



21•08•20-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 ASITE 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 ASNITE-C (General) Accreditation Scheme Document are also applied.

Effective Date of Accreditation: 2019-12-27

Expiry Date of Accreditation: 2023-12-26

Date of Initial Accreditation: 2003-04-01

A handwritten signature in black ink, appearing to read 'Kozo Sakamoto', is written over a horizontal line.

SAKAMOTO Kozo

Chief Executive, International Accreditation Japan (IAJapan)

National Institute of Technology and Evaluation

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- 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 TestDate of Initial Accreditation of the Field: 2003-04-01Laboratory's permanent facility/On-site Calibration: Laboratory's permanent facilityCalibration and Measurement Capabilities

Quantity	items	Instrument or Artifact	Measurand Level or Range	Expanded Uncertainty (level of confidence approximately 95 %)	Effective Date of Accreditation
Blood plasma Blood serum	Total Cholesterol	Isotope dilution mass-spectrometry (ID-MS)	4.5 ~ 7.8 mmol/L	0.02 ~ 0.04 mmol/L	2003-04-01
	HDL Cholesterol	<Fractionation method> CDC reference method for HDL cholesterol in serum <Characterization method> Isotope dilution mass-spectrometry (ID-MS) or Abell-Kendall method	20 ~ 140 mg/dL	0.2 ~ 2.5 mg/dL	2008-03-27
	LDL Cholesterol	<Fractionation method> CDC Beta-quantification reference method for LDL cholesterol in serum < Characterization method> Isotope dilution mass-spectrometry (ID-MS) or Abell-Kendall method	50 ~ 300 mg/dL	0.5 ~ 5.0 mg/dL	
	Creatinine	Isotope dilution mass-spectrometry (ID-MS)	0.4 ~ 7.0 mg/dL	0.01 ~ 0.20 mg/dL	2014-03-25
Whole blood	HbA1c	IFCC reference method (HPLC – electrospray ionization mass spectrometry)	20 ~ 140 mmol/mol	0.5 ~ 3.0 mmol/mol	2008-03-27

(End of Attachment)