CORMAY GLUCOSE HEX

DIAGNOSTIC KIT FOR DETERMINATION OF GLUCOSE CONCENTRATION

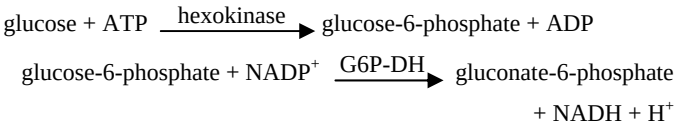
Kit name	Cat. No
CORMAY GLUCOSE HEX 500	1-232
CORMAY GLUCOSE HEX "bulk"	1-233

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

	CORMAY GLUCOSE HEX 500	CORMAY GLUCOSE HEX "bulk"
1-GLUCOSE HEX	3 x 500 ml	--*
2-GLUCOSE HEX	1 x 300 ml	--*

* reagent volume is printed on the label.

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!

Working reagent preparation and stability

Assay can be performed with use of separate 1-GLUCOSE HEX and 2-GLUCOSE HEX reagents or with use of working reagent. For working reagent preparation mix gently 5 parts of 1-GLUCOSE HEX with 1 part of 2-GLUCOSE HEX .

Stability of working reagent: 2 months at 2-8°C

Protect from light and avoid contamination!

Concentrations in the test

1-GLUCOSE HEX	
PIPES buffer (pH 7.5)	87 mmol/l
Mg^{2+}	10 mmol/l
ATP	4 mmol/l
NADP	3.2 mmol/l
2-GLUCOSE HEX	
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 sodium azide (< 0.1%) 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 4ºC.

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 4ºC.

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 4ºC.

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

ADDITIONAL EQUIPMENT

- automatic analyser or photometer able to read at 340 nm;
- thermostat at 37ºC;
- general laboratory equipment;

PROCEDURE

These reagents may be used both for manual assay (Sample Start and Reagent Start method) and in several automatic analysers. Applications for them are available on request.

Manual procedure

wavelength	340 nm
temperature	15-25 / 37°C
cuvette	1 cm

Sample Start method:

Pipette into the cuvettes:

	reagent blank (RB)	test (T)	standard (S)
working reagent	1000 µl	1000 µl	1000 µl

Bring up to the temperature of determination. Then add:

calibrator	-	-	10 µl
sample	-	10 µl	-

Mix well, incubate for 15 min. at 15-25ºC or 5 min. at 37ºC. Read the absorbance of standard A(S) and test A(T) against reagent blank (RB).

Reagent Start method

The determination can be also performed with use of separate 1-GLUCOSE HEX and 2-GLUCOSE HEX reagents.

Pipette into the cuvettes:

	reagent blank (RB)	test (T)	standard (S)
1-GLUCOSE HEX	1000 µl	1000 µl	1000 µl

Bring up to the temperature of determination. Then add:

calibrator	-	-	10 µl
sample	-	10 µl	-

Mix well, incubate for 5 min. Then add:

2-GLUCOSE HEX	200 µl	200 µl	200 µl

Mix well, incubate for 15 min. at 15-25ºC or 5 min. at 37ºC. Read the absorbance of standard A(S) and test A(T) against reagent blank (RB).

Calculation

$$\text{glucose concentration} = \frac{A(T)}{A(S)} \times \text{calibrator concentration}$$

REFERENCE VALUES [7]

	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 the CORMAY MULTICALIBRATOR LEVEL 1 (Cat. No 5-174; 5-176) and LEVEL 2 (Cat. No 5-175; 5-177) is recommended.
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 Biolis 24i Premium. Results may vary if a different instrument or a manual procedure is used.

- **Sensitivity:** 4.4 mg/dl (0.24 mmol/l).

- **Linearity:** up to 670 mg/dl (37.19 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	83.04	1.23	1.48
level 2	291.52	2.09	0.72

Reproducibility (day to day) n = 10	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	84.40	2.17	2.57
level 2	294.78	5.75	1.95

- **Method comparison**

A comparison between glucose values determined at Biolis 24i Premium (y) and at COBAS INTEGRA 400 (x) using 62 samples gave following results:
y = 1.0021 x - 2.6101 mg/dl;
R = 0.9980 (R – correlation coefficient)

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURA

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