GLUCOSE GOD PAP LS MONO

IVD

Quantitative determination of Glucose in serum, plasma or urine. Enzymatic colorimetric method, GOD – PAP, end point.

REF CC1200 R1: 4x100 mL + 1x3 mL

METHOD AND PRINCIPLE

Determination of glucose after enzymatic oxidation by Glucose Oxidase (GOD). The colorimetric indicator is Red Chinonimin, which is generated from 4-Aminoantipyrine and Phenol by Hydrogen Peroxide under the catalytic action of Peroxidase (POD) (Trinder's reaction).

$$\text{Glucose} + O_2 + H_2O \xrightarrow{\text{GOD}} \text{Gluconic Acid} + H_2O_2$$

$$2\,H_2O_2 + \text{4-Aminoantipyrine} + \text{Phenol} \xrightarrow{\text{POD}} \text{Red Chinonimin} + 4\,H_2O$$

CLINICAL SIGNIFICANCE

Glucose is a major energy source for the human body, derived from the breakdown of carbohydrates obtained from daily diet and regulated through the process of glycogenolysis (breakdown of body stored glycogen), and gluconeogenesis (endogenous synthesis from amino acids and other substances). The glucose level in the blood is maintained by diet uptake and regulatory hormones such as insulin, glucagon,or epinephrine. An abnormal increase in blood glucose level can be associated with diabetes mellitus and hyperactivity of thyroid, pituitary or adrenal glands. An abnormal decrease beyond the fasting level is observed in cases of insulin overdose, insulin secreting tumours, mixedema, hypopituitarism, Addison´s disease and conditions interfering with glucose absorption. Glucose measurement in the blood is a key test to evaluate and diagnose any carbohydrate-related disorder.

REAGENT COMPOSITION

Reagent (R1)

Phosphate buffer, pH 7.5	250 mmol/L
Phenol	5 mmol/L
4-Aminoantipyrine	0.5 mmol/L
Glucose Oxidase (GOD)	≥15 kU/L
Peroxidase (POD)	≥1 kU/L

Reagent (R2)

Glucose Standard:	value on label

REAGENT PREPARATION AND STABILITY

Liquid and ready to use reagents, stable until the expiry date shown, if stored as indicated on the label and avoid contamination, evaporation and prolonged exposure to direct light.

Do not freeze the reagents.

Discard the reagent if signs of deterioration appear, such as the presence of particles and turbidity or failure to recover the values of certified control sera.

The measurement is not influenced by occasionally occurring colour changes, as long as the absorbance of the reagent is < 0.150 at 546 nm.

After opening the bottles, it is advisable to withdraw the necessary volume, to immediately close the bottles and store them in the fridge in order to avoid contamination, degradation from direct light and evaporation.

SPECIMEN

Serum, Heparin or EDTA plasma, Urine 24h diluted 1:10 with H_2O (1+9).

Avoid hemolysate or lipemic samples. Separate the serum from the clot at the latest 1h after blood collection.

Plasma stability (after addition of a glycolytic inhibitor as Fluoride or Monoiodacetate): 2 days at 20 – 25°C, 7 days at 4° - 8° C.

Serum stability (separated from clot, no haemolysis): 8 h at 25°C, 72 h at 4°C.

Only freeze once. Discard contaminated specimens.

PROCEDURE

Wavelength:	546 nm (510 - 570)
Temperature:	37° C
Measurement:	against distilled water

Pipette as follow:

Reagent R1	1000 µL
Sample, Std / Cal	10 µL

Mix, incubate 5 minutes, read Absorbance (Abs) within 60 minutes.

CALCULATION

Serum / Plasma:

$$\text{Glucose} = \frac{\text{Abs Sample} - \text{Abs Blank Reagent}}{\text{Abs Std/Cal} - \text{Abs Blank Reagent}} \times \text{Conc.Std/Cal}$$

Urine:

Calculate as for the serum and multiply the result by 10 (initial sample dilution)

$$\text{Glucose (g/Urine 24h)} = \frac{\text{Glucose urine (mg/dL)} \times \text{Vol. in 24h (Liter)}}{100}$$

Conversion Factor: [mg/dL] x 0.0556= [mmol/L]

CALIBRATION

The results depend on the accuracy of the calibration, on the correct setting of the test on the instrument, on the correct volumetric ratio of reagent / sample and on the correct analysis temperature.

