



Medical Laboratory
Accreditation
Certificate

Accreditation No. RML00830

**Department of Clinical Laboratory,
Tokyo Medical and Dental University Hospital**

1-5-45 Yushima, Bunkyo-ku, Tokyo 113-8519, 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 : 2012
- Scope of accreditation : As described in the appendix.
- Premises covered by accreditation : As described in the appendix.
- Expiry date of accreditation : June 30, 2026

Revised	July 13, 2023
Renewed	July 1, 2022
Initial accreditation	June 12, 2014

Y. Iizuka, President

Japan Accreditation Board



Accreditation Certificate Appendix

Department of Clinical Laboratory, Tokyo Medical and Dental University Hospital

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Including primary sample collection in the scope of accreditation

Scope of accreditation :

Item	Type of Samples	Test/Method
Basic Series		
1 General (urine, feces, etc.)		
a Qualitative (urine / feces)		
Urinary Qualitative / semi-Quantitative Examination (general substances) (Gravity, pH, Protein, Glucose, Urobilinogen, Urobilin, Bilirubin, Ketones, Occult blood reaction (Urinary), Bacteria (Test paper), Sodium chloride, Leukocyte (Test paper), Albumin)	Urine	uropaper III Eiken uropaper III Eiken
Protein quantitation	Urine	reagent for automated analyzer-AR WAKO microTP-AR
Glucose quantitation	Urine	qualigent GLU
Hemoglobin, feces	Feces	OC-Hemodia auto III Eiken
Sedimentary test, urine	Urine	Labostain SG
2 Hematology		
a Blood count / blood cell morphology test		
Peripheral blood general test* (complete blood counts)* : RBC, WBC, Hgb, PLT, Hct	Blood	RBC: CELLPACK DST WBC: CELLPACK DCL Hgb: Sulfolyzer PLT: Fluorocell PLT Hct: CELLPACK DST
Reticulocytes	Blood	Fluorocell RET
Hemogram (The microscope method)	Blood	Visual inspection
Hemogram (The automatic analyser method)	Blood	• Fluorescence Flow Cytometry Method Using Semiconductor Laser • Artificial Neural Network • Decision tree
b Thrombus / hemostasis related test		
Prothrombin time (PT)	Plasma	Revohem PT
Activated partial thromboplastin time (APTT)	Plasma	Revohem APTT SLA
Fibrinogen (Quantitative)	Plasma	Thrombocheck Fib (L)
Fibrinogen degradation products (FDP)	Plasma	LIAS AUTO P-FDP
D dimer (Quantitative)	Plasma	LIAS AUTO D-Dimer NEO
3 Biochemistry I		
a Biochemistry		
Total bilirubin	Serum	iatro LQ T-BIL II



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Item	Type of Samples	Test Method
Bilirubin, indirect and direct	Serum	iatrol/ONDABIL(A)
Total protein	Serum	Aqya-auto Kainos TP-II
Albumin	Serum	Aqya-auto Kainos ALB
Protein fractionation	Serum	agarose electrophoresis
Urea nitrogen (BUN)	Serum	serotec UN-ML
Creatinine	Serum	Aqya-auto Kainos CRE-IV
Uric acid	Serum	serotec UA-L
Na and Cl	Serum	LABOSPECT 008a (ion-selective electrode)
K	Serum	LABOSPECT 008a (ion-selective electrode)
Ca	Serum	Aqya-auto Kainos Ca
Inorganic phosphate and phosphoric acid	Serum, Urine	determiner L IPII
Mg	Serum	N-assay L Mg-H nittobo
Total cholesterol	Serum	determiner L TC II
Triglyceride	Serum	determiner L TG II
HDL-cholesterol	Serum	MetaboLead HDL-C
LDL-cholesterol	Serum	MetaboLead LDL-C
Glycated albumin	Serum	Lucica GA-L
Glucose	Serum, Plasma	qualigent GLU GOD immobilized enzyme membrane /hydrogen peroxidase electrode method
Hemoglobin A1c (HbA1c)	Blood	HLC-723 G11 (HPLC method)
Fe	Serum	Quickauto-Neo Fe
Unsaturated iron binding capacity (UIBC)	Serum	Quickauto-Neo UIBC
Ammonia	Plasma	Ammonia-L
Alkaline phosphatase	Serum	CICA liquid ALP-IFCC
Cholinesterase	Serum	serotec ChE-ML
γ-glutamyltranspeptidase (γ-GT)	Serum	labofit γ-GT
Lactate dehydrogenase (LD)	Serum	CICA Fit LD-IFCC
Amylase	Serum	serotec AMY-ML
Creatine kinase (CK)	Serum	IATOROLQ CK RATE J II
Aspartate aminotransferase (AST)	Serum	labofit AST
Alanine aminotransferase (ALT)	Serum	labofit ALT
Blood gas analysis	Blood	ABL820 FLEX (electrode)
5 Immunology		
a Immunochemistry I		
C-reactive protein (CRP)	Serum	N-assay LA CRP-T nittobo
Immunoglobulin (IgG, IgA, IgM, IgD)	Serum, Urine	N-assay TIA IgG-SH nittobo N-assay TIA IgA-SH nittobo N-assay TIA IgM-SH nittobo
C3	Serum	N-assay TIA C3-SH nittobo
C4	Serum	N-assay TIA C4-SH nittobo
Immunoglobulin (RF)	Serum	LZ test 'Eiken' RF
b Immunohematology		
Blood group (ABO type)	Blood	Anti-A/Anti-B/Anti-D/Contorol/Reverse Diluent-Ortho Bio Vue System
Blood group (Rho (D) factor)	Blood	Anti-A/Anti-B/Anti-D/Contorol/Reverse Diluent-Ortho Bio Vue System



