

GLUCOSE (TRINDER) ASSAY

CATALOGUE NUMBER: 220-32

SIZE: 4 x 100 mL + 1 x 15 mL

INTENDED USE

For the IN VITRO quantitative measurement of glucose concentration in serum.

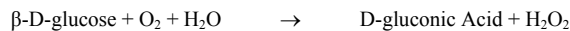
TEST SUMMARY

The measurement of glucose concentrations in biological fluids has been well documented. Glucose testing can be diagnostically significant in diabetes and hypoglycemia.

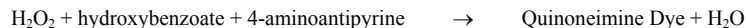
This procedure for the measurement of glucose employs a modification of the glucose oxidase/peroxidase (GOD-POD) method for glucose described by Trinder ⁽¹⁾. Lott and Turner ⁽²⁾, in an evaluation of the Trinder procedure, describe it as highly specific, largely free of interferences, and that good agreement was obtained between the glucose oxidase and the hexokinase procedure. Passey et. al. ⁽³⁾ have recently critically reviewed ten glucose methods including the glucose oxidase method and compared them with the U.S. Food and Drug Administration proposal for a product class standard glucose (1974). Methods for glucose including the glucose oxidase method have been extensively reviewed by Cooper ⁽⁴⁾.

TEST PRINCIPLE

Glucose oxidase



Peroxidase



REAGENTS

Glucose Color Reagent: A solution containing (after reconstitution) a buffer (pH 7.25 at 25°C), 0.25 mmol/L 4-aminoantipyrine, 20 mmol/L p-hydroxybenzoate, > 40,000 U/L glucose oxidase (microbial), > 2000 U/L peroxidase (botanical), and preservatives.

Glucose Calibrator: A solution containing 90 mg/dL (5 mmol/L) glucose and preservatives.

WARNINGS & PRECAUTIONS FOR USE

S24/25: Avoid contact with skin and eyes.
Avoid ingestion.
See Material Safety Data Sheet for additional information.

REAGENT PREPARATION, STORAGE, AND STABILITY

Add the required volume of deionized water. See vial label. Mix gently; allow 5 minutes for reconstitution, then re-mix gently.

Supplied reagents are stable at 2-8°C until expiry.

Prepared reagent is stable at 2-8°C for 30 days.

Stability claims are based on real time studies.

REAGENT DETERIORATION

The reagent solutions should be clear. Turbidity would indicate deterioration.

DISPOSAL

Reagents must be disposed of in accordance with all Federal, Provincial, State and local regulations.

SPECIMEN

Plasma prepared from blood collected with an anticoagulant containing fluoride is the specimen of choice. Other plasmas and serum may be used if they are separated from the cells and assayed promptly.

SAMPLE STORAGE

Fluoridated plasma for glucose assay is stable for 5 days at 2-8°C⁽⁵⁾.

ANALYTICAL SPECIFICITY

Cross contamination studies have not been performed on automated instruments. Certain reagent/ instrument combinations used in sequence with this assay may interfere with reagent performance and test results. The existence of, or effects of, any potential cross contamination issues are unknown.

Ascorbic acid has been extensively studied for potential interference in the measurement of glucose. Lott and Turner⁽²⁾ investigated the effect of ascorbic acid upon the Trinder glucose method and found that only at extremely elevated concentrations did ascorbic acid cause significant interference. Normal concentrations of ascorbic acid, i.e. 11-114 µmol/L are too low to interfere significantly with the glucose analysis.

A summary of the influence of drugs on clinical laboratory tests may be found by consulting Young, D.S.⁽⁷⁾.

ANALYTICAL PROCEDURE

MATERIALS PROVIDED

Genzyme Diagnostics' Glucose (Trinder) reagents.

MATERIALS REQUIRED (BUT NOT PROVIDED)

- 1) Automated analyzer capable of accurately measuring absorbances at 505 nm
- 2) Deionized water for reconstitution.
- 3) Quality Control materials.

TEST CONDITION

For the data presented in this insert, studies using this reagent were performed on an automated analyzer using an endpoint test mode, with a sample to reagent ratio of 1:100, and a wavelength reading of 505 nm. For assistance with applications on automated analyzers within Canada and the U.S, please contact Genzyme Diagnostics Technical Services at (800)565-0265. Outside Canada and the U.S., please contact your local distributor.

CALIBRATION

Calibration material should be used to calibrate the procedure. The frequency of calibration, if necessary, using an automated system is dependent on the system and the parameters used.

QUALITY CONTROL

A normal and abnormal concentration control should be analyzed as required. The results should fall within the acceptable range as established by the laboratory.

CALCULATIONS

The analyzer automatically calculates the glucose concentration of each sample.

TEST LIMITATIONS

A sample with a glucose concentration exceeding the linearity limit should be diluted with 0.9% saline and reassayed, incorporating the dilution factor in the calculation of the value.

REFERENCE INTERVALS⁽⁸⁾

70-105 mg/dL (3.9-5.8 mmol/L)

These values are suggested guidelines. It is recommended that each laboratory establish its own expected range.

PERFORMANCE CHARACTERISTICS

RESULTS

Glucose concentration is reported as mg/dL (mmol/L)

REPORTABLE RANGE

The linearity of the procedure described is 400 mg/dL (22.2 mmol/L). Linearity using automated procedures is dependent on the sample to reagent ratio used.

PRECISION STUDIES

Total precision data was collected on two concentrations of control sera in 20 runs conducted over 10 days.

Concentration		Total SD		Total CV %	Concentration		Within Run SD		Within Run CV %
mg/dL	mmol/L	mg/dL	mmol/L		mg/dL	mmol/L	mg/dL	mmol/L	
68	3.8	1.4	0.08	2.1	68	3.8	1.1	0.06	1.6
247	13.7	4.8	0.27	2.0	249	13.8	2.2	0.12	0.9

Within run precision data was collected on two concentrations of control sera each run 20 times in a single assay.








ACCURACY

The performance of this method (y) was compared with the performance of a similar glucose method on an automated instrument. Forty-seven patient serum samples ranging from 59-319 mg/dL (3.3-17.7 mmol/L) gave a correlation coefficient of 0.9882. Linear regression analysis gave the following equation:

$$\text{This method} = 0.98 (\text{reference method}) + 0.18 \text{ mg/dL (0.01 mmol/L)}$$

REFERENCES

1. Trinder, P., Determination of Glucose in Blood Using Glucose Oxidase with an Alternative Oxygen Acceptor, *Ann. Clin. Biochem* 6, 24-25 (1969).
2. Lott, J.A. and Turner, K., Evaluation of Trinder's Glucose Oxidase Method for Measuring Glucose in Serum and Urine, *Clin. Chem.* 21, 1754-1760 (1975).
3. Passey, R.B., Gillum, R.L., Fuller, J.B., Urry, F.M., Giles, M.L., Evaluation and Comparison of Ten Glucose Methods and the Reference Method Recommended in the Proposed Product Class Standard (1974), *Clin. Chem.* 23, 131-139 (1977).
4. Cooper, G.R., Methods for Determining the Amount of Glucose in Blood, *Critical Reviews in Clinical Laboratory Sciences* 4, 101-145 (1973).
5. Henry, R.J., Cannon, D.C., Winkelman, J.W., *Clinical Chemistry, Principles and Technics*, 2nd ed., Harper and Row Publishers Inc. N.Y., p. 1288 (1974).
6. Schrauzer, G.M., Rhead, W.J., Ascorbic Acid Abuse: Effects of Long Term Ingestion of Excessive Amounts on Blood Levels and Urinary Excretion, *Int. J. Vitam. Nutr. Res.* 43, 201 (1973).
7. Young, D.S., *Effects of Drugs on Clinical Laboratory Tests*, AACC Press, Third Edition, Washington, 1990.
8. Tietz, N.W. (Ed.), *Fundamentals of Clinical Chemistry*, 2nd ed., W.B. Saunders Co., Toronto (1982).

Definitions for Symbols	
 LOT Batch code	 Use by YYYY-MM-DD or YYYY-MM
 Manufacturer	 REF Catalog number
 Consult instructions for use	 Temperature limitation
 IVD <i>In vitro</i> diagnostic medical device	

TRADEMARKS

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