Reference Material Institute for Clinical Chemistry Standards (ReCCS)

Certified Reference Material for Ion Selective Electrode(ISE)

JCCRM 111-10

Certificate of Analysis

■ Intended for use

This Certified Reference Material (CRM) was prepared and certified by Reference Material Institute for Clinical Chemistry Standards(ReCCS). Its specifications were standardized by the Expert Committee on Blood Gases/Electrolytes of the Japan Society of Clinical Chemistry.
This CRM also meets the requirements for a reference material as defined in "Recommendation for Measurement of and Conventions for Reporting Sodium and Potassium by Ion-Selective Electrodes in Undiluted Serum, Plasma or Whole Blood" established by the Ion Selective Electrode Working Group of the international Federation for Clinical Chemistry (IFCC).
This CRM is primarily intended for use in evaluating the accuracy of serum (plasma) Na,K and Cl measurements with (direct and indirect)ion Selective electrodes in clinical laboratory tests. Also, this CRM can be used to assess the accuracy of flame spectrometry for serum Na［2,3］K［3,4］ and routine coulometric titration for serum Cl.［5,6］

■ Instruction for use

1. Take out the materials from the freezer and stand them for thawing at room temperature for about one hour.
2. Hold the top end of an ampoule, and thoroughly stir the content by shaking the ampoule horizontally for 20-30 times. When several ampoules are mixed at the same time, some may not mix completely. Foaming does not affect test results.
3. Tap the ampoule using a finger to collect the contents at the bottom.
4. Repeat procedures 2 and 3 above to get complete homogeneity of the serum inside the ampoule.
5. Warning! See the below precautions and warning for use.
   Wear thick gloves when opening the ampoule. Face the white dot on the ampoule towards you, and open the ampoule by pressing the top section away from you.
   Do not apply excessive force due to the risk of breakage.
6. Immediately after opening the ampoule, use a micropipette to transfer the serum to a sample cup.

■ Precautions

*Once this product is left standing for a long period of time after opening correct results cannot be obtained. Once opened, the serum cannot be stored to reuse.

*Do not apply excessive force to the ampoule to avoid the risk of breakage.

Wear a thick glove to avoid injury in case of breakage. Also, exercise sufficient caution when opening an ampoule and handling opened ampoules since the edge of opened ampoules is very sharp to injure.

*Exercise great caution to avoid the serum from coming into contact with the eyes , mouth ,hands ,and wounds.

■ Warning for use

This CRM is a human source material, and handle as a biohazardous material capable of transmitting infectious diseases. This product was shown to be noncreative for HBs antigen, HCV and HIV antibodies by our test methods. However, no known test methods can give complete assurance of absence of HIV, HCV , HBs antigen, and any other infectious agents.

Thus this CRM is assumed as an infectious material and the same caution for handling with any other clinical specimens having a risk of infectious diseases must be exercised.

Product for in vitro use only

■ Storage and Expiration Date

This CRM is shipped in frozen condition on dry ice. Confirm that the dry ice remains upon receipt, otherwise the materials cannot be used thereafter.

Store this CRM in a freezer immediately after receiving it.

The shelf life is 9 months from the shipping date when stored at －70℃

The shelf life is 3 months from the shipping date when stored at －20℃～－40℃

Do not reuse opened ampoules.

■ Contents

There are L,M, H levels and one vial for each concentration levels. Each vial contains 1.0 mL of frozen liquid containing certified reference material for Na, K & Cl.

■ Preparation and Characteristics

This CRM was prepared according to “Preparation and Measurement Methods of Certified Primary Reference Material for ISE”established by the Expert Committee on Blood Gasses/Electrolytes of the Japan Society of Clinical Chemistry. To eliminate errors attributable to the liquid junction potentials, its pH and bicarbonate ion levels are mostly comparable to those of specimens collected from healthy individuals(this is the point to be indispensable to reference materials for (ISE). Also, to eliminate error factors based on volume displacement, its plasma water mass concentration was adjusted to 0.93 which is in the range of specimens collected from healthy individuals(0.925-0.935kg/l).

