This package insert follows the Pharmaceuticals, Medical devices and Other Therapeutic Products Act of Japan.

In Vitro Diagnostics
Marketing Approval No. 20600AMZ01041000

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This package insert must be read carefully prior to use.

Glucose assay kit
(Classification No.: 30167002)

Pureauto S GLU

Warning
Measured blood glucose levels may be higher than the actual values in patients with pralidoxime methyl iodide treatment. Therefore, obtain information from the manufacturing authorization holder of pralidoxime methyl iodide concerning its influence on measurement of blood glucose in such patients. (Measured blood glucose levels may be higher than the actual values in patients with pralidoxime methyl iodide treatment. If hypoglycemic drugs such as insulin are administered on the basis of false high values, serious symptoms of hypoglycemia such as coma may occur.)

General Precautions **

1. This product is for in vitro diagnostic use, and must not be used for any other purposes.
2. Clinicians should make a comprehensive clinical decision based on assay results in conjunction with clinical symptoms and other examination results.
3. For the effects of an administered drug on the measured value, carefully read the Precautions for Use in the package insert of the drug, especially the section about the effects on laboratory test results. Please also read carefully the "2. Interfering Substances," in the "Procedural Precautions" section, as well as "2. Precautions for Assessment" in the "Assessment of Assay Results" section, of this package insert.
4. This product should be used only as directed in this package insert. Reliability of results cannot be guaranteed if there are any deviations from the instructions in this package insert.
5. If the reagent accidentally comes in contact with eyes and/or mouth, rinse immediately with ample water as first aid, and consult the doctor if required.
6. Carefully read the operating instructions for each type of automated analyzers prior to using this product. Parameters for each type of analyzers are available, and can be requested from SEKISUI MEDICAL CO., LTD. if required.
7. Perform a quality control test prior to assay to ensure accuracy.

Description (Kit Components) * *

Component: Ingredients
GLU Enzyme Solution 1:
Hexokinase
Glycose-6-phosphate dehydrogenase
Nicotinamide adenine dinucleotide phosphate (oxidized form)
GLU Reactant Solution 2

Intended Use

Measurement of glucose in serum, plasma, or urine

The blood level of glucose is increased due to its intestinal absorption, hepatic degradation of glycogen, and gluconeogenesis (formation of glucose from other substances), while it is decreased due to formation of glycogen, oxidative degradation in the tissues, and conversion to lipids. Also, because *in vivo* glucose metabolism is regulated by the endocrine system and the autonomic nervous system, detection of abnormal blood and urinary glucose levels is important in the diagnosis and evaluation of these diseases.

Assay Principle

1. Assay Principle

Glucose is converted to glucose-6-phosphate by the action of hexokinase (HK) in the presence of ATP. Glucose-6-phosphate is converted to 6-phosphogluconic acid by the action of glucose-6-phosphate dehydrogenase (G-6-PDH). At the same time, NADP is converted to NADPH, and the absorbance at 340 nm increases. The glucose level is determined by measuring the change in the absorbance of NADPH.

$$\text{Glucose} + \text{ATP} \xrightarrow[Mg^{2+}]{\text{HK}} \text{Glucose-6-phosphate} + \text{ADP}$$

$$\text{Glucose-6-phosphate} + \text{NADP} \xrightarrow{\text{G-6-PDH}} \text{6-Phosphogluconic acid} + \text{NADPH}$$

2. Features

1) Liquid reagents, ready-to-use.
2) Hemolysis and bilirubin have minimal effects on results.
3) This product shows a high sensitivity and reproducibility.
4) Applicable to various automated analyzers.

Procedural Precautions * *

1. Properties of Samples and Sampling Methods

1) Samples
Serum, plasma（citrated plasma） and urine may be used.
2) Storage of samples[4)]
The glucose level in whole blood deceases over time. Separate cells from the sample immediately after collection of a blood sample.
When serum or plasma samples must be stored after separation, store them at 2–10°C or at -20°C or lower.
Bring samples to room temperature (15–30ºC) before use.
Urine samples should be tested on the same day.

2. Interfering substances

Assay results are not affected by free bilirubin (up to 50 mg/dL), conjugated bilirubin (up to 50 mg/dL), hemoglobin (up to 500 mg/dL), or

ascorbic acid (50 mg/dL).

3. Others

1) Always use Serum Multicalibrater (SEKISUI) or Anaserum GLU standard solution for calibration.
2) Precautions for assay range
If the concentration of sample exceeds assay range, dilute the sample with saline and repeat the measurement.

Dosage/Administration (Assay Procedure) * *

1. Preparation of reagents

Reagent (1): GLU Enzyme Solution 1 is ready to use.
Reagent (2): GLU Reactant Solution 2 is ready to use.

