GLUCOSE PAP SL

In vitro diagnostic reagent, for professional use only

CLINICAL SIGNIFICANCE (1-3)
Glucose is the main source of energy for the human body. Glucose is converted either into glycogen to be stored in the liver or into triglycerides to be stored in fatty tissues. Glucose concentration in blood is regulated by several hormones, including two antagonists: insulin and glucagon. Quantification of glucose in blood is used to diagnose metabolic carbohydrates disorders such as diabetes, neonatal glycaemia, idiopathic hypoglycaemia and pancreatic disease. The main physiological troubles are linked to hyperglycemia (Type I Diabetes mellitus and type II Diabetes mellitus). Type I diabetes mellitus is insulin-dependent, and appears mainly before 30 years old. Type II diabetes mellitus is non-insulin-dependent, and usually appears after 40 years old, but can occur earlier for obese people. Other diabetes have secondary origin, and appear after endocrinical or hepatic diseases.

METHOD (4-5)
Enzymatic colorimetric.

Trinder - Kinetic.

PRINCIPLE (4,5)
Enzymatic determination of glucose according to the following reactions:

- Glucose oxidase
- Peroxidase
- Phenol + 4-Aminoantipyrine
- Quinoneimine + H2O2

REAGENTS COMPOSITION

Reagent: R
- Phosphate buffer, pH 7.4
- Phenol
- 4-Aminoantipyrine
- Glucose oxidase
- Peroxidase
- Distilled Water

Standard: Std
- D-Glucose
- 100 mg/dL
- 1 g/L
- 5.56 mmol/L

This standard is included in kits GPSL-0507/GPSL-0707 and can be sold separately under the reference GLUP-0055.

- MATERIAL REQUIRED BUT NOT PROVIDED
  - CONT-0060 ELITROL I 10 × 5 mL
  - CONT-0160 ELITROL II 10 × 5 mL

- PRECAUTIONS
  - The reagent contains less than 0.1% sodium azide. Sodium azide can react with copper and lead plumbing to form explosive metal azides. If discharge in the canailazations, rinse with plenty of water.
  - Use clean or single use laboratory equipment only to avoid contaminations.
  - The standard should be immediately and tightly capped to prevent contamination and evaporation.

- WASTE MANAGEMENT
  Disposal of all waste material should be according with local and legal requirements.

STABILITY OF REAGENTS
To store at 2-8°C and protected from light.
The reagent and the standard are stable until the expiry date stated on the label.

On board stability:
The stability is specific for each analyser (for Selectra refer to § PERFORMANCE DATA)

PREPARATION AND STABILITY OF WORKING REAGENT
The reagent and the standard are ready to use.

SAMPLES (2,3)
- Specimen
  Serum free of hemolysis.
  Plasma collected on fluorur or heparin/iodoacetate or any inhibitors of glycolysis.
- Storage
  Serum is stable 8 hours at 25°C and up to 3 days at 2-8°C.
  Plasma preserve with sodium fluoride and iodoacetate is stable for 24 hours at room temperature.

REFERENCE VALUES (3)
Serum, plasma:
- 74 - 106 mg/dL
- 0.74 - 1.06 g/L
- 4.1 - 5.9 mmol/L

Note: It is recommended for each laboratory to establish and maintain its own reference values. The data given here are only an indication.

PROCEDURE
This reagent can be used on most analysers, semi automated analysers and manual methods.
The applications are available on request.
Wavelength: 500 nm
Temperature: 37°C

Read against reagent blank.

CALCULATION:

\[ \Delta A = \Delta A \text{ Sample} \times n \quad n = \text{Standard concentration} \]

\[ \Delta A \text{ Standard} \]

- CALIBRATION:
  Concentration value of Glucose Standard 100 mg/dL is traceable to the Standard Reference Material NIST 965a (of the National Institute of Standards and Technology).
  The calibration stability is specific for each analyser (for Selectra refer to § PERFORMANCE DATA).

QUALITY CONTROL:
To ensure adequate quality, control sera such as ELITROL I (normal control) and ELITROL II (abnormal control) are recommended.

PERFORMANCE DATA at 37°C on Selectra:
- Analytical range
  The reagent is linear from 20 to 400 mg/dL (0.2 to 4 g/L; 1.11 to 22.2 mmol/L).
- Detection limit (6)
  Determined according to SFBC protocol, the detection limit is equal to 2 mg/dL (0.02 g/L; 0.111 mmol/L).
GLUCOSE PAP SL

In vitro diagnostic reagent, for professional use only

- Analytical sensitivity
The average variation of the analytical signal is 0.85 x 10^-3 ΔA per mg/dL of glucose (85 x 10^-3 ΔA per g/L, 0.015 ΔA per mmol/L) for a light path of 1 cm.

- Precision:
- Within-run reproducibility on serum
  Low level: n = 20 m = 35 mg/dL CV = 2.3 %
  Medium level: n = 20 m = 97 mg/dL CV = 2.0 %
  High level: n = 20 m = 292 mg/dL CV = 1.5 %

- Between-run reproducibility on serum
  Low level: n = 92 m = 34 mg/dL CV = 3.4 %
  Medium level: n = 91 m = 94 mg/dL CV = 2.8 %
  High level: n = 91 m = 282 mg/dL CV = 3.5 %

- Correlation
A comparative study has been performed between ELITech method and another commercial reagent (enzymatic (hexokinase) – UV method) on 71 human serum samples. The values ranged from 26 to 423 mg/dL. The parameters of linear regression are as follows:
Correlation coefficient: (r) = 0.9993
Linear regression: y = 1.0491 x - 1.8 mg/dL

- Interferences
According to SFBC recommendations, studies have been performed to determine the level of interference from different compounds:
- Turbidity: No significant interference up to 600 mg/dL Triglyceride equivalent (6 g/L, 6.9 mmol/L).
- Unconjugated bilirubin: Negative bias from 6 mg/dL (60 mg/L, 100 µmol/L) on normal serum. Negative bias from 11 mg/dL (110 mg/L, 190 µmol/L) on pathological serum.
- Conjugated bilirubin: Negative bias from 2.1 mg/dL (21 mg/L, 35 µmol/L) on normal serum. No significant interference up to 25 mg/dL (250 mg/L, 427 µmol/L) on pathological serum.
- Hemoglobin: No significant interference up to 500 mg/dL (5 g/L).
- Ascorbic acid: No significant interference up to 7 mg/dL (70 mg/L, 0.40 mmol/L).

Other compounds may interfere. [8-10]

- On board stability/Calibration Frequency on Selectra
  (no refrigerated)
  On – board Stability: 14 days (Capped vials and stored at 2-8 °C during the night)
  Calibration Frequency: 14 days
  Make A new calibration when reagent, when quality control results fall outside the established range, and after a maintenance operation.

BIBLIOGRAPHY

SYMBOLS USED ON LABELS

REVISED: PIT-GPSL-10 01/2010

SEPPIM S.A.S. - Zone Industrielle - 61500 SEES FRANCE