Atlas Medical

Glucose (Mono Reagent)
(GOD/POD method)

IVD For in *vitro* diagnostic use only

2°C 8°C Store at 2-8°C CE

INTENDED USE
For the determination of glucose in human serum or plasma.

INTRODUCTION
Glucose is the major carbohydrate present in blood. Its oxidation in 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 glucose concentration in serum.

REAGENTS COMPOSITION

R	GOD	15ku/L
	POD	1.0ku/L
	Phenol	0.3mmol/L
	4-AP	2.6mmol/L
	BufferpH7.55	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 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 contaminants during their use.
- Do not use reagents beyond 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, non hemolyzed serum, 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.	37°C/15-25°C	**Standard**	100mg/dl
Incub. Time	5min/10min	**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……37°C/15-25°C.
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 = 3.33-6.11 mmol /L
These values are for guidance purposes; 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 half 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%	3.83	4.66	3.50	4.38

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

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

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REF	Catalogue Number		Temperature limit
IVD	*In Vitro* diagnostic medical device		Caution
	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Fragile, handle with care		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry