

Introduction

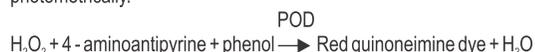
1. AutoPure Glucose is a reagent kit for direct quantitative determination of glucose in human serum and plasma on automated clinical chemistry analyzers.
2. AutoPure Glucose is a single ready-to-use reagent.
3. With AutoPure Glucose, the assay is linear upto 500 mg/dl (27.75 mmol/l).

Principle

Glucose oxidase, oxidizes glucose to gluconic acid in the presence of atmospheric oxygen.



In presence of peroxidase, hydrogen peroxide oxidatively couples with 4 - aminoantipyrine and phenol to produce red quinoneimine dye. The intensity of the red colour formed is directly proportional to the concentration of glucose in the specimen and is measured photometrically.



Reagent Storage, Stability & Handling

AutoPure Glucose is a single ready-to-use reagent.

Shelf life

Stable till the expiry date indicated on the label, when stored at 2°-8°C.

On – Board Reagent Stability

30 days at 2°-8°C after opening. Protect the reagent from light and contamination.

Over a period of time, the reagent may develop a light pink colour. This is expected and does not affect the reagent performance.

Discard the reagent if the absorbance of the same exceeds 0.300 O.D. against distilled water at 505 nm. (500 - 550 nm).

Do not freeze the reagent.

Components & Concentration of Working Solution

Component	Concentration
• Phosphate buffer; pH 7.2	100 mmol/l
• Glucose oxidase, recombinant	≥ 18000 IU/l
• Peroxidase	≥ 2400 IU/l

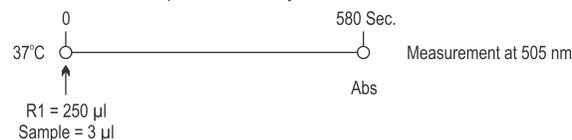
- 4 - aminoantipyrine ≥ 0.25 mmol/l
- Phenol ≥ 10 mmol/l
- Stabilizers, excipients & surface active agents

Specimen Collection & Preservation

Collect sample using standard sampling tube. Serum, iodoacetate plasma, heparinized plasma or EDTA plasma can be used. Serum or plasma should be separated from the cell within 30 minutes, as the rate of glycolysis is approximately 7 mg/dl per hour at room temperature. Sodium Fluoride is preferred as anticoagulant due to its antiglycolytic activity. Glucose in serum/plasma is stable for 1 day at 2°-8°C and 1 month at -20°C. Centrifuge samples containing precipitate before performing assay.

Procedure

AutoPure Glucose can be used on various automated analyzers. The procedure described below is for Sphera auto-analyzer.



Calculations

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

Results in mmol/l = Results in mg/dl x 0.0555

Results in mg/dl = Results in mmol/l x 18.02

Application Sheet

Refer to application sheet for details. For additional system applications, contact our local Accurex representative.

Calibration

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

Calibration frequency

Re - calibration is recommended

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

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

Quality Control

Each batch of AutoPure Glucose is assayed with atleast six quality control sera – Precinorm**, Precipath**, Biorad I***, Biorad II***, Accutrol Normal and Accutrol Abnormal prior to release*.

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

Serum/Plasma

Serum/Plasma	37° C	
Fasting blood glucose	60 - 110 mg/dl	3.33 - 6.11 mmol/l
Postprandial blood glucose	< 145 mg/dl	< 8.05 mmol/l

Note:

Expected range varies from population to population. It is therefore recommended that each laboratory should establish its own normal range. For diagnostic purposes, the glucose results should always be assessed in conjunction with the patient's medical history, clinical examinations and other findings. The whole blood glucose value is generally 10 - 15% lower than the serum or plasma glucose value due to the cell stroma.

Performance Characteristics

Linearity

With AutoPure Glucose, the assay is linear upto 500 mg/dl (27.75 mmol/l). Determine samples with higher concentrations via the rerun function. On instruments without rerun function, manually dilute samples with higher concentrations using 0.9% NaCl or distilled/deionized water (e.g. 1 + 2). Multiply the result by the appropriate dilution factor (e.g. 3).

Interference

There is no significant interference in samples containing upto 20 mg/dl of bilirubin and 750 mg/dl of haemoglobin.

Precision

Reproducibility was determined using quality control sera as shown below:

n = 20

Quality Control Material	Within run			Between run		
	Mean mg/dl	SD mg/dl	%CV	Mean mg/dl	SD mg/dl	%CV
Low Control Serum	83	0.6	0.7	78	2.0	2.4
High Control Serum	322	1.7	0.5	307	2.6	0.9



Application sheet

Co - Relation Studies

A comparison of the glucose determination using AutoPure Glucose and Infinite Glucose reagent gave the following co-relation (mg/dl):

Linear Regression
 $y = -1.863 + 1.042x$
 $r = 0.9976$
 $Sy,x = 2.11$

No. of samples measured : 89
 The sample concentrations measured were between 52 and 160 mg/dl.

