

LiquiMAX GLUCOSE - SLR

(GOD - PAP TRINDER'S METHOD)

ORDERING INFORMATION

Ref. No.	Pack Size	Presentation
AVGLU - 500	4 x 125 ml	Single Liquid Reagent
AVGLU - 1000	4 x 250 ml	
AVGLU - 5000	5 x 1000 ml	

INTENDED USE :

LiquiMAX GLUCOSE is an in-vitro diagnostic kit is use for the quantitative determination of glucose in human serum/plasma.

PRODUCT FEATURES :

1. Single Liquid Reagent.
2. 10 minutes End Point assay.
3. Linearity: 500 mg/dl (End Point), 1000mg/dl (Fixed Time)
4. With Lipid Clearing Factor (LCF)
5. 100 mg/dl standards provided.
6. End Point and Fixed Time procedures.

CLINICAL SIGNIFICANCE : 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 a 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 In the Trinder method the carcinogenic ortho-dianisidine used in earlier formulations has been replaced by phenol and 4-amino-antipyrine.

PRINCIPLE



STORAGE AND STABILITY

All the reagents are to be stored at 2-8°C and are stable till the expiry date mentioned on the labels when properly stored.

KIT COMPONENTS

1. Glucose Reagent
2. Glucose Standard : Concentration as stated on the label

COMPOSITION

Phosphate buffer	250 mmol/l
Glucose oxidase	>25 U/ml
Peroxidase	>2 U/ml
Phenol	5 mmol/l
4-aminoantipyrine	0.5 mmol/l

REAGENT RECONSTITUTION & STABILITY

Reagent are liquid stable no need for reconstitution.

When the reagent is stored properly at 2-8°C & the contamination avoided, it is stable up to the expiry date mention on the label & kit box.

MATERIAL REQUIRED BUT NOT PROVIDED

Laboratory Instrumentation, Spectrophotometer UV/VIS with thermostatic cuvette holder or clinical chemistry analyzer: semi auto, calibrated micropipettes, glass or high quality polystyrene cuvettes, test tube/rack, heating bath controls, saline.

REAGENT DETERIORATION

Discard any turbid reagent or blank reagent absorbance exceeds 0.2 at 505 nm against distilled water.

WARNING & PRECAUTIONS

- Reagent may contain some non reactive and preservative components. It is recommended to handle carefully, avoiding contact with skin and ingestion.
- Specimen should be considered infectious and handled appropriately.
- Contamination by soap or glycerol will affect this assay.
- Perform the test according to the general " Good Laboratory Practice" GLP

SPECIMEN & COLLECTION STORAGE

Serum/Plasma is the preferred specimen. Blood should be collected in a clean dry container. Serum or plasma should be separated from the cells at the earliest possible (within 30 minutes), as the rate of glycolysis is approximately 7 mg% per hour at room temperature.

For plasma separation following anticoagulants may be used.

EDTA	2 mg/mL of blood
CITRATE	6 mg/mL of blood
HEPARIN	200 IU/mL of blood
OXALATE	3 mg/mL of blood
SOD. FLUORIDE	10 mg/mL of blood

Sodium Fluoride is preferred as anticoagulant due to its anti glycolytic activity. Higher concentration of Sodium fluoride i.e. more than 10 mg/ml blood should be avoided as it may inhibit the colour development. Glucose is stable for 24 hours in neatly separated plasma and serum. If the estimation is not possible within 24 hours then the specimen should be preserved at -10° C and should be used within 30 days.

SYSTEM PARAMETERS (End-Point)

Reaction Type	: End-Point
Reaction Time	: 10 mins. at 37° C/15 mins. at R.T
Wavelength	: 505 nm. (490 - 550 nm.)
Zero Setting with	: Reagent Blank
Sample Volume	: 10 µl
Reagent Volume	: 1000 µl
Standard Concentration	: 100
Linearity	: 500
Unit	: mg/dl

PROCEDURE (END POINT METHOD) :

Pipette into three test tubes labeled Blank (B), Standard (S) Test (T) as follows:

Reagent	B	S	T
Glucose Reagent	1000 µl	1000 µl	1000 µl
Glucose Standard (Conc. 100 mg/dl)	----	10 µl	----
Specimen	----	----	10 µl

Mix and incubate for 10 minutes at 37°C or 15 minutes at R.T.

Mix and read absorbances of Standad (S) and Test (T) against Blank (B) at 505 nm (490-550 nm). The final color is stable for 10 hours at R.T.

