

Reference Material Institute for Clinical Chemistry Standards  
ReCCS

Certificate of Analysis  
Certified Reference Material for Ion Selective Electrode (ISE)  
JCCRM111-6

**Intended use**

This material JCCRM111-6 was prepared by Reference Material Institute for Clinical Chemistry Standards (ReCCS) was certified by the Expert Committee on Blood Gases/Electrolytes of the Japan Society of Clinical Chemistry.

This CRM meets requirements for a reference material for ISE 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).

JCCRM 111-6 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. Its major use applications are:

- . Evaluation of routine serum-electrolyte analyzers .
- . Evaluation of newly developed serum-electrolyte analyzers or ion selective Electrodes.

Also, JCCRM111-6 can be used to assess the accuracy of serum Na, K measurements by Flame spectrometry and serum Cl measurements by routine coulometric titration.

**Preparation and Characteristics**

This material was prepared according to the “Preparation and Measurement Methods of Certified Primary Reference Material for ISE” established by The Expert Committee on Blood Gases/Electrolytes of the Japan Society of Clinical Chemistry. To eliminate errors attributable to 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 (0.938) is in the range of specimens Collected from healthy individuals (0.925-0.935kg/l).

### Storage and expiration after purchasing

.Store this product at temperatures below  $-70^{\circ}\text{C}$ .

.Do not reuse opened ampoules.

.Expiration: 9 months from delivery date at an end user when stored at  $-70^{\circ}\text{C}$ .

Note: When stored at temperatures at  $-20^{\circ}\text{C}$ , expiration is 3 months.

### 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 settle the contents at the bottom.
4. Repeat procedures 2 and 3 above to completely homogenize the serum inside the ampoule.
5. 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 due to the risk of breakage, and wear thick gloves to avoid injury in case of breakage. Also, exercise caution when handling opened ampoules since the edge of opened ampoules can be very sharp.

.Exercise great caution to avoid the serum from coming into contact with the Eyes , mouth or wounds.

**Precaution for use**

JCCRM 111-6 is a human source material, and handle as a biohazardous material capable of transmitting infectious disease. This product was shown to be noncreative for HBs antigen, HCV and HIV antibodies by our test methods. However, no known test method can give complete assurance of absence of HIV and HCV antibodies, Hbs antigen, and any other infectious agents. Thus assume that JCCRM111-6 would be infectious, and exercise the same caution for handling any other clinical specimens with the risk of infectious diseases.

**Certified Reference Material for Ion Selective Electrode (ISE)  
JCCRM111-6**

**Certified concentrations**

(unit: mmol/l, 25°C)

	Na (Sodium)	K(potassium)	Cl(Chloride)
High level			
JCCRM111-6H	157.2±0.4	5.662±0.018	120.8±0.4
Midium level			
JCCRM111-6M	141.3±0.4	4.473±0.017	106.4±0.3
Low level			
JCCRM111-6L	123.9±0.3	3.246±0.010	89.8±0.2

#### Uncertainty and measurement methods

The expanded uncertainty  $U$  (95% confidence interval) shown in the above table for each certified value is calculated from the equation  $U=ku$ :  $k$  is coverage factor, 2.262, and  $u$  is combined standard uncertainty calculated according to the ISO guide 35.

Tractability to SI units is assured through calibration against pertinent standards traceable to SI units is assured through calibration against pertinent standards traceable to SI units as well as observance of quality assurance manual in accordance with ISO 17025. 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 isotope dilution mass spectrometry, and the certified Cl values by internal standard ion chromatography and coulometric titration reference method which were evaluated to be accurate by ID/MS using a thermal-ionization mass spectrometer and by comparison with SRM909.

Analyses for the certification and characterization of JCCRM 111-6 were performed by Reference Material Institute for Clinical Chemistry Standards (ReCCS).

JCCRM111-6 was certified by the Expert Committee on Blood Gases and Electrolytes of the Japan Society of Clinical Chemistry.  
(Chairman: Katsuhiko Kuwa, University of Tsukuba).

#### Provider

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