TRUEchemie GLUCOSE TEST KIT

(GOD-POD)

for the quantitative determination of Glucose in human serum or plasma

INTENDED USE

The TRUEchemie Glucose Test Kit for the quantitative determination of total glucose in human serum or plasma.

INTRODUCTION

Glucose is the major carbohydrate present in the peripheral blood. The oxidation of glucose is the major source of cellular energy in the body. Glucose determinations are run primarily to aid in the diagnosis and treatment of diabetes mellitus. Elevated glucose levels may be associated with pancreatitis, pituitary or thyroid disfunction, renal failure and liver disease, whereas low glucose levels may be associated with insulinoma, hypopituitaryism, neoplasms, or insulin induced hypoglycemia.

PRINCIPLE

$$\text{D-Glucose} + H_2O + O_2 \xrightarrow{\text{GOD}} \text{Gluconic acid} + H_2O_2$$

$$2H_2O_2 + \text{4-Aminoantipyrine} + \text{p-Hydroxybenzoic acid} \xrightarrow{\text{POD}} \text{Coloured quinonic derivative} + 4\,H_2O$$

REAGENTS

Kit size	**4 x 125 ml**
Cat. no.	**ADX101**
Kit contents	
1) Glucose Reagent	4 x 125 ml
2) Glucose Standard (100 mg/dl)	1 x 5 ml

REAGENT COMPOSITION

1) Glucose Reagent

Concentrations in the reagent solution are:

Phosphate buffer pH 7.0	120.00	mmol/L
4-Aminoantipyrine	0.80	mmol/L
Phenol	4.50	mmol/L
Glucose Oxidase	< 16.00	KU/L
Peroxidase	> 1.25	KU/L
Preservatives and stabilizers		

2) Glucose Standard

Glucose Concentration – 100 mg/dL (5.55 mmol/L).

STORAGE AND STABILITY

The components of the kit stored at 2-8 °C will remain stable until the expiry date stated on the label. Do not use reagents over the expiration date. Cap the reagent bottle tightly and keep away from light to prevent contamination.

REAGENT PREPARATION

Ready to use reagents.

SPECIMEN COLLECTION

1. Test specimens should be serum, Plasma or CSF free from hemolysis.
2. Serum must be separated from the clot promptly since the rate of glucose decrease is approximately 7% per hour in whole blood.
3. Glucose in serum or plasma is stable for twenty-four (24) hours when stored at 2 - 8° C.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Pipettes to accurately measure required volumes.
2. Test tubes/rack
3. Timer
4. 37° C heating block or water bath
5. Spectrophotometer capable of accurately measuring absorbance at 505 nm

WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use.
2. Do not pipette directly from the Reagent Bottle or Standard Bottle to avoid contamination. Handle in accordance with good laboratory procedures. Avoid ingestion and eye or skin contact.
3. Specimens should be considered infectious and handled appropriately.
4. Use distilled or deionized water where indicated.
5. The disposal of the residues has to be done as per local legal regulations.

TEST PROCEDURE

Wavelength 505 nm
Temperature 37°C
Prewarm the Reagent to reaction temperature.

	Blank (ml)	Standard (ml)	Sample (ml)
Glucose Reagent	1.000	1.000	1.000
Glucose Standard	--	0.010	--
Sample	--	--	0.010

Mix well and incubate for 10 min. at 37º C. or 20-25 min. at 15 – 25 ºC.
After incubation, zero spectrophotometer with the reagent blank. Read and record the incubated Standard and samples.

Final Color stability: A minimum of 1 hour, when protected from direct sunlight.

$$\text{Calculation: } \frac{\text{Sample O.D.}}{\text{Standard O.D.}} \times 100 = \text{mg glucose / dl}$$

S.I. Units (mg/dl) x 0.0555 = mmol/L

QUALITY CONTROLS

Control Sera are recommended to monitor the performance of manual and automated assay procedures. Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

NORMAL VALUES

Normal values Serum, plasma: 75 – 115 mg/dl
C.S.F.: 40 – 80 mg/dl
It is strongly recommended that each laboratory establish its own normal range.

AUTOMATED PROCEDURE

Appropriate Program sheet available for different analyzer are available upon request.

CALIBRATION

The procedures are calibrated with the standard solution which is included with each series of tests. Its absorbance is used to calculate results.

LIMITATIONS OF TEST

Linearity: 600 mg/dl glucose.
Sensitivity: 0.800 mg/dl glucose.
Samples that have glucose values greater than 600 mg/dl should be diluted with water 1:1, reassayed and the results multiplied by 2.

INTERFERENCES

Hemoglobin concentration higher than 200 mg/dl, Bilirubin concentration higher than 20 mg/dl, Uric acid concentration higher than 20 mg/dl, Creatinine concentration higher than 15 mg/dl will interfere
Interferences caused by the anticoagulants of current use such as Heparin, EDTA or Oxalate have not been described.

SYSTEM PARAMETERS

Mode	:	End point
Std. Conc.	:	100
Wave length	:	505 nm (500 – 540)
Units	:	mg/dl
Flow cell Temp	:	37 °C
Blank	:	Reagent
Reagent volume	:	1000 µL
Sample volume	:	10 µL
Incubation	:	10 min. at 37 ºC.
Low Normal	:	75
High Normal	:	115
Sensitivity	:	0.800 mg/dL
Linearity	:	600 mg/dL

REFERENCES

1. Holvey, D.N., ed.: The Merck Manual of Diagnosis and Therapy, erck and Co., Inc. Rahyway, N.J. (1972).
2. Cooper, G.R., CRC Crit Rev. Clin Lab. Sci. 4:101 (1973).
3. Keston, A.S., Colorimetric, "Enzymatic Reagents for Glucose." Abstracts of Papers, 129th Meeting ACS, 131C (1956).
4. Trinder, P., "Determination of blood glucose using 4aminophenazone." J. Clin. Path. 22:246 (1969).
5. Tietz, N.W., Fundamentals of Clin. Chem., Philadelphia, W.B. Saunders (1970). 6. Young, D.S. et al., Clin. Chem. 21:5 (1975).

Index of Symbols

	Consult instructions for use	REF	Catalogue number		
IVD	For *in vitro* diagnostic use only	LOT	Batch code		Use-by date
2 °C – 8 °C	Temperature limit 2-8 °C		Keep away from sunlight		Do not use if package is damaged
	Manufacturer		Date of manufacture		Keep dry
NON STERILE	If device is non-sterile		Warnings / Precautions		