Glucose

GOD-POD

Product information

24GLUCO1-UN	**Meditest Glucose**	**6 x 40 mL**
24GLUC01-AU	**Meditest Glucose**	**6 x 40 mL**
24GLUC01-AB	**Meditest Glucose**	**6 x 40 mL**
24GLUC01-ER	**Meditest Glucose**	**6 x 40 mL**

Purpose

This test is used for the quantitative determination of glucose in human serum, plasma, urine and cerebrospinal fluid.

Summary

Glucose is an important source of energy for most cells of the body; Insulin facilitates the entry of glucose into cells. Diabetes is a disease that manifests itself with hyperglycemia; Patients with diabetes show an inability to produce insulin1,5,6. Clinical diagnosis should not be based on a single test result, but clinical and other laboratory data should be integrated.

Test principle

Glucose oxidase (GOD) catalyzes the oxidation of glucose to gluconic acid. The resulting hydrogen peroxide (H2O2) is detected by phenol, 4 aminophenazone (4-AP), a chromogenic oxygen acceptor in the presence of peroxidase (POD):

β-D-Glucose + O_2 + H2O $\xrightarrow{GOD}$ Gluconic acid + H_2O_2

H2O2 + Phenol + 4-AP $\xrightarrow{POD}$ Quinone+H_2O

The intensity of the resulting color is proportional to the concentration of glucose in the sample1,2.

Reagents - working solutions

R1:	Tris PH:7.4	>50 mmol/L
	Peroxidase	>700 U/L
	Glucose Oxidase	>10000 U/L
	Phenol	<0.5 mmol/L
	4-AP	>1 mmol/L

Precautions warnings

It is intended for in vitro diagnostic use by healthcare professionals. Follow the normal precautions necessary in handling all laboratory reagents.
Infectious or microbial waste:
Warning: handle waste as potentially biohazardous. Dispose of waste according to accepted laboratory instructions and procedures.
Environmental hazards: Follow all relevant local disposal regulations to determine that it has been disposed of safely. If requested, a safety data sheet can be provided to professional users.

Inhibit foam formation in all reagents and sample types (sample, calibrator and control).
If there is any damage on the package, do not use it Read the user manual carefully before use, do not use the expired assay kit Do not mix different lot reagents.
All samples should be considered epidemic material, please dispose of them in accordance with the laboratory working standard of infectious diseases.

Take the necessary protective measures to prevent users from becoming infected during operation.

Use of reagents

The only ready-to-use reagent.

Storage and stability

Until the expiry date indicated on the package at 2-8 0C.
10 weeks after opening the lid on the analyzer.

Sample collection and preparation

Serum or plasma free of haemolysis1. The serum should be removed from the clot as quickly as possible. Stability of the sample: Glucose in serum or plasma is stable at 2-8º for 3 days. The stability of glucose in samples is affected by storage temperature, bacterial contamination and glycolysis. Plasma or serum samples that do not contain preservatives (NaF) should be separated from the cells or clot within half an hour after collection. When blood is drawn and allowed to coagulate at room temperature and stand uncentrifuged, the mean decrease in serum glucose is ~7% at 1 hour (0.28 to 0.56 mmol/L or 5 to 10 mg/dL). This decrease is the result of glycolysis. Glycolysis can be prevented by taking samples into fluoride tubes.

Stability:	8 hours at 1525 °C
	72 hours at 28 °C
Stability in fluoridated plasma:	3 days at 1525 °C,

Urine: Put urine in a dark bottle. For 24-hour urine intake, glucose can be maintained by adding 5 mL of anhydrous acetic acid to the container prior to intake. Unprotected urine samples can lose up to 40% of glucose after 24 hours of storage at room temperature. Therefore, keep the samples on ice during collection.
CSF: Cerebrospinal fluid can be contaminated with bacteria and often contains other cellular components. Therefore, glucose analysis should be performed immediately in CSF samples or samples should be stored at 4 °C or -20 °C. Centrifuge samples containing precipitate before performing the test.

