GLUCOSE SL

Enzymatic colorimetric method

Liquid reagent ready to use

REF 13201240 R 12X20mL

IVD

PRODUCT CODE: GLU-6D20

Company with Quality System ISO 9001 – ISO 13485 Certified by LMS

INTENDED USE

Quantitative determination of glucose in serum, plasma, urine.

PRINCIPLE

The glucose oxidase (GOD) oxidizes glucose to gluconic acid and forms hydrogen peroxide which, in the presence of peroxidase (POD), reacts with 4-AAP and phenol and produces a colored complex, whose color intensity is directly proportional to glucose concentration in the sample.

SAMPLE

Serum, plasma with heparin, urine. Avoid hemolyzed samples.
Separate serum from clot as soon as possible.
Dilute urine 24/h 1:10 with saline.
Glucose in the sample is stable 2 days at 2-8°C and 8 hours at 15-25°C.

KIT COMPONENTS

Reagent (A) GLU Volume = 100/250 ml	Buffer Glucose oxidase POD 4-AAP Phenol	100 mmol/l 10000 U/l 2000 U/l 1 mmol/l 10 mmol/l
Standard GLU Volume = 10 ml	Glucose	Value on label

The reagents are stable until the expiration date indicated on the label if stored at 2-8°C and protected from light. Do not use over expiry date.
Once opened reagents are stable for 2 months at 2-8°C if contamination is avoided. Do not freeze.
Keep bottles closed when not in use.

REAGENT PREPARATION

Liquid reagent, bring to room temperature (15-25°C) before use.
Pale colouring of the reagent (< 0.050 O.D.) due to air-light exposure doesn't compromise the working.

PRECAUTIONS AND WARNINGS

Reagent may contain some non-reactive and preservative components. It is suggested to handle carefully it, avoiding contact with skin and swallow.
Use the normal precautions required in the laboratory.
Dispose of waste according to local laws.

PROCEDURE

Wavelength:	510 nm (500 – 520)
Lightpath :	1 cm
Temperature:	37°C
Reading:	against blank reagent
Method:	Increasing End Point
Sample/Reagent:	1/100

pipette:	**blank**	**sample**	**standard**
Reagent (A)	300 µl	300 µl	300 µl
water	3 µl		
sample		3 µl	
standard			3 µl

Mix, incubate at 37°C for10 minutes, read against blank reagent the absorbance of the sample (Ax) and the standard (As).

RESULTS CALCULATION

Serum, plasma:
Glucose mg/dl = Ax/As x 100 (standard Value)

Urine:
Glucose mg/24h = Ax/As x 100 x 10 x Urine Vol. (dl)
To convert mg/dl to mmol/l divide by 18

EXPECTED VALUES

Serum/plasma: 70 - 105 mg/dl (3.9 - 5.8 mmol/l)

Urine 24h: < 500 mg/24h (2.78 mmol/24h)

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

QUALITY CONTROL

You must perform the controls at each kit's use and verify that the values obtained are within the reference range reported in the operating instructions. For this purpose we recommend the use of Sicurobio control sera: ACUTROL 1 (REF. SB-8334) and ACUTROL 2 (REF. SB-8335).

PERFORMANCE

Sensitivity: the sensitivity of the method is 3 mg/dl.
Linearity: the method is linear up to 800 mg/dl. For higher values, dilute the sample 1:2 and multiply the result by 2.
Precision intra-assay:

	Level 1	Level 2
Mean (mg/dl)	44.05	151.5
SD	0.366	1.179
CV %	0.83	0.78

Precision inter-assay:

	Level 1	Level 2
Mean (mg/dl)	44.83	154.0
SD	0.245	1.333
CV %	0.55	0.87

Interferences: bilirubin does not interfere up to 5 mg/dl. Triglycerides do not interfere up to 300 mg/dl.
Correlation against a reference method:
Y = 0.9865x + 2.2063 r = 0.9941

REFERENCES

1. Trinder P., Ann. Clin. Biochem. 6, 24 (1969)
2. Vassault, A. et al. Ann. Biol. Clin., 44,686 (1986)
3. Kaplan LA, Pesce AJ: " Clinical Chemistry", Mosby Ed. 1989

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