■ Certified Concentrations and Expanded Uncertainties

(unit: mmol/L,25℃)

	Na (Sodium)	K(potassium)	Cl（Chloride）
Low level JCCRM 111-10 L	126.2±1.1	3.231 ±0.029	87.8±1.0
Medium level JCCRM 111-10 M	139.8±1.2	4.039 ±0.040	103.4±1.1
High level JCCRM 111-10 H	158.2±1.4	5.478 ±0.084	123.1±1.6

■ Uncertainty and measurement methods

The expanded uncertainty U(95%confidence interval)shown in the above table for each certified value was calculated from the equation U=*k*u: *k* was coverage factor, 2.0, and u was combined standard uncertainty calculated according to the ISO guide 35.［1］

Tractability to SI units was assured though calibration against pertinent standards traceable to SI units as well as observance of quality assurance manual in accordance with ISO /IEC17025.

Standard solutions and sample solutions used in the measurements were prepared by gravimetric method using a calibrated balance.

The certified Na values were measured by gravimetry-based ion exchange separation method(NIST definitive method) ,the certified K values by Frame photometry calibrated with JCCRM 111-9 and the certified Cl values by both of internal standard ion chromatography and coulometric titration reference method calibrated with NIST SRM 919b.

■ Property of serum of JCCRM 111-10 ［7-8］

		111-10	Units
Property	density water mass conc. pH ABE	1.025(25℃) 0.933(25℃) 7.4 (37℃) 1	g/cm^3 kg/L — mmol/L
Electrolytes	HCO_3^- Br^- NO_3^- PO_4^{3-} SO_4^{2-} Ca Li NH_4^+	25(37℃) less than 0.1 less than 0.1 less than 1.0 less than 0.3 1.9 less than 0.1 0.13	mmol/L
Others	Protein Albumin TG T. Cholesterol Phospholipid	6.9 4.0 107 165 182	g/dL g/dL mg/dL mg/dL mg/dL

【References】

[1] Evaluation of measurement data - Guide to the expression of uncertainty in measurement. ISO/IEC Guide 98-3 (JCGM 100:2008).

[2] US. Department of commerce, NBS Special Publication: Standard Reference Materials: A reference method for the determination of sodium in serum, 260-60 , 1978.

[3] The Japan Society for Clinical Laboratory Automation VOL. 34(Suppl. 1) : 41-50, 2009.

[4] The Japan Society for Analytical Chemistry 38: T26-T29, 1989.

[5] US. Department of commerce, NBS Special Publication: Standard Reference Materials: A reference method for the determination of chloride in serum, 260-67, 1979.

[6] RinsyoKagaku 22: 279-290, 1993.

[7] Burnett RW, Covington AK, et al.: Recommendations for measurement of and conventions for reporting sodium and potassium by ion-selective electrodes in undiluted serum, plasma or whole blood. International Federation of Clinical Chemistry and Laboratory Medicine(IFCC). IFCC Scientific Division Working Group on Selective Electrodes Clin Chem Lab Med 38: 1065-1071, 2000.

[8] Kuwa K, Umemoto M. Standardization and accreditation of sodium, potassium and chloride concentration measurement by ion selective electrode(ISE) method in Japam. Method Clin Appl Blood Gase, pH, Electrolytes, Sesor Techol 13:3-17, 1992.

Analyses for the certification and characterization of this CRM were performed by Reference Material Institute for Clinical Chemistry Standards (ReCCS).

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Hirohito Umemoto Ph.D.

Hirohito Umemoto Ph.D.

(Reference Material Institute for Clinical Chemistry Standards)

1050-35 Ichigaocho, Aoba-ku, Yokohama

225-0024 Japan

Tel: 81-45-507-6145

Fax:81-45-530-9036

URL: http://www.reccs.or.jp

e-mail: overseas@reccs.net