2. Assay Procedure

This product is compatible with various types of automated analyzer. An example of the assay procedure is indicated below.

Sample 3 µL + Reagent (1) 260 µL → (37°C, 5 min) → Measurement (Absorbance I※)
Reagent (2) 130 µL → (37°C, 5 min) → Measurement (Absorbance II※)
→ Calculation of concentration

※Absorbance I and II: The difference in absorbance between 450 nm and 340 nm.
Calibration material: Serum Multicalibrater (SEKISUI) or Anaserum GLU standard solution (Manufacture's assigned value)
Reagent blank: Purified water or saline

Assessment of Assay Results * *

1. Reference standard range[1)]
Fasting blood glucose level:
73–109 mg/dL (Within the JCCLS common standard)
2. Precautions for Assessment
There may be reactions or interfering reactions with non-target substances. If assay results appear to be unreliable, repeat the measurement (if necessary, after dilution) or try another analytical methods.

Performance *

1. Sensitivity

1) Reagent blank: absorbance being equal to or lower than 0.05
2) Sensitivity: The absorbance is 0.58–0.87 per 300 mg/dL of glucose.

2. Accuracy: 90–110% of the expected assay value

3. Within-run Reproducibility:
Coefficient of variation ≤ 3%
(Test methods used for 1.–3.are in-house methods.)

4. Measurement Range[5)]: (On Hitachi 7170S automated analyzer)
1–1000 mg/dL

5. Correlation[5)]

1) Serum N=100 r=0.999 y=0.99x+0.42
Control method: Approved in vitro diagnostic (hexokinase method)
2) Plasma N=50 r=0.999 y=0.99x+0.80
Control method: Approved in vitro diagnostic (glucokinase method)
3) Urine N=50 r=0.999 y=0.99x+1.13
Control method: Approved in vitro diagnostic (hexokinase method)

6. Standard Material

SRM917（NIST）

Precautions for Use or Handling *

1. Precautions for Handling (to Ensure Safety)

1) All samples used in the test should be handled as a material possibly infected with HIV, HBV, HCV, or other viruses. To prevent infection, use disposable gloves and avoid mouth pipetting during the test.
2) Sodium azide is added as an antiseptic agent in the GLU Enzyme Solution 1 and GLU Reactant Solution 2. Therefore, if the reagent comes in accidentally contact with eyes, mouth or skin, rinse immediately with ample water as first aid, and consult the doctor if required.

2. Precautions for use

1) This product should be stored as directed, without freezing. Freezing can deteriorate the reagents, which can produce inaccurate results. Therefore, avoid using the reagents which have been previously frozen.
2) Do not use expired reagents. Use of such reagents cannot guarantee the reliability of measurement values.
3) Do not replenish the reagents.
4) Do not perform the assay under direct sunlight

3. Precautions for Disposal

1) Before disposal, used samples and their containers must be immersed in sodium hypochlorite solution at a concentration of greater than 0.1% for longer than 1 hour or autoclaved at 121ºC for 20 minutes.
2) To prevent infections from spilled samples or solutions containing samples, wipe the spilled area thoroughly with disinfectants such as sodium hypochlorite solution at a concentration of greater than 0.1%.
3) The reagents and treated samples should be discarded as medical waste or industrial waste according to the waste disposal regulations.
4) The reagents should be disposed of in accordance with the Water Pollution Control act or related regulations.
5) Sodium azide has been added as an antisepticagent in the GLU Enzyme Solution 1 and GLU Reactant Solution 2. It can react with lead or copper pipes to produce the highly explosive metal azide. Therefore, the reagent should be flushed with large amounts of water during disposal.

4. Other precautions

Do not use the containers for other purposes.

Storage and Shelf Life *

1. Storage temperature: 2–10°C
2. Shelf life: 1 year from the date of manufacture
(The expiration date is printed on the outer package.)

Packaging

Name			Package
Pureauto S GLU	(1)	GLU Enzyme Solution 1	2×400 mL
	(2)	GLU Reactant Solution 2	2×200 mL

Constituent reagents are available in other configurations. For further details please contact SEKISUI MEDICAL CO., LTD.

References * *

1) Kanai M. (supervising editor): Kanai's manual of clinical laboratory medicine. 35th ed. 519, Kanehara Shuppan, 2020.
2) Meiling G. E. et al.: Clin. Chem, 25, 1581, 1979.
3) Koda K.: Med Tech, 10, 143, 1982.
4) Sasaki M. et al.: Sampling of constituents of the human body, 237, Kodansha, 1972.
5) In house data, SEKISUI MEDICAL CO., LTD.

Contact

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Manufacturer *

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