias
Lipid disturb measurements if present in high concentration (More than 500 mg/dL).

Others
Turbidity caused by tin-soluble uranyl phosphate may result in false high levels.

Reducing Substances
Large amounts of reducing substances as ascorbic acid, creatinine, glutathione and uric acid react with hydrogen peroxide and stimulate low glucose concentration.

Expected Values

Serum, plasma

1-Adults (fasting)	70 - 105 mg/dL (3.9 - 5.8 mmol/L)
2-Children	60 - 110 mg/dL (3.33 - 6.11 mmol/L)
3-Newborns	40 - 60 mg/dL (2.22 - 3.33 mmol/L)

Urine

Random	5.0 - 15 mg/dL (0.28 - 0.83 mmol/L)
24 hours	< 0.5 g/24 hrs (<2.8 mmol/24 hrs)

CSF

Adults	40 - 75 mg/dL (2.2-4.2 mmol/L)

CSF glucose values should be approximately 60% of the plasma values and must always be compared with concurrently measured plasma values for adequate clinical interpretation.

Performance characteristics

A comparison between Glucose reagent and a commercial reagent of the same methodology was performed on 20 human sera.
A correlation of 0.991 was obtained.

Precision
Within run (Repeatability)

	Level 1	Level 2
n	20	20
Mean (mg/dL)	103	228
SD	1.12	1.19
CV%	1.09	0.83

Run to run (Reproducibility)

	Level 1	Level 2
n	20	20
Mean (mg/dL)	109	235
SD	1.23	1.27
CV%	1.17	0.98

Sensitivity
When run as recommended, the minimum detection limit of the assay is 5 mg/dL (0.27 mmol/L).

Linearity

The reaction is linear up to glucose concentration of 500 mg/dl; specimens showing higher concentration should be diluted 1+2 using physiological saline and repeat the assay (result×3).

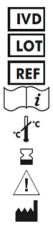
Waste Disposal

This product is made to be used in professional laboratories.
Please consult local regulations for a correct waste disposal.
S56: dispose of this material and its container at hazardous or special waste collection point.
S57: use appropriate container to avoid environmental contamination.
S61: avoid release in environment. refer to special instructions/safety data sheets.

References

1. Trinder, P., Ann. Clin. Biochem (1969).
2. Tietz NW, ed. Clinical guide to laboratory tests 3rd ed philadeliphia.WB saunders,1995.
3.weissman M, klien B. Evaluation,of glucose determination in untreated serum samples.clin chem 1958.

SYMBOLS IN PRODUCT LABELLING



IVD For in-vitro diagnostic use
LOT Batch Code/Lot number
REF Catalogue Number
Consult instructions for use
Temperature Limitation
Use by/Expiration Date
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Manufactured by

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