GLUCOSE

COD 12503 10 x 50 mL
Only for *in vitro* use in the clinical laboratory

Automated Systems

BioSystems

GLUCOSE
GLUCOSE OXIDASE/PEROXIDASE

INTENDED USE

Reagent for the measurement of glucose concentration in human serum, plasma or cerebrospinal fluid. The obtained values are useful as an aid in the diagnosis and monitoring of the diabetes mellitus.

This reagent is for use in the BioSystems A25 and A15 analyzers or in other analyzer with similar performance characteristics.

CLINICAL SIGNIFICANCE

Glucose is the major source of energy in the body. Insulin, produced by islet cells in the pancreas, facilitates glucose entry into the tissue cells. A deficiency of insulin or a decrease of its effectiveness increases blood glucose.

Elevated plasma glucose concentration is found in diabetes mellitus (type I and type II) and in other conditions and syndromes[1,2].

Hypoglycemia can occur in response to fasting, or it may be due to drugs, poisons, inborn errors of metabolism or previous gastrectomy[1,3].

Clinical diagnosis should not be made on the findings of a single test result, but should integrate both clinical and laboratory data.

PRINCIPLE OF THE METHOD

Glucose in the sample originates, by means of the coupled reactions described below, a coloured complex that can be measured by spectrophotometry[4].

$$\text{Glucose} + \tfrac{1}{2}\,O_2 + H_2O \xrightarrow{\text{glucose oxidase}} \text{Gluconate} + H_2O_2$$

$$2\,H_2O_2 + 4\text{–Aminoantipyrine} + \text{Phenol} \xrightarrow{\text{peroxidase}} \text{Quinoneimine} + 4\,H_2O$$

CONTENTS AND COMPOSITION

A. Reagent: 10 x 50 mL. Phosphate 100 mmol/L, phenol 5 mmol/L, glucose oxidase > 10 U/mL, peroxidase > 1 U/mL, 4-aminoantipyrine 0.4 mmol/L, pH 7.5

STORAGE AND STABILITY

Store at 2-8ºC.

Components are stable once opened until the expiry date marked in the label if they are stored well closed and care is taken to prevent contamination during their use.

On board stability: Reagents open and kept in the refrigerated compartment of the analyzer are stable 2 months.

Indications of deterioration: Absorbance of the blank over the limit indicated in "Test Parameters".

WARNING AND PRECAUTIONS

Exercise the normal precautions required for handling all laboratory reagents. Safety data sheet available for professional user on request. Disposal of all waste material should be in accordance with local guidelines.

ADDITIONAL MATERIALS REQUIRED (NOT PROVIDED)

Biochemistry Calibrator (BioSystems cod. 18011) or Biochemistry Calibrator Human (BioSystems cod. 18044).

REAGENT PREPARATION

Reagent is provided ready to use.

SAMPLES

Serum or plasma collected by standard procedures. Serum or plasma must be separated from the red cells promptly to prevent glycolysis. The addition of sodium fluoride to the blood sample prevent glycolysis. Glucose in serum or plasma is stable for 5 days at 2-8 ºC. Heparin, EDTA, oxalate and fluoride may be used as anticoagulants.

Cerebrospinal fluid collected by standard procedures. Cerebrospinal fluid may be contaminated with bacteria or other cells and should therefore be analyzed for glucose immediately.

CALIBRATION

A reagent blank should be done every day and a calibration at least every 2 months, after reagent lot change or as required by quality control procedures.

QUALITY CONTROL

It is recommended to use the Biochemistry Control Serum level I (cod. 18005, 18009 and 18042) and II (cod. 18007. 18010 and 18043) to verify the accuracy of the measurement procedure.

Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if control results are not within the acceptable limits.

REFERENCE VALUES

Serum and plasma[1]:

Children, adult	60-100 mg/dL = 3.30-5.60 mmol/L

Cerebrospinal fluid[1]:

Adult	40-70 mg/dL = 2.22-3.89 mmol/L

According to the National Diabetes Data Group (US)[2], elevation of fasting plasma glucose values over 140 mg/dL (7.77 mmol/L) on more than one occasion is diagnostic of diabetes mellitus.

METROLOGICAL CHARACTERISTICS

The metrological characteristics described below have been obtained using an A25 analyzer. Results are similar with A15.

- Detection limit: 1.6 mg/dL = 0.08 mmol/L.
- Linearity limit: 500 mg/dL = 27.5 mmol/L.
- Precision:

Mean concentration	Repeatability (CV)	Within-laboratory (CV)
84 mg/dL = 4.66 mmol/L	1.3 %	1.2 %
260 mg/dL = 14.43 mmol/L	1.5 %	1.4 %

- Trueness: Results obtained with this reagent did not show systematic differences when compared with reference reagents. Details of the comparison experiments are available on request.

LIMITATIONS OF THE PROCEDURE

- Interferences: Hemolysis (hemoglobin up to 300 mg/dL), bilirubin (up to 10 mg/dL) and lipemia (triglycerides up to 125 mg/dL) do not interfere. Ascorbic acid (up to 25 mg/dL) does not interfere. Other drugs and substances may interfere[5].

BIBLIOGRAPHY

1. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics. 5th ed. Burtis CA. Ashwood ER. Bruns DE. WB Saunders Co. 2012.
2. National Diabetes Data Group: Classification and diagnosis of diabetes mellitus and other categories of glucose intolerance. Diabetes 1979; 28:1039-1057.
3. Friedman and Young. Effects of disease on clinical laboratory tests. 4th ed. AACC Press. 2001.
4. Trinder P. Determination of glucose in blood using glucose oxidase with an alternative oxygen acceptor. Ann Clin Biochem 1969; 6: 24-27.
5. Young DS. Effects of drugs on clinical laboratory tests. 5th ed. AACC Press. 2000.

TEST PARAMETERS

These reagents may be used in several automatic analyzers. Specific instructions for application in many of them are available on request.

R1: use Reagent A.

	A25	A15
GENERAL		
Name	**GLUCOSE**	**GLUCOSE**
Sample type	SER/LIQ	SER/LIQ
Analysis mode	endpoint mon.	endpoint mon.
Units	mg/dL	mg/dL
Turbidimetry test	no	No
Decimals	0	0
Type of reaction	increasing	increasing
PROCEDURE		
Reading mode	bichrom.	bichrom.
Main filter	505	505
Reference filter	670	670
Sample	3	3
Vol. R1	300	300
Vol. R2	-	-
Washing	1.2	1.2
Reading 1 (cycle)	41	26
Reading 2 (cycle)	-	-
Reagent 2 (cycle)	-	-
Predilution factor	-	-
CALIBRATION AND BLANK		
Calibration type	multiple	multiple
Number of calibrators	-	-
Calibration curve	-	-
OPTIONS		
Blank absorbance limit	0.150	0.150
Kinetic blank limit	-	-
Linearity limit	500	500
Substrate depletion	-	-

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