Reference Material Institute for Clinical Chemistry Standards (ReCCS)

Certified Reference Material for Measurement of HbA_{1c} cutoff value test JCCRM 400-1

Certificate of Analysis

Intended use

This Certified Reference Material (CRM) is intended for use in the routine methods to check the diagnostic cutoff value of 6.5 % HbA1c for diabetes.

Preparation

This CRM was prepared as follows: Erythrocytes were separated by centrifuging human whole blood free of abnormal hemoglobin, and then washed and hemolysed. Next, through the use of a high-speed centrifuge, erythrocyte ghost membranes were removed, and after adding a carbonate buffer solution, the resulting solution was dialyzed. The dialyzed solution was divided into smaller portions and stored in liquid nitrogen (As a result, this reference material does not contain plasma components). In order to avoid the use of preservatives, only sterilized tools were used.

Specifications

Configuration:	Frozen liquid
HbA_{1c} levels:	2 levels – cutoff level & H level
Contents:	1 vial for each level , each vial contains 0.1 ml of liquid

Storage after purchasing

1. This CRM is shipped in frozen condition on dry ice. On receipt, some dry ice must still remain in the shipping box. This material is unusable if no dry ice is left upon receipt.
2. Upon receipt, a case containing this CRM is taken out and immediately placed in a deep freezer (< –70 ˚C) where temperature variation is minimal (at the bottom of a freezer).
   Note: When intending to use this CRM on the day when it is received, store it in a refrigerator till use.

Expiration date

This CRM must be received with dry ice remaining and stored immediately at a temperature below –70 ℃.
In this condition this material's shelf life is 12 months after the date of your (end user's) receipt.
*Using this CRM within 2 days from the date of delivery, it can be stored in a refrigerator (+2~8 ℃) .

Instruction for use

1. Take out a plastic vial containing this CRM and allow it to stand at room temperature for about 10 minutes until it naturally thaws.
2. Mix the content of the vial using such devices as a Vortex mixer.
3. Collect the content at the bottom of the vial, and take the necessary amount using such devices as a micro syringe or a micropipette. If the entire content of the vial needs to be collected at the bottom, centrifuge the vial at 1,000 rpm for about 30 seconds.
4. The total Hb concentration of each level is approx. 130 g/L.

Note 1) After thawing, do not allow the vial to stand at room temperature for an extended period of time.
Also, once thawed, this CRM cannot be refrozen to be used again.

Precautions for use *in vitro* use only

This CRM is intended for in-vitro diagnostic use only. This CRM 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 CRM. This CRM 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 〔1〕.

Certified values and uncertainties

The certified HbA1c values (NGSP units: %) and uncertainties in JCCRM 400-1 are as follows:

Lot No.	HbA1c (NGSP) values (%)
JCCRM 400-1 cutoff level	6.5 ± 0.1
JCCRM 400-1 H	10.5 ± 0.2

The NGSP numbers were measured by the JSCC/JDS DCCT Traceable KO 500 method calibrated with JCCRM 411-3 (JDS Lot5). 〔2〕
IFCC numbers corresponding to the NGSP numbers are 48 and 91 mmol/mol, respectively.
These IFCC numbers were calculated according to NGSP=0.0915×IFCC+2.15 or IFCC=10.93×NGSP－23.5.

The expanded uncertainties (calculated with a coverage factor k ＝2, corresponding to 95 % confidence level) were determined according to the ISO GUM . Measurements were done by the Laboratory of ReCCS using KO500 DCCT-Traceable HPLC method. 〔3〕

Characteristics

The characteristics of JCCRM 400-1 are tabulated below:

Item	Specifications	Measurement method
Material	Human whole blood (n>20)	
Additives	None	
Total Hb concentration	130 ± 5 g/L	ICSH method
HbF	<1.0 %	KO500 method
MetHb	2 ~ 5 %	Van Assendelft method
Glutathione adduct	<0.1 %	KO500 method
Abnormal Hb	None	KO500 method
Plasma components	None	

These specifications were established by the Committee on Standardization of Laboratory Testing Related to Diabetes Mellitus of Japan Diabetes Society (JDS).

Agreements between Japanese primary standard JDS Lot 5 and this material JCCRM 400-1.

Lot No.	HbA1c JDS values (%)
JCCRM 400-1 cutoff level	6.1
JCCRM 400-1 H	10.0

Certification body
This CRM was certified by the Reference Material Institute for Clinical Chemistry Standards (ReCCS).
Date of certification: August 19, 2015

References
〔1〕 Andrea Konnert, et al. Uncertainty calculation for calibrators of the IFCC HbA1c standardization network. Accdred Qual Assu **11**(7): 319-328, 2006.
〔2〕 Certified Reference Material for Measurement of HbA1c; JCCRM 411-3 (JDS Lot5) Certificate of Analysis (MRE 4-131 (R10). Reference Material Institute for Clinical Chemistry Standards, 2015.
〔3〕 Guide to the Expression of Uncertainty in Measurement, ISBN 92-67-10188-9, 1st Ed. ISO, Geneva, Switzerland,1993.

Provider of JCCRM 400-1

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