TRUEchemie Glucose Test Kit (GOD-POD)

for the quantitative determination of Glucose in human serum or plasma

INTENDED USE

The TRUEchemie Glucose Test Kit (GOD-POD) is used 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

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

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

PACK SIZE

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).

REAGENT PREPARATION

Ready to use reagents.

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.

CALIBRATION

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

REAGENT STORAGE & 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.

SPECIMEN COLLECTION AND STORAGE

1. Test specimens should be serum or plasma 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

TEST PROCEDURE

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

	Blank (µL)	Standard (µL)	Sample (µL)
Glucose Reagent	1000	1000	1000
Glucose Standard	--	10	--
Sample	--	--	10

Mix well and incubate for 10 min. at 37ºC. or 20-25 min. at 15-25ºC.
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 CONTROL

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

EXPECTED VALUE

Normal values Serum, plasma: 75 – 115 mg/dL

It is strongly recommended that each laboratory establish its own normal range

PERFORMANCE CHARACTERISTICS

Sensitivity: 0.80 mg/dL

Linearity: Up to 600 mg/dL under the described assay conditions. If the concentration is greater than linearity (600 mg/dL), dilute the sample with normal saline and repeat the assay. Multiply the result with dilution factor. The linearity limit depends on the sample / reagent ratio, as well as the analyzers used.

PRECISION:

Intra-assay precision within run (n=10)	Mean (mg/dL)	SD (mg/dL)	CV (%)
Control Level - 1	84.2	0.6	0.7
Control Level - 2	267.5	1.4	0.5

Inter-assay precision run to run (n=12)	Mean (mg/dL)	SD (mg/dL)	CV (%)
Control Level - 1	88.5	0.3	0.3
Control Level - 2	269.9	0.5	0.2

The reagent was tested for 12 days, using two different Glucose concentrations. The coefficient of variation was <5%.

AUTOMATED PROCEDURE

Appropriate program sheet is available for different analyzers upon request.

METHOD COMPARISON

Results obtained using TRUEchemie Glucose reagent (y) did not show systematic differences when compared with another commercial reagent (x) with similar characteristics. The results obtained is below: The correlation coefficient (r^2) was 0.99 and the regression equation is y=1.043x-3.556. The results of the performance characteristics depend on the analyzer used.

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.

WASTE MANAGEMENT

Please refer to local regulation requirements.

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 37ºC.
Low Normal	:	75
High Normal	:	115
Sensitivity	:	0.80
Linearity	:	600
Reaction Slope	:	Increasing

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).
6. ISO 15223-1:2021 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements

Index of Symbols

Consult instructions for use		REF Catalogue number		Caution	
IVD *In vitro* diagnostic medical device		LOT Batch code		Non-sterile	
2°C 8°C Temperature limit 2-8 °C		Do not re-use		Use-by date	
Manufacturer		Date of manufacture		Keep dry	

Do not use if package is damaged — Keep away from sunlight

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