23･06･07- NITE-AC-003
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Certificate of Accreditation

International Accreditation Japan (IAJapan) hereby accredits the following conformity assessment body as a Reference Material Producer of ASNITE accreditation program.

Accreditation Identification: ASNITE 0006 RMP

Name of Conformity Assessment Body: Reference Material Institute for Clinical Chemistry Standards

Name of Legal Entity: Same as above

Location of Conformity Assessment Body: 1050-35 Ichigao-cho, Aoba-ku, Yokohama-shi, Kanagawa 225-0024, JAPAN

Scope of Accreditation: as the following pages

Accreditation Requirement: ISO 17034:2016*

* The relevant accreditation requirements described in the Accreditation Scheme Document for ASNITE-R (General) are also applied.

Effective Date of Accreditation: 2023-11-01

Expiry Date of Accreditation: 2027-10-31

Date of Initial Accreditation: 2003-04-01

K. Saito

SAITO Kazunori
Chief Executive, International Accreditation Japan (IAJapan)
National Institute of Technology and Evaluation

- International Accreditation Japan (IAJapan) is an RMP accreditation body which has signed MRAs of ILAC (International Laboratory Accreditation Cooperation) and APAC (Asia Pacific Accreditation Cooperation).
- MRA requirements are, in addition to relevant international standards and guides, requirements for participation in proficiency testing programs, surveillance and reassessment, and the policy on 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 in accordance with the recognized International Standard ISO 17034:2016.
- The latest accreditation information is publicly available on IAJapan Website as an accreditation certificate.

Category: Chemical Reference Materials
Type: Certified Reference Material
Property Characterized: Concentration
The Approach Used to Assign a Property Value: Measurement by a Single Method in a Single Laboratory (ISO 17034:2016 7.12.3 NOTE 1 d))

Sub-categories	Properties	Range of Property Value	Characterization Technique	Effective Date of Accreditation
Clinical Chemical Reference Materials	Total Cholesterol in Human Serum	100 mg/dL～ 400 mg/dL	Isotope dilution mass-spectrometry (ID-MS)	2023-11-1
	HDL Cholesterol in Human Serum	40 mg/dL～ 80 mg/dL	<Fractionation method> CDC reference method for HDL cholesterol in serum <Characterization method> Isotope dilution mass-spectrometry (ID-MS)	
			<Fractionation method> CDC reference method for HDL cholesterol in serum <Characterization method> Abell-Kendall method	
	LDL Cholesterol in Human Serum	90 mg/dL～ 150 mg/dL	<Fractionation method> CDC beta-quantification reference method for LDL cholesterol in serum < Characterization method> Isotope dilution mass-spectrometry (ID-MS)	
			<Fractionation method> CDC beta-quantification reference method for LDL cholesterol in serum < Characterization method> Abell-Kendall method	
	Creatinine in Human Serum	0.3 mg/dL～ 7.0 mg/dL	Isotope dilution mass-spectrometry (ID-MS)	
	HbA1c in Human Hemolysate	20 mmol/mol～ 140 mmol/mol	IFCC Reference method (HPLC -MS)	

(End of Attachment)