CALCULATIONS

$$\text{Glucose Conc. in mg/dl} = \frac{\text{Abs. of T}}{\text{Abs. of S}} \times 100$$

SYSTEM PARAMETERS (Fixed Time)

Reaction Type	: Fixed Time
Reaction direction	: Increasing
Wavelength	: 505 nm. (490 - 550 nm.)
Flow cell temp	: 37° C
Delay time	: 20 Secs.
Interval	: 40 Secs.
Sample Volume	: 10 µl
Reagent Volume	: 1.0 ml.
Linearity	: 1000 mg/dl

TEST PROCEDURE (Fixed Time Method) :

(Only for Spectrophotometers, Semi and Fully Automated Analyzer Users).
Bring the LiquiMAX Glucose - SLR Reagent to R.T. before use. Pipette into test tubes labeled Standard (S) and Test (T) as follows :

Reagent	S	T
Glucose Reagent	1000 µl	1000 µl
Glucose Standard (conc. 100 mg/dl)	10 µl	–
Specimen	–	10 µl

Reaction Temperature : 37°C

Mix well and read absorbances of Standard (S) and Test (T) against distilled water at 505 nm as follows :

Initial absorbance A_0 = Exactly after 20 Sec.
Final absorbance A_1 = Exactly 40 Sec. After A_0

Determine Δ Abs for S and T

$$\Delta \text{ Abs for S} = \text{Abs } S_1 - \text{Abs } S_0$$

$$\Delta \text{ Abs for T} = \text{Abs } T_1 - \text{Abs } T_0$$

CALCULATIONS :

$$\text{GLUCOSE conc. in mg/dl} = \frac{\Delta \text{ Abs for T}}{\Delta \text{ Abs for S}} \times 100$$

EXPECTED VALUE

Serum / Plasma : 70 - 110 mg/dl (Fasting)
70 - 140 mg/dl (Post Prandial)
CSF : 40 - 70 mg/dl

It is recommended that laboratories should establish their own normal range.

QUALITY CONTROL & CALIBRATOR

To ensure adequate Quality Control, the use of commercial reference control serum is recommended with each assay batch. Use of Quality control material checks both, the instrument and the reagent performances.

PERFORMANCE CHARACTERISTICS

1. Linearity

Linearity : 500 mg/dl (End Point), 1000mg/dl (Fixed Time)

2. Sensitivity/ Limit of Detection (LOD)

The lower limit of detection is 5 mg/dl

3. Interferences

haemoglobin up to 7.5 g/l, bilirubin up to 30 mg/dl, triglycerides up to 750 Mg/dl.

4. Precision:

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

Intra-Assay

Sample	Mean(mg/dl)	SD(mg/dl)	CV%
Sample 1	92.5	1.74	1.88
Sample 2	221	3.94	1.78
Sample 3	483	7.04	1.46

Inter-Assay

Sample	Mean(mg/dl)	SD(mg/dl)	CV%
Sample 1	95.7	0.43	0.45
Sample 2	235	1.28	0.55
Sample 3	501	3.34	0.67

5. Method Comparison:

A comparison of the LiquiMAX Glucose - SLR (y) with a commercial obtainable assay (x) gave the following result (mg/dl): $y = 0.990x - 1.001$; $r = 0.999$

LIMITATIONS

Measuring range: 5-500/1000 mg/dl. Determine samples having higher concentrations manually dilute with 0.9% NaCl or distilled/deionized water (e.g. 1 + 1). Multiply the result by the appropriate dilution factor (e.g. 2).

WASTE DISPOSAL

Reagents must be disposed off in accordance with local regulations.














NOTES

- Contamination of Standard and Reagent must be avoided. After use, all the reagents must be immediately stored back at 2-8°C.
- Replug the Glucose Standard vial after use. Use clean glassware / microtips while pipetting Glucose standard.
- If a larger volume of reagent is required for absorbance reading, requisite volumes can be taken in multiples keeping the same ratio of reagent to specimen / Standard.
- For sample values higher than 500 mg/dl, dilute the sample with normal saline and multiply the result with appropriate dilution factor.
- Programmes for specific autoanalyzers are available on request.

REFERENCE

- Trinder, P. (1969) Annals. Clin. Bio Chem. 6, 24.
- Bergmayer, H.V. (1974) Method of Enzymatic Analysis., P. 1196.

Symbols Used on Pack

	Catalogue Number		Warning/Caution
	Batch No.		In vitro diagnostic device
	Manufacturing Date		Storage Limit
	Expiry Date		Consult instruction for use
	Manufacturer		Keep away from sunlight
	Keep Dry		Do not use if package is damaged
	Contains sufficient no. of test		



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