

Certificate of Analysis

National Bureau of Standards

Standard Reference Material 917 D-Glucose (Dextrose)

B. Coxon and R. Schaffer

This standard reference material 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.

Purity	99.9	percent
α -D-Glucopyranose	greater than 99.0	percent
β -D-Glucopyranose	less than 1.0	percent
Moisture	0.06	percent
Ash	0.002	percent
Insoluble Matte	0.001 to 0.006	percent
Nitrogen	less than 0.001	percent

Specific Rotation

$$[\alpha]_D^{20} = +53.2^\circ \text{ (at equil., } c \text{ 20.1 in water)}$$

$$[\alpha]_{546}^{20} = +62.8^\circ \text{ (at equil., } c \text{ 20.1 in water)}$$

$$[\alpha]_D^{20} = +112.6^\circ \text{ (initial, } c \text{ 10.05 in methyl sulfoxide)}$$

The value for the purity has an estimated inaccuracy of ± 0.1 percent.

The D-glucose used for this standard reference material was obtained from Pfanstiehl Laboratories, Inc., of Waukegan, Illinois. Analyses were performed by R. F. Brady, Jr., B. Coxon, M. M. Darr, T. E. Gills, E. C. Kuehner, R. A. Paulson, T. C. Rains, T. A. Rush, W. P. Schmidt, J. H. Thomas, and W. L. Zielinski of the Analytical Chemistry Division.

The overall direction and coordination of technical measurements leading to the certification were under the chairmanship of R. Schaffer.

The technical and support aspects concerning the preparation, certification, and issuance of this standard reference material were coordinated through the Office of Standard Reference Materials by T. W. Mears.

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J. Paul Cali, Chief
Office of Standard Reference Materials

The only impurities detected in this standard reference material were moisture and traces of inorganic compounds. Paper, thin-layer, and high-pressure ion-exchange chromatographic techniques revealed no organic impurities.

The proportion of the α -D-glucose anomer was estimated by three methods. The ratio of the β -anomer to the α -anomer was found to be 0.5:100 by gas-liquid chromatography (glc) after per(trimethylsilyl)ation of the solid standard material for 10 min at 0 °C using N-(trimethylsilyl)imidazole in anhydrous pyridine to minimize possible mutarotation. Use of this glc technique on partly melted standard material showed that the proportion of the β -anomer increased markedly during melting. Differential scanning calorimetry of the standard material, contained under nitrogen in unsealed aluminum pans, showed the α -D-glucose content to be 99.4 percent. This value represents only the proportion of anhydrous α -D-glucopyranose present, since the method treats β -D-glucose, or hydrates of α -D-glucose that are stable up to the melting point, as impurities. However, proton magnetic resonance spectroscopy at 90 MHz indicated the ratio of β -anomer to α -anomer to be 0.9:100. This determination was performed 10 min after dissolution of 100 mg of D-glucose in 0.5 ml of methyl sulfoxide- d_6 , by integration of the doublets due to the anomeric hydroxyl groups.

Optical rotations were obtained by use of an automatic polarimeter and a high-precision manual polarimeter.

The moisture content reported was determined by the Karl Fischer and near infrared methods. As only 0.01 to 0.02 percent in weight was lost on drying at 70 °C/1-2 torr for 100 hr, the analyses reported herein were performed on the undried standard reference material.

The ash content reported was determined by ignition of 20-g samples at 750 °C; the undissolved residue, on 10-g samples. Turbidimetric assays of solutions of the standard showed the presence of chloride at 2 ppm and sulfate at 3 ppm. Neutron activation indicated chloride at 4 ppm.

Emission spectrometric analysis of the ash from this standard reference material showed calcium to be approximately 5 ppm; magnesium and silicon each less than 0.1 ppm; aluminum, boron and iron each less than 0.05 ppm; and copper, less than 0.01 ppm.

Atomic absorption spectrometry of the standard reference material indicated that it contains less than 0.5 ppm of magnesium. Flame emission spectrometry indicated the content of calcium to be 1 ± 0.5 ppm, and sodium to be 2.9 ppm.

This Standard Reference Material is intended for "in vitro" diagnostic use only.

This material is for use as a standard in clinical chemistry. A 1 percent standard solution of glucose may be prepared by weighing 1.000g of SRM 917 into an 100-ml volumetric flask. The flask is then filled nearly to the mark with 0.2 percent benzoic acid solution and agitated until solution is complete. The flask is then filled to the mark with 0.2 percent benzoic acid solution. One ml of this solution contains 0.01g (10mg) of glucose. The benzoic acid solution should be prepared from ACS Reagent grade benzoic acid. Appropriate size samples of this solution are analyzed by the exact procedure used for the submitted specimen of body fluid.

To prepare glucose solution of lower concentration the appropriate aliquot is pipetted into a 100-ml volumetric flask and diluted with 0.2 percent benzoic acid solution.

This Standard Reference Material should be stored 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. Under proper storage, experience at NBS indicates this material to be stable for at least 5 years. If the material purity degrades beyond the limits certified, purchasers will be notified by NBS. It is recommended that material not be used after 5 years from date of purchase.

The 1 percent standard glucose solution, prepared as described above, is stable indefinitely when stored in a refrigerator at 4 °C and in a well-stoppered, all-glass container. The dilute glucose standard should be prepared daily from the 1 percent stock solution [1,2].

All constituted solutions of D-Glucose should be clear and without indications of bacterial growth of any kind.

References:

- [1] R. D. Henry, *Clinical Chemistry, Principles and Practice*, pp. 625-656, Hoeber Medical Division, Harper & Row, New York, New York 10016 (1967).
- [2] N. W. Tietz, *Fundamentals of Clinical Chemistry*, pp. 154-163, W. B. Saunders Co., Philadelphia, Pa. 19105 (1970).

This Standard Reference Material has been measured and certified at the Laboratories of the National Bureau of Standards, Gaithersburg, Maryland. All inquiries should be addressed to:

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The date of issuance and certification of this Standard Reference Material was November 18, 1970.