[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 sample 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.

Glucose + O2 + H2O → Gluconic acid + H2O2

37 °C for a fixed time

[Composition of the slide]
1. Multi-layered structure

<table>
<thead>
<tr>
<th>Sample</th>
<th>Special spreading layer</th>
<th>Reagent layer</th>
<th>Transparent support</th>
</tr>
</thead>
</table>

Barcode side

2. Ingredients per slide
- Glucose oxidase
  0.95 U

- 1,7-Dihydroxynaphthalene
  0.03 mg (0.19 μmol)

- 4-Aminooantipyrine
  0.086 mg (0.42 μmol)

- Peroxidase
  16 U

[Additional special equipment]
Analyzer: FUJI DRI-CHEM ANALYZER
Other implements: FUJI DRI-CHEM QC CARD (attached)
- FUJI DRI-CHEM CLEAN TIPS or FUJI DRI-CHEM AUTO TIPS
- FUJI HEPARIN/PLAIN TUBE or Blood collection tube

[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.

CAUTION: Do not use expired slides.

[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 the membrane in the center of the slide.

3. A new slide must be used for each measurement. Do not reuse.

4. Handle all patient samples, control serum and used tips carefully as biohazardous samples. Wear proper gloves, glasses and other protective gear for your safety.

5. Used slides are categorized as infectious waste. Make sure to dispose of 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.

6. Keep QC card away from magnetic material.

7. Do not use the slide if the individual package is damaged.

[Sample requirements]
1. After collecting blood sample immediate measurement is recommended.

2. (1) Blood collection tube containing sodium fluoride or monooiodoacetic 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 sample should be performed immediately because glycolysis will proceed gradually even when glycolytic inhibitor is added.

3. Avoid using plasma or serum with precipitate such as fibrin.

4. 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.

[Performance characteristics]
1. Dynamic range

   - Plasma/Serum test for glucose
     - 10–600 mg/dL (0.6–33.3 mmol/L)

2. Accuracy

   - Within ± 15 mg/dL (Within ± 0.8 mmol/L)
   - Within ± 0.8 mmol/L

3. Precision

   - SD ≤ 5 mg/dL (SD ≤ 0.3 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.

[Reference intervals]
70–110 mg/dL (fasting glucose) (3.9–6.1 mmol/L)

As the reference intervals depend on the population of the test, it is required that each laboratory set its own reference intervals.

[Limitation of the examination procedure]
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.

Known interfering substances
No significant effect was observed to the following concentration for each substance:
- Ascorbic acid 10 mg/dL (0.57 mmol/L)
- Bilirubin 20 mg/dL (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.

[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
**Symbols**

- Do not touch the center part of the slide.
- Warmed up to room temperature before opening the individual packages.
- SLIDE CODE
- Do not reuse
- Lot number
- Use by
- Contains sufficient for <n> tests
- Temperature limitation
- Consult instructions for use
- In vitro diagnostic medical devices
- Manufacturer
- Authorized representative in the European Community