Reference Material Institute for Clinical Chemistry Standards (ReCCS)

Certified Reference Material for Measurement of HbA1c (Lyophilised Material)

JCCRM 423-11

Certificate of Analysis

■ Intended use

This CRM has three concentration levels: normal, high and abnormally high, and facilitates the calibration procedure using 3 points, while the higher order JCCRM 411 needs 5 points (levels) for calibration.

Major intended uses are as follows:

(1) To validate working reference materials or calibrators.
(2) To evaluate the accuracy of various routine methods and clinical procedures.
(3) To evaluate the internal and external quality of measurements.

■ Certified values and uncertainty

unit : HbA1c (NGSP) %

Level	M	H	HH
Certified value	5.65	7.60	10.49
Expanded Uncertainty	0.20	0.27	0.34

The expanded uncertainties (calculated with coverage factor k=2.0, corresponding to 95% confidence level) were calculated according to ISO GUM [1] and include the uncertainty of the higher order JCCRM 411-4, the homogeneity and storage stability.

IFCC values corresponding to the NGSP values are 38.3, 59.6 and 91.2 mmol/mol, respectively. These IFCC values were calculated according to the Master Equation (ME) NGSP=0.0915×IFCC+2.15 or IFCC=10.93×NGSP－23.5.

■ Traceability and measurement method for the certified values

The HbA1c (NGSP) values are measured at ReCCS by JSCC/JDS KO500 method [2] and are calibrated by the HbA1c (NGSP) certified values of JCCRM 411-4.

■ Storage and expiration

This CRM must be stored in a freezer or refrigerator upon receipt.
The expiration date is as follows from the shipping (see the label of the outer case).

−20 ℃ ~ −40 ℃ : 12 months　　+2 ℃ ~ +8 ℃ : 3 months

■ Product specifications

Configuration: lyophilised material
three concentration levels, two vials for each level, total six vials

- Normal Level　JCCRM 423-11M
- High Level　JCCRM 423-11H
- Abnormally High Level　JCCRM 423-11HH

Each vial contains lyophilised material, which has to be diluted with 0.2 mL purified water (final volume 0.25 mL). See “Instructions for use” for details.

■ Date of Certification

May 23, 2023

■ Instructions for use

(1) Take out the glass vials of this CRM from a freezer or refrigerator. Allow the vials to return to room temperature. Put them in an upright position.
(2) Tap each vial lightly to collect the content at the bottom. Take off the aluminum cap. Be careful since it can be very sharp.
(3) Remove the rubber stopper. Add 0.2 ml of purified water using a micropipette or a syringe. Securely place the rubber stopper back on the vial. Let the vial to stand for approximately 5 minutes to allow the content to be completely dissolved. Gently turn the vial up-side down 10 times to mix the content.
(4) After being dissolved with 0.2 mL of purified water, the total hemoglobin concentration should be approximately 13g/dL with a total volume of about 0.25 mL. If not, increase or decrease the amount of water.
(5) It is possible to dilute the material to the desired total hemoglobin concentration by using diluent, indicated in the instruction manual of the used reagent or instrument.

Note 1) After thawing, do not allow the vial to stand at a room temperature for an extended period. Also, once thawed, this reference material cannot be re-frozen to be used again.
However, the material can be used for 4 days, if it is tightly closed and refrigerated (+2℃ ~ +8℃).
Note 2) It is recommended to dilute the material on the day of measurement since the stability of the diluted CRM varies depending on the diluent used.

■ Precautions for use *In Vitro Use only*

This CRM is intended for in-vitro diagnostic use only. This is a human source material. Handle this product as a biohazardous material capable of transmitting infectious disease.
However, no known test method can offer complete assurance that hepatitis B virus, hepatitis C virus, HIV, or other infectious agents are absent from this material. This product should be handled at the Biosafety Level 2 or higher as recommended for any potentially infectious human serum or blood specimen in the Center for Disease Control (CDC)/ National Institutes of Health (NIH) Manual.

■ Preparation

Hemoglobin solution obtained from human whole blood, in which plasma and unstable components were removed, was dissolved in physiological saline containing bicarbonate, and dialyzed. After adding non-reducing sugars, the solution was pipetted in glass vials, freeze-dried, and sealed.

■ Storage after purchasing

(1) This CRM is shipped in frozen condition on dry ice.
(2) Upon receiving the CRM, a case containing this CRM is taken out and placed in a freezer or refrigerator.

Reference

■ Characteristics

Item	Specification	Method
Material	Human whole blood (n>20)	
HbF	< 1 %	KO500 method
MetHb	< 6 %	UV spectrometry
Glutathione adducts	< 0.5 %	KO500 method
Abnormal Hb	None	KO500 method
Plasma components	None	

Specifications were established by the Committee on Standardization of Laboratory Testing Related to Diabetes Mellitus of Japan Diabetes Society (JDS).[2)]

■ References

1) Evaluation of measurement data - Guide to the expression of uncertainty in measurement. ISO/IEC Guide 98-3 (JCGM 100:2008).
2) Committee on Diabetes Mellitus Indices, Japan Society of Clinical Chemistry: JSCC/JDS standard operating procedure for HbA1c Measurement (Version 2.8: 2009-03-06) Rinsyo Kagaku 38:163-176,2009.

Provider of JCCRM 423-11

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