ROBONIK®

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prietest™ ...Clinical Chemistry Reagents

GLUCOSE

In vitro diagnostic test kit, for professional use only

INTENDED USE : Quantitative in vitro determination of concentration of Glucose in serum, plasma on photometric systems.

ORDERING INFORMATION

Pack Size	Cat No.
5 X 100 ml	GLUL 05 100
2 X 500 ml	GLUL 02 500
2 X 1000 ml	GLUL 02 1000

CLINICAL SIGNIFICANCE : Determination of Glucose concentration is important in the diagnosis and treatment of disorders of carbohydrate metabolism. Values higher or lower than the reference are of as diagnostic significance. The levels are increased in diabetes mellitus, hyperthyroidism and in the hyperactivity of the pituitary gland. Decreased levels are observed in cases of over production of insulin by the pancreas, with tumors of the pancreas, as well as with hypofunction of the organs involved in glucose synthesis and carbohydrate metabolism. The main physiological troubles are linked to hyperglycemia (type I Diabetes mellitus and type II Diabetes mellitus). Type I diabetes mellitus is insulin-dependent, and appears mainly before 30 years old. Type II diabetes mellitus is non-insulin-dependent, and usually appears after 40 years old, but can occur earlier for obese people. Other diabetes have secondary origin, and appear after endocrinal or hepatic diseases.

METHOD :
Enzymatic (GOD/POD), Photometric, Trinder Reaction, End Point.
Enzymatic (GOD/POD), Photometric, Trinder Reaction, Fixed Time.

PRINCIPLE :
Glucose oxidase (GOD) converts the sample Glucose into gluconate. The Hydrogenperoxide (H_2O_2) produced in the reaction is degraded by peroxidase (POD) and gives a colored product Phenol and 4-Aminoantipyrine which is measurable using Trinder indicator reaction at 505 nm. The increase in absorbance correlates with the glucose concentration of the sample.

$$Glucose + O_2 \xrightarrow{GOD} Gluconic\ acid + H_2O_2$$

$$2H_2O_2 + Phenol + 4\text{-}Aminoantipyrine \xrightarrow{POD} Red\ quinone + 4H_2O$$

REAGENTS
COMPONENTS AND CONCENTRATIONS :

Phosphate Buffer	:	100 mmol/l
Glucose Oxidase	:	>8 U/ml
Peroxidase	:	>0.6 U/l
4 - Amino Antipyrine	:	0.28 mmol/l
Preservative & Stabilizer		
Standard	:	100 mg/dl (5.55 mmol/L)

STORAGE INSTRUCTIONS AND REAGENT STABILITY :
The reagents are stable up to the end of the indicated date of expiry on the vial label, if stored at 2 to 8°C and contamination is avoided. Do not freeze the reagents!
The standard is stable up to the end of the indicated date of expiry on the vial label, if stored at 2 to 8°C

WARNING AND PRECAUTIONS :
Discard cloudy reagent. Avoid contamination by using clean laboratory material (pipettes, plastic vials for analyzers etc). The reagent contains sodium azide (0.1 %). To avoid the possible build-up of azide compounds, flush waste-pipes with water after the disposal of undiluted reagent.

WASTE MANAGEMENT :
Please refer to local regulation requirements.

REAGENT PREPARATION :
The Reagent and standard are ready to use.

MATERIALS REQUIRED BUT NOT PROVIDED :
NaCl solution 9g/l, General laboratory equipment, Analyser/Photometer, Pipettes etc.

SPECIMEN :
Serum free of hemolysis. Plasma collected with sodium fluoride or any inhibitors of glycolysis.
Stability : Serum is stable for 8 hours at 25°C and up to 3 days at 2 to 8°C.
Plasma is stable for 24 hours at room temperature.

ASSAY PROCEDURE: (I) End Point Mode
Application sheets for automated systems are available on request.

Wavelength	:	Hg 510 nm, 546 nm or 505 nm
Optical Path	:	1 cm
Temperature	:	37°C
Mode	:	End Point

Bring all the contents of the kit to Room Temperature prior to use.
Read absorbance of sample against reagent blank.
Label the test tube as blank, standard, sample, control and pipette into respective test tube the reagent, standard, sample, control sample as per the table given below:

	Blank	Standard	Sample / Control
Reagent	1000 µl	1000 µl	1000 µl
Distilled Water	10 µl	—	—
Standard	—	10 µl	—
Sample / Control	—	—	10 µl

Mix and read the absorbance (A) after 10 minutes of incubation at 37°C but within 60 minutes.

CALCULATION :
With standard or calibrator.

$$\text{Conc. of unknown Sample} = \frac{\text{Concentration of Standard}}{\text{Abs. Standard} - \text{Abs. of Reagent Blank}} \times \text{Abs. of unknown Sample} - \text{Abs. of Reagent Blank}$$

CONVERSION FACTOR :
Glucose [mg/dl] X 0.0555 = Glucose [mmol/L]

CALIBRATION :
For the calibration of automated photometric systems use of the commercially available calibrator is recommended.

QUALITY CONTROL :
To ensure adequate quality, use of the commercially available control sera is recommended.

PERFORMANCE CHARACTERISTICS :
MEASURING RANGE :
The test has been developed to determine Glucose concentrations within a measuring range from 1 to 500 mg/dl (0.056 to 27.75 mmol/L). When values exceed higher limit of the range samples should be diluted 1+1 with NaCl solution (9 g/l) and the result multiplied by 2.

SPECIFICITY / INTERFERENCES :
No interference was observed by Bilirubin up to 20 mg/dl (342 µmol/L), Triglycerides up to 500 mg/dl (5.7 mmol/L) and Ascorbic Acid up to 10 mg/dl (568 µmol/L). A list of drugs and other interfering substances with Glucose determination has been reported by Young et al.

