COD 11803 1 x 50 mL	COD 11503 1 x 200 mL	COD 11504 1 x 500 mL	COD 11538 1 x 1 L
STORE AT 2-8ºC			
Reagents for measurement of glucose concentration Only for *in vitro* use in the clinical laboratory			

BioSystems

CE

GLUCOSE
GLUCOSE OXIDASE/PEROXIDASE

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[1].

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

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

CONTENTS

	COD 11803	COD 11503	COD 11504	COD 11538
A. Reagent S. Standard	1 x 50 mL 1 x 5 mL	1 x 200 mL 1 x 5 mL	1 x 500 mL 1 x 5 mL	1 x 1 L 1 x 5 mL

COMPOSITION

A. Reagent: 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

S. Glucose/Urea/Creatinine Standard. Glucose 100 mg/dL (5.55 mmol/L), urea 50 mg/dL, creatinine 2 mg/dL. Aqueous primary standard.

STORAGE

Store at 2-8ºC.

Reagent and Standard are stable until the expiry date shown on the label when stored tightly closed and if contaminations are prevented during their use.

Indications of deterioration:

- Reagent: Presence of particulate material, turbidity, absorbance of the blank over 0.150 at 500 nm (1 cm cuvette).
- Standard: Presence of particulate material, turbidity.

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.

REAGENT PREPARATION

Reagent and Standard are provided ready to use.

ADDITIONAL EQUIPMENT

- Thermostatic water bath at 37ºC
- Analyzer, spectrophotometer or photometer able to read at 500 ± 20 nm

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 2-8ºC. 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.

PROCEDURE

1. Bring the Reagent to room temperature.
2. Pipette into labelled test tubes: (Note 1)

	Blank	Standard	Sample
Glucose Standard (S)	—	10 µL	—
Sample	—	—	10 µL
Reagent (A)	1.0 mL	1.0 mL	1.0 mL

3. Mix thoroughly and incubate the tubes for 10 minutes at room temperature (16-25ºC) or for 5 minutes at 37ºC.
4. Measure the absorbance (A) of the Standard and the Sample at 500 nm against the Blank. The colour is stable for at least 2 hours.

CALCULATIONS

The glucose concentration in the sample is calculated using the following general formula:

$$\frac{A_{\text{Sample}}}{A_{\text{Standard}}} \times C_{\text{Standard}} = C_{\text{Sample}}$$

If the Glucose Standard provided has been used to calibrate (Note 2):

$\frac{A_{\text{Sample}}}{A_{\text{Standard}}}$	x 100 = mg/dL glucose x 5.55 = mmol/L glucose

REFERENCE VALUES

Serum and plasma[2]:

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

Cerebrospinal fluid[2]:

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

These ranges are given for orientation only; each laboratory should establish its own reference ranges.

According to the National Diabetes Data Group (US)[3], elevation of fasting plasma glucose values over 140 mg/dL (7.77 mmol/L) on more than one occasion is diagnostic of diabetes mellitus.

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 performance of the measurement procedure.

Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if controls do not recover within the acceptable tolerances.

METROLOGICAL CHARACTERISTICS

- Detection limit: 0.23 mg/dL = 0.0126 mmol/L
- Linearity limit: 500 mg/dL = 27.5 mmol/L. For higher values dilute sample 1/4 with distilled water and repeat measurement.
- Repeatibility (within run):

Mean Concentration	CV	n
88 mg/dL = 4.84 mmol/L	1.2 %	20
326 mg/dL = 17.93 mmol/L	0.9 %	20

- Reproducibility (run to run):

Mean Concentration	CV	n
88 mg/dL = 4.84 mmol/L	2.7 %	25
326 mg/dL = 17.93 mmol/L	1.9 %	25

- Sensitivity: 4 mA·dL/mg = 0.22 mA·L/mmol
- Trueness: Results obtained with this reagent did not show systematic differences when compared with reference reagents (Note 2). Details of the comparison experiments are available on request.
- 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[4].

These metrological characteristics have been obtained using an analyzer. Results may vary if a different instrument or a manual procedure are used.

DIAGNOSTIC CHARACTERISTICS

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 serum or plasma glucose concentration is found in diabetes mellitus (insulin dependent, non-insulin dependent) and in other conditions and syndromes[2,3].

Hypoglycemia can occur in response to fasting, or it may be due to drugs, poisons, inborn errors of metabolism or previous gastrectomy[2,5].

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

NOTES

1. These reagents may be used in several automatic analysers. Specific instructions for application in many of them are available on request.
2. Calibration with the provided aqueous standard may cause a matrix related bias, specially in some analyzers. In these cases, it is recommended to calibrate using a serum based standard (Biochemistry Calibrator, cod. 18011 and 18044).

BIBLIOGRAPHY

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

BioSystems S.A. Costa Brava, 30. 08030 Barcelona (Spain)
www.biosystems.global