National Institute of Standards & Technology

Certificate of Analysis

Standard Reference Material 909a

Human Serum

This Standard Reference Material (SRM) is primarily intended for use in evaluating the accuracy of clinical procedures for the determination of specified constituents in human serum. It is also intended for use in validating working or secondary reference materials. A unit of SRM 909a consists of six bottles of freeze-dried serum, three bottles each of two different analyte concentration levels. The serum is to be reconsituted with 10.00 mL of high-purity water (ASTM Type I reagent water or equivalent).

Certified Values of Analytes: The certified concentrations of the analytes were determined by methods having the highest accuracy, i.e., definitive methods (1-9). The certified concentrations of the electrolytes were confirmed by other analytical methods. The concentrations and their uncertainties for the two concentration levels (SRM 909a-1 and SRM 909a-2) are listed in Tables 1 and 2, respectively.

The certified concentrations apply only to reconstituted serum at room temperature (20-25 °C), see Instructions for Use.

NOTICE AND WARNINGS TO USERS

Use: HANDLE AS IF CAPABLE OF TRANSMITTING DISEASE! The supplier of this serum has tested the source material from which the reference serum was derived and found it to be nonreactive for hepatitis B surface antigen (HBsAG) and HIV by FDA-approved testing. However, no known test method can guarantee completely that a product derived from human blood does not contain HIV, hepatitis, or other infectious agents.

SRM 909a IS INTENDED FOR "IN VITRO" DIAGNOSTIC USE ONLY.

Storage: The freeze-dried serum should be stored in a refrigerator at a temperature between 2 and 8 °C. It should not be frozen nor exposed to sunlight or ultraviolet radiation.

Stability: Under the recommended storage conditions the certified concentrations, except for glucose, of the unreconstituted SRM is expected to be stable for at least three (3) years from the date of shipment from NIST. The glucose values degrade with time and NIST will recertify the glucose value every two years. This certificate revision reflects a new certified value for glucose. The glucose certified value covers the best estimates of what the value is now and its predicted value by the fall of 1994. NIST routinely monitors this SRM and should any of the certified values change significantly, purchasers will be notified. Please return the attached registration card to facilitate notification.

The statistical analysis of the data was performed in the NIST Statistical Engineering Division by S.B. Schiller.

The overall direction and coordination of the analyses were under the chairmanship of J.R. Moody of the Organic Analytical Research Division and M.J. Welch of the Organic Analytical Research Division.

The technical and support aspects involved in the preparation, certification, and issuance of this SRM were coordinated through the Standard Reference Materials Program by J.C. Colbert.

Gaithersburg, MD 20899
February 24, 1993
(Revision of certificate dated 7-24-91)

William P. Reed, Chief
Standard Reference Materials Program

(over)

Table 1

Certified Concentrations and Uncertainties for Analytes in Reconstituted SRM 909a-1

Analyte[1]	Concentration and Uncertainty[2], mmol/L			Concentration and Uncertainty[2], mg/dL		
Calcium[a,b]	2.322	±	0.041	9.31	±	0.16
Chloride[a,c]	92.4	±	1.7	328	±	6
Cholesterol[a]	4.892	±	0.061	189.2	±	2.4
Creatinine[a]	0.084	±	0.001	0.95	±	0.01
Glucose[a]	4.95	±	0.30	89.2	±	5.4
Lithium[a,d]	0.465	±	0.008	0.323	±	0.006
Magnesium[a,b]	0.868	±	0.016	2.10	±	0.04
Potassium[a,b]	3.656	±	0.075	14.3	±	0.3
Sodium[e,f]	148.5	±	2.4	341.4	±	5.5
Urea[a]	5.535	±	0.071	33.2	±	0.4
Uric Acid[a]	0.234	±	0.003	3.93	±	0.05

Note: The concentration of bilirubin in 909a-1 is approximately 0.01_6 mmol/L (0.9_5 mg/dL). This value is not certified but provided for information only.

Table 2

Certified Concentrations and Uncertainties for Analytes in Reconstituted SRM 909a-2

Analyte[1]	Concentration and Uncertainty[2], mmol/L			Concentration and Uncertainty[2], mg/dL		
Calcium[a,b]	3.338	±	0.047	13.4	±	0.2
Chloride[a,c]	119.1	±	2.2	422.2	±	7.8
Cholesterol[a]	4.463	±	0.073	172.6	±	2.8
Creatinine[a]	0.463	±	0.006	5.24	±	0.07
Glucose[a]	15.41	±	0.80	277.6	±	14.4
Lithium[a,d]	2.657	±	0.037	1.844	±	0.026
Magnesium[a,d]	1.846	±	0.028	4.49	±	0.07
Potassium[a,b]	6.21	±	0.11	24.3	±	0.4
Sodium[e,f]	126.5	±	2.1	291	±	5
Urea[a]	19.47	±	0.25	116.9	±	1.5
Uric Acid[a]	0.525	±	0.009	8.83	±	0.15

Note: The concentration of bilirubin in 909a-2 is approximately 0.08_9 mmol/L ($5._2$ mg/dL). This value is not certified but provided for information only.

