GLUCOSE FL

GL F400 CH	4 x 100 ml
GL 100F CH	4 x 250 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

The enzyme glucose oxidase catalyzes the oxidation of glucose to gluconic acid and H_2O_2. The H_2O_2 reacts with phenol and 4-aminoantipyrine in the presence of peroxidase to form a quinoneimine dye. The intensity of color formed is proportional to the glucose concentration and can be measured photometrically between 480 and 520 nm.

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 R1 **F400: 4 x 100 ml (liquid) blue cap**
100F: 4 x 250 ml (liquid) blue cap

Composition: phosphate buffer pH 6.50 220 mM, GOD ≥ 15000 U/l, POD ≥ 500 U/l, 4-AAP 1 mM, phenol 10 mM, surfactant.

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

Use reagent ready to use.
Stability: up to expiration date on labels at 2-8°C.
Stability since first opening of vials: preferably within 60 days at 2-8°C.

PRECAUTIONS

GLU R1: Warning. May cause an allergic skin reaction. (H317).
Wear protective gloves (P280). Avoid breathing dust / fume / gas / mist / vapours / spray (P261). If skin irritation or rash occurs: Get medical advice / attention (P333+P313). Take off contaminated clothing and wash it before reuse. (P362+P364).

Standard: It is not classified as hazardous

N-acetylcysteine (NAC), metamizole and acetaminophen may cause interference in the Trinder reaction.[1,2]
To avoid interference, the blood withdrawal should be performed before drug administration.

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

Wavelenght: 510 nm (allowed 480 ÷ 520 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 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:
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 500 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	≤ 400 mg/dl
bilirubin	≤ 20 mg/dl
lipids	≤ 400 mg/dl

Precision

intra-assay (n=10)	mean (mg/dl)	SD (mg/dl)	CV%
sample 1	91.8	0.65	0.70
sample 2	241.1	3.34	1.39

inter-assay (n=20)	mean (mg/dl)	SD (mg/dl)	CV%
sample 1	92.2	2.37	2.60
sample 2	240.6	8.11	3.40

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

Glucose FL Chema = x
Glucose competitor = y
n = 111

y = 0.960x + 0.39 mg/dl r^2 = 0.984

WASTE DISPOSAL

This product is made to be used in professional laboratories.
P501: Dispose of contents according to national/international regulations.

REFERENCES

1) N-acetylcysteine interference of Trinder-based assays. Genzen JR, Hunsaker JJ, Nelson LS, Faine BA, Krasowski MD. Clin Biochem. 2016 Jan;49(1-2):100-4
2) Drug interference in Trinder reaction.
3) Trinder P., - J. Clin. Path. 22, 158 (1969);
4) Tietz Textbook of Clinical Chemistry, Second Edition, Burtis-Ashwood (1994).

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SYMBOLS

IVD	*in vitro* diagnostic medical device
LOT	batch code
REF	catalogue number
	temperature limit
	use-by date
	caution
	consult instructions for use