

National Institute of Advanced Industrial Science and Technology

National Metrology Institute of Japan



Reference Material Certificate

NMIJ CRM 7407-a

No. +++



Organic Contaminants in Human Serum

This certified reference material (CRM) is produced in accordance with the NMIJ's management system and is in compliance with ISO 17034 and ISO/IEC 17025. This CRM is intended for use in the accuracy control of analysis and validation of analytical techniques for the determination of PCBs in serum.

Certified Values

The certified value of this CRM is given in the table below. The uncertainty of the certified value is the expanded uncertainty obtained by multiplying the combined standard uncertainty by a coverage factor (k) of 2, and it is the half-width of an interval estimated to have a level of confidence of approximately 95 %.

Substance	CAS No.	Certified value, Mass fraction (ng/kg)	Expanded uncertainty Mass fraction (ng/kg)
PCB118 (2,3',4,4',5-pentachlorobiphenyl)	31508-00-6	27.4	9.0
PCB138 (2,2',3,4,4',5'-hexachlorobiphenyl)	35065-28-2	55.6	6.8
PCB153 (2,2',4,4',5,5'-hexachlorobiphenyl)	35065-27-1	129.8	16.6
PCB194 (2,2',3,3',4,4',5,5'-octachlorobiphenyl)	35694-08-7	9.7	2.4

Analysis

The certified values of this CRM were based on the analytical results of PCBs by liquid-liquid extraction and isotope dilution-gas chromatography/high resolution mass spectrometry (ID-GC/HRMS) described as follows. Each PCB was measured using two different types of GC column, and certified values were calculated as arithmetic means of the respective results obtained by each column;

[Extraction] Liquid-liquid extraction by shaking with ethanol/hexane (1:3, v/v)

[Clean-up] The extract was shaken with sulfuric acid (98 %). The hexane layer was then cleaned up by a solid phase extraction (silica gel).

[GC/HRMS] GC column: HT8-PCB (applied for all certified PCB congeners); DB-5ms (applied for PCB118, PCB138 and PCB194); or DB-XLB (applied for PCB153); Mass resolution: 10000 or more; electron impact ionization (EI); selected ion monitoring (SIM)

Metrological Traceability

The certified values were determined by isotope dilution mass spectrometry (IDMS). NMIJ CRM 7906-a (Polychlorinated Biphenyl Mixture in Nonane) was used as the calibration solution for the determination. Therefore, the certified value is traceable

to the International System of Units.

Mutual Recognition Arrangement under Metre Convention

The certified values of this CRM are recognized for international equivalence based on the Mutual Recognition Arrangement under the Metre Convention (CIPM MRA). The calibration measurement capabilities (CMC) of NMIJ related to this CRM are registered in the Key Comparison Database (KCDB) (see <https://www.bipm.org/kcdb/>) of the International Bureau of Weights and Measures (BIPM).

Expiration of Certification

This certificate is valid for six months from the date of shipment, provided that the material remains unopened and is stored in accordance with the instructions given in this certificate.

Description of the material

A pool of commercially available liquid human serum stabilized by inert gas replacement was used as a raw material of this CRM. This CRM is in the form of a yellow liquid. The material is bottled in a plastic vial (4 g for each vial).

Instructions for Storage

This CRM should be stored at a temperature between $-20\text{ }^{\circ}\text{C}$ and $-30\text{ }^{\circ}\text{C}$ under dark conditions.

Instructions for Use

About two hours prior to use, the CRM to be analyzed should be taken out from the freezer and allowed to stand at room temperature ($20\text{ }^{\circ}\text{C}$ to $25\text{ }^{\circ}\text{C}$) until thawed. After confirming the cap on the vial is tightly closed, the vial is gently inverted several times to ensure complete mixing. The thawed material should be used immediately. More than 2.0 g of the material should be used. Storage of the thawed material may result in changes in PCB concentrations.

Precautions for Handling

Wear a mask, gloves, and other protective equipment during handling. NMIJ CRM 7407 IS INTENDED FOR IN VITRO LABORATORY USE ONLY. THIS IS A HUMAN SOURCE MATERIAL. HANDLE THE PRODUCT AS A BIOHAZARDOUS MATERIAL CAPABLE OF TRANSMITTING INFECTIOUS DISEASE. The supplier of this material has reported that the serum material used in the preparation of this product has been tested and found non-reactive/negative for hepatitis B surface antigen, hepatitis C virus, and human immunodeficiency virus antigen. 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. Accordingly, this human blood-based product should be handled as recommended for any POTENTIALLY INFECTIOUS HUMAN SERUM. The use, handling and storage and disposal of this CRM should be performed while observing the laws regulating the components of this CRM. Refer to the safety data sheet (SDS) on this CRM before use.

Preparation

This CRM was prepared by FUJIFILM Wako Pure Chemical Corporation (Osaka, Japan) using a pool of commercially available human serum (Liquid control serum I Wako C&C, FUJIFILM Wako Pure Chemical Corporation) as a raw material. The serum sample was mixed for homogenization and placed in plastic vials.

Technical Information

The concentration of PCB 180 (2,2',3,4,4',5,5'-heptachlorobiphenyl) obtained by measurement using the DB-XLB column, described in the Analysis section, was 78 ng/kg. The concentration of fat calculated from the residual weight after evaporation of the extraction solvent, based on the Provisional Manual on Determination of Dioxins in Blood (Ministry of Health, Labor and Welfare, Japan), was 3.8 g/kg.

NMIJ Analysts

The technical manager for this CRM is NUMATA M. The production manager and analyst is OTAKE T.

Date of Shipment: XXXXX XX, 20XX

7407a00-160309-210930

Information

If substantive technical changes occur that affect the certification before the expiration of this certificate, NMIJ will notify the registered customers. Customer registration on the NMIJ Website (given below) will facilitate notification. Technical reports regarding this CRM can be obtained from the contact details given below.

Reproduction of Certificate

In reproducing this certificate, it should be clearly indicated that the document is a copy.

Note

This CRM was developed by a collaborative study with National Institute for Environmental Studies, Japan (Research subject: Collaborative study related to serum certified reference material for the analysis of organic contaminants).

April 1, 2020

ISHIMURA Kazuhiko
President

National Institute of Advanced Industrial Science and Technology

If you have any questions about this CRM, please contact:
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Revision history

Nov. 16, 2018: The description on "Mutual Recognition Arrangement under Meter Convention" was added.