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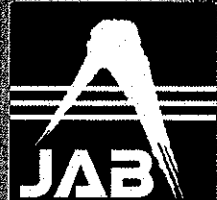
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Item	Type of Samples		Test Method
c Infectious disease			
HBs antigen	Serum		LUMIPULSE Presto HBsAg-HQ
HCV antibody (Quantitative, Qualitative)	Serum		LUMIPULSE Presto Ortho HCV Ortho Quick chase HCV Ab
HIV-1/2 antigen and antibody simultaneous measurement	Serum		LUMIPULSE Presto HIV Ag/Ab
Serologic test for syphilis (STS) (Qualitative)	Serum		LASAYAuto RPR
Serologic test for syphilis (Qualitative)	Serum		LUMIPULSE Presto TP ESPLINE TP
6 Microbiology			
a Microscopic examination for stained film (general bacteria)			
Other	Sputum	Punctured fluid	Gram stain, Ziehl-Neelsen stain
Use a fluorescent microscope	Sputum	Punctured fluid	Auramine O stain
b Bacterial culture and identification / Antimicrobial sensitivity test (general bacteria)			
Bacterial culture and identification	Sputum	Punctured fluid	Blood agar, Chocolate agar, BTB lactose agar
Anaerobic culture	Punctured fluid	Secretions	Brucella HK agar (RS)
Antimicrobial sensitivity test (general bacteria)	Sputum	Secretions	Microscan Pos series, Microscan Neg series, MICROFAST series strept, MICROFAST series Haemophilus, RAISUS [Nissui]
Mycobacterial culture and Isolation (liquid medium)	Sputum	Punctured fluid	Mycobacteria Growth Indicator Tube
Mycobacterial culture and Isolation (other)	Sputum	Punctured fluid	Kyokuto 2% Ogawa medium
Mycobacterial identification	Sputum	Punctured fluid	μTASWAKO MTB, μTASWAKO MAC
Non-Basic Series			
11 General (urine, feces, etc.)			
a General urinalysis			
Albumin (Quantitative) (Urinary)	Urine		LZ test 'Eiken' U-ALB
Osmolarity	Urine		Freezing-point depressin method using ultra super cooling
N-acetyl glucosaminidase (NAG) (Urinary)	Urine		N-assay L NAG nittobo
Urinary sediment by flow cytometry (Urinary)	Urine		UF-CELLSHEATH UF-CELLPACK SF UF-CELLPACK CR UF-Fluorocell SF UF-Fluorocell CR
b Scatolscopy			
Hemoglobin (Qualitative) (feces)	Feces		OC-Hemodia auto III Eiken
Calprotection (feces)	Feces		OC-Calprotectin Eiken
c Basic analysis for punctatum, sperm, sputum and others			
Test of cerebrospinal fluid (protein quantification, glucose quantification, cell numbers, specific gravity, globulin reaction, cell classify)	Punctured fluid		protein: reagent for automated analyzer - AR WAKO microTP-AR glucose: qualigent GLU cell numbers - differential: CELLPACK DST Lysercell WDF Fluorocell WDF Samson's Solution



