

## DIAGNOSTIC KIT FOR DETERMINATION OF GLUCOSE CONCENTRATION



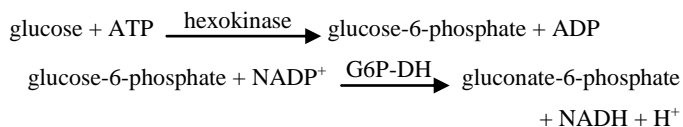
### HC – GLUCOSE HEX

#### 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

Enzymatic method with hexokinase and glucose-6-phosphate dehydrogenase (G6P-DH).



The rate of NADPH formation is directly proportional to the glucose concentration in the sample.

#### REAGENTS

##### Package

1-Reagent	6 x 81.5 ml
2-Reagent	6 x 16.9 ml

The reagents when stored at 2-8°C are stable up to expiry date printed on the package. The reagents are stable for 12 weeks on board the analyser at 2-10°C. Do not freeze reagents. Protect from light and avoid contamination!

#### Concentrations in the tests

##### 1-Reagent

PIPES buffer (pH 7.5)	87 mmol/l
Mg <sup>2+</sup>	10 mmol/l
ATP	4 mmol/l
NADP	3.2 mmol/l

##### 2-Reagent

hexokinase	≥ 4500 U/l
glucose-6-phosphate dehydrogenase (G6P-DH)	≥ 14000 U/l

#### Warnings and notes

- Product for in vitro diagnostic use only.
- The reagents must be used only for purpose intended by suitably qualified laboratory personnel, under appropriate laboratory conditions.
- Do not use after expiry date.
- Do not interchange caps.
- Reagents should be mixed before use by gentle inverting the bottles several times.
- The reagents contain < 0.1% sodium azide as a preservative. Avoid contact with skin and mucous membranes.

#### SPECIMEN

Serum, EDTA or heparinized plasma free from hemolysis, cerebrospinal fluid, urine.

Serum and plasma specimens should be separated from cells within 60 minutes after collection.

Plasma 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.

Serum and plasma can be stored up to 3 days at 4°C.

Glucose concentration in cerebrospinal fluid should be measured directly after specimen collection. Cerebrospinal fluid must be analysed simultaneously with a blood sample.

After centrifuge CSF sample can be stored up to 3 days at 4°C.

Preserve 24-hour urine sample by adding 5 ml of glacial acetic acid to the container before starting the collection. The final pH of the sample should be between 4 and 5.

Urine can be stored up to 24 hour at 4°C.

Nevertheless it is recommended to perform the assay with freshly collected samples!

#### PROCEDURE

The reagents are ready to use.

These reagents 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 <sup>7</sup>

	mg/dl	mmol/l
serum, plasma	74 – 106	4.1 – 5.9
urine	1 – 15	0.1 – 0.8
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) or CORMAY URINE CONTROL LEVEL 1 (Cat. No 5-161) and LEVEL 2 (Cat. No 5-162) for determination in urine with each batch of samples.

For the calibration of automatic analyser the CORMAY MULTICALIBRATOR LEVEL 1 (Cat. No 5-174; 5-176) and LEVEL 2 (Cat. No 5-175; 5-177) 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 automatic analyser Hitachi 912. Results may vary if a different instrument or a manual procedure is used.

- **Sensitivity:** 4.8 mg/dl (0.27 mmol/l).
- **Linearity:** up to 690 mg/dl (38.30 mmol/l).  
If glucose concentration exceeds the range of linearity, dilute sample with 0.9% NaCl and repeat the assay. Multiply the result by the dilution factor.

▪ **Specificity / Interferences**

Haemoglobin up to 0.5 g/dl, bilirubin up to 35.4 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	83.24	0.31	0.37
level 2	294.82	2.06	0.70

Reproducibility (day to day) n = 10	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	82.60	1.78	2.16
level 2	292.23	5.96	2.04

▪ **Method comparison**

A comparison between glucose values determined at Hitachi 912 (y) and at COBAS INTEGRA 400 (x) using 90 samples gave following results:

$$y = 1.0411 x - 4.9303 \text{ mg/dl};$$

$$R = 0.9910 \quad (R - \text{correlation coefficient})$$

**WASTE MANAGEMENT**

Please refer to local legal requirements.

**LITERATURE**

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