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 primarily intended for use in calibration of manufacturer reference method which is traceable to the ICSH reference method (e.g. cyanmethemoglobin method).

■ Certified concentration values and expanded uncertainties

Certified concentration values and expanded uncertainties of total hemoglobin at 25 ℃ are 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% confidence interval) shown in the tables is obtained by combining standard uncertainty calculated according to the ISO GUM [1]. The coverage factor (k) is 2.

■ Measurement of certified values

This CRM was measured by Reference Material Institute for Clinical Chemistry Standards (ReCCS) according to the ICSH reference method (Cyanmethemoglobin method [2][3]).

■ Traceability

The certified values of this CRM were determined by ICSH reference method. Furthermore, our ICSH reference method was evaluated by the measurement of WHO International standard Haemiglobincyanide (NIBSC code:98/708) and JCCRM 912-3.

■ Instructions for use

1. Remove the plastic vial containing this CRM from a freezer and thaw it at room temperature for 10 minutes.
2. Mix the content thoroughly using a vortex mixer or similar equipment.
3. 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: about 1,000 rpm at the maximum spin radius of 15 cm) for about 10-20 seconds.
4. Take measurements following the instructions for the reagent and the instrument used to measure total hemoglobin.
   Note 1: Do not leave the reference material at room temperature for an extended period of time after thawing. This material 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

1. This CRM is shipped on dry ice. Dry ice must remain upon delivery. The product cannot be used if there is no dry ice left in the accommodation box, when delivered.
2. Immediately upon delivery, remove the material case containing this CRM out of the box and store it in a deep freezer at a temperature below －70 ℃. Place the material on the bottom of the freezer where there are fewer fluctuations in temperature.

■ Expiration Date

This CRM is effective for 6 months after the shipped date shown on the label, if it is stored at a temperature below －70 ℃.

■ Product specifications

Type: frozen liquid
Total hemoglobin concentration: L, M, H levels
Contents: 0.5 mL in one vial. 2 vials for each concentration level. Total of 6 vials per case.

Date of certification
June 8 , 2022
Provider of JCCRM 912-4

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Reference

■ Characteristics

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

Item	Results	Measurement Method
Material origin	Human whole blood	–
Additives	None	–
Plasma components	None	–
Abnormal Hb	None	HPLC method
Methemoglobin	5 %	Van Assendelft method
HbA1c	5.9 % (NGSP value)	HPLC method
Density	1.036 g/cm^3 (25 ℃)	–
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] [2] Recommendations for reference method for haemoglobinometry in human blood (ICSH Standard EP 6/2: 1977) and specifications for international haemiglobincyanide 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 haemiglobincyanide standard (4th edition), J Clin Pathology 1996;49:271-274.