1 Analytical Methods

a. Isotope dilution mass spectrometry, (with gas chromatography for organic analytes).
b. Inductively coupled plasma spectrometry.
c. Ion chromatography.
d. Flame atomic absorption spectrometry.
e. Gravimetry with ion-exchange separation.
f. Flame emission spectrometry

2 The uncertainties are 99%/95% statistical tolerance intervals and reflect the combined effects of measurement imprecision and the variability of the mass of dry/serum among vials. The intervals are constructed so that at a confidence level of 95% they will include the true concentrations for 95% of all vials of SRM 909a when reconstituted according to the instructions for use.

Instructions for Use: HANDLE AS IF CAPABLE OF TRANSMITTING DISEASE! Remove metal closure and lightly tap bottom of vial to dislodge any serum particles adhering to the stopper. Carefully remove stopper to avoid possible loss of serum particles. Use a Type 1 Class A volumetric transfer pipet or other dispenser of known accuracy to add slowly 10.00 ± 0.02 mL of high purity water (not supplied) at 20-25 °C to the sides of the vial while continually turning the vial. Replace stopper, swirl vial two or three times, and let stand for 10 min. Mix contents by gently swirling, let stand for approximately 30 min, swirl again, let stand for 10 min, and finally invert the vial several times. Do NOT shake vigorously because this will cause frothing. Total time for reconstitution is approximately one hour. After reconstitution, use contents as soon as possible. If not used immediately, store between 2 and 8 °C until ready for use, preferably within 8 h.

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REFERENCES

[1] Moore, L.J., and Machlan, L.A., "High Accuracy Determination of Calcium in Blood Serum by Isotope Dilution Mass Spectroscopy", Anal. Chem. 44, 2291 (1972).

[2] Ellerbe, P., Meiselman, S., Sniegoski, L.T., Welch, M.J., and White V, E., "Determination of Serum Cholesterol by a Modification of the Isotope Dilution Mass Spectrometric Definitive Method", Anal. Chem. 61, 1718-1723 (1989).

[3] Welch, M.J., Cohen, A., Hertz, H.S., Ng, K.J., Schaffer, R., Van Der Lijn, P., and White V, E., "Determination of Serum Creatinine by Isotope Dilution Mass Spectrometry as a Candidate Definitive Method", Anal. Chem. 58, 1681-1685 (1986).

[4] White V, E., Welch, M.J., Sun, T., Sniegoski, L.T., Schaffer, R., Hertz, H.S., and Cohen, A., "The Accurate Determination of Serum Glucose by Isotope Dilution Mass Spectrometry - Two Methods", Biomed. Mass Spectrom. 9, 395-405 (1982).

[5] Welch, M.J., Cohen, A., Hertz, H.S., Ruegg, F.C., Schaffer, R., Sniegoski, L.T., and White V, E., "Determination of Serum Urea by Isotope Dilution Mass Spectrometry as a Candidate Definitive Method", Anal. Chem. 56, 713-719 (1984).

[6] Ellerbe, P., Cohen, A., Welch, M.J., and White V, E., "Determination of Serum Uric Acid by Isotope Dilution Mass Spectrometry as a New Candidate Definitive Method", Anal. Chem. 62, 2173-2177 (1990).

[7] Velapoldi, R.A., Paule, R.C., Schaffer, R., Mandel, J., and Moody, J.R., "A Reference Method for the Determination of Sodium in Serum", NBS Spec. Pub. 260-60, (1978).

[8] Velapoldi, R.A., Paule, R.C., Schaffer, R., Mandel, J., Machlan, L.A., and Gramlich, J.W., "Standard Reference Materials: A Reference Method for the Determination of Potassium in Serum", NBS Spec. Pub. 260-63 (May 1979).

[9] Velapoldi, R.A., Paule, R.C., Schaffer, R., Mandel, J., Murphy, T.J. and Gramlich, J.W., Standard Reference Materials: " A Reference Method for the Determination of Chloride in Serum", NBS Spec. Pub. 260-67 (November 1979).