

GLUCOSE UV FL

GL F601 CH

5 x 120 ml

SUMMARY OF TEST

Glucose is the primary energy source for the human body. It is derived from the breakdown of carbohydrates in the diet and in body stores, as well as by endogenous synthesis from protein or the glycerol moiety of triglycerides. When energy intake exceeds expenditure, the excess is converted to fat and glycogen for storage in adipose tissue and liver or muscle, respectively. When energy expenditure exceeds calorie intake, endogenous glucose formation occurs from the breakdown of carbohydrate stores and from noncarbohydrate sources.

The glucose level in the blood is maintained within a fairly narrow range under diverse conditions by regulatory hormones such as insulin, glucagon, or epinephrine. Measurement of glucose is one of the most commonly performed procedures in most hospital chemistry laboratories. The most frequently encountered disorder of carbohydrate metabolism is high blood glucose due to diabetes. The incidence of hypoglycemia (low blood glucose) is unknown but is much lower.

Diabetes mellitus is a group of metabolic disorders of carbohydrate metabolism in which glucose is underutilized, producing hyperglycemia. Some patients may develop acute life-threatening hyperglycemic episodes, such as ketoacidosis or hyperosmolar coma. As the disease progresses, patients are at increased risk of developing specific complications, including retinopathy leading to blindness, renal failure, neuropathy and atherosclerosis. The last may result in stroke, gangrene, or coronary disease. The diagnosis of diabetes mellitus depends solely on the demonstration of hyperglycemia. For type I diabetes, the diagnosis is usually easy because hyperglycemia appears abruptly, is severe, and is accompanied by serious metabolic derangements. It is in type II diabetes that diagnosis is difficult because glucose abnormalities may be mild, but the development of complications makes it important to identify people with the disease.

Hypoglycemia is a blood glucose concentration below the fasting range, but it is difficult to define specific limits. A transient decline may occur 1^{1/2} to 2 h after a meal, and it is not uncommon for a plasma glucose concentration as low as 50 mg/dl to be observed 2 h after ingestion of an oral glucose load. Even in the fasting state, extremely low blood glucose values may occasionally be noted without symptoms or evidence of underlying disease. No symptoms are specific for hypoglycemia. A rapid decrease in plasma glucose to hypoglycemic levels usually triggers a sympathetic response, with the release of epinephrine, which produces the classical signs and symptoms of hypoglycemia: weakness, shakiness, sweating, nausea, rapid pulse, lightheadedness, hunger, and epigastric discomfort. The brain is totally dependent on blood glucose, and very low levels of plasma glucose (less than 20 or 30 mg/dl) cause severe central nervous system (CNS) dysfunction.

Many analytical procedures are used to measure blood glucose levels. In the past, analyses were often performed with relatively nonspecific methods that resulted in falsely elevated values. Almost all commonly used techniques are now enzymatic (e.g., hexokinase or glucose oxidase), and older methods, such as colorimetric or oxidation-reduction techniques, are rarely used.

PRINCIPLE OF THE METHOD

Glucose, in presence of hexokinase, reacts with ATP forming glucose-6-phosphate and ADP. The glucose-6-phosphate reacts with NAD⁺ in presence of G-6-PDH to form D-glucono-δ-lactone-6-phosphate and NADH. The intensity of absorbance at 340 nm is proportional to the glucose concentration and can be measured photometrically.

KIT COMPONENTS

For in vitro diagnostic use only.

The components of the kit are stable until expiration date on the label.

Keep away from direct light sources.

Reagent A: 4 x 120 ml (liquid) blue cap

Reagent B: 1 x 120 ml (liquid) red cap

Composition in the test: TRIS pH 7.80 80 mM, MgCl₂ 5 mM, ATP 2mM, NAD 2 mM, hexokinase > 2 KU/l, glucose-6-phosphate dehydrogenase > 2 KU/l.

Standard: glucose solution 100 mg/dl - 5 ml

Store all components at 2-8°C.

MATERIALS REQUIRED BUT NOT SUPPLIED

Current laboratory instrumentation. Spectrophotometer UV/VIS with thermostatic cuvette holder. Automatic micropipettes. Glass or high quality polystyrene cuvettes. Saline solution.

REAGENT PREPARATION

Mix 4 parts of reagent A with 1 part of reagent B. Stability of working reagent: ≥ 90 days at 2-8°C, well capped and away from light sources.

Stability of unmixed reagents: up to expiration date on labels at 2-8°C;

Stability since first opening of vials of unmixed reagents: ≥ 60 days at 2-8°C.

PRECAUTIONS

Reagent may contain some non-reactive and preservative components. It is suggested to handle carefully it, avoiding contact with skin and swallow.

Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.

SPECIMEN

Serum, plasma, urine, CSF (cerebrospinal fluid).

Separated and nonhemolyzed samples are stable 8 hours at 25°C and 3 days at 2-8°C. Variable stability is observed with longer storage periods.

Glycolysis decreases serum glucose by approximately 5 to 7% in 1 h (5 to 10 mg/dl) in normal uncentrifuged coagulated blood at room temperature. The rate of in vitro glycolysis is higher in the presence of leukocytosis or bacterial contamination.

Plasma, removed from the cells after moderate centrifugation, contains leukocytes that also metabolize glucose, although cell-free sterile plasma has no glycolytic activity.

Glycolysis can be inhibited and glucose stabilized for as long as 3 d at room temperature by adding sodium iodoacetate or sodium fluoride (NaF) to the specimen. Although fluoride maintains long-term blood glucose stability, the rate of decline in the first hour after sample collection is not altered.

Cerebrospinal fluid (CSF) may be contaminated with bacteria or other cells and should be analyzed for glucose immediately. If a delay in measurement is unavoidable, the sample should be centrifuged and stored at 4°C or -20 °C.

In 24-h collections of urine, glucose may be preserved by adding 5 ml of glacial acetic acid to the container before starting the collection. The final pH of the urine is usually between 4 and 5, which inhibits bacterial activity. Urine samples may lose as much as 40% of their glucose after 24 h at room temperature.

TEST PROCEDURE

Wavelength:	340 nm		
Lightpath:	1 cm		
Temperature:	37°C		
dispense:	blank	standard	sample
reagent	2 ml	2 ml	2 ml
water	20 µl	-	-
standard	-	20 µl	-
sample	-	-	20 µl
Mix, incubate at 37°C for 5 minutes. Read absorbances of standard (As) and samples (Ax) against reagent blank.			

RESULTS CALCULATION

Serum/plasma/random urine sample:

glucose mg/dl = Ax/As x 100 (standard value)

24 hours urine sample (glucose mg/24h):

glucose mg/24h = Ax/As x 100 x diuresis (dl)
(standard value and diuresis in dl)

EXPECTED VALUES

Plasma/serum (fasting patient)

adults: 70 - 105 mg/dl

children: 70 - 105 mg/dl

premature neonates: 25 - 80 mg/dl

term neonates: 30 - 90 mg/dl

CSF: 40 - 75 mg/dl

(60% of plasma value)

Urine (fasting patient)

random urine: < 30 mg/dl

24h urine: < 500 mg/24h

Each laboratory should establish appropriate reference intervals related to its population.

QUALITY CONTROL AND CALIBRATION

It is suggested to perform an internal quality control. For this purpose the following human based control sera are available:

QN 0050 CH **QUANTINORM CHEMA** 10 x 5 ml
with normal or close to normal control values

QP 0050 CH **QUANTIPATH CHEMA** 10 x 5 ml
with pathological control values.

If required, a multiparametric, human based calibrator is available:

AT 0030 CH **AUTOCAL H** 10 x 3 ml

Please contact Customer Care for further information.

TEST PERFORMANCE

Linearity

the method is linear up to 1000 mg/dl.

If the limit value is exceeded, it is suggested to dilute sample 1+9 with saline and to repeat the test, multiplying the result by 10.

Sensitivity/limit of detection (LOD)

the limit of detection is 2 mg/dl.

Interferences

no interference was observed by the presence of:

hemoglobin ≤ 850 mg/dl

bilirubin ≤ 30 mg/dl

lipids ≤ 1500 mg/dl

Precision

intra-assay (n=10)	mean (mg/dl)	SD (mg/dl)	CV%
sample 1	95.20	1.32	1.40
sample 2	224.30	2.36	1.10

inter-assay (n=20)	mean (mg/dl)	SD (mg/dl)	CV%
sample 1	96.47	2.78	2.90
sample 2	252.06	9.56	2.70

Methods comparison

a comparison between Chema and a commercially available product gave the following results:

Glucose UV FL Chema = x

Glucose competitor = y

n = 100

y = 0.953x + 1.05 mg/dl r = 0.99

WASTE DISPOSAL

This product is made to be used in professional laboratories. Please consult local regulations for a correct waste disposal.

S56: dispose of this material and its container at hazardous or special waste collection point.

S57: use appropriate container to avoid environmental contamination.

S61: avoid release in environment. Refer to special instructions/safety data sheets.








REFERENCES

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SYMBOLS

	for in vitro diagnostic use only
	lot of manufacturing
	code number
	storage at temperature interval
	expiration date (year/month)
	warning, read enclosed documents
	read the directions