SPECTRUM

The Creative Approach to Bioscience

Glucose Liquizyme GOD-PAP (Single Reagent)

REF: 250 001	(2 x 100 ml)	200 test
REF: 250 002	(4 x 100 ml)	400 test
REF: 250 003	(8 x 100 ml)	800 test
REF: 250 004	(2 x 500 ml)	1000 test
REF: 250 005	(2 x 250 ml)	500 test
REF: 250 006	(4 x 250 ml)	1000 test
REF: 250 007	(1 x 250 ml)	250 test
REF: ZL- 250 001		200 test

Intended Use

Spectrum 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.

Background

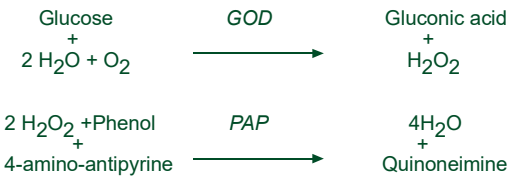
Oxidation of glucose present in the peripheral blood represents the major source of cellular energy in the body. Dietary glucose is stored in the liver in the form of glycogen or converted to fatty acids and stored in the adipose tissues. The accurate estimation of glucose is important in the diagnosis 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.

Assay 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.



Reagents

Glucose standard (St)	100 mg/dL 5.55 mmol/L
Reagent (R)	
Phosphate Buffer	100 mmol/L
Phenol	4.0 mmol/L
4-amino-antipyrine	1.0 mmol/L
Glucose oxidase	> 20 KU /L
Peroxidase	> 2.0 KU/L
Sodium Azide	8 mmol/L

For further information, refer to the Glucose reagent material safety data sheet.

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.

SYMBOLS IN PRODUCT LABELLING

EC REP	Authorised Representative		Use by/Expiration Date
IVD	For in-vitro diagnostic use		CAUTION. Consult instructions for use
LOT	Batch Code/Lot number		
REF	Catalogue Number		Manufactured by
	Consult instructions for use		(Xi) - Irritant
	Temperature Limitation		

Reagent Preparation, Storage and Stability

Spectrum Glucose liquizyme reagents are supplied ready-to-use and stable up to the expiry date labeled on the bottles when properly stored refrigerated at 2 – 8 ^{o}C. Once opened, the reagent and standard are stable for 3 months at the specified temperature if contamination is avoided.

Deterioration

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

Specimen Collection and Preservation

Serum or plasma
Individuals should be fasting before sample collection.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. The average decrease in serum glucose is 7% in 1 hour (0.28 to 0.56 mmol/l or 5 to 10 mg/dl). This decrease is the result of glycolysis. Unhemolyzed serum glucose is stable up to 8 hours at 25^{o}C or up to 72 hours at 4^{o}C. In order to inhibit glycolysis, samples should be collected into tubes containing sodium fluoride.

Urine
Urine samples are stable 1 day at 4^{o}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^{o}C.

System Parameters

Wavelength	546 nm (492 – 550 nm)
Optical path	1 cm
Assay type	End-point
Direction	Increase
Sample : Reagent Ratio	1 : 100
e.g.: Reagent volume	1 ml
Sample volume	10 µl
Temperature	37 ^{o}C or 20 – 25 ^{o}C
Incubation time	20 minutes at 20 – 25 ^{o}C or 10 minutes at 37 ^{o}C
Zero adjustment	Reagent Blank
Reagent Blank Limits	Low 0.00 AU High 0.2 AU
Sensitivity	5 mg/dL (0.27 mmol/L)
Linearity	500 mg/dL (27.7 mmol/L)

Procedure

	Blank	Standard	Specimen
Reagent (R)	1.0 ml	1.0 ml	1.0 ml
Standard	.....	10 µl	.....
Specimen	.....	.....	10 µl

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

Calculation

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

Quality Control

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

Performance Characteristics

Precision

Within run (Repeatability)

	Level 1	Level 2
n	20	20
Mean (mg/dL)	103	228
SD	1.12	1.19
CV%	1.09	0.52

Run to run (Reproducibility)

	Level 1	Level 2
n	20	20
Mean (mg/dL)	109	235
SD	1.23	1.27
CV%	1.13	0.54

Methods Comparison

A comparison between Spectrum Glucose reagent and a commercial reagent of the same methodology was performed on 200 human sera. A correlation of 0.991 was obtained.

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).

Interfering Substances

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).

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

Others
Turbidity caused by insoluble 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

Adults (fasting)	70 - 105	mg/dL	(3.9 -5.8 mmol/L)
Children	60 - 110	mg/dL	(3.33-6.11 mmol/L)
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.

Spectrum Diagnostics does not interpret the results of a clinical laboratory procedure; interpretation of the results is considered the responsibility of qualified medical personnel. All indications of clinical significance are supported by literature references.

Dynamic Range

5 - 500 mg/dL (0.27 - 27.7 mmol/L).

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. Caraway WT, Watts NB. Carbohydrates In : Tietz NW, ed.Fundamentals of Clinical Chemistry. 3ry ed. Philadephia WB saunde-rs 1987:422-447.
2. Howanitz PJ, Howanitz JH. Carbohydrates. In: Henry JB,ed. Clinical diagnosis and mana-Gement by laboratory methods. 17th ed Philadelphia: WB saunders 1984:165-179
3. Trinder, P., Ann. Clin. Biochem. (1969), 6:24.
4. Tietz NW, ed. Clinical guide to laboratory tests. 3rd ed.Philadelphia: WB saunders; 1995:268-273.
5. Weissman M, klien B. Evaluation, of glucose determination In untreated serum samples. Clin Chem.1958;4:420-422.

ORDERING INFORMATION

CATALOG NO.	QUANTITY
250 001	2 x 100 ml
250 002	4 x 100 ml
250 003	8 x 100 ml
250 004	2 x 500 ml
250 005	2 x 250 ml
250 006	4 x 250 ml
250 007	1 x 250 ml
ZL-250 001	200 test

Egyptian Co for Biotechnology - Spectrum Diagnostics (S.A.E)
Obour city industrial area. block 20008 piece 19 A. Cairo. Egypt.
Tel: +202 4489 2248 - Fax: +202 4489 2247
www.spectrum-diagnostics.com
E-mail:info@spectrum-diagnostics.com

EC REP **MDSS GmbH**
Schiffgraben 41
30175 Hannover, Germany

CE

TÜV SOUTHWEST CERTIFIED ISO 13485:2016