

Reference Material Institute for Clinical Chemistry Standards (ReCCS)

**Certified Reference Material for Measurement of Glucose
JCCRM 523-2
Certificate of Analysis**

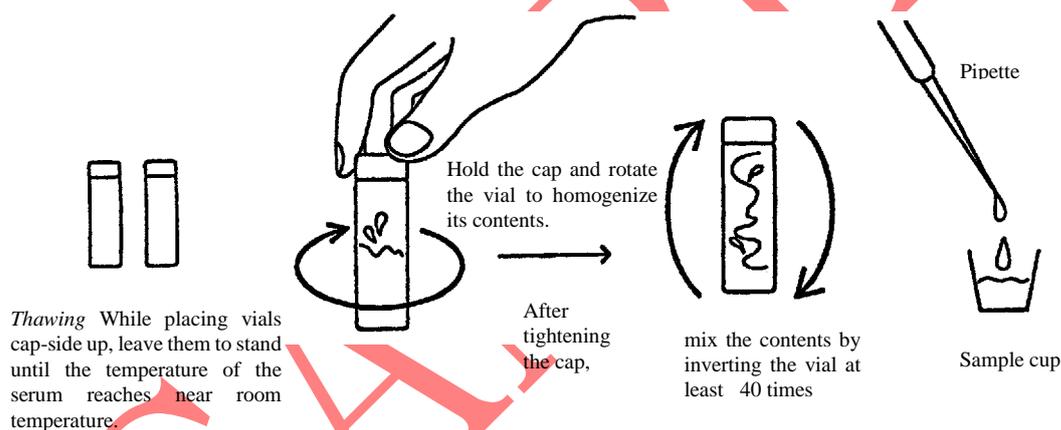
■ **Intended for Use**

This Certified Reference Material (CRM) is intended for use in evaluating the accuracy of routine methods which use the glucose electrode analysis or enzymatic analysis (for example hexokinase-G-6-PD enzymatic method).

Note) It is recommended to use JCCRM521, supplies by ReCCS, for applying other than routine methods as described above.

■ **Instruction for Use**

A vial is taken out from its case and is thawed at room temperature while placing it cap-side up. Next, the vial is left standing for about 1 or 2 hours to bring the temperature of the serum to room temperature. Once this procedure is completed, hold the cap of the vial; gently rotate the vial in complete circles; and then mix the contents of the vial by inverting the vial up and down at least 40 times. Note) After thawing, do not allow the vial to stand at room temperature for an extended period of time. Also, once thawed, this reference material cannot be refrozen to be used again.



■ **Precautions**

This CRM was prepared of equine serum free from possible pathogens and infections. However, please exercise cautions when handling as you would do with human specimens.

In Vitro Use Only

■ **Storage and Expiration**

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

1 month in a freezer (-20°C), and 12 months below -70°C

■ Specifications

A single set of JCCRM 523-2 consists of 30 vials indicated below, each vial contains 1.0ml of equine serum.

JCCRM 523-2L – 10/vial

JCCRM 523-2M – 10/vial

JCCRM 523-2H – 10/vial

■ Serum Characteristics

This CRM prepared from equine serum, is virtually the same as human serum with regard to glucose electrodes and enzymatic .

■ Certified Concentration Values and Expanded Uncertainties

Glucose concentrations and expanded uncertainties unit: mg/dL (25°C)	
	Glucose
JCCRM 523-2L	75.1 ± 1.0
JCCRM 523-2M	105.3 ± 1.4
JCCRM 523-2H	203.7 ± 2.7

The expanded uncertainties were given as 95% confidence intervals according to the ISO guidelines (GUM: Guide to the Expression of Uncertainty in Measurement)[1], by combining measurement uncertainty and the uncertainty associated with Certified Reference Material JCCRM 521-12 which was used as a primary calibrator of the measurements.

■ Measurement Methods for Certified Values

The above concentrations of glucose were assayed by hexokinase-G-6-PD enzymatic method [2] calibrated with JCCRM 521-12 as matrix(serum) primary reference material. Measurements were performed at ReCCS.

■ Verification

This CRM was verified to be the same with human serum JCCRM 521-12 with regard to routine methods which use glucose electrodes analysis and enzymatic analysis by comparing measurement values of this CRM and JCCRM521-12.

<Date of Certification>

June 10, 2016

Reference Documents

- [1] Guide to the Expression of Uncertainty in Measurement, ISBN 92-67-10188-9, 1st Ed, ISO, Geneva, Switzerland, 1995.
- [2] Reagent Committee, Japan Society of Clinical Chemistry: Recommended methods for measuring serum glucose, *Rinsho Kagaku*, 20: 247-254, 1991
(in Japanese)

< Provider of JCCRM 523-2 >

Hirohito Umemoto Ph.D.

Hirohito Umemoto Ph.D. (President)

Reference Material Institute for Clinical Chemistry Standards (ReCCS)

<http://www.reccs.or.jp/>

1-3-3 Azaminominami, Aoba-ku, Yokohama 225-0012 Japan

Tel (order/general inquiry): 81-45-507-6145 Fax: 81-45-507-6045