Bioway Chemistry Reagent Series

The Serum Glu Reagent Kit

Detection of Glucose in Human Serum on Chemistry Analyzers

Cat. No. R030K11 ***The Serum Glu Reagent Kit***

SUMMARY OF TEST PROCEDURE

Figure 1: Procedure Diagram

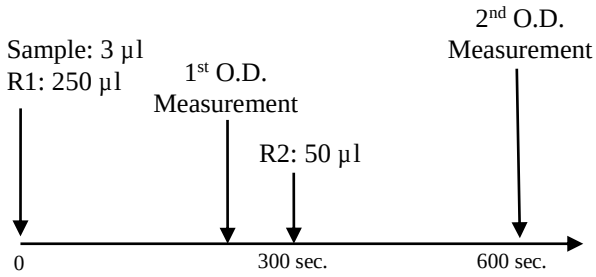

Table 1: Instrument Parameters*

Calibration method	2-point linear	Slope of reaction	Increase
Wavelength	Dλ : 340 nm Sλ : 405 nm	Sample volume	3 µl
Test method	Hexokinase method	R1 volume	250 µl
Reaction temperature	37℃	R2 volume	50 µl

*Refer to Figure 1 and the package insert for detail

INTENDED USE

Bioway Chemistry Reagent Series **Glucose Reagent Kit** (the Kit) is an enzymatic assay intended for *in vitro* quantitative detection of glucose in human serum on automated clinical chemistry analyzers.

SUMMARY AND EXPLANATION

Glucose is the major carbohydrate present in human bodies, and it plays an important role in maintaining cellular energy. Glucose determination is the main way in diagnosis and treatment of diabetes mellitus. Abnormal glucose levels are usually associated with insulinemia, insulinoma or insulin-induced hypoglycemia. There are a lot of possibilities, including pancreatitis, pituitary, renal failure, thyroid dysfunction or liver diseases, contribute to influence the blood glucose concentration.

TEST PRINCIPLES

The detecting method adopted in this kit is using hexokinase to catalyze Glucose and produce glucose-6-phosphate (G-6-P). Then the glucose6-phosphate-dehydrogenase (G-6-PDH) oxidizes glucose-6-phosphate to 6-phosphogluconate (6-PG) in the presence of NAD. The formation of NADH elevates in absorbance at 340 nm.

$$\text{Glucose} + \text{ATP} \xrightarrow{\text{Hexokinase}} \text{G-6-P} + \text{ADP}$$

$$\text{G-6-P} + \text{NAD}^+ \xrightarrow{\text{G-6-PDH}} \text{6-PG} + \text{NADH} + \text{H}^+$$

The increase is directly proportional to the glucose concentration in the sample.

MATERIALS PROVIDED

Reagent:

R1	Adenosine triphosphate Nicotinamide adenine dinucleotide Magnesium sulfate	1.4 mmol/L 0.8 mmol/L 2.0 mmol/L
R2	Glucose6-phosphate-dehydrogenase Hexokinase Sodium azide	3800 U/L 2500 U/L 0.1 %

MATERIALS NEEDED BUT NOT PROVIDED

1. Automated chemistry analyzer.
2. Glucose control set (commercially available).

INSTRUMENT

The Kit is applicable on most automated chemistry analyzers. Refer to specific instrument application for suggested settings.

STORAGE AND STABILITY

Store the reagents at 2-8℃. Avoid direct sunlight. The Kit is stable through the expiration date when stored properly. Reagent is stable for 1 month at 2-8℃ after opening.

PRECAUTIONS

1. The Kit is for *in vitro* diagnostic use only. Not for use in humans or animals.
2. The instructions must be followed to obtain accurate results.
3. Do not use the reagents beyond the expiration date.
4. Treat all specimens as infectious. Proper handling and disposal procedures of specimens and test materials should be strictly followed.

SPECIMEN COLLECTION AND HANDLING

Follow standard laboratory procedures to collect plasma or serum preventing hemolysis. Do not use contaminated samples.

TEST PROCEDURE (see Figure 1)

Reagent 1 and 2 liquid stable ready-to-use, no preparation needed.

Calibration: Recommend using commercially available calibrators for optimal results. Use 2-point linear calibration method.

Test procedure: see Figure 1 and Table 1 for instrument parameter setup. Refer to specific instrument application for suggested setting.

1. Add 3 µl of sample and 250 µl of R1; mix well and incubate at 37℃ for 300 seconds.
2. Take optical density measurement OD 1 just before addition of R2.
3. Add 50 µl of R2, mix well and incubate at 37℃.
4. Take optical density measurement OD 2 at 600 seconds.
5. Calculate ΔOD = OD 2 – OD 1

RESULT

$$\frac{\text{Abs. sample}}{\text{Abs. standard}} \times \text{Standard Conc. (mmol/L)} = \text{Glucose Conc. (mmol/L)}$$

EXPECTED VALUES

Fasting glucose 3.9~6.1 mmol/L
It is recommended for each laboratory to establish its own reference range.

QUALITY CONTROL

Using controls included in the package with known concentration is recommended before each batch of tests to ensure the test is properly performed and all reagents and the instrument are functional as specified.

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LIMITATIONS

1. The Kit is for *in vitro* use on automated chemistry analyzers only.
2. The normal dose of heparin, EDTA and sodium fluoride does not affect the test result.
3. Samples exceeding the maximum measurement range should be diluted with saline and retested.
4. The test result from the Kit should not be used as the only basis for definite diagnosis.

PERFORMANCE CHARACTERISTICS

Linearity: 0 – 22.4 mmol/L (R≥0.99)

Accuracy: control recovery relative deviation ≤ 10%

Precision: Within Run: CV≤3%;
Run-to-Run: CV≤5%

Interference: no interference detected for: ascorbic acid(≤50mg/dl), unconjugated bilirubin(≤40mg/dl), bilirubin(≤20mg/dl), hemoglobin (≤500mg/dl) and chylomicrons(≤3000U/dl),

Reagent Blank Absorbance: at 340nm wavelength and 10 mm optical diameter, O.D. ≤ 0.1

REFERENCES

1. R. Deeg *et al.*, J. Clin. Chem. Clin. Biochem. 18:49-52 (1980)
2. Shephard MDS *et al.*, Clin.Biochem. 4:61-67 (1983)
3. Farrance I. *et al.*, Clin.Biochem Reviews 8:48-50 (1987)

Not Intended for Sale in the United States.

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