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Liquick Cor GLUCOSE

Kit name	Cat. No
Liquick Cor-GLUCOSE mini	2-218
Liquick Cor-GLUCOSE 30	2-219
Liquick Cor-GLUCOSE 60	2-201
Liquick Cor-GLUCOSE 120	2-202
Liquick Cor-GLUCOSE 500	2-203

INTENDED USE

Diagnostic kit for determination of glucose concentration used both for manual assay 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

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

	Liquick Cor-GLUCOSE mini	Liquick Cor-GLUCOSE 30	Liquick Cor-GLUCOSE 60
1-GLUCOSE	2 x 60 ml	6 x 30 ml	6 x 60 ml
2-STANDARD	1 x 1 ml	1 x 2 ml	1 x 2 ml

	Liquick Cor-GLUCOSE 120	Liquick Cor-GLUCOSE 500
1-GLUCOSE	6 x 120 ml	4 x 500 ml
2-STANDARD	-	-

2-STANDARD is glucose standard solution: 5.5 mmol/l (100 mg/dl).

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.

Concentrations in the test

phosphate buffer (pH 7.0)	< 240 mmol/l
phenol	< 6 mmol/l
glucose oxidase (GOD)	< 480 µkat/l
peroxidase (POD)	< 44 µkat/l
4-aminoantipyrine (4-AA)	< 0,9 mmol/l
stabilizers and preservatives	

Warnings and notes

- Protect from direct sunlight and avoid contamination!
- The reagents are usable when the absorbance is less than 0.300 (read against distilled water, wavelength λ=500 nm, cuvette l=1 cm, at temp. 25°C).

ADDITIONAL EQUIPMENT

- automatic analyzer or photometer able to read at 500 nm (Hg 546 nm);
- thermostat at 37ºC;
- general laboratory equipment;

SPECIMEN

EDTA or heparinized plasma in tubes containing sodium fluoride or sodium iodoacetate additive/ serum, free from hemolysis, cerebrospinal fluid.
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 4ºC.[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 analysed simultaneously with a blood sample.
After centrifuge CSF sample can be stored up to 24 hours at 4ºC.[4]
Nevertheless it is recommended to perform the assay with freshly collected samples!

PROCEDURE

The reagent is ready to use.
Applications for analysers are available on request.

Manual procedure

wavelength	500 nm (Hg 546 nm)
temperature	20-25ºC / 37°C
cuvette	1 cm

Pipette into the cuvettes:

	reagent blank (RB)	test (T)	standard (S)
1-GLUCOSE	1000 µl	1000 µl	1000 µl
Bring up to the temperature of determination. Then add:			
standard / calibrator	-	-	10 µl
sample	-	10 µl	-

Mix well, incubate for 5 min. at 37ºC or 10 min at 20-25ºC. Read the absorbance of the test A(T) and standard A(S) against reagent blank A(RB).

Calculation

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

REFERENCE VALUES

	mg/dl	mmol/l
plasma, serum[5,6,7]	70 – 99	3.9 – 5.5
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 CORMAY SERUM HN (Cat. No 5-172) and CORMAY SERUM HP (Cat. No 5-173) with each batch of samples.
For the calibration the CORMAY MULTICALIBRATOR LEVEL 1 (Cat. No 5-174; 5-176), LEVEL 2 (Cat. No 5-175; 5-177) or GLUCOSE STANDARD 100 (Cat. No 5-121), GLUCOSE STANDARD 300 (Cat. No 5-122) are 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:** 0.41 mg/dl (0.023 mmol/l).

- **Linearity:** up to 500 mg/dl (27.5 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 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	96.30	1.37	1.42
level 2	302.61	2.87	0.95

Reproducibility (day to day) n = 80	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	96.27	3.58	3.72
level 2	303.38	7.04	2.32

- **Method comparison**

A comparison between glucose values determined at Biolis 24i Premium (y) and at Prestige 24i (x) using 100 samples gave following results:
y = 1.0096 x - 1.5851 mg/dl;
R = 0.9954 (R – correlation coefficient)

TRACEABILITY

GLUCOSE STANDARD 100 and GLUCOSE STANDARD 300 are traceable to the SRM 965B reference material.

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

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