ITEM CODE 01

SPOTCHEM™ II Glucose [Glu]

CLIA complexity: Waived

INTENDED USE
For the *in vitro* quantitative determination of glucose in human plasma from whole blood samples. This product is intended for use with the SPOTCHEM EZ analyzer.

Cat. No. SE77101 25 Test Strips

CLINICAL SIGNIFICANCE
Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia and idiopathic hypoglycemia and of pancreatic islet cell carcinoma.

Diabetes mellitus is a group of metabolic diseases characterized by hypoglycemia resulting from defects in insulin secretion, insulin action, or both. The chronic hyperglycemia of diabetes is associated with long-term damage, dysfunction, and failure of various organs, especially the eyes, kidneys, nerves, heart, and blood vessels.[1]

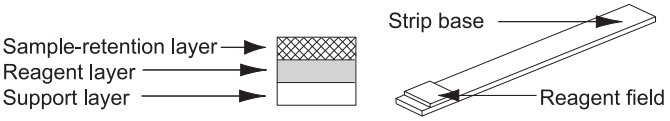
PRINCIPLE OF THE PROCEDURE[2,3,4,5,6]
A fixed amount of plasma is placed on the test field of the reagent strip. The plasma spreads in a uniform fashion across the entire surface of the sample retention layer. The plasma then permeates into the reagent layer where the reaction is initiated. Glucose in plasma is oxidized in a concentration-dependent manner by glucose oxidase (GOD) found in the reagent layer. GOD oxidizes the glucose with the quantitative production of hydrogen peroxide. The hydrogen peroxide oxidizes and condenses 4-aminoantipyrine (4AAP) and 1-Naphthol-3,6-disulfonic acid disodium (NDD) by the catalytic action of peroxidase to form a reddish-purple color.
During the reaction, the reagent layer is completely dissolved and is absorbed by the sample-retention layer. These two layers thus form a single detection layer. The intensity of the reddish-purple color as determined by reflectance spectrophotometry is proportional to the concentration of Glucose in plasma.

$$\text{Glucose} + O_2 + H_2O \xrightarrow{\text{GOD}} \text{D-gluconic acid} + H_2O$$

$$H_2O_2 + 4AAP + NDD \xrightarrow{\text{POD}} \text{reddish-purple chromogen} + H_2O \quad \text{(measured at 550 nm)}$$

SPECIMEN COLLECTION
Whole Blood
- Collect heparinized blood by venipuncture using either a syringe or evacuated tube.
- Using a transfer pipette, transfer whole blood to a centrifuge cup and fill to the line (250 - 500 µL).
- Cap cup and invert several times.

REAGENT COMPOSITION
The SPOTCHEM II Glucose Reagent Strip is composed of a plastic strip to which a multi-layered test field is affixed. The layers consist of a sample-retention layer, a layer containing the reagents and a support layer.



Reactive Ingredients per 100 Reagent Strips

Component	Concentration/100 Strips
Glucose oxidase *(Aspergillus niger)*	286 unit
4-Aminoantipyrine	6.8 mg
1-Naphthol-3,6-disulfonic acid disodium salt	9.6 mg
Peroxidase (POD) *(Horseradish)*	286 unit

WARNINGS and PRECAUTIONS
- For *in vitro* diagnostic use only.
- Exercise the normal precautions required for handling blood samples, containers, used reagent strips and pipette tips. Follow local regulations for disposal of biohazardous waste.

STORAGE and STABILITY
- Store the reagent strip in a refrigerator at temperatures between 2° - 8 °C (35.6° - 46.4°F).
- Use reagent strips before expiration date listed on each aluminum foil package and reagent strip box.
- Once the aluminum foil package containing the reagent strip has been opened, the reagent strip must be used immediately.

MATERIALS PROVIDED
- Twenty Five Aluminum Foil Packages containing Reagents Strips
- One Reagent Card
- Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED
- SPOTCHEM EZ Analyzer (SP-4430)
- SPOTCHEM EZ manual and Quick Instruction guide, included with analyzer
- Centrifuge Cups (SE10712)
- Pipette tips (SE10743)
- Serum cuvette (SE10191)
- Transfer pipettes
- Assayed Multisera, Level 1 (HNC200)
- Assayed Multisera, Level 2 (HEC200)

QUALITY CONTROL
Assayed Multisera, Level 1 and Level 2, are recommended for daily quality control. Two levels of controls should be assayed at least once a day, and when using a new lot, shipment, or carton of reagent strips. Always perform quality control testing after calibration of the SPOTCHEM EZ analyzer. Each laboratory should follow their federal, state, and local requirements for quality control testing. Refer to package insert included with the controls for instructions on storage of the controls. Values obtained should fall within a specified range. If these values fall outside the range, and repetition excludes error, the following steps should be taken:
1. Check instrument settings and light source.
2. Check cleanliness of all equipment in use.
3. Check expiration date of kit and contents.
4. Contact ARKRAY Technical Service at 877.538.8872.

