

Medical Laboratory Accreditation Certificate

Accreditation No.RML00170

The University of Tokyo Department of Clinical Laboratory, The University of Tokyo Hospital

7-3-1, Hongo, Bunkyo-ku, Tokyo, 113-8655 Japan

meets the following criteria. On the basis of this, Japan Accreditation Board (JAB) grants accreditation to the said medical laboratory.

Applicable accreditation criteria

: ISO 15189 : 2022

Scope of accreditation

: As described in the appendix.

Premises covered by accreditation

· As described in the appendix.

Expiry date of accreditation

: January 31, 2027

Revised Renewed Initial accreditation May 3, 2025 February 1, 2023 January 19, 2007

Y. M.J., President

Japan Accreditation Board



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The University of Tokyo Department of Clinical Laboratory, The University of Tokyo Hospital

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Field: ■ Basic Series

■ Non-Basic Series

■ Specific program I

■ Pathology

■ Physiology

Type of test: Accreditation by Flexible Scope

Element to be fixed: Test / Analyte

Flexible element: Sample and Method

Note: Details of accreditation by flexible scope ('list of activities') are available on the

laboratory's intranet (HIS)

Including primary sample collection in the scope of accreditation

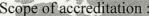
Scope of accreditation :

	Test / Analyte
Basic Series	
1 Urine	: / feces test
	D000 Urinary Qualitative / semi-Quantitative Examination
	D001 Urinary special substance qualitative and quantitative test
	D002 Urinary Sedimentary by microscopy
2 Hema	atology
	D005 Blood morphology/function test
	D006 Bleeding/coagulation test
3 Bioch	nemistry I
	D007 Blood chemistry test
5 Immi	unology
	D011 Immunohematology
	D012 Infectious disease
	D013 Hepatitis and relates
	D014 Autoantibody
	D015 Immunology for plasma protein



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Scope of accreditation:
Test / Analyte
6 Microbiology
D017 Microscopic examination for stained film
D018 Bacterial culture and identification
D019 Antimicrobial sensitivity test
D020 Mycobacterial culture and Isolation
Non-Basic Series
11 Urine / feces test
D001 General urinalysis
D002-2 Urinary sediment by flow cytometry (Urinary)
D003 Scatoloscopy
D004 Basic analysis for punctatum, sperm, sputum and others
12 Hematology
D005 General hematology, hemogram
D006 Bleeding/coagulation test
13 Biochemistry I
D007 Blood chemistry test
14 Biochemistry II
D008 Endocrinology
D009 Tumor marker
15 Immunology
D011 Immunohematology
D012 Immunology for infectious disease
D013 Hepatitis and relates
D014 Autoantibody
D015 Immunology for plasma protein
D016 Cellular functional test (cellular immunity related test)
16 Microbiology
D019-2 Examination for drug sensitivity test, yeastlike fungi
D021 Identification of mycobacteria (per series regardless of the
number of events)
D022 Drug susceptibility test for mycobacteria
D023-2 Other microbiological tests
D011 Immunohematology D012 Immunology for infectious disease D013 Hepatitis and relates D014 Autoantibody D015 Immunology for plasma protein D016 Cellular functional test (cellular immunity related test) 16 Microbiology D019-2 Examination for drug sensitivity test, yeastlike fungi D021 Identification of mycobacteria (per series regardless of the number of events) D022 Drug susceptibility test for mycobacteria





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Scope of accredi	tation:
	Test / Analyte
17 Gene	e-related test / Chromosome test
	a-1 Somatic cell genetic test (Hematopoietic specimens such as hematological malignancies and transplants) (non-NGS)
	b Pathogenic nucleic acid homologation (D023 Microbial nucleic acid identification and quantification testing) (non-NGS)
	e NGS (Insurance coverage items only, Pathogenic nucleic acid homologation, Somatic cell genetic test, Chromosome test and Germline gene test)
Specific program	n I
	ified health checkup testing (health checkup for metabolic syndrome)
	a Basic Series
	b Additional Series
Pathology	
31 Path	ology specimen preparations
	N000 Preparation for histodiagnosis
	N001 Preparation for electron microscope (per organ)
	N002 Preparation for immunological stain (histodiagnosis)
	N003 Preparation for operative rapid pathologic daiagnosis (per surgery)
	N003-2 Rapid cytology
	N004 Cytodiagnosis (per part)
	N005 Preparation for HER2 gene specimen
	N005-3 Preparation for PDL1 protein immunological stain
	N005-4 Preparation for mismatch repair protein immunological stain



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Scope of accreditation:

scope of accree	intation:	
	Test / Analyte	
Physiology		
101 Ph	nysiology	
	a Respiratory function test	
	D200 Spirography	
	D202 Closing volume	
	D203 DLCO	
	b Circulatory function test	
	D208 Electrocardiogram	
	D210 Holter Electrocardiogram	
	c Ultrasonography	
	D215 Ultrasonography	
	d Electroencephalography	
	D235 Electroencephalography (PS, HV)	

Japan Accreditation Board