



Sphera System Packs

# Glucose (Hexokinase)

## Introduction

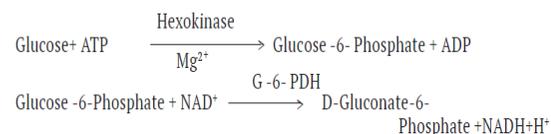
1. Autopure Glucose (Hexokinase) is a reagent kit for quantitative determination of Glucose concentration in human serum or plasma based on Hexokinase method.
2. Autopure Glucose (Hexokinase) is a ready-to-use, two liquid reagent system.
3. With Autopure Glucose (Hexokinase), the assay is linear upto 600 mg/dL.

## Clinical Significance

Estimation of glucose concentration is important in the diagnosis and management of hyperglycaemia and hypoglycaemia. Condition of Hyperglycaemia may occur as a result of diabetes mellitus, patients intravenously receiving glucose containing fluids, during severe stress and cerebrovascular accidents. Hypoglycaemia may be the result of an insulinoma, insulin administration, inborn errors of carbohydrate metabolism or fasting.

## Principle

Enzymatic determination of glucose is carried out as per the following reaction:



\*\*G-6-PDH=Glucose-6-phosphate-dehydrogenase

The amount of NADH formed is directly proportional to the concentration of Glucose in the specimen and is measured photometrically at 340 nm.

## Reagent Storage, Stability & Handling

Autopure Glucose (Hexokinase) is a ready-to-use, two liquid reagent system.

### Shelf life

Unopened reagents are stable till the expiry date indicated on the label, when stored at 2°- 8°C and protected from light.

## On-Board Reagent Stability

Once opened, the reagents are stable up to 60 days at 2° - 8° C, if protected from light and contamination. Open bottle stability may vary from analyzer to analyzer. Do not freeze the reagent.

## Components & Concentration of Working Solution

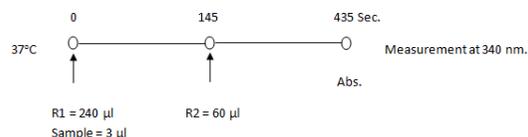
Component	Concentration
• Hexokinase	≥ 1500 U/L
• G6PDH	≥ 2000 U/L
• ATP	≥ 1 mmol/L
• Coenzymes, stabilizers & excipients	

## Specimen Collection & Preservation

Collect sample using standard sampling tube. Serum or plasma (heparin or fluoride) is the specimen of choice. Serum or plasma should be separated from the cell within 30 minutes, as the rate of glycolysis is approximately 7mg/dL per hour at room temperature. Sodium fluoride is preferred as anticoagulant due to its antiglycolytic activity. Glucose in samples is stable for 1 day if stored at 2°-8°C.

## Procedure

Autopure Glucose (Hexokinase) can be used on various automated analyzers. The procedure given below is for Sphera auto-analyzer.



## Calculations

Fully automated system automatically calculates the Glucose concentration of each sample.

## Calibration

For calibration, it is recommended to use c.f.a.s.\* or Accucal or any other suitable calibrator material.

### Calibration frequency

The frequency of calibration is dependent on the analyzer. Re-calibration is recommended

- Whenever the reagent lot is changed.
- As per the requirement of quality control procedures.

\*C.f.a.s. is brand name of Roche Diagnostics, Germany.

## Quality Control

Each batch of Autopure Glucose (Hexokinase) is assayed with atleast six control sera - Precinorm\*\*, Precipath\*\*, Biorad I\*\*\*, Biorad II\*\*\*, Accutrol normal and Accutrol Abnormal prior to release<sup>▲</sup>.

To ensure adequate quality control, it is recommended that the laboratory should use a normal and an abnormal commercial reference control material. It should be realized that the use of quality control material checks both reagent and instrument functions together.

If the control values fall outside the specified limits, each of the below criteria should be cross-checked and corrected:

- Proper instrument function – wavelength setting, light source and temperature control
- Cleanliness of probes and cuvettes.
- Bacterial contamination of wash water used by the instrument
- Expiry date of the reagent kit

\*\*Brand name of Roche Diagnostics, Germany; \*\*\*Brand name of Biorad, USA; ▲subject to availability of control serum.

## Expected Values

Fasting	60 - 110 mg/dL (3.33 – 6.11 mmol/L)
Postprandial	< 145 mg/dL (< 8.05 mmol/L)

Expected range varies from population to population. It is therefore recommended that each laboratory should establish its own reference range. For diagnostic purposes, Glucose results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

## Performance Characteristics

### Linearity

With Autopure Glucose (Hexokinase), the assay is linear upto 600 mg/dL. Determine samples with higher concentration via the rerun function. On instruments without rerun function, manually dilute samples with higher concentration using normal saline (0.9% NaCl) or distilled/deionized water and repeat the assay. The result obtained should be then multiplied with dilution factor to obtain correct Glucose concentration.

## Precision

Reproducibility was determined using quality control sera as shown below:

n = 20	Within run			Between run		
	Mean mg/dL	SD mg/dL	%CV	Mean mg/dL	SD mg/dL	%CV
Low Control	93	0.76	0.82	96.5	1.83	1.90
High Control	235.5	1.81	0.77	239	2.89	1.21

## Correlation Studies

A comparison of Glucose determination using Autopure Glucose (Hexokinase) and reference competitor's product gave the following correlation(mg/dL):

Linear Regression:

$$y = 1.0123x - 1.4318$$

$$R^2 = 0.9983$$

## References

1. Tietz, N. W. (Ed): Fundamentals of Clinical Chemistry, W. B. Saunders Co., Philadelphia.
2. CLSI Method Evaluation Protocols, Clinical & Laboratory Standards Institute, Wayne, PA
3. Young, D.S., Effects of Drugs on Clinical Laboratory Tests 3<sup>rd</sup> ed., AACC Press, Washington (1990).
4. In-house test data. Accurex Biomedical Pvt. Ltd.; 2018

 IVD	<i>In Vitro</i> Diagnostic Use		Date of Manufacturing
 i	Consult Instructions for use		Use by (YYYY-MM-DD)
 REF	Catalogue Number		Temperature Limitation
 LOT	Batch Code		Manufacturer

AR. No.: I134

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## Accurex Biomedical Pvt. Ltd.

Head Office - Mumbai, Tel. : 91(022)67446744

Plant : G-54/55, MIDC, Tarapur, Boisar – 401 506. INDIA.

Customer support no.: 1800 209 8456

E-mail: [support@accurex.net](mailto:support@accurex.net) / URL : [www.accurex.net](http://www.accurex.net)