23･06･07- NITE-AC-002
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Certificate of Accreditation

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

Accreditation Identification: ASNITE 0006 Calibration

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/IEC 17025:2017*
ISO 15195:2018

* The relevant accreditation requirements described in the Accreditation Scheme Document for ASNITE-C(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 a laboratory 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 for the traceability of measurement for MRA purpose.
- This laboratory fulfills ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories. This accreditation means this laboratory meets both the technical competence requirements and management system requirements that are necessary for it to consistently deliver technically valid test results and calibrations (refer to joint ISO-ILAC-IAF Communiqué dated April 2017).
- The latest accreditation information is publicly available on IAJapan Website as an accreditation certificate.

General Field of Calibration: Biochemical Test
Date of Initial Accreditation of the Field: 2003-04-01
Laboratory's permanent facility/On-site Calibration: Laboratory's permanent facility
Calibration and Measurement Capabilities

Quantity	items	Measurand Level or Range	Expanded Uncertainty (level of confidence approximately 95 %)	Instrument or Artifact	Effective Date of Accreditation
Blood plasma Blood serum	Total Cholesterol	40 mg/dL～400 mg/dL	0.6 %	Isotope dilution mass-spectrometry (ID-MS)	2023-11-01
	HDL Cholesterol	40 mg/dL～150 mg/dL	0.6 %	<Fractionation method> CDC reference method for HDL cholesterol in serum <Characterization method> Isotope dilution mass-spectrometry (ID-MS)	
			0.8 %	<Fractionation method> CDC reference method for HDL cholesterol in serum <Characterization method> Abell-Kendall method	
	LDL Cholesterol	90 mg/dL～200 mg/dL	0.6 %	<Fractionation method> CDC Beta-quantification reference method for LDL cholesterol in serum < Characterization method> Isotope dilution mass-spectrometry (ID-MS)	
			1.2 %	<Fractionation method> CDC Beta-quantification reference method for LDL cholesterol in serum < Characterization method> Abell-Kendall method	
	Creatinine	0.3 mg/dL～7.0 mg/dL	0.7 %	Isotope dilution mass-spectrometry (ID-MS)	
Whole blood	HbA1c	20 mmol/mol～140 mmol/mol	1.6 %	IFCC reference method (HPLC – MS)	

(End of Attachment)