

Medical Laboratory
Accreditation
Certificate

Accreditation No. RML00120

***Kyushu University
Department of Clinical Chemistry and Laboratory of Medicine,
and Division of Diagnostic Pathology,
Kyushu University Hospital***

***3-1-1, Maidashi, Higashi-ku, Fukuoka-shi, Fukuoka,
812-8582 Japan***

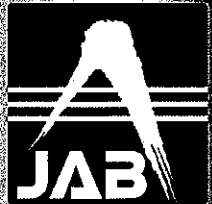
meets the following criteria. On the basis of this, Japan Accreditation Board (JAB) grants accreditation to the said medical laboratory.

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	: March 31, 2026

Revised	December 24, 2021
Renewed	April 1, 2022
Initial accreditation	March 29, 2006

Y. Iizuka, President

Japan Accreditation Board



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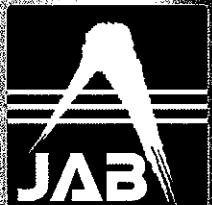
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Excluding primary sample collection from the scope of accreditation

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 α.III
Protein quantitation	Urine	AR-wako microTP-AR
Glucose quantitation	Urine	Kuorijyento GLU
Sedimentary test, urine	Urine	urinary sediment staining solution NEWURISTAIN
2 Hematology		
a Blood count / blood cell morphology test		
Peripheral blood general test*(complete blood counts)* : RBC, WBC, Hgb, PLT, Hct	Blood	ADVIA 2120i Flow cytometry assay cyanfree method (AAO method—alkylamine oxide method) laser optical method
Reticulocytes	Blood	ADVIA 2120i Flow cytometry assay
Hemogram (The microscope method)	Blood	MICROX stain (May-Gruenwald stain solution) (sysmex) , MICROX stain (Giemsa) (sysmex) , MICROXbuffer (May-Gruenwald · Giemsa) (sysmex) ,
Hemogram (The automatic analyser method)	Blood	ADVIA 2120i Flow cytometry assay
b Thrombus / hemostasis related test		
Prothrombin time(PT)	Plasma	Thromborel S
Activated partial thromboplastin time(APTT)	Plasma	ThromboCheck APTT-SLA
Fibrinogen (Quantitative)	Plasma	ThromboCheck Fib(L)
Fibrinogen degradation products(FDP)	Plasma	riasauto P-FDP
D dimer(Quantitative)	Plasma	riasauto D dimer
3 Biochemistry I		
a Biochemistry		
Total bilirubin	Serum	iatoroLQ T-BIL II
Bilirubin, indirect and direct	Serum	iatoroLQ D-BIL (A)



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Scope of accreditation :

Item	Type of Samples		Test Method
Total protein	Serum		Aqua-auto-kainos TP- II
Albumin	Serum		Aqua-auto-kainos ALB
Proteins fractionation	Serum		minicap protein 6Maxi kit sokutei sousahou
Urea nitrogen(BUN)	Serum	Urine	「Serotekku」 UN-SL
Creatinine	Serum	Urine	「Serotekku」 CRE-N
Uric acid	Serum		quickauto-neo UA II
Na and Cl	Serum	Urine	naibu-hyoujyun-eki-B kishaku-eki-B hikaku-denkyoku-eki
K	Serum	Urine	naibu-hyoujyun-eki-B kishaku-eki-B hikaku-denkyoku-eki
Ca	Serum	Urine	akyurasauto Ca
Inorganic phosphate and phosphoric acid	Serum	Urine	daiyacolor liquid IP-S
Mg	Serum		「Serotekku」 Mg-L
Total cholesterol	Serum		「Serotekku」 TCHO-L
Triglyceride	Serum		「Serotekku」 TG-L
HDL-cholesterol	Serum		Cholestest® N HDL
LDL-cholesterol	Serum		Cholestest® LDL
Glycated albumin	Serum		Lucica® GA-L
Glucose	Serum		Kuorijento GLU
Hemoglobin A1c (HbA1c)	Blood		Tosoh-glycohemoglobin automatic anaizer HLC-723G9
Fe	Serum		quickauto-neo Fe
Unsaturated iron binding capacity (UIBC)	Serum		quickauto-neo UIBC
Ammonia	Plasma		sikarikiddo NH3
Alkaline phosphatase	Serum		Ltype-wako ALP IFCC
Cholinesterase	Serum		quickauto-neo ChE-E
γ-glutamyltranspeptidase (γ-GT)	Serum		sikarikiddo γ-GT J
Lactate dehydrogenase (LD)	Serum		Ltype-wako LD·IF
Amylase	Serum	Urine	akyurasauto AMY-IF
Creatine kinase (CK)	Serum		Signas-auto CK
Asparate aminotransferase (AST)	Serum		Ltype-wako AST
Alanine aminotransferase (ALT)	Serum		Ltype-wako ALT
Blood gas analysis	Blood		rapidpoint500 measurement cartridge
5 Immunology			
a Immunochemistry I			
C-reactive protein (CRP)	Serum		CRP-latex X2 「seiken」
Immunoglobulin (IgG, IgA, IgM, IgD)	Serum		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



