GLUCOSE

Trinder Method - Endpoint

4 x 50 ml	CL35-200S
4 x 100 ml	CL35-400S

INTENDED USE

Kit for quantitative determination of Glucose in serum and plasma according to Trinder reaction.

CLINICAL MEANING

This test indicates the direct level of glucose in blood. Glucose is made from the digestion of carbohydrates and from the conversion of glycogen which happens in the liver. This measurement is helpful in detecting many metabolic diseases. Generally, high levels of glucose are indicative of diabetes mellitus and many other issues: Cushing syndrome, traumas, pheochromocytoma, corticosteroid therapy, general anesthesia, infection, myocardial infarction and other forms of stress.
Hypoglycemia may be caused by many factors, such as altered insuline dosage, anabolic steroid intake, MAO inhibitors, alcohol and other substances, Addison disease, hypothyroidism, insulinoma etc.

PRINCIPLE

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

SAMPLE

Serum, plasma. Avoid hemolyzed samples. Remove from blood cells as soon as possible as glycolysis burns glucose (approximately 5% per hour) and gives falsely low values.
Glucose in serum or plasma is stable up to 3 days at 2-8°C.

REAGENTS

Only for in Vitro diagnostics. Liquid monoreagent ready to use.

Package content	CL35-200S	CL35-400S
REAGENT 1 Phosphate buffer (pH 7,4) 200 mmol/L, phenol 10 mmo/L, 4-aminophenazone 0,28 mmol/L, GOD 20000 U/L, POD 5000 U/L, sodium azide 15 mmol/L	4 x 50 ml	4 x 100 ml
STANDARD (Std) Glucose 100 mg/dl (5,55 mmol/L), benzoic acid 15 mmol/L	1 x 4 ml	1 x 4 ml

Stability: reagents are ready to use. Store at 2-8°C and protect from light to keep the reagents stable up to the expiration date on the label. Once opened the reagents are stable for 2 months at 2-8°C if contamination is avoided. Keep bottles closed when not in use. Do not use turbid reagents.

NECESSARY ITEMS – NOT PROVIDED

Usual laboratory equipment: UV/VIS Spectrophotometer with temperature control; automatic micropipettes; Optical glass cuvettes or, alternatively, disposable ones in optical polystyrene; Saline solution.

MANUAL ASSAY PROCEDURE

Method:	increasing endpoint
Wavelength:	510 nm (500 - 520)
Optical path:	1 cm
Temperature:	37°C
Reaction time:	10 minutes
Reading:	against blank reagent
Sample/reagent:	1/125

Let the reagent required to perform the test reach the chosen temperature for the analysis.

Pipette in cuvette:

	Blank Reagent	Standard	Sample
Distilled water	10 µl	-	-
Standard	-	10 µl	-
Sample	-	-	10 µl
Reagent 1	1000 µl	1000 µl	1000 µl

Mix. Incubate for 10 minutes at 37°C. Then read the absorbance of the standard (AbsStd) and the sample (AbsS) against the blank reagent.

Reaction volumes can be proportionally varied without any change in calculation.

CALCULATION

Calculate glucose concentration in the sample using the following formula:

[mg/dl] glucose = AbsS / AbsStd x 100

[mmol/L] glucose = AbsS / AbsStd x 5,55

REFERENCE VALUES

Serum / Plasma:

70 ÷ 110 mg/dl (3.88 ÷ 6.10 mmol/L)

Concentration levels in newborn babies:

20 ÷ 80 mg/dl (1.11 ÷ 4.44 mmol/L)

Glucose concentration in children under 5 years is approximately 10-15% lower than adults'.

Each laboratory should define its own reference values for this method.

QUALITY CONTROL – CALIBRATION

All Clinical Chemistry laboratories should implement a quality control program. Control serums of human origin are available for this purpose on request:
PRE-NORM serums with normal values
PRE-PATH serums with pathological values
If the method requires it, a multiparameter calibrator of human origin is available.

PERFORMANCE CHARACTERISTICS

Sensitivity: the sensitivity of the method is 3 mg/dl.

Linearity: up to 500 mg/dl.
For higher values, dilute the samples 1:10 with saline solution and multiply the result by 10.

Precision:

Within run (n=10)	Average [mg/dl]	SD	CV %
Sample 1	99	2,6	2,7
Sample 2	257,2	5,6	2,2

Between run (n=20)	Average [mg/dl]	SD	CV %
Sample 1	97,5	251,4	2,3
Sample 2	2,3	7,8	3,1

Interferences: up to 300 mg/dl of triglycerides and up to 20 mg/dl of bilirubin do not interfere with the test.
Correlation against a reference method: the correlation of FAR method (Y) against a reference method (X) gives this equation:

Y = 0,9865X + 2,2063 r = 0,9941

DISPOSAL

The product must be used for professional analysis only. The product must be disposed of according to national/international laws.

WARNINGS AND PRECAUTIONS

The reagents may contain non-reactive components and various preservatives. Contact with the skin and ingestion should be avoided. Use the normal precautions expected with correct behavior in laboratory.

REFERENCES

1 Trinder P: Determination of glucose in blood using glucose oxidase with an alternative oxygen acceptor. Ann Clin Bioch, 6:24 (1969).

2 Kaplan LA, Pesce AJ: "Clinical Chemistry", Mosby Ed. 1989

3 NCCLS Document, "Procedures for the collection of arterial blood specimens", Approved Standard, 3rd Ed. (1999).

4 EU-Dir 1999/11 Commission Directive of 8 March 1999 adapting to technical progress the principles of good laboratory practice as specified in Council Directive 87/18/EEC

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KEY SYMBOLS

IVD	In Vitro diagnostic medical device
LOT	batch number
REF	catalog number
	temperature limits
	use by
	caution
	consult accompanying documents

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