National Certified Reference Material (NCRM)

Code：GBW09861~09864

Reference Material Certificate

Homocysteine in Frozen Human Serum

Batch Number：

Certification Date：

Period of Validity：

Reference Material Producer：National Institute of Metrology

Address：No.18, Bei San Huan Dong Lu, Chaoyang Dist, Beijing P.R.China, 100029

Telephone：+86(10)64524710

Email：crm-service@nim.ac.cn

Version：1.0

The present CRM was used for calibrating analysis instruments, evaluating analytical methods reliability of similar component samples and ensuring the accuracy and comparability of analysis results.

1. Sample Preparation

The candidate material of the present CRM was prepared from fresh serum samples. According to the concentration of homocysteine determined by a routine method, the serum samples were divided into three concentration levels. Each pool was mixed after abandoning the infected samples at room temperature (20-25°C) for 30 min, and then sub-packed in amber vials, stored at -80°C.

2. Traceability and Characterization Method

The standard value of total homocysteine was determined by ID/LC/MS/MS. The demonstration of commutability is carried out in 9 measurement systems, using four measurement methods: enzyme method, enzyme cycle, Roche enzyme colorimetric method, and Roche enzyme method. The results showed that the four concentration levels of serum homocysteine candidate reference materials had no matrix effect in these routine detection systems, indicating that the four concentration levels of serum homocysteine CRM developed by National Institute of Metrology have good commutability between the reference method and the conventional method.

Through the use of reference material, validated quantitative measurement method and calibrated measuring instruments meeting metrological traceability requirements, the property value of this CRM can be traced to SI unit mole (mol), and the National Legal Unit of volume, liter (L).

3. Property Values and Uncertainties

The property values and expanded uncertainties for the concentration of Homocysteine in Frozen human serum are listed as bellow:

Code	Name	Certified Value (μmol/L)	Expanded uncertainty (k=2, μmol/L)
GBW09861	Homocysteine in Frozen Human Serum	8.01	0.5
GBW09862		14.4	0.6
GBW09863		17.9	0.7
GBW09864		28.8	1.4

The coverage factor was chosen to obtain an approximate 95% level of confidence. The uncertainty evaluation considered sources from characterization, homogeneity, and stability.

4. Homogeneity and Stability Assessment

According to national technical specification of JJF1343 (equivalent to ISO Guide 35), the homogeneity and stability study for these certified reference materials were carried out

through random sampling of subpackaged samples followed by enzyme method. The results demonstrated good homogeneity and stability of the CRMs.

The certification of the CRMs is valid until 14 December 2022. The stability of the CRMs is regularly monitored by NIM, during this period the customer will be informed of any change of the certified values just-in-less-time.

5. Packaging, Storage and Use

Packaging: Each pool of reference material is divided into amber vials with screw-top; each one contains 0.5 mL material.

Storage and transportation: Thess CRM are stored at -80°C and should be transported at -80°C under the protection of dry ice.

Use: The standard material should be completely used after opening. When taken from the freezer, it should be balanced to room temperature and be prevented from contamination while using.

6. Reference

Yu Liu，Dewei Song*， Bei Xu，Hongmei Li，Xinhua Dai，Baorong Chen，Development of a matrix-based candidate reference material of total homocysteine in human serum， Anal Bioanal Chem (2017)409:3329-3335. DOI 10.1007/s00216-017-0272-3

Statement

1. The reference material is only for lab study and analytical testing. In case of any complaint due to the improper use or storage by the user, the institute will bear no responsibility.
2. After receiving it, please immediately check variety, quantity and packaging. Relevant compensation is only limited to the reference material itself.
3. The institute is only responsible for the complete certificate affixed with the “Dedicated Seal for Reference Material of National Institute of Metrology”. Please properly keep this certificate.
4. To obtain more application related information, please contact the Department of Technical Consultation.

National Institute of Metrology P.R. China
Tel.:+86(10)64524776,64524793,64524794,64524795(Technical Consultation)
Fax: +86(10) 64524716, 64524715
Website: www.nim.ac.cn,www.ncrm.org.cn (National Sharing Platform for Reference Materials)