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Item	Type of Samples		Test Method
C4	Serum		N-assay TIA C4-SH nitrobo
Immunoglobulin (RF)	Serum		Iatoro RF II
b Immunohematology			
Blood group (ABO type)	Blood		Column. Agglutination Technology, Tube Test
Blood group (Rho (D) factor)	Blood		Column. Agglutination Technology, Tube Test
Indirect Coombs, direct Coombs	Blood	Plasma	Column. Agglutination Technology, Tube Test
c Infectious disease I			
HBs antigen	Serum		LumipulsePresto HBsAg-HQ
HBs antibody	Serum		LumipulsePresto HBsAb-III
HCV antibody (Quantitative, Qualitative)	Serum		LumipulsePresto ortho-HCV
HIV-1,2 antigen and antibody simultaneous measurement	Serum		LumipulsePresto HIV Ag/Ab
HTLV-I antibody (Qualitative)	Serum		LumipulsePresto HTLV-I/II
Serologic test for syphilis (STS) (Qualitative)	Serum		LASAY auto RPR
Serologic test for syphilis (Qualitative)	Serum		LASAY auto TPAb
6 Microbiology			
a Microscopic examination for stained film (general bacteria)			
Other	Sputum	Others	Gram stain (Feiba G 「NISSUI」), Acid fast stain (Ziehl-Neelsen stain)
b Bacterial culture and identification / Antimicrobial sensitivity test (general bacteria)			
Bacterial culture and identification	Sputum	Others	culture medium, VITEK MS, Others
Anaerobic culture	Punctured fluid	Others	Brucella HK Agar
Antimicrobial sensitivity test (general bacteria)	Sputum	Others	VITEK2 Antimicrobial sensitivity testing card, Antimicrobial sensitivity testing dryplate 'EIKEN'
Mycobacterial culture and Isolation (liquid medium)	Sputum	Others	BACTEC MGIT
Mycobacterial culture and Isolation (other)	Sputum	Others	NALC-NaOH method, 2% OGAWA Agar (SP)
Mycobacterial identification	Sputum	Others	Mycobacterium tuberculosis complex antigen kit (Capilia TB-Neo), DNA amplification assay for Mycobacterium tuberculosis complex (GENE CUBE), DNA amplification assay for Mycobacterium avium/intracellulare (GENE CUBE)
Non-Basic Series			
11 General (urine, feces, etc.)			
a General urinalysis			
Albumin (Quantitative) (Urinary)	Urine		TIA-ALBG
Latty acid binding protein, L-type (L-FABP) (Urinary)	Urine		Nordia L-FABP
b Scatoloscropy			
Hemoglobin and transferrin (Quantitative, Qualitative) (feces)	Feces		QuickChaser bensenketu



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Scope of accreditation :

Item	Type of Samples	Test Method
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	ADVIA 2120i Flow cytometry assay microTP-AR Kuorijento GLU
12 Hematology		
a General hematology, hemogram		
Erythrocyte sedimentation rate	Blood	Photometrical capillary stopped flow kinetic analysis
HemoglobinF (HbF)	Blood	Tosoh-glycohemoglobin automatic anaizer HLC-723G9
Hemogram (special stain)	Blood	PO-K stain kit Esterase stain kit, Esterase AS-D stain kit Fe stain kit ALP stain kit
Myelogram	Others	MICROX stain (May-Gruenwald stain solution) (sysmex), MICROX stain (Giemsa) (sysmex), MICROXbuffer (May-Gruenwald + Giemsa) (sysmex),
Myelogram (special stain)	Others	PO-K stain kit Esterase stain kit, Esterase AS-D stain kit Fe stain kit ALP stain kit
b Thrombus / hemostasis related test I		
Antithrombin (activity)	Plasma	L system AT III
Plasminogen (activity)	Plasma	L system PLG
Plasmin inhibitor/plasmin complex(PIC)	Plasma	HISCL PIC
Protein C (activity)	Plasma	STA Staclot Protein C II
Protein S (activity)	Plasma	STA Staclot Protein S
PIVKA II	Serum	LumipulsePresto PIVKA II -N
tPA/PAI-1 complex	Plasma	HISCL tPAI + C
Thrombomodulin	Plasma	HISCL TM
Thrombin anti-Thrombin complex (TAT)	Plasma	HISCL TAT
13 Biochemistry I		
a Biochemistry I		
Calcium, ionized	Blood	rapidpoint500 measurement cartridge
Zn	Serum	akyurasanto Zn
Ketones	Serum	3-HB-L kainos
Monocarboxylate	Plasma	N-assay L LAC nittobo
Bile acids	Serum	Aqua-auto-kainos TBA
Bicarbonate	Serum	daiyacolor + CO2
Ferritin Quantitative	Serum	FER-latex RX 「seiken」



