ANA BIO ISP Glucose

(GOD-POD Method)

For Miura Instruments

Intended Use

Glucose is a reagent kit used for the determination of true glucose in serum or plasma, based on enzymatic method; using glucose oxidase and peroxidase enzymes.

Principle

Glucose oxidase (GOD) converts glucose into gluconic acid and Hydrogen peroxide (H_2O_2). Hydrogen peroxide, in presence of peroxidase (POD), oxidatively couples with 4-aminoantipyrine and phenol to produce red quinoneimine dye. The intensity of the colored complex is directly proportional to the concentration of glucose in specimen.

$$\beta\text{-D Glucose} + O_2 + H_2O \xrightarrow{GOD} \text{Gluconic Acid} + H_2O_2$$

$$H_2O_2 + \text{4-aminoantipyrine} + \text{phenol} \xrightarrow{POD} \text{Red dye} + H_2O$$

Components & Concentration of Reagents

Reagent	Component	Concentration
Enzyme Reagent	**Phosphate Buffer PH 7.1**	**200 mmol/L**
	Phenol	**10 mmol/L**
	4-AAP	**0.28 mmol/L**
	GOD	**<20 KU/L**
	POD	**<5 KU/L**

Reagent storage and stability

The reagent and standard are ready-to-use and are stable till expiry, when stored at 2° - 8°C. **DO NOT FREEZE THE REAGENT.**

Reagent Preparation

Liquid reagent ready for use. After opening the reagent is stable for 30 days if closed, stored at 2° - 8°C, and protect from direct light. Do not mix different batches.

Specimen collection and preservation

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 (25° - 30°C).

For plasma separation following anticoagulants may be used.

- EDTA 2 mg/ml of blood
- CITRATE 6 mg/ml of blood
- HEPARINE 200 IU/ml of blood
- OXALATE 3 mg/ml of blood
- SODIUM FLUORIDE 10 mg/ml of blood

Sodium fluoride is preferred anticoagulant due to its antiglycolytic activity. Higher concentration of sodium fluoride i.e. more than 10 mg/ml of blood should be avoided as it may inhibit the colour development.

Glucose is stable for 24 hours in neatly separated plasma and serum at 2° - 8°C. If the estimation is not possible within 24 hours then the specimen should be preserved at -20°C and should be used within 30 days.

Automation

This kit, though developed and manufactured to be used as manual assay and with I.S.E. Miura Analyzer, can be used also with other analyzers able to meet the specifications indicated in section "Reaction conditions – Test procedure" Application sheets are available for automatic instruments.

All applications not explicitly approved by KDPL. Cannot be guaranteed in terms of performance, and must there be established by the operator.

Calibration

For Calibration use the "Multicalibrator"

Calibration Stability

For the instrumentation series Miura, the calibration is recommended to be done every 10 days.

Materials required but not supplied in the kit

Calibrators and controls

Assay guidelines for Analyzer I.S.E. Miura

Analyte Name	Glucose	
Method Code	GLU	
Type	End-Point	
Unit	Mg/dl	
Filter F1	505 nm	
Blank in	Use	
Step	Reaction Volume	U.M.
Volume reagent R1	200	µl
Sample Volume	2	µl
Final Incubation	600	Sec.

Normal Range

Guidance value for Fasting serum / Plasma : 70 - 110 mg/dl
Guidance value for Post Prandial / Random : Up to 140 mg/dl
Note: Expected range varies from population to population and each laboratory should establish its own normal range.

Limitation

Reaction is linear up to 500 mg/dl. For higher values, dilute the sample with normal saline and perform the assay. Multiply the final result by dilution factor to get the real value.

Quality Control

To ensure adequate quality control measures, it is recommended that each batch should include a normal and an abnormal commercial reference control serum. It should be realized that the use of quality control material checks both instrument and reagent functions together. Factors which might affect the performance of this test include proper instrument function, temperature control, cleanliness of glassware, Wavelength setting, Expiration date of reagents and accuracy of prob aspiration.

Accuracy-Recovery

Glucose added to a serum matrix containing known amounts of glucose gave an average recovery of 96.5%.

Interference

The high dilution of the sample with the reagent reduces to a minimum possible interference by lipids. In the casa that these are present, the concentration must not exceed 300 mg/dl of Triglycerides. Bilirubin below 20 mg/dl does not interfere in the reaction. Haemoglobin influences the reaction at concentrations over 12.0 g/L.

Precision of the Method

Within-run					
Range	U.M	Mean	S.D.	C.V.(%)	No. run
Low	mg/dl	95.7	1.14	1.19	20
High	mg/dl	305.1	1.35	0.44	20
Between run					
Range	U.M	Mean	S.D.	C.V.(%)	No. run
Low	mg/dl	95.7	1.25	1.30	60
High	mg/dl	305.1	1.85	0.61	60

Sensitivity

At 505 nm a concentration of 2.0 mg/dl of Glucose can estimate.

References

1. Trinder P. Clin. Biochem. 6, 24 (1969).
2. Bergmayer H. V., Methods of enzymatic Analysis", A. P., N. Y. (1974). Page 1196.
3. Young, D.S., Pestaner, L.C., Gibberman, B., *Clin. Chem.* 21, 1D (1975).
4. Young D, Effects of drugs on clinical laboratory tests. 5th Edition, AACC Press, Washington, DC, 3-349 – 3-367, 2000.
5. Kanagasabapathy, as and Kumari S, Guidelines on standard operating procedures for clinical chemistry, WHO 2000, pp 206-208 (2008).

Symbols

IVD	In Vitro Diagnostics		Caution
LOT	Batch No.		Product Expiry Date
CONT	Content		Manufactured By
	Read Instructions		Date of Manufacture
	Storage Temperature		Keep Dry
REF	Catalogue No.		Fragile
			Keep away from sun light

Kee Diagnostics
because life matters

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