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Item	Type of Samples	Test Method
12 Hematology		
a General hematology, hemogram		
Erythrocyte sedimentation rate	Blood	Westergren rate method
Serum osmolality	Serum	Freezing-point depression method using ultra super cooling
Myelogram	Others	Visual inspection
Myelogram (special stain)	Others	Visual inspection
Malignant tumor cell	Blood	Others
		Fluorescence Flow Cytometry Method Using Semiconductor Laser
b Thrombus/hemostasis related test I		
Antithrombin (activity)	Plasma	Revohem AT
Plasmin inhibitor/plasmin complex (PIC)	Plasma	HISCL PIC
Coagulation factor inhibitor Qualitative (cross mixing test)	Plasma	Revohem PT
Thrombin anti-Thrombin complex (TAT)	Plasma	Revohem APTT SLA
		HISCL TAT
c Thrombus / hemostasis related test II		
Bleeding time	Blood	Duke method
Platelet aggregation	Plasma	Agglutination test
13 Biochemistry I		
a Biochemistry I		
Ferritin Quantitative	Serum	FER-LATEX RX"SEIKEN"
Leucine-Rich $\alpha 2$ -Glycoprotein (LRG)	Serum	Nanopia LRG
Procalcitonin (PCT) (Quantitative)	Serum	LUMIPULSE Presto Brahms PCT
b Biochemistry II		
Lipase	Serum	Cygnus-auto LIP
KL-6	Serum	LUMIPULSE Presto KL-6
Cystatin C	Serum	LZ test'Eiken'Cystatin C
Mac-2 binding protein glycosylated isomers	Serum	HISCL M2BPGi
c Isozyme		
CK-MB	Serum	LUMIPULSE Presto CK-MB
d Immunochemistry		
Cardiac troponin I	Serum	LUMIPULSE Presto hs Troponin I
14 Biochemistry II		
a Endocrinology I		
Human chorionic gonadotropin (HCG) (Quantitative)	Serum	LUMIPULSE Presto β HCG
Thyroid-stimulating hormone (TSH)	Serum	ECLusys TSH v2 (S300)
Free triiodothyronine (FT3)	Serum	ECLusys FT3 III (S300)
Free thyroxine (FT4)	Serum	ECLusys FT4 III (S300)
C-peptide (CPR)	Serum	Urine
		LUMIPULSE Presto C-peptide
Insulin (IRI)	Serum	LUMIPULSE Presto Insulin
Growth hormone (GH)	Serum	ECLusys hGH(S100)
Follicle-stimulating hormone (FSH)	Serum	ECLusys FSH(S300)
Luteinizing hormone (LH)	Serum	ECLusys LH(S300)
Prolactin (PRL)	Serum	ECLusys Prolactin(S300)



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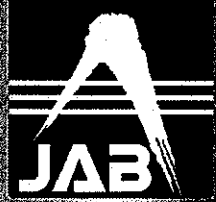
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Progesterone	Serum	ECLusys Progesteron(S300)
Parathyroid hormone (PTH)	Serum	ECLusys PTH(S300)
Brain natriuretic peptide (BNP)	Plasma	LUMIPULSE Presto BNP
Estradiol (E2)	Serum	ECLusys E2IV (S300)
Cortisol	Serum	ECLusys Cortisol(S200)
N-terminal pro brain natriuretic peptide (NT-proBNP)	Serum	ECLusys NT-proBNP
Adrenocorticotrophic hormone (ACTH)	Plasma	ECLusys ACTH(S100)
b Tumor marker		
α-fetoprotein (AFP)	Serum	ECLusys AFP II (S300)
Carcinoembryonic antigen (CEA)	Serum	ECLusys CEA II (S300)
CA19-9	Serum	ECLusys CA19-9 II (S300)
CA125	Serum	ECLusys CA125 II (S300)
Prostate-specific antigen (PSA)	Serum	ECLusys PSA(S300)
Squamous cell cancer related antigen (SCC)	Serum	LUMIPULSE Presto SCC
Free PSA/Total PSA ratio	Serum	ECLusys Free-PSA(S300)
PIVKA-II (Quantitative)	Serum	HISCL PIVKA-II reagent
Interleukin 2 receptor, soluble (sIL-2R)	Serum	LUMIPULSE Presto IL-2R
15 Immunology		
a Immunohematology		
Irregular antibody	Plasma	Anti-IgG-Ortho BioVue System Neutral-Ortho BioVue System
b Immunology for infectious disease II		
Mycoplasma antigen (Qualitative) (Immunochromatography method)	Secretions	Ribotest Mycoplasma
c Immunology for infectious disease III		
Escherichia coli serotyping	Feces	E.coli antisera "SEIKEN"
RS virus antigen (Qualitative)	Secretions	Immunoace RSV Neo
Clostridium difficile toxin A (Qualitative)	Feces	TECHLAB C.DIFF QUIK CHEK COMPLETE
Adenovirus antigen (Qualitative) (Feces)	Feces	Quick Chaser Rota/Adeno
Rotavirus antigen (Qualitative) (Feces)	Feces	Quick Chaser Rota/Adeno
(1→3)-β-D-Glucan	Plasma	β-Glucan test WAKO
Serologic test for syphilis (STS) (Quantitative)	Serum	LASAYAuto RPR
Group A-β Streptococcal-rapid Detection (Qualitative)	Secretions	QuickNavi-StrepA2
Influenza virus antigen (Qualitative)	Secretions	ESPLINE Influenza A&B-N
Streptococcus pneumoniae capsular antigen (fluid, urinary)	Urine	Punctured fluid Immuno catch Streptococcus pneumoniae (Urine・Cerebrospinal fluid)
Norovirus antigen (Qualitative)	Feces	QuickNaviTM-Norovirus3
adenovirus antibody (Qualitative) (remove feces)	Secretions	Immunoace Adeno
Endotoxin	Plasma	Endotoxin-Single test Wako
Legionella pneumophila antigen (Urinary)	Urine	RIBOTEST® Legionella
d Hepatitis and relates		
HBs antibody (Quantitative)	Serum	LUMIPULSE Presto HBsAb-III
HBc antibody (Semi-quantitative, Quantitative)	Serum	LUMIPULSE Presto HBcAb-III



