GLUCOSE MONOREAGENT LR

liquid reagent

REF 3656100 6x100 ml
3650650 6x50 ml

CE IVD For in vitro medical device

Use

Kit for measurement of glucose in serum, plasma and urine
Colorimetric enzymatic method GOD-PAP.

Summary

Glucose measurements are used in the diagnosis and treatments of disorders of carbohydrate metabolism such as diabetes mellitus, hypoglycaemia and hyperglycemia.

Principle

Glucose is oxidized, in presence of glucose oxidase (GOD), into gluconic acid and hydrogen peroxide. This one reacts, by peroxidase (POD), with 4-aminophenazone and phenol giving a coloured compound whose colour intensity is directly proportional to the glucose concentration in the tested sample.

Reagents

R1 Phosphate buffer pH 7.4	100.0	mmol/l
Phenol	9.0	mmol/l
GOD ≥	25000	U/l
POD ≥	1500	U/l
4-aminophenazone	2.3	mmol/l

Reagent Preparation

Reagent is liquid and ready to use.

Storage And Stability

- Store the kit at 2-8°C. Do not freeze the reagents.
- After opening, the reagents is stable 90 days if recapped immediately and protected from contamination, evaporation, direct light, and stored at the correct temperature.

Precaution In Use

The product is not classified as dangerous (DLg. N. 285 art. 28 l. n. 128/1998 The final concentration of the components is below the limits imposed by Regulation (EC) No. 1272/2008 - CLP (and subsequent amendments) and Directive 88/379/CEE and subsequent amendments to the classification-packaging and labeling of dangerous substances.

However the reagent should be handled with care, according to good laboratory practice. Caution: the reagents contain Sodium Azide (0.095%) as preservative. Avoid swallowing and contacting with skin, eyes and mucous membranes.

Waste Management

Please refer to the local legal requirements.

Sample

- Serum heparinized plasma or EDTA plasma
- Diluted urine 1:10
- Do not use samples with haemolysis
- Specimens should be separated from cells as soon as possible after collection to avoid loss due to glycolysis
- The glucose is stable in the samples up to 3 days at 2-8°C, after the addition of a glycolitic inhibitor as NaF, KF

Note

- The kit, according to this method, must be used in manual procedures. About automatic using follow specific applications.
- Avoid direct light, contamination and evaporation.
- The volumes in the procedure can be changed proportionally.
- In case of complaint or quality control request, refer to the lot number on the package or the lot number on the singles vials.

Procedure

Wavelength	λ: 510 (500-550) nm
Working Temperature	37°C
Optical Path	1 cm
Reaction	"end point"

Bring the reagents at 15-25°C before use them.

Monoreagent Procedure "sample starter"

	Blank	STD	Sample
Reagent	1000µl	1000µl	1000µl
Distilled Water	10 µl	–	–
Sample	–	–	10 µl
Standard	–	10 µl	–

Mix, then incubate 10' at 37°C. Measure the absorbance of sample (EC) and standard (ESTD) against the reagent blank.

Calculation

Glucose [mg/dl] o [mmol/l] =
EC/ESTD x Conc. STD

Conversion Factor

Glucose [mg/dl] x 0.05551 =Glucose [mmol/l]

Reference Values

Serum - plasma	70 - 105 mg/dl	(3.9-5.8 mmol/l)
Urine	< 0.5 g/24h	(<28 mmol/24h)

Reference values are considered indicative since each laboratory should establish reference ranges for its own patient population. The analytical results should be evaluated with other information coming from patient's clinical history.

ANALYTICAL PERFORMANCES

Linearity

The reaction is linear in concentration range between 3,1 mg/dl (0.17 mmol/l) and 500 mg/dl (34.6 mmol/l). Samples with values exceeding 500 mg/dl must be diluted with saline solution. Multiply, then, the result for diluting factor.

"Intra-Assay" precision (within-Run)

Determined on 20 samples for each control (N-H) (Normal-High). Results:

MEAN [mg/dl]	N =111.85	H = 279.45
S.D.	N = 2.29	H = 3.11
C.V.%	N = 2.04	H = 1.11

"Inter-Assay" precision (between-Run)

Determined on 20 samples for each control (N-H).Results:

MEAN [mg/dl]	N = 109.8	H = 279.85
S.D	N = 3.43	H = 3.18
C.V.%	N = 3.12	H = 1.14

Analytical sensitivity

The test sensitivity in terms of detection limit is 3.1 mg/dl (0.17 mmol/l).

Correlation

A study based comparing this method with a similar method on 20 samples has given a correlating factor **r = 0.99**

y = 1.0303x -0.2666

Interferences

No interference was observed by the presence of

Bilirubin	≤ 15 mg/dl
Triglycerides	≤ 1000 mg/dl
Haemoglobin	≤ 300 mg/dl
Ascorbate acid	≤ 35 mg/dl

Quality Controls

It's necessary, each time the kit is used, to make the quality controls and to check that values obtained are within the acceptance range provided in the insert. Each laboratory should establish its own mean and standard deviation and adopt a quality control program to monitor laboratory testing.

Bibliography

Henry, R.J., Clin.Chem., Hoeber N.Y., 625. (1964).
Trinder, P., Ann. Clin. Biochem., 6, 24, (1969).
Sharp, P., Clin. Chem. Acta, 40,115, (1972).
Kaplan, L.A., Pesce, A..J.: "Clinical Chemistry", Mosby Ed. (1996).

Symbols

CE	CE Mark (98/79 CE regulation)
IVD	in vitro medical device
LOT	Batch Code
	Use by
	Storage temperature limits
	Read instruction for use
	Gesan Production srl