

GLUCOSE HEX

Kit name	(EN)	1-Reagent	
CORMAY GLUCOSE HEX 30	Cat. No	PIPES buffer (pH 7.5)	80 mmol/l
CORMAY GLUCOSE HEX 60	1-229	Mg ²⁺	10 mmol/l
CORMAY GLUCOSE HEX 120	1-230	ATP	4 mmol/l
HC-GLUCOSE HEX	1-231	NAD	3 mmol/l
OS-GLUCOSE HEX	4-523	2-Reagent	
	9-477	hexokinase	≥ 4500 U/l
		glucose-6-phosphate dehydrogenase (G6P-DH)	≥ 14000 U/l

INTENDED USE

Diagnostic kit for determination of glucose concentration used both for manual assay (Sample Start and Reagent Start method) and in several automatic analysers.

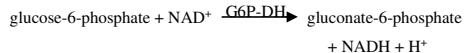
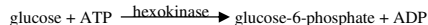
The reagents must be used only for *in vitro* diagnostic, by suitably qualified laboratory personnel, only for the intended purpose, under appropriate laboratory conditions.

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 NADH formation is directly proportional to the glucose concentration in the sample.

REAGENTS

Package	CORMAY GLUCOSE HEX 30	CORMAY GLUCOSE HEX 60	CORMAY GLUCOSE HEX 120
1-REAGENT	5 x 25 ml	5 x 50 ml	5 x 100 ml
2-REAGENT	1 x 25 ml	1 x 50 ml	1 x 100 ml
	HC- GLUCOSE HEX	OS- GLUCOSE HEX	
1-REAGENT	6 x 81.5 ml	4 x 43 ml	
2-REAGENT	6 x 16.9 ml	4 x 11 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.

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!

Warnings and notes

- Do not use after expiry date.
- Do not freeze reagents.
- Do not interchange caps.
- Protect from direct sunlight and avoid contamination!
- 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

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

Plasma / Serum. Serum and plasma specimens should be separated from cells within 30 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 2 days at 4°C.³

Plasma is the specimen recommended for the glucose determination in the blood.⁵

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

After centrifuge CSF sample can be stored up to 24 hours at 4°C.⁴

Urine. Collect 24-hour sample in dark bottle and keep on ice. Preserve 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. Centrifuge samples with visible turbidity or precipitates before analysis.

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

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 37°C;
- general laboratory equipment;

PROCEDURE

Applications for analyzers are available on request.

Manual procedure

wavelength	340 nm
temperature	15-25°C / 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 15-25°C or 5 min. at 37°C. 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
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Mix well, incubate for 15 min. at 15-25°C or 5 min. at 37°C. 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

	mg/dl	mmol/l
plasma, serum ^{5,6,7}	70 – 99	3.9 – 5.5
urine (24h) ⁸	1 – 15	0.1 – 0.8
cerebrospinal fluid ⁸	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 following controls for each batch of samples:

CORMAY SERUM HN (Cat. No 5-172) and CORMAY SERUM HP (Cat. No 5-173) for determination in serum; CORMAY URINE CONTROL LEVEL 1 (Cat. No 5-161) and LEVEL 2 (Cat. No 5-162) for determination in urine.

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

The following results 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).

For higher concentration dilute the sample with 0.9% NaCl and repeat the assay. Multiply the result by dilution factor.

Specificity / Interferences

Haemoglobin up to 1.25 g/dl, bilirubin up to 40 mg/dl, ascorbate up to 62 mg/L and triglycerides up to 1000 mg/dl do not interfere with the test. Some medicines can interfere.⁹

Precision

Repeatability (run to run) n = 20	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	86.55	1.15	1.32
level 2	276.89	2.87	1.04

Reproducibility (day to day) n = 10	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	85.70	0.98	1.14
level 2	281.62	5.00	1.77

Method comparison

A comparison between glucose values determined at Biolis 24i Premium (y) and at COBAS INTEGRA 400 (x) using 39 samples gave following results:

$$y = 0.972 x + 3.479 \text{ mg/dl;}$$

$$R = 0.999 \quad (R - \text{correlation coefficient})$$

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURA

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