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Item	Type of Samples	Test Method
e Autoantibody		
Matrix metalloproteinase-3 (MMP-3)	Serum	panacria MMP-3 [latex]
Anti-TSH receptor antibody (TRAb)	Serum	ECLusys TRAb v2 (S300)
f Immunology for plasma protein		
CH50	Serum	complement value HIA test WAKO
Bence Jones protein, quantitative (Urinary)	Urine	Agarose gel electrophoresis
β 2-microglobulin	Serum	Urine LZ test Eiken β 2-M
Immunoelectrophoresis (Anti-Human serum)	Serum	Urine agarose electrophoresis
Immunoelectrophoresis (Singular antiserum)	Serum	Urine agarose electrophoresis
Non-specific immunoglobulin IgE (Quantitative)	Serum	LUMIPULSE Presto Ige
Transferrin (Prealbumin)	Serum	N-assay TIA Prealbumin Nitob6
16 Microbiology		
b Bacterial culture and identification / Antimicrobial sensitivity test (general bacteria)		
Examination for drug sensitivity test, yeastlike fungi	Blood	RAISUS [Nissui]
Drug susceptibility test for mycobacteria	Sputum	Punctured fluid Kyokuto VITE Spectrum SR, Kyokuto M. tuberculosis susceptibility PZA liquid medium
c Identification of nucleic acid (genetic testing)		
E. coli vero cytotoxin (Qualitative)	Feces	Capilia VT
17 Gene-related / Chromosome test		
a Somatic gene test		
Preparation for HER2 gene specimen	Tissues	Histra HER2 FISH kit
b Identification of pathogen nucleic acid		
Nucleic acid identification of MRSA	Blood	Xpert MRSA/SA BC [Cepheid]
DNA amplification assay for Mycobacteria tuberculosis complex	Sputum	Punctured fluid μ TASWAKO MTB Xpert MTB/RIF [Cepheid]
Mycobacterium avium / intracellulare DNA	Sputum	Punctured fluid μ TASWAKO MAC
Nucleic acid identification of Rifampicin resistant M. tuberculosis Complex	Sputum	Xpert MTB/RIF [Cepheid]
Influenza virus DNA	Others	BioFire Respiratory Panel 2.1, cobas SARS-CoV-2 & Flu A/B
SARS-CoV-2 RNA detection	Others	Sputum Ampdirect 2019-nCoV, Xpert Xpress SARS-CoV2 [Cepheid], cobas SARS-CoV-2, cobas SARS-CoV-2 & Flu A/B BioFire Respiratory Panel 2.1
Simultaneous detection of multiple items of viral and bacterial nucleic acids	Others	BioFire Respiratory Panel 2.1 FilmArray Torch
Clostridioides difficile toxin B gene detection	Feces	Xpert C.difficile [Cepheid]
d Germline gene test		
UDP uridine diphosphate glucuronosyltransferase	Blood	i-densy Pack UGT1A1 (*28/*6)