Aternatively to the standard included in the package, it is possible to use **MTD Diagnostics Multicalibrator**:

Chemistry Multicalibrator - REF CAL1010 (10 x 3 mL)

QUALITY CONTROL

Normal and abnormal control sera of known concentration should be analysed routinely with each group of unknown samples utilizing **MTD Diagnostics** Quality Control Material:

Chemistry Control N - REF CNN1010 10x5 mL (Level 1)
Chemistry Control P - REF CNP1020 10x5 mL (Level 2)

EXPECTED VALUES

	[mg/dL]	[mmol/L]
New-borns:		
Cord blood	63 - 158	3.5 - 8.8
1 h	36 - 99	2.0 - 5.5
2 h	36 - 89	2.2 - 4.9
5 – 14 h	34 - 77	1.9 - 4.3
44 – 52 h	48 - 79	2.7 - 4.4
Children (fasting):		
1 – 6 years	74 - 127	4.1 - 7.0
7 – 19 years	70 - 106	3.9 - 5.9
Adults):		
Serum/plasma	60 - 110	3.3 - 6.1
Urine (24h)	< 0,5 g	< 27,7 mmol

Each laboratory should establish a range of expected values based on its patient population and, if necessary, determine its own reference interval. For diagnostic purposes, results should always be assessed together with the patient's medical history, clinical examination and other results.

PERFORMANCE

PRECISION:
Low Level: Samples= 20; Average = 89; S.D. = 0.72; CV = 0.81%
High Level: Samples = 20; Average = 297; S.D. = 2.45; CV = 0.82%

ACCURACY (CORRELATION): A comparison between this method (x) and a certified method of trade (y) gave the following correlation:

y = 1.00 x + 1.00 r = 0.999

SENSITIVITY: 5 mg/dL.

LINEARITY: 5 – 500 mg/dL

SPECIFICITY / INTERFERENCES

No interference was observed by Ascorbic Acid up to 15 mg/dL, Bilirubin up to 20 mg/dL, Haemoglobin up to 200 mg/dL and Lipemia up to 1000 mg/dL triglycerides.

NOTES

1. This method may be used with different instruments. Any application to an instrument should be validated to demonstrate that results meet the performance characteristics of the method. It is recommended to validate periodically the instrument. Contact your distributor for any question on the application method.
2. Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and other laboratory data.

PRECAUTIONS

R1 conteins PHENOL 5 mmol/L – CAS 108-95-2 T R23/24/25 (H331 – H301 – H311) - C R34 (H314)
4-AMINOANTIPYRINE 0.3 mmol/L – CAS 83-07-8 Xn R22 (H302).

H301 – Toxic if swalloved
H302 – Harmful if swalloved
H311 – Toxic in contact with skin.
H314 – Causes severe skin burns and eye damage
H331 – Toxic if inhaled

The product does not contain any other hazardous substances or mixtures according to EC Regulation No. 1272/2008 (CLP) or their concentrations are such that they are not considered to be persistent, bioaccumulative or toxic (PBT). Therefore, it is not subject to the special labeling required by the aforementioned regulation. The product is labeled according to the directive for CE marking (98/79 / EC). Sodium Azide less than 0.1%.
However, in compliance with the normal prudential rules that everyone has to keep managing any chemical or laboratory reagent, in case of contact of reagents with the operator, you must apply the following first aid:
S26 (P305 – P351 – P338): In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S28 (P302 – P352): After contact with skin, wash immediately with plenty of water.
S36/37/39 (P280): Wear suitable protective clothing, gloves and eye/face protection.
S46 (P301 – P310): If swallowed, seek medical advice immediately and show container or label. If victim is conscious and alert, wash out mouth with water.
S56 (P273): Dispose of this material and its container at hazardous or special waste collection point.
S63 (P304 – P340): In case of accident by inhalation: remove casualty to fresh air and keep at rest. If breathing is difficult, give oxygen and get medical aid.

All samples, calibrators and controls should be treated as potentially infectious material capable of transmitting HIV and hepatitis.

FOR MORE INFORMATION, REQUEST SAFETY DATA SHEET FOR REAGENT (MSDS) AT THE MANUFACTURER.

SIMBOLOGY

CE	CE Mark (EC Directive 98/79)		
IVD	In Vitro Diagnostic		Temperature Limitation
	Consult instructions for use		Contains sufficient for <n> test
REF	Catalog Number		Use By
LOT	Batch Code		Manufacturer

BIBLIOGRAPHY

Barham, D. and Trinder, P. Analyst. 97: 142 (1972).

Tietz. N.W. Clinical Guide to Laboratory Tests, 3rd Edition.W.B. Saunders Co. Philadelphia, PA. (1995).

Trinder, P. Ann. Clin. Biochem. 6 : 24 (1969).

Young DS. Effects of drugs on clinical laboratory tests, 5th ed. AACC Press, 2000.

Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press 2000.