National Institute of Standards & Technology

Certificate of Analysis

Standard Reference Material® 917c

D-Glucose (Dextrose)

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 for glucose determinations employed in clinical analysis, and for routine critical evaluation of the daily working standards used in these procedures. A unit of this SRM consists of one bottle containing 50 g of crystalline D-glucose.

Certified Purity and Uncertainty: A NIST Certified Value is a value for which NIST has the highest confidence in its accuracy in that all known or suspected sources of bias have been investigated or taken into account [1]. The certified chemical purity value of glucose was determined by measuring the mass fractions of impurities, including water, summing the impurities, and subtracting this sum from 100.0 %.

Certified Purity of D-Glucose as a Mass Fraction: 99.7 % ± 0.3 %

The uncertainty in the certified value is expressed as an expanded uncertainty, U, at the 95 % level of confidence, and is calculated according to the method described in the ISO/JCGM Guides [2,3]. The expanded uncertainty is calculated as $U = ku_c$, where u_c is intended to represent, at the level of one standard deviation, the uncertainty in the measurement of the impurities. The coverage factor, $k = 2$, is determined from the Student's t-distribution corresponding to the appropriate degrees of freedom and approximately 95 % confidence.

Expiration of Certification: The certification of **SRM 917c** is valid, within the measurement uncertainty specified, until **01 March 2021**, provided the SRM is handled and stored in accordance with instructions given in this certificate (see "Instructions for Use"). The certification is nullified if the SRM is damaged, contaminated, or otherwise modified.

Maintenance of SRM Certification: NIST will monitor this SRM over the period of its certification. If substantive technical changes occur that affect the certification before the expiration of this certificate, NIST will notify the purchaser. Registration (see attached sheet or register online) will facilitate notification.

Metrological Traceability: The measurand is the total mass fraction for D-Glucose. Metrological traceability is the SI derived unit for mass fraction (expressed as a percent).

Overall direction and coordination of the technical measurements leading to certification was performed by K.W. Phinney of the NIST Biomolecular Measurement Division.

Analytical measurements were performed by D.W. Bearden, B.J. Porter, M.M. Schantz, L.T. Sniegoski, and M.J. Welch of the NIST Chemical Sciences Division, and B.E. Lang of the NIST Biosystems and Biomaterials Division.

Statistical analysis of data was provided by N.F. Zhang of the NIST Statistical Engineering Division.

Support aspects involved in the issuance of this SRM were coordinated through the NIST Office of Reference Materials.

Carlos A. Gonzalez, Chief
Chemical Sciences Division

Gaithersburg, MD 20899
Certificate Issue Date: 10 February 2016
Certificate Revision History on Last Page

Steven J. Choquette, Acting Director
Office of Reference Materials

NOTICE AND WARNING TO USERS

SRM 917c IS INTENDED FOR RESEARCH USE.

INSTRUCTIONS FOR USE

Storage: The SRM should be stored in its original bottle at temperatures between 20 °C and 25 °C. The bottle must be tightly re-capped after use and protected from heat, excessive moisture, and direct sunlight. Refrigeration in a desiccator is recommended for prolonged storage. However, the bottle and contents should be allowed to warm to room temperature before opening.

Drying Instructions: For laboratory environments where the relative humidity is below 75 %, there are no special drying requirements before use. *For laboratory environments where the relative humidity is 75 % or above, the sample must be dried under vacuum at 60 °C for 24 hours before use.* The surface of the material absorbs a significant amount of moisture when exposed to a relative humidity of approximately 75 %. Because the certified purity is based on a specific moisture content, any added moisture will lower the purity. NIST experience indicates that moisture gain is not a significant problem at a relative humidity of approximately 50 %.

Instructions for Use as a Standard in Clinical Applications: A 1 % (mass concentration) standard solution of glucose may be prepared by transferring 1.003 g (mass in air) of SRM 917c into a 100 mL volumetric flask, filling to approximately 100 mL with a 0.2 % (mass concentration) benzoic acid solution (a preservative), and swirling to dissolve. Adjust to volume with the 0.2 % benzoic acid solution. The benzoic acid should be ACS Reagent grade. The final glucose mass concentration of this solution is 10 mg/mL.

SOURCE AND ANALYSIS

Source: The D-glucose used for this SRM was obtained from a commercial supplier.

NIST Analyses for Purity: The purity of SRM 917c was assessed by differential scanning calorimetry (DSC) and gas chromatography-mass spectrometry (GC-MS).

Additional Analyses: Moisture was determined by the Karl Fischer method. Karl Fischer titration yielded a moisture content of 0.66 mg/g. Results of nuclear magnetic resonance (NMR) analysis were consistent with a purity >99 % and indicated that there was no significant contribution from other saccharides.

Homogeneity Assessment: The homogeneity of SRM 917c was assessed at NIST by differential scanning calorimetry (DSC). An analysis of variance did not show inhomogeneity for the test portions analyzed.

REFERENCES

[1] May, W.; Parris, R.; Beck, C.; Fassett, J.; Greenberg, R.; Guenther, F.; Kramer, G.; Wise, S.; Gills, T.; Colbert, J.; Gettings, R.; MacDonald, B.; *Definitions of Terms and Modes Used at NIST for Value-Assignment of Reference Materials for Chemical Measurements*; NIST Special Publication 260-136, U.S. Government Printing Office: Gaithersburg, MD (2000); available at http://www.nist.gov/pml/pubs/sp811/index.cfm (accessed Feb 2016).

[2] JCGM 100:2008; *Evaluation of Measurement Data — Guide to the Expression of Uncertainty in Measurement* (GUM 1995 with Minor Corrections); Joint Committee for Guides in Metrology (2008); available at http://www.bipm.org/utils/common/documents/jcgm/JCGM_100_2008_E.pdf (accessed Feb 2016); see also Taylor, B.N.; Kuyatt, C.E.; *Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results*; NIST Technical Note 1297; U.S. Government Printing Office: Washington, DC (1994); available at http://www.nist.gov/physlab/pubs/tn1297/index.cfm (accessed Feb 2016).

[3] Levenson, M.S.; Banks, D.L.; Eberhardt, K.R.; Gill, L.M.; Guthrie, W.F.; Liu, H.K.; Vangel, M.G..; Yen, J.H.; Zhang, N.F.; *An Approach to Combining Results From Multiple Methods Motivated by the ISO GUM;* J. Res. Natl. Inst. Stand. Technol., Vol. 105, pp. 571–579 (2000).

Certificate Revision History: 10 February 2016 (Editorial changes); 21 November 2013 (Extension of certification period; editorial changes); 30 June 2009 (Original certificate date).

Users of this SRM should ensure that the Certificate of Analysis in their possession is current. This can be accomplished by contacting the SRM Program: telephone (301) 975-2200; fax (301) 948-3730; e-mail srminfo@nist.gov; or via the Internet at http://www.nist.gov/srm.