Required Materials (not included in the kit)

1. Cat# 24BIO01-DC Meditest Diachem Calibrator
2. Cat# 24BIO01-DQ Meditest Diacheck Control L1
3. Cat# 24BIO02-DQ Meditest Diacheck Control L2
4. General laboratory equipment
5. Distilled or deionized water

Working Procedure

If you are using a spectrophotometer to perform this test, work with the following procedure. Ask your representative for the application data for fully automatic devices.

1. Test Conditions:
Wavelength: . 505 nm (490-550)
Cuvette: . 1 cm light path
Temperature: . 37ºC / 15-25ºC
2. Set the appliance to zero with distilled water.
3. Place the straws in a bathtub:

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	Blank	Standard	Sample
R (mL)	1.0	1.0	1.0
Standard (µL)	---	10	---
Sample (µL)	---	---	10

4. Stir and incubate for 10 minutes at 37ºC or 30 minutes at room temperature (15-25ºC).
5. Read the absorbance of samples and standard (A) against the gap. The color is stable for at least 30 minutes.

Calculation

$$\frac{\text{(A) Sample - (A) Blank}}{\text{(A) Standard – (A) Blank}} \times 100 \text{ (Standard Concentration)} = \text{mg/dL}$$

Dialing factors

mmol/L x 18.02 = mg/dL
mmol/L x 0.1802 = g/L
mg/dL x 0.0555 = mmol/L

Expected values
Serum or plasma: 60 - 110 mg/dL 3.33 - 6.10 mmol/L These values are for guidance purposes; Each laboratory should establish its own reference range.

Limitations
Criterion: Recovery within 10% of baseline at a glucose concentration of 3.9 mmol/L (70.3 mg/dL) ±.
Icterus:6 No apparent interaction for conjugated and unconjugated bilirubin until the I index is 60 (approximate concentration of conjugated and unconjugated bilirubin: 1026 µmol/L or 60 mg/dL).
Lipemia (Intralipid): 6 No obvious interaction until the L index is 1000. There is a weak correlation between the L index (which corresponds to turbidity) and the concentration of triglycerides.
Medications: No interactions in therapeutic concentrations have been found when common drug panels are used.7,8 In very rare cases, gammopathy, especially type IgM (Waldenström macroglobulinemia), can cause unreliable outcomes.9 When making a diagnosis, the results must be evaluated in conjunction with the patient's medical history, clinical examination, and other findings.

Performance characteristics
Measuring range: Detection limit from 0.3709 mg/dL to linearity limit up to 500 g/dL. If the concentration is greater than the linearity limit, dilute 1/2 of the sample with ClNa 9 g/L and multiply the result by 2.
Precision:

Intra-assay (n=20)		Inter-assay (n=20)		
Mean (mg/dL)	98.5	264.6	40.0	126
SD	0.58	1.27	1.06	2.07
CV (%)	0,59	0,48	2.65	1.65

Sensitivity: 1 mg/dL = 0.0039(A).
Accuracy: Results obtained using BSM reagents (y) did not show systematic differences when compared with other commercial reagents (x).
The results obtained using fifty samples are as follows:
Correlation coefficient (r): 0.99492
The regression equation is: y= y= 1,104x - 1,249.
The results of the performance characteristics depend on the analyzer used.

References

1. Kaplan L.A. Glucose. Kaplan A et al. Clin Chem The C.V. Mosby Co. St Louis. Toronto. Princeton 1984; 1032-1036.
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3. Young DS. Effects of drugs on Clinical Lab. Tests, 4th ed AACC Press, 1995.
4. Young DS. Effects of disease on Clinical Lab. Tests, 4th ed AACC 2001.
5. Burtis A et al. Tietz Textbook of Clinical Chemistry, 3rd ed AACC 1999.
6. Tietz N W et al. Clinical Guide to Laboratory Tests, 3rd ed AACC 1995.

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