

GLUCOSE UV FL	
GL F251 CH	5 x 50 ml

INTENDED USE

Reagent for quantitative in vitro determination of glucose in biological fluids.

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.

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.

GLU-UV R1: F251: 4 x 50 ml (liquid) blue cap

GLU-UV R2: F251: 1 x 50 ml (liquid) red cap

Composition in the test: TRIS pH 7.40 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 R1 with 1 part of reagent R2.

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: preferably within 60 days at 2-8°C and away from light sources

PRECAUTIONS

GLU-UV R1: It is not classified as hazardous.

GLU-UV R2: It is not classified as hazardous.

Standard: It is not classified as hazardous.

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	1 ml	1 ml	1 ml
water	10 µl	-	-
standard	-	10 µl	-
sample	-	-	10 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 = $Ax/As \times 100$ (standard value)

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

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

EXPECTED VALUES	
Serum (fasting patient)	
adults:	74 - 100 mg/dl
children:	60 - 100 mg/dl
premature neonates:	20 - 60 mg/dl
term neonates:	30 - 60 mg/dl
Urine	
random urine:	1 - 15 mg/dl
24h urine:	< 500 mg/24h

in general population. 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:

QUANTINORM CHEMA - MULTINORM CHEMA
with normal or close to normal control values

QUANTIPATH CHEMA - MULTIPATH CHEMA
with pathological control values.

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

AUTOCAL H

Please contact Customer Care for further information.

TEST PERFORMANCE

Linearity

the method is linear up to 700 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 1 mg/dl.

Interferences

no interference was observed by the presence of:

hemoglobin	≤ 500 mg/dl
bilirubin	≤ 30 mg/dl
lipids	≤ 1000 mg/dl

In very rare cases gammopathy, especially monoclonal IgM (Waldenström's macroglobulinemia), may cause unreliable results in serum.

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	3.80

Methods comparison

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

$$\begin{aligned} \text{Glucose UV FL Chema} &= x \\ \text{Glucose competitor} &= y \\ n &= 100 \\ y &= 0.953x + 1.05 \text{ mg/dl} \quad r^2 = 0.99 \end{aligned}$$

WASTE DISPOSAL

This product is made to be used in professional laboratories.

P501: Dispose of contents according to national/international regulations.

REFERENCES

Methods in Enzymatic Analysis, Vol. VI, Verlagsgesellschaft, Germany 1984-1988, pp. 163-171.

N. Rifai, A.R. Horvath et al. Tiez Textbook of Clinical Chemistry and Molecular Diagnostics, sixth edition 2018.

A. J. Bakker, M. Mücke. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. *ClinChemLabMed* 2007;45(9):1240-1243.

MANUFACTURER

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SYMBOLS	
	in vitro diagnostic medical device
	batch code
	catalogue number
	temperature limit
	use-by date
	caution
	consult instructions for use