References

1. Trinder P. *Annals. Clin. Biochem* 6,24 (1969).
2. Young D.S. etal., *Clinical Chemistry*, 21,1d (1975).
3. Bergmayer H.V., "*Methods of Enzymatic Analysis*", A.P.,N.Y. (1974). Page 1196.
4. In-house test data. *Accurex Biomedical Pvt. Ltd.*, 2014.

Code: <input type="text" value="GLU"/>		Name: <input type="text" value="GLUCOSE"/>		Designations		Type: <input type="text" value="Endpoint self blank"/>		Group: <input type="text" value="ACCUREX"/>																		
1 - Pipetting Reagent 1 ID: <input type="text" value="GLU"/> Reagent 1 bottle: <input type="text" value="Large"/> Reagent 2 ID: <input type="text" value=""/> Reagent 2 bottle: <input type="text" value="Large"/> Sample vol: 1st <input type="text" value="3"/> μ l 2nd <input type="text" value=""/> μ l Reagent 1 vol: <input type="text" value="250"/> μ l Reagent 2 vol: <input type="text" value=""/> μ l Diluent vol: <input type="text" value="5"/> μ l		3 - Wavelengths Wavelength 1: <input type="text" value="505"/> nm		7 - Autodilution Rate: <input type="text" value="*"/> <input type="text" value="3"/> Max OD: <input type="text" value="**"/> <input type="text" value="2"/> Abs		9 - Pathological ranges <table border="1"> <thead> <tr> <th>Minimum</th> <th>Sample type</th> <th>Maximum</th> </tr> </thead> <tbody> <tr> <td>60</td> <td>Fasting</td> <td>110</td> </tr> <tr> <td>60</td> <td>PP</td> <td>145</td> </tr> <tr> <td> </td> <td> </td> <td> </td> </tr> <tr> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table>		Minimum	Sample type	Maximum	60	Fasting	110	60	PP	145							8 - Dilutions Serum <input checked="" type="checkbox"/> 1:1 <input type="checkbox"/> 1:2 <input type="checkbox"/> 1:4 <input type="checkbox"/> 1:10 <input type="checkbox"/> 1:40 <input type="checkbox"/> 1:100 Urine <input checked="" type="checkbox"/> 1:1 <input type="checkbox"/> 1:2 <input type="checkbox"/> 1:4 <input type="checkbox"/> 1:10 <input type="checkbox"/> 1:40 <input type="checkbox"/> 1:100		10 - Results units Units 1: <input type="text" value="mg/dl"/> Units 2: <input type="text" value=""/> Conversion : <input type="text" value="1"/> Decimal digits: <input type="text" value="1"/>	
Minimum	Sample type	Maximum																								
60	Fasting	110																								
60	PP	145																								
2 - Time Incubation 1: <input type="text" value="580"/> Sec Incubation 2: <input type="text" value=""/> Sec Reading: <input type="text" value="58"/> Sec		4 - Washing Needle: <input type="text" value="1"/> Cuvette: <input type="text" value="1"/>		5 - Incompatibility 1 <input type="text" value=""/> <input type="text" value=""/> 2 <input type="text" value=""/> <input type="text" value=""/> 3 <input type="text" value=""/> <input type="text" value=""/> 4 <input type="text" value=""/> <input type="text" value=""/>		6 - Limits Blank OD min: <input type="text" value="0"/> Abs Blank OD max: <input type="text" value="2"/> Abs Reaction slope: <input type="text" value="Positive"/>		OD Range min: <input type="text" value="0"/> Abs Min conc: <input type="text" value="0"/> mg/dl OD Range max: <input type="text" value="**"/> <input type="text" value="2"/> Abs Max conc: <input type="text" value="500"/> mg/dl																		

* User defined ** User defined based on calibration

Code: <input type="text" value="GLU"/>		Name: <input type="text" value="GLUCOSE"/>		Designations		Type: <input type="text" value="Endpoint self blank"/>		Group: <input type="text" value="ACCUREX"/>	
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OK									
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3	CFAS	1	3	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>		
Reagent blank	<input checked="" type="checkbox"/> Blank Correction	Validity <input type="text" value="24"/> # hours	OD <input type="text" value=""/>	Date <input type="text" value=""/>	<input type="button" value="Print calibration"/> <input type="button" value="Curve chart"/>				
Correlation $Y = X + $									

Recommended value

AR. No.: I38A ASGU1-2014-07-001

ISO 13485, ISO 9001 CERTIFIED COMPANY

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