

Reference Material Institute for Clinical Chemistry Standards (ReCCS)
Certified Reference Material for Total Hemoglobin Measurement

JCCRM 912-4
Certificate of Analysis

■ **Intended use**

This Certified Reference Material (CRM) is a reference for the determination of total haemoglobin concentration. This CRM is primarily intended for use in calibration of manufacturer reference method which is traceable to the ICSH reference method such as the cyanomethaemoglobin method.

■ **Certified values**

Certified values and expanded uncertainties of total hemoglobin at 25 °C is as follows.

Unit: g/dL

Level	Certified value	Uncertainties
JCCRM 912-4 L	7.95	0.20
JCCRM 912-4 M	13.50	0.24
JCCRM 912-4 H	18.44	0.32

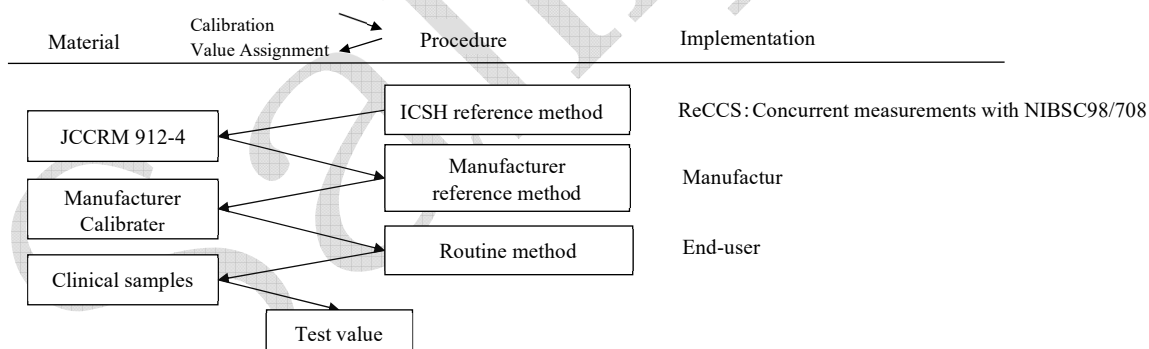
The expanded uncertainty U (95 % level of confidence) shown in the tables are obtained by combining standard uncertainty calculated according to the ISO GUM¹. The coverage factor (*k*) is 2.

■ **Measurement method for certified values**

The certified values of this CRM were determined by the Cyanmethemoglobin method^{2,3}, an ICSH reference method.

■ **Traceability**

The certified values of this CRM were determined by ICSH reference method and are traceable to the reference method values. The equivalence of JCCRM 912-4 and WHO International standard Haemiglobincyanide (NIBSC code:98/708) is confirmed by the concurrent measurements with both CRMs.



■ **Instructions for use**

A vial is taken from a freezer and thaw it at room temperature for 10 minutes. Mix the content thoroughly using a vortex mixer or similar equipment. Collect the content at the bottom of the vial. To collect all of the content at the bottom, use a centrifuge at about 170 G (example: 1,000 rpm at the maximum spin radius of 15 cm) for about 10-20 seconds. Take measurements following the instructions for the reagent and the instrument.

Don't leave this CRM at room temperature for an extended period of time after thawing. This CRM cannot be re-frozen.

■ **Precautions for use *In vitro* use only**

This CRM is prepared from human serum and shown to be negative to the HBs antigens, HCV antibodies and HIV antibodies. However, since other infectious agents are not completely ruled out, handle this CRM as a biohazardous material capable of transmitting infectious diseases.

■ **Storage and expiration**

This CRM shipped in frozen condition on dry ice. Store this CRM in a deep freezer immediately after receiving it. Confirm that dry ice remains on arrival and If no dry ice remains, the CRM cannot be used.

The expiration date from the shipping date; See the outer label

Expiration (from the shipping date) below -70 °C : 6 month

■ Product specifications

Type: frozen liquid
 Total hemoglobin concentration: L, M, H levels
 Contents: 3 Levels, 2 vial each (containing 0.5 mL), 6 vials in total

■ Date of certification

July 29 , 2024

■ Provider of JCCRM 912-4

Hirohito Umemoto Ph.D.

Hirohito Umemoto, Ph.D. (President)
 Reference Material Institute for Clinical Chemistry Standards (ReCCS)

Reference

■ Characteristics

This CRM was prepared of human hemoglobin originated from human blood.
 The characteristics of this CRM are shown below.

	Results	Measurement Method
Material origin	Human whole blood	—
Additives	None	—
Plasma components	None	—
Abnormal Hb	None	HPLC method
Methemoglobin	5.1 %	Van Assendelft method
HbA1c	5.9 % (NGSP value)	HPLC method
Density	1.036 g/cm ³ (25 °C)	—
Ionic concentration	156 mmol/kg	Calculated from electrolyte concentration

■ References

- 1) Evaluation of measurement data - Guide to the expression of uncertainty in measurement. ISO/IEC Guide 98-3 (JCGM 100:2008)
- 2) Recommendations for reference method for haemoglobinometry in human blood (ICSH Standard EP 6/2: 1977) and specifications for international haemoglobinocyanide reference preparation (ICSH Standard EP 6/3: 1977), J Clin Pathology 31:139-143
- 3) Recommendations for reference method for hemoglobinometry in human blood (ICSH Standard 1995) and specifications for international haemoglobinocyanide standard (4th edition), J Clin Pathology 1996;49:271-274.

Certificate Revision

R0	2022.6.8	Original certificate issue date
R1	2024.7.29	Equivalence with NIBSC 98/708 added.

Reference Material Institute for Clinical Chemistry Standards (ReCCS)

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