Cat. No 4-501

DIAGNOSTIC KIT FOR DETERMINATION OF GLUCOSE CONCENTRATION

HC – GLUCOSE

INTRODUCTION

Glucose is a simple six-carbon sugar. Oxidative metabolism of glucose provides the energy for most cellular processes. Glucose level in the blood is tightly controlled by several hormones. Elevated glucose level is the classic sign of diabetes mellitus. Glucose level abnormalities (hyper- or hypoglycemia) might be caused also by pancreas tumors and diseases of liver, thyroid gland or adrenal glands.

METHOD PRINCIPLE

Colorimetric, enzymatic method with glucose oxidase.

$$\text{glucose} + H_2O + O_2 \xrightarrow{GOD} \text{gluconic acid} + H_2O_2$$

$$2\,H_2O_2 + \text{phenol} + \text{4-aminoantipyrine} \xrightarrow{POD}$$

$$\text{4-(p-benzochinonomonoimino)-phenazone} + 4\,H_2O$$

(red colour)

The colour intensity is proportional to the glucose concentration.

REAGENTS

Package

1-Reagent	6 x 96.5 ml

The reagent when stored at 2-8°C is stable up to expiry date printed on the package. The reagents are stable for 12 weeks on board the analyser at 2-10°C. Protect from light and contamination!

Concentrations in the test

phosphate buffer (pH 7.0)	250 mmol/l
phenol	5 mmol/l
glucose oxidase (GOD)	> 250 µkat/l
peroxidase (POD)	> 20 µkat/l
4-aminoantipyrine (4-AA)	500 µmol/l

Warnings and notes

- Product for in vitro diagnostic use only.

SPECIMEN

Serum, EDTA or heparinized plasma (recommended: heparine lithium, sodium or ammonium salt) free from hemolysis, cerebrospinal fluid.
Specimen which is not assayed immediately after collection should be kept in tubes containing sodium fluoride or sodium iodoacetate. These compounds adding prevent glycolysis and stabilize glucose level.
Glucose concentration in cerebrospinal fluid should be measured directly after specimen collection.
Serum and plasma can be stored up to 3 days at 2-8ºC.
Nevertheless it is recommended to perform the assay with freshly collected samples!

PROCEDURE

The reagent is ready to use.
This reagent may be used in automatic analyser Hitachi 911/912.
Application should be entered using handheld barcode scanner and attached barcodes sheet, according to procedure described below:

1. Delete previous version of application and calibrators assigned to it and restart the analyser.
2. Enter codes of calibrators according to the attached list.
3. Enter barcoded application and assign proper values to calibrators.
4. To activate entered application go to the tab UTILITY | APPLICATION | RANGE and change value of field DATA MODE from INACTIVE to ON BOARD. Confirm the change using UPDATE button.
5. Put reagents on board the analyser – they will be assigned to relevant tests automatically. Perform also measurement of level of reagents inside the bottles.
6. After calibration analyser is ready to use.

REFERENCE VALUES [7]

	mg/dl	mmol/l
serum, plasma	74 – 106	4.1 – 5.9
cerebrospinal fluid	40 – 70	2.2 – 3.9

It is recommended for each laboratory to establish its own reference ranges for local population.

QUALITY CONTROL

For internal quality control it is recommended to use the CORMAY SERUM HN (Cat. No 5-172) and CORMAY SERUM HP (Cat. No 5-173) with each batch of samples.
For the calibration of automatic analysers systems the CORMAY MULTICALIBRATOR LEVEL 1 (Cat. No 5-174; 5-176) is recommended. **Calibrator and deionised water** should be used for calibration.
The calibration curve should be prepared every 12 weeks, with change of reagent lot number or as required e.g. quality control findings outside the specified range.

PERFORMANCE CHARACTERISTICS

These metrological characteristics have been obtained using the automatic analyser Hitachi 912. Results may vary if a different instrument or a manual procedure is used.

- **Sensitivity:** 0.8 mg/dl (0.044 mmol/l).

- **Linearity:** up to 730 mg/dl (40.15 mmol/l).
  If glucose concentration exceeds 730 mg/dl, dilute sample with 0.9% NaCl and repeat the assay. Multiply the result by the dilution factor.

- **Specificity / Interferences**
  Haemoglobin up to 2.50 g/dl, ascorbate up to 62 mg/l, bilirubin up to 20 mg/dl and triglycerides up to 1000 mg/dl do not interfere with the test.

- **Precision**

Repeatability (run to run) n = 20	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	94.34	0.69	0.73
level 2	294.97	1.09	0.37

Reproducibility (day to day) n = 80	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	96.20	0.93	0.97
level 2	301.90	1.65	0.55

- **Method comparison**

A comparison between glucose values determined at Hitachi 912 (y) and at Cobas Integra 400 (x) using 100 samples gave following results:
y = 1.0126 x - 1.3147 mg/dl;
R = 0.997 (R – correlation coefficient)

WASTE MANAGEMENT
Please refer to local legal requirements.

LITERATURE

1. Barham P., Trinder P.: Analyst 97, 142-145 (1972).
2. Kaplan L.A., Pesce A.J.: Clinical Chemistry. Theory, analysis and correlation, The C. V. Mosby Company, St. Louis (1989).
3. Kaplan L.A., Pesce A.J., ed. Chemistry Theory, Analysis, and Correlation, 3rd ed. St Louis, MO: Mosby, 635 (1996).
4. Tietz N.W., ed. Clinical Guide to Laboratory Tests, 3rd ed. Philadelphia, PA: WB Saunders, 268-272 (1995).
5. Burtis C.A., Ashwood E.R., ed. Tietz Textbook of Clinical Chemistry, 2nd ed. Philadelphia, PA: WB Saunders, 959, 968 (1994).
6. Dembińska-Kieć A., Naskalski J.W.: Diagnostyka laboratoryjna z elementami biochemii klinicznej, Volumed, 24-25, (1998).
7. Burtis C.A., Ashwood E.R., ed. Tietz Textbook of Clinical Chemistry, 3rd ed. Philadelphia, PA: WB Saunders, 776-777, 1815, (1999).

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