

Certificate of Accreditation

To Reference Material Institute for Clinical Chemistry Standards

IAJapan accredits the following organization as a Certified Reference Material Producer under the ASNITE Accreditation Program.

This accredited RMP meets the requirements of ISO Guide 34: 2009.

Accreditation No. and Additional Information : ASNITE 0006 R Name and Address of Producer :

Reference Material Institute for Clinical Chemistry Standards Biochemistry Reference Laboratory of ReCCS,

(3-2-1, Sakado, Takatsu-ku, Kawasaki-shi, Kanagawa, JAPAN)

Fundamental Reference Laboratory of ReCCS,

(1-3-3, Azamino-minami, Aoba-ku, Yokohama-shi, Kanagawa, JAPAN)

and Products Center of ReCCS

(533-1, Kamisakunobe, Takatsu-ku, Kawasaki-shi, Kanagawa, JAPAN)

Scope of Accreditation: As attached Date of Initial Accreditation: 2003-04-01 Latest Date of Issue: 2015-04-14

Hideyuki OTA Chief Executive, IAJapan National Institute of Technology and Evaluation

ISO Guide 34:2009 includes the requirements of ISO/IEC 17025 for testing, calibration and related activities in the assignment of property values to certified reference materials.

⁻ International Accreditation Japan (IAJapan) is an accreditation body which has signed MRAs of APLAC (Asia Pacific Laboratory Accreditation Cooperation).

⁻ MRA requirements are, in addition to relevant international standards and guides, requirements for participation in proficiency testing programmes, surveillance and reassessment, and the policy for the traceability of measurement for MRA purpose.

⁻ This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system.

Attachment

Accreditation Category for Reference Materials Producer

: Chemical Reference Materials

| Sub Categories | Name of Materials | Name of Properties | Range of Characterization | Range of Expanded Uncertainties (k=2) | Date of Accreditation |
|--|--------------------------------------|-----------------------|------------------------------|---------------------------------------|-----------------------|
| Clinical Chemical Reference Materials | Cholesterol Reference Material | Total Cholesterol | 4.5 ~ 7.8 mmol/L | 0.02 ~ 0.04 mmol/L | 2003-04-01 |
| | HbA1c Reference Material | HbA1c | 20 ~ 140 mmol/mol | $0.5 \sim 3.0$ mmol/mol | |
| | Cholesterol Reference Material | HDL- Cholesterol | 20 ~ 140 mg/dL | $0.2 \sim 2.5$ mg/dL | 2008-03-27 |
| | Cholesterol Reference Material | LDL- Cholesterol | 50 ~ 300 mg/dL | $0.5 \sim 5.0$ mg/dL | |
| | Creatinine Reference Material | Creatinine | 0.4 ~ 7.0 mg/dL | $0.01 \sim 0.20$ mg/dL | 2014-03-25 |

(End of Attachment)