



SPOTCHEM™ II Creatinine

[Cre]

CLIA complexity: Waived

This is a waived test under the Clinical Laboratory Improvement Amendment of 1988 (CLIA '88). A CLIA Certificate of Waiver is needed to perform testing in a waived setting. If the laboratory does not have a Certificate of Waiver, the Application (Form CMS-116), can be obtained from CMS. The form should be mailed to the address of the local State Agency of the State in which the laboratory resides. Both the form and the list of contacts can be obtained from CMS or the CMS website. If the laboratory modifies the test system instructions, the test no longer meets the requirements for waived categorization. A modified test is considered to be highly complex and is subject to all applicable CLIA requirements.

INTENDED USE

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

Cat. No. SE77116

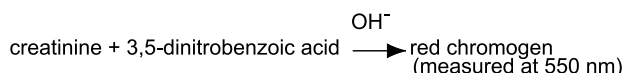
25 Test Strips

CLINICAL SIGNIFICANCE^(1,2,3)

Creatinine is a waste product produced in muscle tissue from creatine. It is produced and excreted at a constant rate proportional to the lean body mass of the individual. Measurements of creatinine levels in serum or plasma are used in the diagnosis of renal diseases. Elevated levels of creatinine are indicative of under-excretion, which suggests impairment of kidney function.

PRINCIPLE OF THE PROCEDURE⁽⁴⁾

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. Creatinine in plasma reacts with 3,5-dinitrobenzoic acid under alkaline conditions to form a red 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 red color as determined by reflectance spectrophotometry is proportional to the concentration of creatinine in plasma.



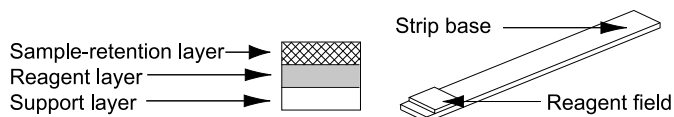
SPECIMEN COLLECTION

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 Creatinine 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
3,5-Dinitrobenzoic acid	86.03 mg

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. Assay the controls the same way as the patient samples following the instructions under the Test Procedure Overview section in the package insert. More detailed instructions for quality control may be found in the SPOTCHEM EZ manual.

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:

- Check instrument settings and light source.
- Check cleanliness of all equipment in use.
- Check expiration date of kit and contents.
- 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.

- Place centrifuge cup containing heparinized whole blood into position on the SPOTCHEM EZ analyzer.
- Place pipette tip into position on the SPOTCHEM EZ analyzer.
- Place a reagent strip onto the reagent table.
- Proceed to analyze the sample. See Operating Manual for the SPOTCHEM EZ analyzer.

INTERFERING SUBSTANCES

The interference studies were performed on samples with creatinine concentrations of approximately 1.1, 1.9 and 4.2 mg/dL.

- No interference was observed up to a level of 300 mg/dL of hemoglobin.
- No interference was observed up to a level of 15.2 mg/dL of bilirubin.
- No interference was observed up to a level of 285 mg/dL of triglyceride.

CALCULATIONS

After the completion of the measurement, the SPOTCHEM EZ analyzer calculates the concentration of creatinine $[D]$ 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 creatinine concentration of 37.9 mg/dL (3350.4 µmol/L). Results above this concentration will be reported as >37.9 mg/dL by the analyzer.

SENSITIVITY

The minimum detectable concentration of creatinine with an acceptable level of precision was determined as 0.66 mg/dL (58.3 µmol/L). Results below this concentration will be reported as <0.66 mg/dL by the analyzer.

PRECISION

Within run precision was performed with ten replicates of a whole blood sample. The mean was 2.66 mg/dL, the standard deviation was 0.126 mg/dL, and the coefficient of variation was 4.7%. 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)	1.23	1.51	4.45
SD	0.055	0.060	0.076
CV(%)	4.5	4.0	1.7
n	20	20	20

Between Run Precision

	Level 1	Level 2	Level 3
Mean (mg/dL)	1.29	1.50	4.40
SD	0.091	0.069	0.110
CV(%)	7.1	4.6	2.5
n	20	20	20

CORRELATION

This method (Y) was compared with another commercially available method (X) and the following linear regression equation obtained: $Y = 0.93X + 0.18$ and a correlation coefficient of $r = 0.997$.

- 50 patient samples were analyzed spanning the range 0.7 to 11.8 mg/dL (61.9 to 1043.1 µmol/L).

Creatinine test results generated on the SPOTCHEM EZ analyzer from plasma specimens (X) were compared against the results generated from whole blood specimens (Y) and the following linear regression equation obtained: $Y = 1.00X + 0.04$ and a correlation coefficient of $r = 0.999$.

- 23 patient samples were analyzed spanning the range 0.8 to 9.7 mg/dL (70.7 to 857.5 µmol/L).

CLIA WAIVER PERFORMANCE

Results of Untrained User Study

An "untrained user" study was conducted in which participants were given only the test instructions and asked to perform testing of four (4) samples in random order. The samples contained creatinine concentrations at four target levels of 0.9 mg/dL, 1.5 mg/dL, 2.9 mg/dL and 4.5 mg/dL. The participants were not given any training on the use of the test. A total of 60 participants were enrolled from 3 sites, representing a diverse demographic (educational, age, gender, etc.) population.

	Level 1	Level 2	Level 3	Level 4
n	60	60	60	60
Target Conc.	0.9	1.5	2.9	4.5
SP-EZ mean	0.9	1.48	2.93	4.47
SD	0.1	0.074	0.140	0.147
%CV	7.1	5.0	4.8	3.3
Observed Range	0.7 - 1.0	1.3 - 1.6	2.7 - 3.5	4.1 - 4.8
Allowable Range Mean \pm 15% of Mean	0.7 - 1.0	1.3 - 1.7	2.5 - 3.4	3.8 - 5.1
% Value in Allowable Range	100(60/60)	100(60/60)	98.3(59/60)	100(60/60)
95% CI	94%; 100%	94%; 100%	91%; 100%	94%; 100%

Assay standardization verified with NIST SRM 0909b.

REFERENCE VALUES⁽³⁾

Serum

Males: 0.7 - 1.3 mg/dL (62 - 115 µmol/L)

Females: 0.6 - 1.1 mg/dL (53 - 97 µmol/L)

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

REFERENCES

- Tietz, N. W. *Fundamentals of Clinical Chemistry*. 2nd ed. W. B. Saunders Co., Philadelphia (1976).
- Henry, J. B. *Clinical Diagnosis and Management by Laboratory Methods*. 20th ed. W. B. Saunders Co., Philadelphia (1976).
- Tietz, N. W. *Textbook of Clinical Chemistry*. 2nd ed. W. B. Saunders Co., Philadelphia (1994).
- Benedict, S. R. and J. A. Behre. *J. Biol. Chem.* 114: 515-532 (1936).

DISTRIBUTED BY

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