

Reference Material Institute for Clinical Chemistry Standards (ReCCS)

Certified Reference Material for Measurement of Electrolytes in Human Serum

JCCRM 321-10

Certificate of Analysis

■ Intended use

This certified reference material (CRM) is intended primarily for use in evaluating the accuracy of routine methods, validating working reference materials and evaluating the internal and external quality of measurements.

■ Certified values and uncertainties

Table 1. Na,K, Cl

unit: mmol/L (25 °C)

| Name | Na | | K | | Cl | |
|----------------|-----------------|-------------|-----------------|-------------|-----------------|-------------|
| | Certified value | Uncertainty | Certified value | Uncertainty | Certified value | Uncertainty |
| JCCRM 321-10 L | 124.0 | 1.1 | 3.29 | 0.03 | 88.6 | 1.1 |
| JCCRM 321-10 M | 140.0 | 1.2 | 4.12 | 0.04 | 105.0 | 1.3 |
| JCCRM 321-10 H | 156.4 | 1.4 | 5.56 | 0.06 | 124.6 | 1.6 |

Table 2. Total Calcium (TCa) & Total Magnesium (TMg)

unit: mg/dL (mmol/L) (25 °C)

| Name | TCa | | TMg | |
|----------------|-----------------|----------------|-----------------|----------------|
| | Certified value | Uncertainty | Certified value | Uncertainty |
| JCCRM 321-10 M | 9.45 (2.36) | 0.13 (0.03) | 2.07 (0.85) | 0.03 (0.01) |
| JCCRM 321-10 H | 12.34 (3.08) | 0.16 (0.04) | 3.01 (1.24) | 0.05 (0.02) |

Note:

The expanded uncertainty U (95 % level of confidence) shown for each certified values in the above table is obtained from equation $U=ku$, where u is the combined standard uncertainty calculated according to the ISO Guide 36 [1], and k is a coverage factor. The coverage factor, k , is 2.0.

■ Preparations

This CRM was prepared by pooling different human serum. JCCRM 321-10 L was prepared by conducting ion-exchange and adding sodium chloride, potassium chloride and sodium hydrogen carbonate. JCCRM 321-10 M and JCCRM 321-10 H were prepared by adding sodium chloride, potassium chloride, sodium hydrogen carbonate, calcium chloride and magnesium chloride.

■ Measurement methods for certified values

Na, K and Cl : Flame photometry (Na,K) [2] and coulometric titration (Cl) [2] calibrated with JCCRM 111-9. TCa and TMg: Atomic absorption spectrometry [3] [4] calibrated with NIST SRM 956d.

■ Traceability

The measurement for Na, K and Cl were conducted using JCCRM 111-9 as a calibrator and the measurement for TCa and TMg were conducted using NIST SRM 956d as a calibrator.

■ Precautions for use

This CRM was prepared from human serum and shown to be negative to HBs antigens, HCV antibodies and HIV antibodies. However, this does not completely deny its infectivity, and take strictly the same caution used for any other infections specimens. *in vitro* use only

■ Storage and expiration

This CRM shipped in frozen condition on dry ice.

Confirm that dry ice remains upon receipt; otherwise the materials could not be used thereafter.

Store this product in a deep freezer immediately after receiving it.

9 months when stored at $-70\text{ }^{\circ}\text{C}$ from the shipping date

1 month when stored at $-20\text{ }^{\circ}\text{C}$ from the shipping date

■ Product specifications

Low, Medium and High concentration, 1mL/vial, 2 vials for each concentration. Total 6 vials.

JCCRM 321-10L: Na, K, Cl,

JCCRM 321-10M: Na, K, Cl, TCa, TMg

JCCRM 321-10H: Na, K, Cl, TCa, TMg

■ Instructions for use

- (1) Take out a serum vial tube of this CRM and thaw the frozen serum by allowing the tube to stand with the cap-side up at room temperature ($25\text{ }^{\circ}\text{C}$) for approximately 30 minutes.
- (2) While holding the serum tube vertically with the cap-side up, hold the cap with fingers, and confirm that the cap is tightly screwed on. If the cap is loose, tighten it securely. Next, turn the tube upside-down slowly at least 40 times to secure homogeneity.
- (3) conduct sampling of the mixed serum for measurements. Unless used immediately, tighten the vial cap and refrigerate it for use in the same day. Once thawed, the serum should not be frozen again for future use.

■ Characteristics

| Item | Value | Unit | Measurement method |
|---------------------------------------|-------------|-------------------|--------------------------------|
| Density (25 °C) | 1.024 | g/cm ³ | Pycnometer method |
| Water conc (25 °C) | 0.938 | kg/L | Dry weight method |
| pH (37 °C) | 7.41 | — | Glass electrode method |
| HCO ₃ ⁻ (37 °C) | 24.7 | mmol/L | Henderson-Hasselbalch equation |
| Br ⁻ | Less than 1 | mmol/L | Ion chromatography |
| NO ₃ ⁻ | Less than 1 | mmol/L | Ion chromatography |
| PO ₄ ³⁻ | 1.1 | mmol/L | Ion chromatography |
| SO ₄ ²⁻ | 0.4 | mmol/L | Ion chromatography |
| NH ₄ ⁺ | 0.2 | mmol/L | Colorimetric method |
| Total protein | 7.0 | g/dL | Biuret method |
| Albumin | 4.1 | g/dL | Modified BCP method |
| Total cholesterol | 171 | mg/dL | Enzyme method |
| Phospholipid | 187 | mg/dL | Enzyme method |

■ References

- [1] Guide to the expression of uncertainty in measurement ISBN 92-67-10188-9, 1st Ed., ISO, Geneva, Switzerland (corrected and reprinted, 1995)
- [2] Rinsyo Kagaku 47:291-319, 2018.
- [3] Rinsyo Kagaku 37:383-392, 2008
- [4] A reference method for the determination of calcium in serum, NIST Special Publication 260-36, 1972
- [5] 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.
- [6] 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

■ Certification

Date of certification : April 5 , 2022

■ Provider of JCCRM 321-10

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