Reactivos GPL

Barcelona, España

CE

-GLUCOSE LS-

GLUCOSE
Liquid. GOD-POD

Store at: +2+8ºC.

Presentation:
Cod. SU018 CONT: *R 2 x 125 mL.+ CAL 1 x 5 mL.*
Cod. SU019 CONT: *R 4 x 250 mL.+ CAL 1 x 5 mL.*

Procedure

Quantitative determination of glucose.

Only for *in vitro use in clinical laboratory* (IVD)

TEST SUMMARY

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-aminophenazone in the presence of peroxydase (POD):

$$\beta\text{-D-Glucose} + 2H_2O + O_2 \xrightarrow{GOD} \text{Gluconic acid} + H_2O_2$$

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

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

REAGENTS COMPOSITION

R	TRIS pH 7.4 Phenol Glucose oxydase (GOD) Peroxidase (POD) 4-Aminophenazone (4-AP)	92 mmol/L. 0.3 mmol/L. 15000 U/L. 1000 U/L. 2.6 mmol/L.
Glucose Cal	Gucose aqueous primary Calibrator	100 mg/dL.

REAGENT PREPARATION AND STABILITY

All the reagents are ready to use.
All the components of the kit are stable until the expiration date on the label when stored at 2-8ºC, protected from light and contamination prevented during their use.
Do not use reagents over the expiration date.
Glucose Cal: Proceed carefully with this product because due its nature it can get contaminated easily.
Signs of Reagent deterioration:

- Presence of particles and turbidity.
- Blank absorbance (A) at 505 nm. $\geq$ 0.32

All the reagents of the kit are stable up to the end of the indicated month and year of expiry. Store tightly closed at 2-8ºC. Do not use reagents over the expiration date.

SPECIMEN

Serum or plasma, free of hemolysis[1]
Stability: Glucose is stable at 2-8ºC for 3 days.
Serum shoud be removed from the clot as quickly as possible.

MATERIAL REQUIRED BUT NOT PROVIDED

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

General laboratory equipment.

TEST PROCEDURE

1. Assay Conditions
   - Wavelenght : ..... 505 nm. (490-550).
   - Cuvette: ..... 1 cm light path.
   - Temperature .....37ºC. 15-25ºC.
2. Adjust the instrument to zero with Blank of reagent.
3. Pipette into a cuvette:

	Blank	Standard	Sample
R (mL.)	1.0	1.0	1.0
Calibrator(note1-2) (µL.)	--	10	--
Sample (µL.)	--	--	10

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

CALCULATIONS

$$\text{Glucose (mg/dL.)} = \frac{(A)\,\text{Sample}}{(A)\,\text{Standard}} \times 100 \text{ (Calibrator conc.)}$$

Conversion Factor. mg/dL. x 0.0555 = mmol/L.

QUALITY CONTROL

Control sera are recommended to monitor the performance of the procedure, H Normal and H Pathological (QC003, QC004).
If control values are found outside the defined range, check the instrument, reagents and calibrator for problems.

Serum controls are recommended for internal quality control. Each laboratory should establish its own Quality Control scheme and corrective actions.

REFERENCE VALUES

Serum or Plasma:
60 – 110 mg/dL. 3.33 – 6.10 mmol/L.
(These values are for orientation purpose).

It is suggested that each laboratory establish its own reference range.

CLINICAL SIGNIFICANCE

Glucose is major source of energy for most cells of the body; insulin facilitates glucose entry into the cells.
Diabetes is a disease manifested by hyperglucemia; 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.

REAGENT PERFORMANCE

– *Measuring Range*:
From *detection limit* of 1 mg/dL. to *linearity limit* of 500 mg/dL., under the described assay conditions.
If results obtained were greater than linearity limit, dilute the sample ½ with NaCl 9 g/L. and multiply result by 2.

– *Precision*:

	Intra-assay n= 20		Inter-assay n= 20	
Mean (g/dL)	94.9	238	98.6	246
SD	1.99	4.11	3.04	5.00
CV (%)	2.10	1.73	3.09	2.03

- *Sensitivity:*
1 mg/dL. = 0.0035A
- *Accuracy:*
Results obtained GPL reagents did not show systematic differences when compared with other commercial reagents.
The results obtained using 50 samples were the following:
Correlation coefficient (r): 0.9929
Regression Equation: y=0.9901 x + 1.0515
The results of the performance characteristics depend on the analyzer used.

INTERFERING SUBSTANCES

– Interference:
No interferes[1] were observed to bilirubin up to 100 mg/L, hemoglobin up to 19 g/L.
Other substances may interfere. A list of drugs and other substances that could interfere has been reported by Young et. al[3,4].

NOTES

1. Calibration with the aqueous standard may cause a systematic error in automatic procedures. In these cases, it is recommended to use a serum Calibrator.
2. Use clean disposable pipette tips for its dispensation.

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GPLBSDTT46-I
Rev. 01/2014