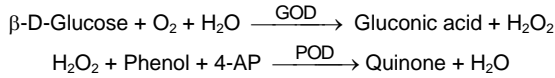


**Quantitative determination of glucose IVD**

Store at 2-8°C

**PRINCIPLE OF THE METHOD**

Glucose oxidase (GOD) catalyses the oxidation of glucose to gluconic acid. The formed hydrogen peroxide (H<sub>2</sub>O<sub>2</sub>), is detected by a chromogenic oxygen acceptor, phenol, 4 – aminophenazone (4-AP) in the presence of peroxidase (POD):



The intensity of the color formed is proportional to the glucose concentration in the sample<sup>1,2</sup>.

**CLINICAL SIGNIFICANCE**

Glucose is a major source of energy for most cells of the body; insulin facilitates glucose entry into the cells.

Diabetes is a disease manifested by hyperglycemia; patients with diabetes demonstrate an inability to produce insulin<sup>1,5,6</sup>.

Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

**REAGENTS**

<b>R</b>	TRIS pH 7,4	92 mmol/L
	Phenol	0,3 mmol/L
	Glucose oxidase (GOD)	15000 U/L
	Peroxidase (POD)	1000 U/L
	4 – Aminophenazone (4-AP)	2,6 mmol/L
<b>GLUCOSE CAL</b>	Glucose aqueous primary standard 100 mg/dL	

**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 prevented during their use.

Do not use reagents over the expiration date.

**Signs of reagent deterioration:**

- Presence of particles and turbidity.
- Blank absorbance (A) at 505 nm ≥ 0,32.

**ADDITIONAL EQUIPMENT**

- Spectrophotometer or colorimeter measuring at 505 nm.
- Matched cuvettes 1,0 cm light path.
- General laboratory equipment.

**SAMPLES**

Serum or plasma, free of hemolysis<sup>1</sup>:

Serum should be removed from the clot as quickly as possible.

Stability of the sample: Glucose in serum or plasma is stable at 2-8° for 3 days.

**PROCEDURE**

1. Assay conditions:  
 Wavelength: ..... 505 nm (490-550)  
 Cuvette: ..... 1 cm light path  
 Temperature: ..... 37°C / 15-25°C
2. Adjust the instrument to zero with distilled water.
3. Pipette into a cuvette:

	Blank	Standard	Sample
R (mL)	1,0	1,0	1,0
Standard <sup>(Note 1,2,3)</sup> (µL)	--	10	--
Sample (µL)	--	--	10

4. Mix and incubate for 10 min at 37°C or 20 min at room temperature (15-25°C).
5. Read the absorbance (A) of the samples and standard, against the Blank. The colour is stable for at least 30 minutes.

**CALCULATIONS**

$$\frac{(A)\text{Sample} - (A)\text{Blank}}{(A)\text{Standard} - (A)\text{Blank}} \times 100 \text{ (Standard conc.)} = \text{mg/dL glucose in the sample}$$

**Conversion factor:** mg/dL x 0,0555= mmol/L.

**QUALITY CONTROL**

Control sera are recommended to monitor the performance of assay procedures: CONTROL Normal and Pathologic .

If control values are found outside the defined range, check the instrument, reagent and calibration for problems.

Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

**REFERENCE VALUES<sup>1</sup>**

Serum or plasma:

$$60 - 110 \text{ mg/dL} \cong 3,33 - 6,10 \text{ mmol/L}$$

These values are for orientation purpose; each laboratory should establish its own reference range.

**PERFORMANCE CHARACTERISTICS**

**Measuring range:** From detection limit 0,3709 mg/dL to linearity limit 500 mg/dL.

If the concentration is greater than linearity limit dilute 1/2 the sample with CINA 9 g/L and multiply the result by 2.

**Precision:**

	Intra-assay (n=20)		Inter-assay (n=20)	
	Mean (mg/dL)	SD	CV (%)	CV (%)
Mean (mg/dL)	86,7	235	92,5	250
SD	0,44	0,86	2,76	6,44
CV (%)	0,51	0,37	2,98	2,57

**Sensitivity:** 1 mg/dL = 0,0039 (A).

**Accuracy:** Results obtained using Audit Diagnostics reagents (y) did not show systematic differences when compared with other commercial reagent (x).

The results obtained using 50 samples were the following:

Correlation coefficient (r): 0,99492.

Regression equation: y=1,104x - 1,249.

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

**INTERFERENCES**

Hemoglobin up to 19 g/L and bilirubin up to 100 mg/L, do not interfere<sup>1</sup>.

A list of drugs and other interfering substances with glucose determination has been reported<sup>3,4</sup>.

**NOTES**

1. GLUCOSE CAL: Proceed carefully with this product because due its nature it can get contaminated easily.
2. Calibration with the aqueous standard may cause a systematic error in automatic procedures. In these cases, it is recommended to use a serum Calibrator.
3. Use clean disposable pipette tips for its dispensation.
4. **Audit Diagnostics has instruction sheets for several automatic analyzers.**

**BIBLIOGRAPHY**

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