CHRONOLAB

CE
IVD

Glucose-LQ

GOD-POD. Liquid

Quantitative determination of glucose

PACKAGING

Ref.: 101-0442	Cont.: 4 x 250 mL
Ref.: 101-0578	Cont.: 3 x 100 mL

Store at 2-8º C

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[1,5,6].

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

PRINCIPLE OF THE METHOD

Glucose oxidase (GOD) catalyses the oxidation of glucose to gluconic acid. 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):

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

$$H_2O_2 + \text{Phenol} + \text{4-AP} \xrightarrow{POD} \text{Quinone} + H_2O$$

The intensity of the color formed is proportional to the glucose concentration in the sample[1,2].

REAGENTS

R	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
GLUCOSE CAL	Glucose aqueous primary standard	100 mg/dL

Optional (not included in the kit)

Contro-N	Ref.: 101-0252	4 x 5 mL	Lyophilized human control serum
	Ref.: 101-0083	20 x 5 mL	
Contro-P	Ref.: 101-0253	4 x 5 mL	Lyophilized human control serum
	Ref.: 101-0084	20 x 5 mL	

PREPARATION

Reagent and calibrator 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 2-8º 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 $\geq$ 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[1]:

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

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

PROCEDURE

Notes: CHRONOLAB SYSTEMS has instruction sheets for several automatic analyzers. Instructions for many of them are available on request.

GLUCOSE CAL: Proceed carefully with this product because due its nature it can get contamined easily.

Calibration with the aqueous standard may cause a systematic error in automatic procedures. In these cases, it is recommended to use a serum Calibrator.

Use clean disposable pipette tips for its dispensation.

1. Assay conditions:
   Wavelength: . . . . . 505 nm (490-550)
   Cuvette: . . . . . 1 cm light path
   Temperature. . . . . 37º C / 15-25º 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[(Note 1,2)] (µL)	--	10	--
Sample (µL)	--	--	10

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

CALCULATIONS

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

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

QUALITY CONTROL

Control sera are recommended to monitor the performance of assay procedures.

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[1]

Serum or plasma:

60 – 110 mg/dL $\cong$ 3.33 – 6.10 mmol/L

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

PERFORMANCE CHARACTERISTICS

Measuring range*:* From detection limit 0.033 mg/dL to linearity limit 500 mg/dL.

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

Precision:

	Intra-assay (n=20)		Inter-assay (n=20)	
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).

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Accuracy: Results obtained using CHRONOLAB 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[1].
A list of drugs and other interfering substances with glucose determination has been reported[3,4].

BIBLIOGRAPHY
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