

*Reference Material Institute for Clinical Chemistry Standards  
(ReCCS)*

Trueness Control Material for Ion-Selective Electrode

**JCTCM 131-2**

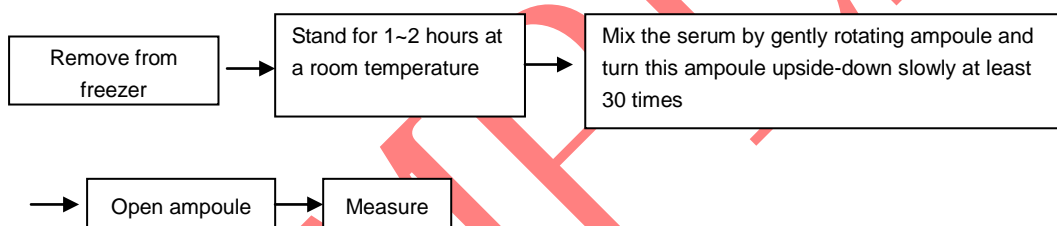
Handling Instructions

■ **Intended use**

This material is intended to be used for the calibration of routine ISE analyzers (Ion Selective Electrode) measuring Na, K, and Cl in blood serum (blood plasma) using ion-selective electrode (ISE) (diluted or undiluted) in clinical testing. [1]

■ **Instruction for use**

Ampoules should stand for 1~2 hours at room temperature. The second method reduces the time of thawing process.



■ **Precautions**

This material was prepared using equine serum identical with human serum from ISE point of view.

This material is free from possible pathogens and infections. However, please exercise cautions when handling as you would do with human specimens.

Do not apply excessive force to the ampoule to avoid the risk of ampoule breakage. Wear thick protective gloves to avoid injury in case of unexpected breakage. Exercise cautions when handling opened ampoules since the edge of opened ampoules can be sharp.

■ **Storage and expiration date**

Shelf life of the material after the date of shipment (indicated on the product label) is as follows.

6 months in a refrigerator (2°C~8°C), and 12 months below -20°C.

This material distribute in cool or frozen.

**“In vitro” Use Only**

■ **Specification**

Concentration levels and content: M level only, 1.0 mL/ampoule x 20, total of 20 ampoules.

**Trueness Control Material for Ion-Selective Electrode**  
**JCTCM 131-2**  
**Certificate of Analysis**

■ **Certified values and expanded uncertainties**

Certified value and expanded uncertainty are shown below:

	(mmol/L)		
	sodium	potassium	chloride
Medium concentration JCTCM 131-2M	$141.8 \pm 0.6$	$4.45 \pm 0.03$	$103.0 \pm 0.6$

The expanded uncertainties for the certified values of sodium, potassium, and chloride were given as 95% confidence intervals according to the ISO guidelines (GUM: Guide to the Expression of Uncertainty in Measurement. See Reference Document [2] , by combining measurement uncertainty and the uncertainty associated with Certified Primary Reference Material for Ion-Selective Electrode (JCCRM 111) which was used as a primary calibrator of the measurements. Note that uncertainties in the above table are not for ISE but for the reference method used.

■ **Measurement method for certified values**

The concentration of sodium and potassium were assayed by using flame photometry (Na, K), and that of chloride was by coulometric titration (Cl), calibrated with JCCRM 111 [3,4,5] .

Measurements were performed at the Reference Material Institute for Clinical Chemistry Standards (ReCCS).

■ **Instruction for use, storage, and expiration date**

Indicated on the first page of the Handling Instructions.

■ **Verification of comparability with human serum**

The difference between a human serum reference material (JCCRM 111) and this material was at or below 0.5%.with diluted ISE, and the difference was at or below 1.0% with undiluted ISE.

### ■ Properties of Blood Serum

This material is prepared from selected equine serum which has virtually the same with the human serum with regard to ISE. The main properties are shown in the table below: [1,6,7]

	Item	Reference Value	Unit of Measurement	Method of Measurement
Physicochemical Properties	Density (25°C)	1.024	g/cm <sup>3</sup>	
	Viscosity (20°C)	1.6	mPa · s	
	Water mass (25°C)	0.934	kg/L	
	pH(37°C)	7.4	—	Glass electrode
	HCO <sub>3</sub> <sup>-</sup> (37°C)	27	mmol/L	Siggaard-A.Chart
	Br <sup>-</sup>	0.18	mmol/L	Ion
	NO <sub>3</sub> <sup>-</sup>	≤ 0.1	mmol/L	
	PO <sub>4</sub> <sup>3-</sup>	≤ 1.5	mmol/L	Chromatography
	SO <sub>4</sub> <sup>2-</sup>	≤ 1.0	mmol/L	
	Li	≤ 0.1	mmol/L	Flame Photometry
	Total Ca	2.8	mmol/L	MXB Method
	NH <sub>4</sub> <sup>+</sup>	0.3	mmol/L	Colorimetric Method with Deproteinization
Other Properties	Total protein	7.2	g/dL	The biuret test
	albumin	3.1	g/dL	BCG
	Total cholesterol	81	mg/dL	Enzymatic method
	Triglyceride	11	mg/dL	Enzymatic method
	Phospholipid	128	mg/dL	Enzymatic method

### Reference Documents

- [1] Rinsyokagaku 47:291-319,2018.
- [2] Evaluation of measurement data - Guide to the expression of uncertainty in measurement. ISO/IEC Guide 98-3 (JCGM 100:2008)
- [3] Velapoldi RA, et al. Standard reference materials : A reference method for the determination of sodium in serum.NBS Spec Pub 260-60, 1978.
- [4] Velapoldi RA, et al. Standard reference materials :A reference method for the determination of potassium in serum.NBS Spec Pub 260-63, 1979.
- [5] Velapoldi RA, et al. Standard reference materials :A reference method for the determination of chloride in serum.NBS Spec Pub 260-67, 1979.
- [6] Burnett RW, et al. Recommendations for measurement of and conventions for reporting sodium and potassium by ion-selective electrodes in undiluted serum, plasma or whole blood. Clin Chem Lab Med 38:1065-1071, 2000.
- [7] Ben Rayana MC, et al. Recommendation for measuring and reporting chloride by ISEs undiluted serum, plasma or blood. Clin Chem Lab Med 44:346-352, 2006.

### ■ Date of Certification

December 10 , 2019

### Provider of JCTCM 131-2

---

Hirohito Umemoto Ph.D. (President)

1-3-3, Azaminominami, Aoba-ku, Yokohama

225-0012 Japan

Tel (order/general inquiry): 81-45-507-6145 Fax: 81-45-530-9036