National Institute of Standards & Technology

Certificate of Analysis

Standard Reference Material 914a

Creatinine

This Standard Reference Material (SRM) is certified as a chemical of known purity. It is intended primarily for use in the calibration and standardization of procedures used for determination of creatinine concentration in clinical analysis and for routine evaluations of daily working standards used in these procedures. The purity of this SRM is:

$$99.7 \pm 0.3\%$$

The estimated uncertainty of the purity is based upon scientific judgment and statistical analysis of the numerous analytical tests applied to the material in the certification process.

Contributions to the certification and characterization of this SRM were made by A. Cohen, B. Coxon, S.A. Margolis, and E. White V of the Organic Analytical Research Division and M. Knoerdel, W.F. Koch, G. Marinenko, and S.F. Stone of the Inorganic Analytical Research Division.

This Certificate of Analysis has undergone editorial revision to reflect program and organizational changes at NIST and at the Department of Commerce. No attempt was made to reevaluate the certificate values or any technical data presented on this certificate.

The overall direction and coordination of the technical measurements leading to the certification were provided by R. Schaffer of the Organic Analytical Research Division.

Statistical consultation and analyses were provided by R.C. Paule, of the National Measurement Laboratory.

The technical and support aspects concerning the preparation, certification, and issuance of this SRM were coordinated through the Standard Reference Materials Program by R.L. McKenzie. Revision of this certificate was coordinated through the Standard Reference Materials Program by J.C. Colbert.

Gaithersburg, MD 20899
February 8, 1994
(Revision of certificate dated 10-1-87)

Thomas E. Gills, Acting Chief
Standard Reference Materials Program

(over)

The homogeneity of the SRM was measured by acidimetric titration. Purity of the SRM was determined by an evaluation of both the results of acidimetric titration and the results of a number of analytical procedures to detect and measure potential impurities in the SRM. A number of additional analyses, which provide values of components of the material were performed to characterize the material. These are described below and are provided for informational purposes only.

The following values are not certified but are provided as they may be of interest to the user of this SRM. Moisture was determined by Karl Fischer titration to be 0.07% by weight. The total ash of the material was 0.002%. Insoluble matter upon dissolution in water was 0.005%. Soluble chloride by ion chromatography was 0.0014%; total chloride by neutron activation analysis was approximately 0.002%. Nuclear magnetic resonance spectroscopy detected no impurities except methanol at 0.003%. Elemental analysis by neutron activation analysis indicates, in addition to chloride, the presence of the following elements at the indicated approximate levels: Na, 0.4 μmol/mole; Mg, 3 μmol/mole; Al, 0.4 μmol/mole; K, 4 μmol/mole; Mn, 0.02 μmol/mole; Cu, 0.4 μmol/mole; Cr, 0.1 μmol/mole; Fe, 1.5 μmol/mole; Fe,1.5μmol/mole; Co, 0.2 μmol/mole; and Zn, 0.2 μmol/mole.

NOTICE AND WARNINGS TO USER

This SRM is for "in vitro" diagnostic use only and is intended for use as a standard in clinical analytical chemistry.

Drying Instructions: We do not recommend heat and/or vacuum treatment for reducing the water content of the material.

Directions for Use: A "stock" standard solution containing 1 mg/mL of creatinine may be prepared by weighing 0.1003 g of SRM 914a into a 100 mL volumetric flask, filling the flask nearly to the mark with 0.1 mol/L hydrochloric acid, agitating until dissolution of the creatinine is achieved, followed by filling the flask to the mark with 0.1 mol/L hydrochloric acid. This solution should be stored in a refrigerator. A "working" standard containing 20 μg/mL of creatinine may be prepared by diluting 2.0 mL of the "stock" standard solution to 100 mL with distilled water in a volumetric flask. [1] This "working" standard solution should be prepared daily.

Storage of Crystalline SRM 914a: This SRM should be stored tightly closed, preferably in its original container in a well-closed container at room temperature (30 °C or less). It should not be subjected to heat or direct sunlight during storage. Refrigerated storage is recommended.

Expiration of Certification: Experience at NIST indicates this material to be stable for at least 5 years under proper storage conditions. If the material degrades beyond the limits certified, purchasers will be notified by NIST. It is recommended that material not be used after 5 years from the date of shipment from NIST.

Stability of Prepared Solutions: The "stock" standard solution containing 1 mg/mL, prepared as described above, is stable indefinitely when stored in a refrigerator at 4 °C in a well-stoppered, all-glass container. The dilute "working" standard solution should be prepared daily from the "stock" standard solution. [2]

REFERENCES

[1] Tietz, N.W., Fundamentals of Clinical Chemistry, pp. 722-726. W.B. Saunders Co., Philadelphia, PA, 1970.

[2] Henry, R.D., Clinical Chemistry, Principles and Technics, pp. 292-302, Hoeber Medical Division, Harper & Row, New York, NY, 1967.