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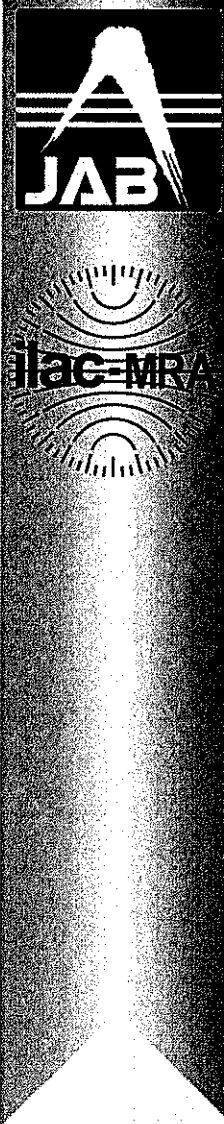
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Scope of accreditation

Item	Type of Samples		Test Method
18 Others (excluding I, II to IV class)			
a Therapeutic drug monitoring			
Digoxin	Plasma	Serum	Nanopia TDM Digoxin
Valproic acid/Carbamazepine	Plasma	Serum	Nanopia TDM Valproic acid Nanopia TDM Carbamazepine
Phenytoin/Phenobarbital	Plasma	Serum	Nanopia TDM Phenytoin Nanopia TDM Phenobarbital
Lithium		Serum	espa Lithium II
Vancomycin	Plasma	Serum	Nanopia TDM Vancomycin
Cyclosporin/Tacrolimus hydrate	Blood		Flex reagent cartridge Cyclosporine CSA Flex reagent cartridge Tacrolimus TAC
Methotrexate	Plasma	Serum	Nanopia eTDM Methotrexate
Pathology			
31 Preparation			
a Preparation for histodiagnosis			
Organize slices	Tissues		Hematoxylin-Eosin stain
CELL BLOCK	Others		Cell block method
b Preparation for electron microscope			
Preparation for electron microscope	Tissues		Electron stain
c Preparation for immunological stain (histodiagnosis)			
Estrogen receptor	Tissues		BONDIII Leica
Progesterone receptor	Tissues		BONDIII Leica
Human epidermal growth factor receptor-2	Tissues		Histfine HER2 Kit (MONO) Nichirei
Epidermal growth factor receptor protein	Tissues		EGFR pharmDx [DAKO] Agilent Technologies
Anaplastic lymphoid kinase fusion protein	Tissues		Histfine ALK iAEP Kit Nichirei
Others	Tissues		Manual method BONDIII Leica
d Preparation for rapid pathologic diagnosis			
Preparation for operative rapid pathologic diagnosis	Tissues		Hematoxylin-Eosin stain
Preparation for operative rapid cytodiagnosis	Others		Papanicolaou stain
e Cytodiagnosis			
Gynecology	Others		Papanicolaou stain
Fine needle aspiration cytology, Body cavity washing	Others		Papanicolaou stain Cytology giemsa stain
32 Pathological diagnosis			
a Pathological diagnosis			
Histology	Tissues		Diagnosis by Pathologist
Cytology	Others		Diagnosis by Pathologist



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Scope of accreditation:

Item	Type of Samples	Test Method
Physiology		
101 Physiology		
a Respiratory function test (Spirography)		
Slow vital capacity		FUDAC-7
Forced vital capacity		FUDAC-7
Functional Residual Capacity		FUDAC-7
Closing volume		FUDAC-7
DLCO (diffusing capacity of CO)		FUDAC-7
b Electrocardiogram		
At least 12 leads including limb monopole lead and the chest leads		FCP-9900
Stress Electrocardiogram		FCP-9900
Holter Electrocardiogram		FM-180s, FM-960, FM-970, WR-100, SpiderView
c Ultrasonography		
Cardiac ultrasonography		Vivid7 Dimension, EPIQ CVx, VividE95
Abdominal ultrasonography		SSA-790A, TUS-A500, TUS-AI800, TUS-AI900
Body surface ultrasonography		SSA-790A, TUS-A500, TUS-AI800, TUS-AI900
Vascular ultrasonography		TUS-A500, VividE95, EPIQ CVx
d Electroencephalography		
Electroencephalography (PS, HV)		EEG-1224, EEG-1214