ACCUCARE®

Glucose - Hexokinase

Enzymatic colorimetric test (HK)

Quantitative determination of Glucose in Serum / Plasma / Urine
Only for *In Vitro* Diagnostic use

ORDER INFORMATION

REF	Cont.
GHK 500	1 X 500 mL
GHK 500	5 X 100 mL
GHK 1000	1 X 1000 mL

CLINICAL SIGNIFICANCE

Glucose is a major source of energy for most cells of the body; insulin facilitates glucose entry into the cells. Diabetes is a disease manifested by hyperglycemia patients with diabetes demonstrate an inability to produce insulin. Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

Method

"Hexokinase": enzymatic photometric test

PRINCIPLE

The enzyme hexokinase (HK) catalyzes the reaction between glucose and adenosine triphosphate (ATP) to form glucose-6-phosphate (G-6-P) and adenosine diphosphate (ADP). In the presence of nicotinamide adenine dinucleotide (NAD), G-6-P is oxidized by the enzyme glucose-6-phosphate dehydrogenase (G-6-PD) to 6-phosphogluconate and reduced nicotinamide adenine dinucleotide (NADH).

REAGENT

Reagent I : Buffer Reagent
Reagent II : Enzyme Reagent
Glucose standard : 100 mg/dl (5.54 mmol/L)

REAGENT PREPARATION

Mix 4 Part (4 ml) of Enzyme Reagent I with 1 Part (1 ml) of Enzyme Reagent II.

REAGENT STORAGE AND STABILITY

Reagent is stable till expiry when stored at 2 - 8°C.
Store protected from light.

WARNING AND PRECAUTIONS

- For in vitro diagnostic use.
- Do not use components beyond the expiration date.
- Do not mix materials from different kit lot numbers.
- Exercise the normal precautions required for handling all laboratory reagents.
- The reagent contains preservative. Do not swallow. Avoid contact with skin and mucous membranes.
- For detailed information refer Material Safety Data Sheet.

WASTE MANAGEMENT

Please refer to local legal requirements.

MATERIALS REQUIRED BUT NOT PROVIDED

- NaCl solution 9 g/L
- General laboratory equipment

SAMPLE COLLECTION AND PRESERVATION

Serum or heparin plasma
Separate at the latest 1h after blood collection from cellular contents.
Stability in serum (separated from cellular contents, hemolysis free) without adding a glycolytic inhibitor
8 h at 25°C
72 h at 4°C
In Urine
2 days at 4 – 8°C
Only freeze once! Discard contaminated specimens!

ASSAY PROCEDURE

Operating Instructions

- Check reagent inventories at least daily to ensure that quantities are sufficient for the planned work load.
- Bring all reagents, standard and samples to room temperature 18 - 28°C, prior to analysis.

AUTOMATED PARAMETERS	
Wavelength	340 nm
Reaction Type	End Point
Cuvette	1 cm light path
Reaction Temperature	37°C
Reaction Type	Increasing
Measurement	Against Reagent Blank
Sample Volume	10µl
Reagent Volume	1000µl
Incubation	03 minutes
Blank Absorbance Limit	< 0.300
Low Normal at 37°C	60mg/dl (3.33 mmol/L)
High Normal at 37°C	110 mg/dl (6.1 mmol/L)
Linearity at 37°C	400mg/dl (22.2 mmol/L)

MANUAL ASSAY PROCEDURE

Pipette into Test Tubes

	BLANK	STD	SAMPLE
Sample	-	-	10µl
Standard	-	10µl	-
Reagent	1000µl	1000µl	1000µl

Mix reagent I&II wait for 4 minutes at R.T. and then add Sample or Standard Incubate for 3 minutes at 37°C. Measure absorbance of Sample (AT) and Standard (AS) against Reagent Blank at 340 nm.

SAMPLE DILUTIONS

- This method is linear upto a concentration of 400 mg/dL.
- Dilute samples above this concentration 1:1 with 0.9% saline
- Repeat assay. Multiply the result by 2.

CALCULATION

Results are calculated, usually automatically by the instrument, as follows:

Total Glucose (mg/dl) = AT/AS x Conc. of Standard

CALIBRATORS AND CONTROLS

For the calibration of automated photometric systems the commercially available suitable multi-calibrator is recommended.

The assigned values of this **Glucose Standard** have been made traceable to the reference method gas chromatography – isotope dilution mass spectrometry (GC-IDMS).

It is recommended to run a normal and a pathological control serum which is commercially available to verify the performance of the measured procedure. The value of controls should fall within the established limit.

Each laboratory should establish corrective action in case of deviations in control recovery.

PERFORMANCE CHARACTERISTICS

WITHIN RUN

Sample	Mean Concentration	SD	CV %
Norm	86.37	3.22	3.72%
Path	230.52	5.57	2.41%

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Revision No.: 01

RUN TO RUN

Sample	Mean Concentration	SD	CV %
Norm	87.02	2.94	3.38%
Path	229.05	3.20	1.40%

LINEARITY

The method is linear upto a concentration of 400mg/dL. Dilute samples above this concentration 1:1 with 0.9% saline solution and repeat assay. Multiply the result by 2.

Limit of detection: The limit of detection for Glucose is 2 mg/dL.

METHOD COMPARISON

A comparison of Accucare Glucose with a commercially available assay (x) using 20 samples gave following results: $R^2 = 0.9972$

REFERENCE VALUES

Serum/Plasma (Fasting)	70 - 110 mg/dl
(2 hrs. P. P.)	upto 150 mg/dl
Urine	<0.5 g/24 h

The reference values are to be considered as indicative only. Every laboratory should establish its own normal range.

LIMITATION OF THE PROCEDURE

- For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

INTERFERENCE

- Hemoglobin: No interference found upto 1000 mg/dL.
- Bilirubin: No interference found upto 46mg /dL.
- Lipemia: No interference found upto 2000 mg/dL.
- These characteristics have been obtained using an automatic analyzer. Results may vary if a different instrument or a manual procedure is used.

BIBLIOGRAPHY

1. Teitz, N.W., Fundamentals of Clin. Chem., Philadelphia. W.B. Saunders (1970) Trinder.P., "Determination of Blood Glucose Using 4 Aminophenazone."

GLOSSARY OF SYMBOL

	Consult Instruction for Use	LOT	Lot Number
REF	Catalog Number		Date of Manufacturing
	Store between		Use By or Expiration Date
	Manufacturer	IVD	For *in vitro* Diagnostic use only
	Keep away from sunlight	CONT	Content of the kit

LAB-CARE DIAGNOSTICS (INDIA) PVT. LTD.
C1 Type, Shed No.: 3225, Chemical Zone,
GIDC Sarigam – 396155, Dist. Valsad, Gujarat, India.
Tel.: +91 22 2554 2109 /1558
Email: accucare@labcarediagnostics.com;
Website: www.labcarediagnostics.com

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