National Institute of Standards & Technology

Certificate of Analysis

Standard Reference Material 956

Electrolytes in Human Serum for Ion Selective Electrodes

Standard Reference Material (SRM) 956 is intended primarily for use in calibrating ion selective electrodes for the determination of potassium and sodium in either diluted or undiluted human serum or plasma. A unit consists of 12 vials of frozen human serum, 4 each of 3 different concentration levels. Twice the number of vials are provided because of possible breakage of the glass vials on freezing to -50 °C. A vial contains approximately 3 mL of serum.

WARNING: FOR IN VITRO DIAGNOSTIC USE ONLY.
PLACE VIALS INSIDE OTHER CONTAINERS TO THAW CONTENTS.
HANDLE AS IF CAPABLE OF TRANSMITTING DISEASE!
FOLLOW STORAGE INSTRUCTIONS.

Certified Concentrations of Analytes: The certified concentrations of potassium and sodium are listed below.

Concentration Level	Concentration, mmol/L	
	Potassium	Sodium
I	6.03 ± 0.04	121.9 ± 1.0
II	4.03 ± 0.04	141.1 ± 1.0
III	2.05 ± 0.04	160.8 ± 1.0

The uncertainty is based on scientific judgment and includes estimates of material variability and measurement imprecision.

The density of the serum at 21 °C is 1.024 ± 0.004 g/mL.

The analytes were determined by methods having the highest accuracy, i.e., definitive and reference methods. The definitive method for potassium is based on isotope dilution, thermal ionization mass spectrometry; and, for sodium, on gravimetry after ion exchange separation of sodium. The reference methods for potassium and sodium are based on flame atomic emission techniques (1,2).

The SRM is the result of a cooperative research effort of NIST and manufacturers and users of clinical ISE analyzers under the auspices of the National Reference System for Clinical Laboratories (NRSCL) of the National Committee for Clinical Laboratory Standards (NCCLS). George N. Bowers, Jr., M.D. of Hartford Hospital is acknowledged as the project leader of the research effort.

The material was supplied by the Technicon Instruments Corporation, a subsidiary of Miles, NA.

Analytical measurements were performed by D.S. Braverman, T.A. Butler, L.J. Machlan, J.R. Moody, and T.W. Vetter of the NIST Inorganic Analytical Research Division. Cooperative analytical measurements were performed at Hartford Hospital by A.O. Okorodudu under the direction of G.N. Bowers, Jr. and at Eastman Kodak Co. by C. Peters under the direction of Neil Greenberg.

Statistical analysis of the experimental data was provided by R.C. Paule, NIST National Measurement Laboratory.

Gaithersburg, MD 20899
June 13, 1990

William P. Reed, Acting Chief
Standard Reference Materials Program

The overall direction and coordination of the technical measurements leading to the certification of this SRM were performed by W.F. Koch.

The technical support aspects concerning the preparation, certification, and issuance of this Standard Reference Material were coordinated through the Standard Reference Materials Program by R. Alvarez.

Instructions for Use: Place a vial to be used inside another container, such as a plastic test tube, to ensure containment of the serum in case the vial cracks. Each vial should be inspected carefully for circular cracks at the base. If the vial is cracked, it should not be used. The serum in intact vials should be thawed, warmed to room temperature, and mixed by inverting gently at least five times before sampling. An NCCLS proposed standard provides information on standardizing ion selective electrode analyzers to the flame photometric reference methods (3).

Storage: The vials should be stored at a temperature of -50 °C or below.

Expiration of Certification: SRM 956 is certified for two years from date of shipment when stored as indicated. Please return the attached form to register your SRM.

Infectious Disease Testing: The supplier of this serum has tested, by FDA-approved methods, the source materials used to prepare this product and found them to be negative for Hepatitis B Surface Antigen (HBsAg) and for antibody to human immunodeficiency virus (HIV). However, because no test method can offer complete assurance that HIV, hepatitis B virus, or other infectious agents are absent, these specimens should be handled at the Biosafety Level 2 as recommended for any potentially infectious human serum or blood specimen in the Centers for Disease Control/National Institutes of Health manual "Biosafety in Microbiological and Biomedical Laboratories," 1984, 11-13.

References

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

[2] Velapoldi, R.A.; Paule, R.C.; Schaffer, R.; Mandel, J.; Moody, J.R.; Standard Reference Materials: A Reference Method for the Determination of Sodium in Serum. NBS Spec. Publ. 260-60 (August 1978).

[3] National Committee for Clinical Laboratory Standards. Standardization of sodium and potassium ion-selective electrode systems to the flame photometric reference method; Proposed Standard. NCCLS Document C29-P. Villanova, PA: NCCLS; 1989.

APPENDIX

Noncertified Values. Estimated concentrations of other analytes including enzymes activity concentration in SRM 956 were determined at Hartford Hospital, CT, under the direction of G.N. Bowers, Jr., M.D. to provide additional information on the composition.

Analyte	Units	Level I	Level II	Level III
Chloride	mmol/L	97	112	126
Carbon dioxide	mmol/L	18	19	18
pH		7.41	7.41	7.38
Ionized calcium	mmol/L	1.45	1.15	0.86
Total calcium	mmol/L	2.66	2.20	1.73
Total magnesium	mmol/L	1.50	0.94	0.44
Lithium	mmol/L	2.05	1.35	0.60
Phosphorus	mmol/L	0.67	0.65	0.64
Ammonia	μmol/L	507	511	526
Total protein	g/L	71	70	70
Albumin	g/L	38	38	37
Cholesterol	mg/L	1670	1700	1670
Triglycerides	mmol/L	1.28	1.28	1.25
Glucose	mg/L	470	470	470
Blood Urea Nitrogen	mg/L	40	40	40
Creatinine	mg/L	5	5	5

Enzymes in Levels I, II, and III - Reported as U/L at 37 °C

Name	Reference Limit	*Values
Amylase	< 130	60
Aspartate aminotransferase	< 50	45
Alanine aminotransferase	< 55	25
Alkaline phosphatase	< 130	75
Lipase	< 200	100
Lactate dehydrogenase	< 500	250
Gamma glutamyltransferase	< 80	60

* Estimated Uncertainty, in U/L, is ± 10%.