Atlas Medical

Glucose (Mono Reagent) (GOD/POD method)

For the determination of glucose in serum or plasma

IVD *For in vitro diagnostic use only*

2°C 8°C (Store at 2-8°C.)

INTENDED USE

For the determination of glucose in serum or plasma.

INTRODUCTION

Glucose is the major carbohydrate present in blood. Its oxidation in the cells is the source of energy for the body. Increased levels of glucose are found in diabetes mellitus, hyperparathyroidism, pancreatitis, and renal failure. Decreased levels are found in insulinoma, hypothyroidism, hypopituitarism, and extensive liver disease.

PRINCIPLE OF THE METHOD

Glucose oxidase (GOD) catalyses the oxidation of glucose to gluconate. The formed hydrogen peroxide (H_2O_2) is detected by a chromogenic oxygen acceptor, phenol, 4-Aminophenazone (4-AP) in the presence of peroxidase (POD):

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

$$H_2O_2 + \text{Phenol} + (4\text{-AP}) \xrightarrow{POD} \text{Red Quinone dye} + H_2O$$

The intensity of the color formed is proportional to the glucose concentration in the serum.

REAGENTS COMPOSITION

R	GOD	15ku/L
	POD	1.0ku/L
	Phenol	0.3mmol/L
	4-AP	2.6mmol/L
	Buffer pH 7.55	92mmol/L
	Stabilizers and activators	
GLUCOSE STD	Glucose aqueous primary standard 100mg/dl	

EQUIPMENTS NEEDED BUT NOT PROVIDED

- Spectrophotometer or colorimeter measuring at 505nm.
- Matched cuvettes 1.0 cm light path.
- General laboratory equipment.

PREPARATION

- Reagent and standard provided are ready to use.

STORAGE AND STABILITY

- All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8°C, protected from light and contaminations during their use.
- Do not use reagents over the expiration date.
- Signs of reagent deterioration:
  - Presence of particles and turbidity.
  - Blank absorbance against water is more than 0.2.

COLLECTING AND HANDLING OF SPECIMENS

Use serum, or plasma free of hemolysis.
When blood is drawn and permitted to clot and to stand uncentrifuged at room temperature, the average decrease in serum glucose is 7% 1h (5-10mg/dl).
In separated, unhemolyzed serum, the glucose concentration is generally stable up to 8h at 25°C or 72h at 4°C, if kept free of bacterial contamination.

ASSAY PARAMETER

Reaction	End point	Interval	----
Wavelength	505nm	Sample Vol.	0.01ml
Blank	Reagent blank	Reagent Vol.	1.0ml
Incub. Temp.	37C/15-25C	Standard	100mg/dl
Incub. Time	10min/30min	Factor	-----
Reac. Slope	increasing	linearity	Up to 600mg/dl
Units	mg/dl		

ASSAY PROCEDURE

1. Wavelength……505nm (500-510)
2. Cuvette……1cm.light path
3. Temperature……37C/15-25C.
4. Adjust the instrument to zero with distilled water.
5. Pipette into clean dry test tubes labeled as Blank (B), Standard(S), and Sample.

Addition Sequence	Blank	Standard	Sample
Glucose mono reagent	1.0ml	1.0ml	1.0ml
Glucose standard	-	0.01ml	-
Sample	-	-	0.01ml

6. Mix well and incubate at 37°C for 5 min or at 15-25°C. (25°C) for 10 min.
7. Measure the absorbance of the standard and test sample against blank.
8. After incubation the color is stable between 15-30min.

CALCULATIONS

$$\text{Glucose (mg/dl)} = \frac{\text{(A) Sample}}{\text{(A) STD}} \times 100 (\text{Standard Conc.})$$

Conversion factor: mg/dL x 0.0555= mmol/L.

QUALITY CONTROL

To ensure adequate quality control, it is recommended that each run includes assayed normal and abnormal controls. If control values are found outside the defined range, check the instrument calibration, and reagent for problems. Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

REFERENCE VALUES

Serum or plasma:
60-110 mg/dL = 3.89-6.10 mmol /L
These values are for guidance purpose; each laboratory should establish its own reference range, according to its own geographic area.

PERFORMANCE CHARACTERISTICS

Measuring range (Linearity):

The assay is linear between 10mg/dl and 600 mg/dl.
If the results obtained were greater than 600mg/dl, dilute the sample to 1/2 with Nacl 9g/L and multiply the result by 2.

Sensitivity:

1 mg/dl = 0.0032 (A)

Accuracy:

Results obtained using the reagent compared well with other commercial reagents.

Precision:

	Intra-assay(n=20)		Inter-assay(n=20)	
Mean(mg/dl)	91.73	228.51	97.68	244.17
STD	3.51	10.64	3.42	10.69
C.V%	3.82	4.66	3.51	4.38

The results of the performance characteristics depend on the analyzer used.

INTERFERENCES

The following compounds will affect the glucose results if found in the sample at the below mentioned concentrations:
Ascorbic acid: 250mg/L
L-Cysteine: 1.5g/L
Citric acid: 15g/L
Uric acid: 150mg/L
L-Dopa:100mg/L

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REF	Catalogue Number		Store at
IVD	For In-Vitro Diagnostic use		Caution
Σ	Number of tests in the pack		Read product insert before use
LOT	Lot (batch) number		Manufacturer
	Fragile, handle with care		Expiry date
	Manufacturer fax number		Do not use if package is **damaged**
	Manufacturer telephone number		