

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

**Certified Reference Material for Measurement of  
Dialysate**

**JCCRM 300-18**

**Certificate of Analysis**

■ **Intended use**

This certified reference material (CRM) is intended for calibration and evaluating accuracy of instrument for dialysate measurement (pH,  $p\text{CO}_2$ ,  $\text{HCO}_3^-$ , Na, K and Cl).

This CRM has an acetic acid component and a citric acid component <sup>1),2)</sup>.

■ **Certified values and expanded uncertainties**

Certified values and expanded uncertainties of the acetic acid component and the citric acid component are shown in Table 1 and Table 2, respectively.

Table 1. Acetic acid component: JCCRM 300A-18

Analyte	JCCRM 300A-18M		JCCRM 300A-18H		Unit
	Certified value	Uncertainty*	Certified value	Uncertainty*	
pH	7.29	0.04	—	—	— (37 °C)
$p\text{CO}_2$	62.5	2.4	—	—	mmHg (37 °C)
$\text{HCO}_3^-$	28.5	1.0	—	—	mmol/L (37 °C)
Na	139.8	0.8	160.2	0.9	mmol/L
K	1.97	0.03	3.99	0.03	mmol/L
Cl	109.8	0.9	130.9	0.8	mmol/L

Table 2. Citric acid component: JCCRM 300C-18

Analyte	JCCRM 300C-18M		JCCRM 300C-18H		Unit
	Certified value	Uncertainty*	Certified value	Uncertainty*	
pH	7.58	0.04	—	—	— (37 °C)
$p\text{CO}_2$	35.1	0.9	—	—	mmHg (37 °C)
$\text{HCO}_3^-$	32.5	0.9	—	—	mmol/L (37 °C)
Na	138.9	0.0	159.2	0.8	mmol/L
K	1.97	0.03	3.99	0.03	mmol/L
Cl	110.9	0.7	131.9	0.9	mmol/L

\*The expanded uncertainty  $U$  (95 % level of confidence) shown for each certified value in the above table is obtained from the equation  $U=ku$ , where  $u$  is the combined standard uncertainty calculated according to the ISO Guide <sup>3)</sup>, and  $k$  is a coverage factor. The coverage factor  $k$ , determined from the Student's  $t$  distribution, is  $k=2.0$ .

## ■ Measurement methods and Traceability

### (1) pH

After a pH electrode, which is a glass electrode with an internal liquid of saturated KCl, was calibrated at 37 °C using NIST SRM 186g, the pH of this CRM was measured <sup>6)</sup>.

### (2) $p\text{CO}_2$

After the blood gas analyzer for  $\text{CO}_2$  was calibrated by standard tonometry <sup>7)</sup> where standard  $\text{CO}_2$  gas (nitrogen diluted grade 1: 4.033 % and 8.569 %: JCSS certification), the  $p\text{CO}_2$  of this CRM was measured.

### (3) $\text{HCO}_3^-$

The certified value for  $\text{HCO}_3^-$  was obtained by the Henderson-Hasselbalch formula using measured pH and  $p\text{CO}_2$ , and the phosphoenolpyruvate carboxylase- malate dehydrogenase method (PEPC-MD method) <sup>9)</sup>.

### (4) Na, K, Cl

Na and K were measured by flame photometry <sup>1)</sup>. Cl was measured by coulometric titration <sup>2)</sup>. Calibration was conducted using a standard solution prepared from NIST SRM 919b and NIST SRM 918b, respectively.

## ■ Preparation

This CRM was prepared by referencing to theoretical values <sup>1), 4), 5)</sup> of the reagent composition for an acetic acid system dialysate and a citric acid system dialysate, which are commonly used in routine medical treatment. After preparation of solution, the solution was dispensed up to full of a 3 mL ampoule.

The theoretical component concentration of this CRM is shown in table 3. .

Table 3. Theoretical component concentration of this CRM

Component	Acetic acid	Citric acid	Unit
$\text{CH}_3\text{COOH}^-$	8.0	—	mEq/L
Citrate <sup>3-</sup>	—	2.0	mEq/L
$\text{Ca}^{2+}$	3.0	3.0	mEq/L
$\text{Mg}^{2+}$	1.0	1.0	mEq/L
Glucose	100	100	mg/dL

## ■ Storage and Expiration

This CRM should be stored in a refrigerator (2 °C~8 °C). Do not freeze.

