



Glicemia

enzimática AA

For glucose determination in serum, plasma, urine or cerebrospinal fluid

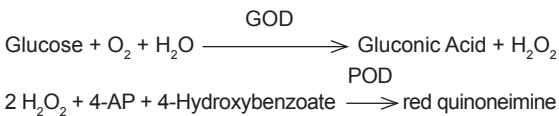
SUMMARY

Diabetes mellitus is the pathology most commonly related to carbohydrates metabolism. Early diagnosis and the periodic check of diabetic patients are aimed to prevent both ketoacidosis as well as complications of the symptoms coming from hyperglycemia, by means of a proper therapy.

Due to the existence of many causative factors of hypo- or hyperglycemia, physiological conditions and specific pathological features should be individually considered for each patient.

PRINCIPLE

The reaction system is as follows:



PROVIDED REAGENTS

S. Standard*: 100 mg/dl (1 g/l) glucose solution.

A. Reagent A: solution containing glucose oxidase (GOD), peroxidase (POD), 4-aminophenazone (4-AP), phosphates buffer pH 7.0 and 4-hydroxybenzoate, in the following concentrations:

GOD (microbial).....	≥ 10 KU/l
POD (horse-radish)	≥ 1 KU/l
4-AP.....	0.5 mmol
Phosphate	100 mmol, pH 7.0
Hydroxybenzoate.....	12 mmol

NON-PROVIDED REAGENTS

Wiener lab.'s **Calibrador A plus**.

INSTRUCTIONS FOR USE

Provided Reagents: ready to use.

WARNINGS

Reagents are for "in vitro" diagnostic use.

Use the reagents according to the working procedures for clinical laboratories.

The reagents and samples should be discarded according to the local regulations in force.

STABILITY AND STORAGE INSTRUCTIONS

Provided Reagents: stable in refrigerator (2-10°C) until the expiration date shown on the box. Do not expose to high temperatures for long periods of time.

INSTABILITY OR DETERIORATION OF REAGENTS

During its use, the Reagent A may develop a light pink coloration which does not affect its performance as long as a Blank is processed for each determination lot and a Standard periodically. Discard when the Blank readings are higher than 0.160 O.D.

SAMPLE

Serum, plasma, urine or cerebrospinal fluid (CSF)

a) Collection:

- Serum or plasma: obtain serum in the usual way, by checking the complete clot formation. If plasma is used, collect with ordinary anticoagulants, centrifuging sample before testing.
- Urine: if the urine specimen is a random sample, preferably use fresh urine. If the assay cannot be performed immediately, store sample at 2-10°C. Urine testing may be performed within 24 hours. In such case, collect the urine in a dark container with 5 ml of glacial acetic acid and store in ice.
- CSF: if CSF is used, perform the assay immediately after sample collection.

b) Additives: if plasma is used as sample, it is recommended to use Wiener lab.'s **Anticoagulante G** (EDTA/fluoride).

c) Known interfering substances: no interferences are observed from bilirubin up to 10 mg/dl, triglycerides up to 500 mg/dl and hemoglobin up to 350 mg/dl. The ascorbic acid interferes with one concentration of urine determination. See Young, D.S. in References for effect of drugs on the present method.

d) Stability and storage instructions: the enzymatic destruction of blood glucose (glycolysis) by red blood cells and leukocytes is proportional to the temperature at which blood is stored, reaching its maximum at 37°C. This process is not inhibited by freezing, thus, blood should be centrifuged within 2 hours after collection. The clear supernatant must be transferred to another tube for storage. In this manner, glucose is stable for 4 hours at room temperature or 24 hours refrigerated.

When it is not possible to process the sample as indicated above, add a preservative to the blood when collecting. The CSF may be contaminated with bacteria and other cells. Thus, the test should be immediately performed. Otherwise, centrifuge the CSF and store for 3 days at 2-10°C or for 5 hours at 20-25°C.

REQUIRED MATERIAL (non-provided)

- Spectrophotometer or photocolormeter.
- Micropipettes and pipettes capable of measuring the stated volumes.

- Tubes or spectrophotometric cuvettes.
- Water bath at 37°C.
- Watch or timer.

ASSAY CONDITIONS

- Wavelength: 505 nm in spectrophotometer or in photocol-
orimeter with green filter (490-530 nm).
 - Reaction temperature: 37°C
 - Reaction time: 5 minutes
 - Sample volume: 10 ul
 - Reagent volume: 1 ml
 - Final reaction volume: 1.01 ml
- Sample and Reagent A volumes may be varied proportionally (e.g. 20 ul Sample + 2 ml Reagent A).

