FUJIFILM

Use after reading this "Instructions for Use"

IVD

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Plasma/Serum test for glucose

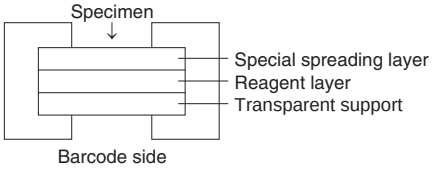
FUJI DRI-CHEM SLIDE GLU-PIII

[Warnings and precautions]

1. Only the required number of slides should be taken out of the refrigerator and warmed up to room temperature before opening the individual packages.
2. Do not touch either the center part of the surface or the back of the slide.
3. Do not use a yellow-colored slide on barcode side.
4. A new slide must be used for each measurement. Do not reuse.
5. Handle all patient specimens, control serum and used tips carefully as biohazardous samples. Wear proper gloves, glasses and other protective gear for your safety.
6. Used slides are categorized as infectious waste. Make sure to dispose them in accordance with the Waste Disposal Law and other related regulations, which prescribe the proper method of disposal, such as incineration, melting, sterilization or disinfection.

[Composition of the slide]

1. Multi-layered structure



2. Ingredients per slide

• Glucose oxidase	0.95 U
• 1,7-Dihydroxynaphthalene	0.03 mg (0.19 µmol)
• 4-Aminoantipyrine	0.086 mg (0.42 µmol)
• Peroxidase	16 U

[Intended use]

Quantitative measurement of glucose concentration in plasma or serum.
For *in vitro* diagnostic use only.

[Principle of the measurement]

10 µL of plasma or serum is deposited on a FUJI DRI-CHEM SLIDE GLU-PIII. After depositing, the specimen spreads uniformly on the spreading layer and diffuses into the underlying layer. As the process proceeds, large molecular components such as proteins or dye components are filtrated, and only small molecular components are able to permeate and diffuse into the reagent layer. Glucose oxidase (GOD) catalyzes the oxidization of sample glucose to generate hydrogen peroxide. In the presence of peroxidase (POD), hydrogen peroxide reacts with dye precursors and finally forms red dye. The slide is incubated at 37 °C for a fixed time in the FUJI DRI-CHEM ANALYZER and the optical reflection density is measured at 505 nm. The optical reflection density is then converted into the glucose concentration using a calibration curve preinstalled in the analyzer.

$$\text{Glucose} + O_2 + H_2O \xrightarrow{\text{GOD}} \text{Gluconic acid} + H_2O_2$$

$$\text{1,7-Dihydroxynaphthalene} + \text{4-Aminoantipyrine} + H_2O_2 \xrightarrow{\text{POD}} \text{Red dye}$$

[Additional special equipment]

Analyzer: FUJI DRI-CHEM ANALYZER
Other implements: FUJI DRI-CHEM QC CARD (attached)
: FUJI CLEAN TIPS or FUJI AUTO TIPS
: FUJI HEPARIN/PLAIN TUBE or Blood collection tube specified in the "INSTRUCTION MANUAL" for FUJI DRI-CHEM ANALYZER

[Specimen requirements]

1. (1) Blood collection tube containing sodium fluoride or monoiodoacetic acid as glycolytic inhibitor is acceptable. When sodium fluoride is used as glycolytic inhibitor, the amount of sodium fluoride should be 2.5 mg per 1 mL of whole blood or less.
   (2) Measurement of the specimen should be performed immediately because glycolysis will proceed gradually even when glycolytic inhibitor is added.
2. Avoid using plasma or serum with precipitate such as fibrin.
3. When the measured value exceeds the upper limit of the dynamic range, dilute the sample with distilled water or saline. Since the data obtained by dilution may deviate more widely than usual, the data should be treated as estimation.

[Procedure]

1. Read in the new QC-card when you switch to a new box of slides.
2. Set slides on FUJI DRI-CHEM ANALYZER.
3. Set a sample tube in the specified sample rack.
4. Input a sequence No. and a sample ID if appropriate.
5. Press the "START" key to initiate testing.
   For further details of operation procedure, consult "INSTRUCTION MANUAL" for FUJI DRI-CHEM ANALYZER.

[Reference interval]

3.9–6.1 mmol/L (fasting glucose) (70–110 mg/dL)
As the reference intervals depend on the population of the test, it is required that each laboratory set its own reference intervals. The clinical diagnosis must be made by the doctor in charge based on the measured results in the light of clinical symptoms and other test results.

[Performance characteristics]

1. Dynamic range 0.6–33.3 mmol/L (10–600 mg/dL)

2. Accuracy

Concentration range	Accuracy
0.6–5.6 mmol/L	Within ± 0.8 mmol/L
5.6–33.3 mmol/L	Within ± 15 %

3. Precision

Concentration range	Precision
0.6–5.6 mmol/L	SD ≦ 0.3 mmol/L
5.6–33.3 mmol/L	CV ≦ 5 %

4. Correlation

Correlation was evaluated between hexokinase method and FUJI DRI-CHEM system. Hexokinase method was run on a HITACHI automated analyzer. This examination was carried out at the laboratory of FUJIFILM Corporation

	n	Slope	Intercept	Correlation coefficient
Plasma	65	1.013	0.11	0.999
Serum	55	1.016	-0.17	0.999

5. Known interfering substances

(1) Increase of ascorbic acid gives minus bias.
(2) The effects on the measured value were examined by adding substances as shown below to a plasma specimen obtained from a healthy volunteer or a control serum. No significant effect was observed to the following concentration for each substance.

Bilirubin	340 µmol/L
Hemoglobin	5000 mg/L
Total protein	50–90 g/L

These results are representative;
• Test condition may have some influence on your results.
• Interferences from other substances are not predictable.

[Internal quality control]

The accuracy and precision of this product can be evaluated with FUJI DRI-CHEM CONTROL QP-L and/or QP-H.

1. Select control level in accordance with your purpose.
2. Measure FUJI DRI-CHEM CONTROL QP-L and/or QP-H in the same way as patient specimens.
3. When the results obtained are outside the expected range shown in the sheet attached to FUJI DRI-CHEM CONTROL QP-L or QP-H, investigate the cause. For additional information, consult "Instructions for Use" for FUJI DRI-CHEM CONTROL QP-L or QP-H.

[Traceability of calibrators and control materials]

Glucose…NIST (SRM917)
Note: This reference material is applied to the reference method of FUJIFILM Corporation and is not directly applicable to FUJI DRI-CHEM SLIDE.
NIST: National Institute of Standards & Technology

[Storage and shelf life]

1. Storage: This product must be stored between 2–8 °C (35.6–46.4 °F) before use.
2. Expiry date is printed on the carton.
3. Use immediately after opening the individual package.

[Contents]

: Slide 24
: QC card 1

http://www.fujifilm.com/products/medical/

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