

National Institute of Advanced Industrial Science and Technology

National Metrology Institute of Japan



Reference Material Certificate

NMIJ CRM 6402-c

No. +++

Aldosterone in Human Serum
(3 Concentration Levels)

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 primarily for use in calibration of analytical instrument and evaluating the accuracy and validation of analytical procedures or instruments for the determination of aldosterone in human serum by instrumental analysis. In addition, this CRM can be used in evaluating the accuracy and validation of analytical instrument and quantitative values by the immunoassay of the aldosterone analysis, after the commutability has been verified by the user.

Certified Values

The certified values of this CRM for samples of Level 1 to 3, expressed as mass concentration of aldosterone at 25 °C are given in the following table. 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 %.

Sample name	Aldosterone (CAS: 52-39-1)	
	Certified value Mass concentration (pg/mL)	Expanded uncertainty Mass concentration (pg/mL)
Level 1	198	20
Level 2	388	42
Level 3	773	39

Analysis

The certified values were based on the results of isotope dilution liquid chromatography tandem mass spectrometry (ID-LC-MS/MS). Mass concentration was calculated from obtained mass fraction of aldosterone and density of the material.

Metrological Traceability

The certified values were determined by isotope dilution mass spectrometry (IDMS) as a primary method of measurement and density of the material. The calibration solution for IDMS was prepared with aldosterone standard, purity of which was assessed by mass balance method. The density was determined by vibration type density meter calibrated by JCSS Accredited Density Standard Liquid. The certified values, therefore, are traceable to the International System of Units (SI).

Indicative Values

The indicative values of this CRM for samples of Level 1 to 3, expressed as mass fractions, are given in the following table.

The uncertainty of the certified values are the half-width of the expanded uncertainty interval calculated using a coverage factor (k) of 2, which gives a level of confidence of approximately 95 %.

Sample name	Aldosterone	
	Indicative Value Mass fraction (pg/g)	Expanded uncertainty Mass fraction (pg/g)
Level 1	193	19
Level 2	378	41
Level 3	755	38

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 capability (CMC) of NMIJ related to this CRM is 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 three months from the date of shipment, provided that this CRM remains unopened and is stored in accordance with the instructions given in this certificate.

Description of the Material

This CRM is human serum sample and yellow liquid at room temperature. 0.5 mL of the each material was bottled in the vial, and a set of 3 materials was kept in an aluminum-laminated bag.

Homogeneity

The homogeneity of this CRM was determined by analyzing 10 vials selected from among 300 vials. The homogeneity of the element has been incorporated in the uncertainty of the certified value.

Instructions for Storage

This CRM should be kept under -20 °C and protected from light.

Instructions for Use

At about one hour prior to use, the CRM to be analyzed should be removed from the freezer and allowed to stand at 20 °C to 25 °C until thawed. After confirming the cap of the vial is tightly closed, the vial is turned upside down gently several times for complete mixing. Thawed material should be used immediately. Do not use the samples once they are thawed and refrozen.

Precautions for Handling

THIS CRM IS INTENDED FOR IN-VITRO LABORATORY USE ONLY AND NOT FOR IN-VIVO USE. THIS IS A HUMAN SOURCE MATERIAL. HANDLE PRODUCT AS A BIOHAZARDOUS MATERIAL CAPABLE OF TRANSMITTING INFECTIOUS DISEASE. The supplier of this material has reported that 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 at higher as recommended for any POTENTIALLY INFECTIOUS HUMAN SERUM. Refer to the safety data sheet (SDS) on this RM before use.

Preparation

This CRM was prepared by Reference Material Institute for Clinical Chemistry Standards (Kanagawa, Japan). The serum material used was processed according to Clinical Laboratory Standards Institute (CLSI) Publication C37-A [1]. The base serum sample was prepared by mixing with serum containing a low concentration of aldosterone. Serum samples of suitable concentrations of aldosterone were prepared by mixing the base serum and the serum to which a small amount of aldosterone in

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ethanol was added.

[1] "Preparation and Validation of Commutable Frozen Human Serum Pools as Secondary Reference Materials for Cholesterol Measurement Procedures; Approved Guideline", NCCLS Publication C37-A, Clinical Laboratory Standard Institute.

Technical Information

At the time of certification, the density of this CRM was 1.024 g/cm³ for level 1 to 3 samples.

NMIJ Analysts

The technical manager for this CRM is KATO M., the production manager is KAWAGUCHI M., and the analysts are KAWAGUCHI M. and EYAMA S.

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.

January 26, 2023

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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