SENSITIVITY / LIMIT OF DETECTION :
The lower limit of detection is 1 mg/dl (0.056 mmol/L)

PRECISION :

Intra-assay precision n = 20	Mean [mg/dl]	SD [mg/dl]	CV [%]
Sample 1	284.2	1.48	0.52
Sample 2	297.8	2.27	0.76
Sample 3	243.1	2.11	0.87

Inter-assay precision n = 20	Mean [mg/dl]	SD [mg/dl]	CV [%]
Sample 1	295.5	4.61	1.56
Sample 2	250.4	3.90	1.56
Sample 3	287.3	3.90	1.36

METHOD COMPARISON :
A comparison between Robonik Prietest Glucose (y) and a commercially available test (x) using 20 samples gave following results:
Linear Regression : y = 0.9633 x + 5.5687 mg/dl
Correlation Coefficient : r = 0.9955

REFERENCE RANGE : Serum or Plasma

Fasting Sample	:	70 to 110 mg/dl	(3.89 to 6.10 mmol/L)
Postprandial Sample	:	100 to 140 mg/dl	(5.55 to 7.77 mmol/L)
Random Sample	:	up to 150 mg/dl	(8.32 mmol/L)

It is recommended that each laboratory should assign its own reference range.

LITERATURE :

1. Sacks, D.B., Carbohydrates. Tietz Fundamentals of Clinical Chemistry, 5th Ed.,
2. Tietz., N.W., Clinical guide to laboratory tests, 3rd Ed.,
3. Young DS. Effects of drugs on Clinical Lab. Tests, 4th ed. AACC Press, 1995

ASSAY PROCEDURE: (I) End Point Mode.

INSTRUMENT APPLICATION prietest TOUCH
Name : GLUCOSE, Mod : END-P Pri.: 510 , Sec.: 0 Temp: 37C , KF : 1.000 Vol : 500ul , Unit : mg/dl Lag : 5 , Read : NA Blk : Y, QC : Y, Norm : Y Std : 1 , Concen : Std.: 1 = 100 Normal HI = 110 Normal LO = 70 QCNH : * QCNL : * QCABH = * QCABL = * Rgnt. Linearity : 500 NOTE : * Indicates user definable parameter. NA Implies Not Applicable

PARAMETERS FOR INSTRUMENT SETTING	
TEST NAME	GLUCOSE
Reaction	End Point
Reaction Slope	Increasing
Wavelength 1	510 nm
Temperature	37°C
Zero Setting	Reagent Blank
Standard Conc.	100
Units	mg/dl
Sample Volume	10 µl
Reagent Volume	1000 µl
Incubation Time	10 minutes
Reference Range	70 to 110
Reagent Linearity	500

Please refer overleaf for the assay procedure with fixed time mode.

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ASSAY PROCEDURE: (II) Initial Rate / Fixed Time Mode

Application sheets for automated systems are available on request.

Wavelength : Hg 510 nm, 546 nm or 505 nm
Optical Path : 1 cm
Temperature : 37°C
Mode : Fixed Time

Bring all the contents of the kit to Room Temperature prior to use.
Read rate of change of absorbance of standard, sample against distilled water.
Label the test tube as standard, sample, control and pipette into respective test tube the reagent, standard, sample, control sample as per the table given below :

Pre warm the working reagent at 37°C for 2 minutes prior to addition of sample

	Standard	Sample / Control
Reagent	1000 µl	1000 µl
Standard	10 µl	—
Sample / Control	—	10 µl

Mix well & read the variation of absorbance (Δ A) between 30 seconds & 90 Seconds.

CALCULATION :

With standard or calibrator.

$$\text{Conc. of unknown Sample} = \frac{\text{Concentration of Standard}}{\Delta \text{ A of standard}} \times \Delta \text{ A of unknown Sample}$$

ASSAY PROCEDURE: (II) Initial Rate / Fixed Time Mode

INSTRUMENT APPLICATION *prietest TOUCH*
Name : GLUCOSE , Mod : FIX_T Pri.: 510 , Sec.: 0 Temp: 37C , KF : 1.000 Vol : 500ul , Unit : mg/dl Lag : 30 , Read : 90 Blk : N, QC : Y, Norm : Y Std : 1 , Concen : Std.: 1 = 100 Normal HI = 110 Normal LO =70 QCNH : * QCNL : * QCABH = * QCABL = * Init. OD : = 0.400 H Max Delta : = 0.78 Rgnt. Linearity : 500 NOTE : * Indicates user definable parameter. NA Implies Not Applicable

PARAMETERS FOR INSTRUMENT SETTING	
TEST NAME	GLUCOSE
Reaction	I. R. / Fixed Time
Reaction Slope	Increasing
Wavelength 1	510 nm
Temperature	37°C
Zero Setting	Distilled Water
Standard Conc.	100.0
Units	mg/dl
Sample Volume	10 µl
Reagent Volume	1000 µl
Lag / Delay Time	30 Sec.
Read Time	90 Sec.
Reference Range	70 to 110
Reagent Linearity	500
Init. OD	< 0.400
Max Delta	0.78

ROBONIK®
An ISO 9001 : 2008 Certified Company
An ISO 13485 : 2012 Certified Company

Manufactured and Marketed by:
ROBONIK (INDIA) PVT. LTD.,
A-374, TTC Industrial Area, Mahape,
Navi Mumbai - 400710, INDIA.
Tel. No.: + 91 (22) 67829700
Fax. No.: + 91 (22) 67829701
Orders : sales.reagents@robonikindia.com
Queries : feedback@robonikindia.com
Website : www.robonik.in

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