**Expiration date: Two months from shipping date**

## ■ Product specifications

JCCRM 300A-18M; acetic acid component, two ampoules

JCCRM 300A-18H; acetic acid component, one ampoule

JCCRM 300C-18M; citric acid component, two ampoules

JCCRM 300C-18H; citric acid component, one ampoule

Total six ampoules and each ampoule contains 3 mL liquid.

## ■ Date of Certification

**October 17, 2022**

## ■ Instruction for use

This CRM is a liquid product sealed in a glass ampoule to maintain constant partial pressure of CO<sub>2</sub> gas and pH.

**To obtain the predescribed certified values, measurements of this material must be taken after equilibrating gases and liquids in the ampoule at a constant temperature range of 23 °C to 28 °C.** The instructions for use to do so are shown below.

(1) Ensure the room temperature is between 23 °C to 28 °C. If there is a dialysate mode on the measuring device, set the device to that mode, and prepare for measurement.

(2) Remove only the number of ampoules required for measurement of this CRM from the refrigerator, and stand them at room temperature for one hour or more\*<sup>1</sup> to equalize the temperatures of inside the ampoule and the room.

Note 1: After placing the ampoules in a water bath of 23 °C to 28 °C for more than fifteen minutes, measurements are possible via the following operations of (3) onwards.

Note 2: It is also possible to remove the ampoules from the refrigerator and place them at room temperature the previous day or two days prior to measurement.

Note 3: Do not use vial stands made of styrofoam or other insulation materials as they are difficult to bring to room temperature.

(3) Holding the tip of the ampoule, shake it quickly horizontally 20 times for 10 seconds so as to suck in bubbles. By repeating the mixing operation once more after about one minute, you will completely equilibrate the gases and liquids in the ampoule. Holding the ampoule upright, lightly flick the tip with your fingertip so the liquid falls to the bottom.

(4) Keeping the ampoule upright, turn the red dot above the notch on the ampoule towards you, and slowly insert the supplied ampoule opener\*<sup>4</sup> from the top section. Fold the opener so it pushes into the opposite side.

Note 4: The ampoule opener can be used repeatedly. For the second time onwards, the previously cut top section of the ampoule will come out from the opener when the opener is inserted into the ampoule. Exercise caution removing it, and use the opener repeatedly by the same procedure as stated above.

(5) Prioritizing pH, pCO<sub>2</sub> and HCO<sub>3</sub><sup>-</sup> that are easily changed by air contact, take measurement\*<sup>5</sup> immediately within one minute of opening.

Note 5: Because CO<sub>2</sub> gas rapidly flies off on opening the ampoule, for measurement of pH, pCO<sub>2</sub> and HCO<sub>3</sub><sup>-</sup>, sampling from one ampoule is done only once.

## ■ References

- 1) RinsyoKagaku 45:140-165,2016.
- 2) RinsyoKagaku 46:60-63,2017.
- 3) Evaluation of measurement data - Guide to the expression of uncertainty in measurement, ISO/IEC Guide 98-3 (JCGM 100:2008).
- 4) Information ; Dialysate for artificial Kidney, Kindaly 2E,3E,4E
- 5) Information; Dialysate for artificial Kidney, Carboster · P
- 6) Approved IFCC methods. Reference method (1986) for pH measurement in blood. Clin Chim Acta165:97-109,1987.
- 7) IFCC Method (1988) for tonometry of blood : Reference materials forPCO<sub>2</sub>and PO<sub>2</sub>. J Clin Chem Clin Biochem 27:403-408,1989.
- 8) Ole Siggaard-Andersen: The acid-base status of the blood, Munksgaard, Copenhagen, 1976.
- 9) Forrester RL, Wataji LJ, Silverman DA, Pierre KJ: Enzymatic method for determination of CO<sub>2</sub>in serum. Clin Chem 22:243-245,1976.

## ■ Provider of JCCRM 300-18

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