PROCEDURE

In three test tubes labeled B (Blank), S (Standard) and U (Unknown) place:

	B	S	U
Standard	-	10 ul	-
Sample	-	-	10 ul
Reagent A	1 ml	1 ml	1 ml

Incubate tubes for 5 minutes in water bath at 37°C or for 25 minutes at 15-25°C. Read in spectrophotometer at 505 nm or in photocol-
orimeter with green filter at 490-530 nm, setting the instrument to zero O.D. with Blank.

STABILITY OF FINAL REACTION

Final reaction color is stable for 30 minutes, thus absorbance should be read within that period.

CALCULATIONS

$$\text{Glucose (mg/dl)} = U \times f \quad f = \frac{100 \text{ mg/dl}}{S}$$

QUALITY CONTROL METHOD

Each time the test is performed, analyze two levels of a quality control material (**Standatrol S-E 2 niveles**) with known glucose concentration.

REFERENCE VALUES

In a study performed with Wiener lab.'s **Glicemia enzimática AA líquida** among 120 fasting individuals from Rosario (Argentina), from both sexes (between 20 and 45 years old), without presenting symptoms of diabetes or other diseases, 95% of results, cover this range:

Serum or plasma: 70 - 110 mg/dl

In the literature (Tietz, N.W.) the following Reference Value range is mentioned:

Serum or plasma

Adults: 74-106 mg/dl (4.11-5.89 mmol/l)
Children: 60-100 mg/dl (3.33-5.55 mmol/l)

Newborns: 1 day old: 40-60 mg/dl (2.22-3.33 mmol/l)
> 1 day old: 50-80 mg/dl (2.78-4.44 mmol/l)

Fresh random urine

1-15 mg/dl (0.06-0.83 mmol/l)

24-hour urine

< 0.5 g/24 hrs (< 2.78 mmol/24 hrs)

CSF

Children: 60-80 mg/dl (3.33-4.44 mmol/l)

Adults: 40-70 mg/dl (2.22-3.89 mmol/l)

It is recommended that each laboratory establishes its own reference values for their own patients, considering age, sex, dietary habits and other factors.

SI SYSTEM UNITS CONVERSION

Glucose (mg/dl) x 0.0555 = Glucose (mmol/l)

Glucose (g/24 hours) x 55.5 = Glucose (mmol/24 hrs)

PROCEDURE LIMITATIONS

See Known interfering substances under SAMPLE.

PERFORMANCE

The assays were performed in an Express plus analyzer[®].

a) Reproducibility: testing 20 replicates from the same sample in 5 different days, the following results were obtained:

Intra-assay precision

Level	S.D.	C.V.
90.7 mg/dl	±1.26 mg/dl	1.39 %
278 mg/dl	± 3.08 mg/dl	1.11 %

Inter-assay precision

Level	S.D.	C.V.
90.1 mg/dl	± 1.73 mg/dl	1.92 %
299 mg/dl	± 4.86 mg/dl	1.62 %

b) Recovery: adding known amounts of glucose to different sera, a recovery between 99 and 101% was obtained.

c) Linearity: reaction is linear up to 500 mg/dl. For higher values, dilute the sample with saline solution, repeat the test and multiply final result by the dilution factor.

d) Correlation: glucose values of 154 serum specimens covering a range from 23 mg/dl to 503 mg/dl were determined using the Wiener lab's **Glicemia enzimática AA líquida** kit and a commercial kit based on same principle. The correlation coefficient was:

$r = 0.9997$, slope $b = 1.0257$ and intercept $a = 1.9485$.

e) Sensitivity studies: minimum detection limit is 0.54 mg/dl and analytical sensitivity is 4.2 mg/dl.

PARAMETERS FOR AUTOANALYZERS

For programming instructions check the user manual of the autoanalyzer in use.

For calibration can be use Wiener lab's **Calibrador A plus**, following the autoanalyzer requirements.

WIENER LAB PROVIDES

- 4 x 250 ml (Cat. N° 1400060).

- 6 x 60 ml (Cat. N° 1009313).
- 6 x 60 ml (Cat. N° 1009617).
- 12 x 50 ml (Cat. N° 1009260).

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SYMBOLS

The following symbols are used in packaging for Wiener lab. diagnostic reagents kits.



This product fulfills the requirements of the European Directive 98/79 EC for "in vitro" diagnostic medical devices

	Authorized representative in the European Community
	"In vitro" diagnostic medical device
	Contains sufficient for <n> tests
	Use by
	Temperature limitation (store at)
	Do not freeze
	Biological risks
	Volume after reconstitution
	Contents
	Batch code
	Manufactured by:
	Harmful
	Corrosive / Caustic
	Irritant
	Consult instructions for use
	Calibrator
	Control
	Positive Control
	Negative Control
	Catalog number

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