



Reference Material Certificate

NIMD-02 Human Urine

This reference material is homogenized human urine produced under a quality management system, which meets JIS Q 0035 (ISO Guide 35). NIMD-02 can be used to validate analytical methods or equipment, or to operate quality management in quantitative analysis of trace elements in urine or related matrices.

1. Certified Value

Certified values of NIMD-02 shown below are traceable to the International System of Units (SI). Expanded uncertainties of certified values were obtained by multiplying standard uncertainties by the coverage factor $k = 2$.

Element	Value (µg/L)	Expanded Uncertainty (µg/L)	Analytical Method (refer to annotations below)
Total Mercury (THg)	0.292	0.057	1),2),3),4)
Cadmium (Cd)	0.154	0.030	4)

Analytical method

- 1) Thermal decomposition atomic absorption
- 2) Cold vapor atomic absorption
- 3) Cold vapor atomic fluorescence
- 4) Inductively coupled plasma mass spectrometry

2. Characterization and Value Assignment

The certified values were assigned on the basis of valid datasets (9 sets for total mercury, 6 sets for cadmium) after evaluation of validity and exclusion of statistical outliers of the original dataset reported from participants of an inter-laboratory study. This process was based on instructions and reporting formats that meet the criteria of JIS Q 0035 (ISO Guide 35).

Uncertainties of the certified values were determined by combining uncertainties obtained from the inter-laboratory study, a homogeneity test, and a stability test.

3. Period of Validity

The period of validity of NIMD-02 is November 30, 2027, if stored unopened and under the condition satisfying the instructions on storage shown below. The period of validity can be

prolonged when further stability is ensured. Updated information on the period of validity will be announced on the website of the producer (<http://nimd.env.go.jp/english/index.html>).

4. Product Form

NIMD-02 is provided in a plastic tube. Four tubes are sealed as a set and each tube contains approximately 4 mL of NIMD-02.

5. Homogeneity

After NIMD-02 was put into 4000 tubes, 20 of them were selected by stratified sampling and analyzed for total mercury and cadmium. The homogeneity of the sample was evaluated by analysis of variance. The value of uncertainty, which is derived from homogeneity, is included in the uncertainty of the certified value. Therefore, the homogeneity of NIMD-02 is ensured within the range of uncertainty of the certified value. In the homogeneity examination, the sample volume for analysis of total mercury and cadmium was 1.5 mL and 0.4 mL, respectively.

6. Instructions on Storage

A short-term stability test for 4 weeks at 37°C was conducted to consider overseas shipment. A temperature indicator for 37°C is enclosed with the actual product. Immediately after receiving the product, store in a clean place at less than -20°C and avoid light.

7. Instructions on Handling and Use

- (1) Although NIMD-02 is sterilized with γ -ray irradiation, the potential risk as a source of disease should be considered.
- (2) To homogenize the contents, shake the bottle well before use.
- (3) Ensure that the sample is at room temperature when measuring sample mass for analytical use.

8. Production Method

To produce NIMD-02, urine materials were collected in Japan and were homogenized by mixing and placed into plastic tubes. All of the processing operations were conducted by IDEA Consultants, Inc.

9. Reference Material Producer

The producer of NIMD-02 is the National Institute for Minamata Disease, Ministry of the Environment, Japan.

10. Participants Involved in Characterization of NIMD-02

Property values of NIMD-02 were characterized by an inter-laboratory study that was conducted by the institutions shown below.

No.	Institution	Country
1	Dong-A University	Korea
2	IDEA Consultants, Inc.	Japan
3	Institut national de santé publique du Québec	Canada
4	Jožef Stefan Institute	Slovenija
5	Kagoshima University	Japan
6	Lumex Instruments	Russia
7	Metropolitan Council Environmental Services	US
8	National Institute for Minamata Disease (NIMD)	Japan
9	Nippon Instruments Corporation (NIC)	Japan
10	SHIMADZU Techno-Research, Inc.	Japan
11	University of Ottawa	Canada
12	University of Rochester School of Medicine and Dentistry	US
13	Vietnam Academy of Science and Technology	Vietnam

Institutions are in alphabetical order

11. Access to Information

Information on any important revision regarding NIMD-02 will be announced on the website of the producer (<http://nimd.env.go.jp/english>). Technical information on NIMD-02 can be acquired from the contact address shown below.

12. Replicate of Certificate

Indicate as a copy when replicating this certificate.

August 1, 2024
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4058-18 Hama, Minamata City,
Kumamoto, 867-0008, Japan
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<http://nimd.env.go.jp/english/index.html>

Certification Revision History
August 1, 2024 (Change of expiration)
December 1, 2022 (Change of expiration)
January 31, 2022 (Change of expiration)
February 1, 2021 (original certificate date)