

Reference Material Institute for Clinical Chemistry Standards
(ReCCS)

Certified Reference Material for Ion-Selective Electrode

JCTCM 130-3

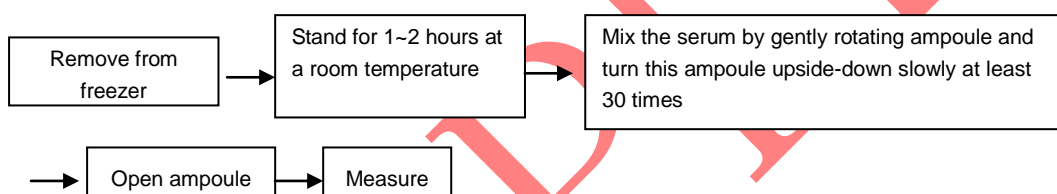
Handling Instructions

■ **Intended use**

This Certified Reference Material (CRM) 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 CRM 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 product 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 CRM distribute in cool or frozen

“In vitro” Use Only

■ **Specification**

Concentration levels and content: 3 concentration levels, 10 glass ampoules for each concentration levels (1.0 ml), total of 30 ampoules.

**Certified Reference Material for Ion-Selective Electrode
JCTCM 130-3
Certificate of Analysis**

■ **Certified values and expanded uncertainties**

Certified values and expanded uncertainties are shown below:

	mmol/L(25 °C)		
	sodium	potassium	chloride
Low concentration JCTCM 130-3 L	125.3 ± 0.6	3.43 ± 0.03	89.0 ± 0.5
Medium concentration JCTCM 130-3M	140.7 ± 0.7	4.38 ± 0.03	104.3 ± 0.6
High concentration JCTCM 130-3 H	154.2 ± 0.6	5.41 ± 0.03	118.6 ± 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).

■ Verification of comparability with human serum

The difference between a human serum reference material (JCCRM 111) and this CRM 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 CRM 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)	1.023	g/cm ³	Pycnometer method
	Viscosity (20 °C)	1.6	mPa · s	Capillary method
	Water mass (25 °C)	0.932	kg/L	dry mass method
	pH (37 °C)	7.4	—	Glass electrode
	HCO ₃ ⁻ (37 °C)	25	mmol/L	Siggaard-A.Chart
	Br ⁻	≤ 0.1	mmol/L	Ion
	NO ₃ ⁻	≤ 0.1	mmol/L	
	PO ₄ ³⁻	≤ 1.5	mmol/L	Chromatography
	SO ₄ ²⁻	≤ 1.0	mmol/L	
	Li	≤ 0.1	mmol/L	Flame Photometry
	Total Ca	2.5	mmol/L	MXB Method
	NH ₄ ⁺	0.3	mmol/L	Colorimetric Method with Deproteinization
Other Properties	Total protein	7.5	g/dL	The biuret test
	albumin	3.1	g/dL	BCG
	Total cholesterol	78	mg/dL	Enzymatic method
	Triglyceride	11	mg/dL	Enzymatic method
	Phospholipid	123	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

October 1 , 2019

Provider of JCTCM 130-3

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