

National Institute of Advanced Industrial Science and Technology

## National Metrology Institute of Japan



## Reference Material Certificate

NMIJ CRM 6402-a  
No. +++

## Aldosterone in Human Serum (3 Concentration Levels)

This certified reference material (CRM), aldosterone in human serum (3 concentration levels), was produced in accordance with the NMIJ's management system and in compliance with ISO GUIDE 34:2009 and ISO/IEC 17025:2005. This CRM is intended primarily for use in the calibration of analytical instruments, for the validation of analytical procedures and instruments, and for evaluating the accuracy of the determination of aldosterone in human serum by instrumental analysis. In addition, this CRM can be used in the validation of analytical instruments and evaluation of the accuracy of quantitative values in the analysis of aldosterone by immunoassay, after the commutability has been verified by the user.

**Certified Values**

The certified values for mass concentration of aldosterone at 25 °C are given in the table below. The uncertainty of the certified value is 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 %.

	Aldosterone (CAS No.: 52-39-1)	
	Certified value Mass concentration (pg/mL)	Expanded uncertainty Mass concentration (pg/mL)
Level 1	201	26
Level 2	411	54
Level 3	792	76

**Analysis**

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

**Metrological Traceability**

The certified value of this CRM was determined by ID-LC-MS/MS as a primary method of measurement. The calibration solution for the measurements was prepared with an aldosterone standard, the purity of which was assessed by NMIJ. The certified values are traceable to the International System of Units (SI).

**Indicative Values**

The indicative values for samples of Levels 1 to 3, expressed as mass fractions, are given in the table below. The uncertainty of the indicative value is 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 %.

	Aldosterone	
	Indicative value Mass fraction (pg/g)	Expanded uncertainty Mass fraction (pg/g)
Level 1	196	25
Level 2	401	53
Level 3	774	74

### Expiration of Certification

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

### Sample Form

This CRM is in the form of a yellow liquid. This CRM of ca. 0.5 mL in net volume for each level is kept in a vial, and a set of 3 vials is sealed in an aluminum-laminated plastic bag.

### Homogeneity

The homogeneity of this CRM was determined by analyzing 10 vials selected from 100 vials by random sampling. The homogeneity is reflected in the uncertainty of the certified value.

### Instructions for Storage

This CRM should be stored below  $-20^{\circ}\text{C}$  and shielded from light.

### NOTICE AND WARNINGS TO USERS

NMIJ CRM 6402 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.

### Instruction 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  $20^{\circ}\text{C}$  to  $25^{\circ}\text{C}$  until thawed. After confirming the cap of the vial is tightly closed, the vial is gently inverted several times to ensure complete mixing. The thawed material should be used immediately. Storage of the thawed material may result in changes in the aldosterone concentrations.

### Precautions for Handling

Refer to the safety data sheet (SDS) on this CRM 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 this 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 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**

The density of this CRM is 1.0235 g/cm<sup>3</sup> for all level samples.

**NMIJ Analysts**

The technical manager for this CRM is A. Takatsu, and production manager is M. Kawaguchi. The analysts are M. Kawaguchi and S. Eyama.

**Information**

If substantive technical changes occur that affect the certification before the expiration of this certificate, NMIJ will notify the registered customer. 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.

March 9, 2016

Ryoji Chubachi  
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

January 11, 2017: The term of validity of the certificate was extended from “one month” to “three months.”