TEST PROCEDURE OVERVIEW
The test procedure is shown in the Quick Instruction guide, included with the SPOTCHEM EZ analyzer.
1. Place centrifuge cup containing heparinized whole blood into position on the SPOTCHEM EZ analyzer.
2. Place pipette tip into position on the SPOTCHEM EZ analyzer.
3. Place a reagent strip onto the reagent table.
4. Proceed to analyze the sample. See Operating Manual for the SPOTCHEM EZ analyzer.

INTERFERING SUBSTANCES
The interference studies were performed on samples with glucose concentrations of approximately 100, 250 and 300 mg/dL.
- No interference was observed up to a level of 150 mg/dL of hemoglobin.
- No interference was observed up to a level of 9.0 mg/dL of bilirubin.
- No interference was observed up to a level of 200 mg/dL of triglyceride.

CALCULATIONS
After the completion of the measurement, the SPOTCHEM EZ Analyzer calculates the concentration of glucose *[D]* as follows:

$$D = a \cdot (K/S)^3 + b \cdot (K/S)^2 + c \cdot (K/S) + d$$

Where (*K/S*) is the Kubelka-Munk value for reflectance and a, b, c and d are coefficients derived from the calibration curve.

LIMITATIONS OF PROCEDURE

- Assay whole blood samples immediately after collection, and discard after use.
- Occasionally, air bubbles may adhere to the walls of the centrifuge cup. Aspiration of an air bubble may affect measurement results. If air bubbles are observed, tap the centrifuge cup to dislodge the bubble from the sample.
- Store strips in a refrigerator at 2° - 8 °C (35.6° - 46.4°F). Improper storage may affect the performance of the strip.
- Allow sealed reagent strips to come to room temperature for 10 minutes before use.
- Do not touch the reagent field of the reagent strip with your fingers.
- Do not reuse a reagent strip. These strips are designed to be used on a single sample and then discarded.
- Reagent Calibration Cards are lot specific. Re-calibration is required with change of lot numbers.

CALIBRATION

The Reagent card, provided in the reagent strip box, is required for calibration. When opening a new box of reagent strips, perform the calibration procedure with the card included in the carton. See the SPOTCHEM EZ Analyzer manual for procedure. It is recommended that quality control be performed after each calibration. See the section on Quality Control in this insert.

LINEARITY

The test is linear up to a glucose concentration of 416 mg/dL (23.1 mmol/L). Results above this concentration will be reported as >416 mg/dL by the analyzer.

SENSITIVITY

The minimum detectable concentration of glucose with an acceptable level of precision was determined as 27 mg/dL (1.4 mmol/L). Result below this concentration will be reported as <27 mg/dL by the analyzer.

PRECISION

Within run precision was performed with ten replicates of a whole blood sample. The mean was 127 mg/dL, the standard deviation was 3.58 mg/dL, and the coefficient of variation was 2.8%. Other precision studies were conducted with plasma and the results are as follows:

Within Run Precision

	Level 1	Level 2	Level 3
Mean (mg/dL)	64	107	267
SD	0.73	2.49	8.71
CV(%)	1.14	2.32	3.26
n	20	20	20

Between Run Precision

	Level 1	Level 2	Level 3
Mean (mg/dL)	63	106	262
SD	1.52	3.91	9.45
CV(%)	2.42	3.69	3.61
n	20	20	20

CORRELATION

This method (Y) was compared with another commercially available method (X) and the following linear regression equation obtained: Y = 0.99X - 0.57 and a correlation coefficient of r = 0.985.

- 116 patient samples were analyzed spanning the range 49 to 372 mg/dL (2.70 - 20.46 mmol/L).

Glucose test results generated on the SPOTCHEM EZ Analyzer from plasma specimens (Y) were compared against the results generated from whole blood specimens (X) and the following linear regression equation obtained: Y = 0.99X + 0.38 and a correlation coefficient of r = 0.999.

- 31 patient samples were analyzed spanning the range 70 to 312 mg/dL (3.85 - 17.16 mmol/L).

REFERENCE VALUES[7,8]

70-105 mg/dL

The American Diabetes Association recommends the following interpretive guidelines[1]:

Impaired Fasting Glucose	Diabetic	Unit
110-126	>126	mg/dL
6.1-7.0	>7.0	mmol/L

Note: Each laboratory should establish its own reference ranges to reflect the age, sex, diet, and geographical location of the population.

REFERENCES

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4. Burtis, C. A, Ashwood, E. R.: Tietz *Textbook of Clinical Chemistry,* Second Edition, WB Sanders Company, Philadelphia.
5. Richterich, R., Colombo, J. P.: *Klinische Chemie,* 4, 531, 570. Basel: Karger, 1978.
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DISTRIBUTED BY

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P/N 7482-00 Rev. 01/09