Glucose Assay Kit (GLU)

Method: Glucose Oxidase

Cat .No.	size	Instrument
GB120T	5×100ml	For Hitachi 717 & ShimadzuCL7200/8000
GS121T	6×70 ml	For Hitachi917 & OlympusAU640/400/600
GH121T	6×50 ml	For Hitachi902
GT121T	7×50 ml	For TOSHIBA
GX121T	2×100 ml	For SYNCHRON CX4-5-7-9/LX20/DXC600-800

INTENDED USE

For the *in vitro* quantitative determination of glucose in serum.

CLINICAL SIGNIFICANCE[1]

Determination of glucose concentration is important in the diagnosis and treatment disorders of carbohydrate metabolism. Increased levels of glucose are found in diabetes mellitus, hyperparathyroidism, pancreatitis, renal failure. Decreased levels are found in insulinoma, hypothyroidism, hypopituitarism and extensive liver disease.

ASSAY PRINCIPLE

Glucose oxidase (GOD) converts the sample glucose into gluconate. The hydrogen peroxide (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.

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

$$2H_2O_2 + \text{Phenol} + \text{4-Aminoantipyrine} \xrightarrow{\text{POD}} \text{Red quinine} + 4H2O$$

REAGENT COMPOSITION

Contents	Concentration
phosphate buffer	250 mmol/L, pH 7.5
phenol	5 mmol/L
4-amino-antipyrine	0.5 mmol/L
GOD	＞15 KU/L
POD	＞3 KU/L

SAMPLE COLLECTION AND PREPARATION

Serum samples. Glucose is stable for 24 hours at 2-8°C, if the serum is prepared within 30 mins of collection.

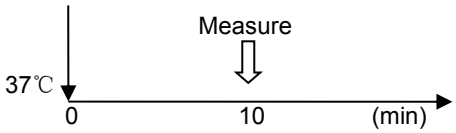
STABILITY AND PREPARATION OF REAGENTS

All reagents are ready to use.
Stable up to the expiry date when stored at 2-8℃.
The reagent is stable for 28 days on-board the analyzer after opening and kept at 2-8℃.

ASSAY PROCEDURE

Assay Mode: endpoint
Wave Length (main/sub): 505 nm / 700 nm

Sample: 2 µl
R1: 200 µl



1. Mix 2 µl sample with 200 µl R1 and incubate at 37℃ for 10 minutes.
2. Measure the absorbance of the sample (A_{sample}) and calibrator ($A_{calibrator}$) against reagent blank.

CALCULATION

$$\text{Concentration} = \frac{A_{sample} - A_{blank}}{A_{calibrator} - A_{blank}} \times \text{Calibrator value}$$

CALIBRATION

Recommend that this assay should be calibrated using Gcell calibration serum, calibration trace to NIST965b. Randox calibration also can be used, Randox calibration choosing method: (Glucose oxidase)

QUALITY CONTROL

Use Gcell multi quality control serum serum or Randox control serum, Values obtained should fall within a specified range. If these values fall outside the range, the following steps should be taken:

1. Check instrument settings and light source.
2. Check reaction temperature.
3. Check expiration date of kit and contents.
4. Check the quality of the water used for reagents reconstitution.

NORMAL VALUE

Serum : 3.89-6.1 mmol/L.
It is recommended that each laboratory establish its own reference range to reflect the age, sex, diet and geographical location of the population.

UNIT CONVERSION

mg/dl×0.055 = mmol/L

SPECIFIC PERFORMANCE CHARACTERISTICS

LINEARITY

The method is linear up to 25 mmol/L. Sample above this concentration should be diluted with 0.9% NaCl and reassay. Multiply the result by dilution factor.

PRECISION

The CV of the test should be less than 5%.

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Intra assay precision		
N=20	Level1	Level 2
Mean (mmol/L)	6.10	16.12
SD (mmol/L)	0.05	0.13
CV	0.80%	0.08%
Inter assay precision		
N=5	Level1	Level 2
Mean (mmol/L)	5.96	15.44
SD (mmol/L)	0.06	0.16
CV	0.96%	1.05%

SENSITIVITY

The minimum detectable level that can be distinguished from zero has been determined as 0.02 mmol/L.

INTERFERENCE

A Reagent blank may be performed by replacing sample or standard with double deionized water. The following analytes were tested up to the levels indicated and found not to interfere:

Hemoglobin: 200 mg/dl
Intralipid: 500 mg/dl
Bilirubin: 20 mg/dl
Ascorbic Acid: 5 mg/dl

CORRELATION

This method (Y) was compared with another commercially available method (X) and the following linear regression equation obtained:

Y=1.013X-0.068, and r^2= 0.998; 70 patient samples were analyzed.

SAFETY PRECAUTIONS AND WARNINGS

1. For in vitro diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handing laboratory reagents.
2. Reagent contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention.
3. Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents flush with large volumes of water to prevent azide build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.
4. All specimens used in this test should be considered potentially infectious. Universal Precautions, as they apply at your facility, should be used for handling and disposing of materials during and after testing.

REFERENCES

1. Barham, D, and Trinder, P. Analyst 1972; 97: 142.
2. Teuscher, A. and Richterich, P. Schweiz Med. Wschr. 1971; 101: 345 and 390.

INDEX OF SYMBOLS


Manufacture


Catalogue Number


Lot number


Date of manufacture


Use by(Expiration date)


For In-Vitro Diagnostic use only


Stored at 2-8℃


Attention:See instruction for use


Authorized Representative in the European Company

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