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Item	Type of Samples	Test Method
Procalcitonin (PCT) (Quantitative)	Serum	Accuraced PCT
b Biochemistry II		
Adenosine-I-converting enzyme (ACE)	Serum	ACE color
Lipase	Serum	Signas-auto LIP
KL-6	Serum	LumipulsePresto KL-6 eisai
Mac-2 binding protein glycosylated isomers	Serum	HISCL M2BPGi
c Isozyme		
Alkaline phosphatase Isozyme	Serum	quick EP BAP-IF reagent
Amylase Isozyme	Serum	akyurasauto P-AMY-IF
Lactate dehydrogenase Isozyme	Serum	Taitangel S-LD reagent (QG)
CK Isozyme	Serum	Signas-auto CK-MB MtO
d Immunochemistry		
Cardiac troponin T (TnT) (Qualitative, Quantitative)	Serum	Accuraced Troponin T
14 Biochemistry II		
a Endocrinology I		
Human chorionic gonadotropin (HCG) (Qualitative)	Urine	Gonastick25
Human chorionic gonadotropin (HCG) (Quantitative)	Serum	AIA - PackCL βHCG
Thyroid-stimulating hormone (TSH)	Serum	Ekurusis reagent TSH v2
Free triiodothyronine (FT3)	Serum	Ekurusis reagent FT3 III
Free thyroxine (FT4)	Serum	Ekurusis reagent FT4 III
C-peptide (CPR)	Serum	Urine AIA-PackCL C-peptide
Insulin (IRI)	Serum	AIA-PackCL insulin
Growth hormone (GH)	Serum	AIA-PackCL GH
Follicle-stimulating hormone (FSH)	Serum	AIA-PackCL FSH
Luteinizing hormone (LH)	Serum	AIA-PackCL LH
Prolactin (PRL)	Serum	AIA-PackCL Prolactin
Progesterone	Serum	AIA-PackCL Progesterone
Parathyroid hormones (PTH)	Serum	Ekurusis reagent PTH
Brain natriuretic peptide (BNP)	Plasma	AIA - PackCL BNP
Estradiol (E2)	Serum	Ekurusis reagent E2IV
Cortisol	Plasma	Ekurusis reagent Cortisol II
Testosterone	Serum	Ekurusis reagent Testosterone
Renin (Quantitative)	Plasma	Accuraced Renin
Androsterone	Plasma	Accuraced Androsterone
Thyroglobulin	Serum	Ekurusis reagent Tg
Adrenocorticotrophic hormone (ACTH)	Plasma	Ekurusis reagent ACTH
b Tumor marker		
α-fetoprotein (AFP)	Serum	Ekurusis reagent AFP II
Carcinoembryonic antigen (CEA)	Serum	Ekurusis reagent CEA II
CA19-9	Serum	Ekurusis reagent CA19-9 II
CA125	Serum	Ekurusis reagent CA125 II
Prostate-specific antigen (PSA)	Serum	Ekurusis reagent PSA II v2
Squamous cell cancer related antigen (SCC)	Serum	Ekurusis reagent SCC
CA15-3	Serum	Ekurusis reagent CA15-3 II
Neuron specific enolase (NSE)	Serum	Ekurusis reagent NSE
Cytokeratin 19 fragment	Serum	Ekurusis reagent CYFRA



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Item	Type of Samples		Test Method
Free PSA/Total PSA ratio	Serum		Ekurusis reagent free PSA v2
Progastorin releasing peptide(ProGRP)	Plasma		HISCL ProGRP
PIVKA-II (Quantitative)	Serum		Lumipulse Presto PIVKA II -N
Inteleukin 2 receptor, soluble (sIL-2R)	Serum		Lumipulse Presto IL-2R
c Special analysis			
Urea breath test (UBT)	Others		POCone U-Bit
15 Immunology			
a Immunohematology			
Irregular antibody	Serum	Plasma	Column. Agglutination Technology, Tube Test
Heparin indused thrombocytopenia antibody (IgG, IgM and IgA)	Plasma		Himos IL HIT - Ab(PF4 ⁺ -H)
c Immunology for infectious disease III			
Escherichia coli serotyping	Feces		Antiserum for Enteropathogenic E.coli
RS virus antigen (Qualitative)	Others		Check RSV
Varicella virus antigen (in the epithelial cell)	Others		DermaQuick VZV
Clostridium difficile toxin A (Qualitative)	Feces		C.DIFF QUIK CHEK Complete
Adenovirus antigen (Qualitative) (Feces)	Feces		BD Rota/Adeno examan TM stick
Rotavirus antigen (Qualitative) (Feces)	Feces		BD Rota/Adeno examan TM stick
(1→3)-β-D-Glucan	Plasma		β-Glucan Test Wako
Serologic test for syphilis (STS) (Quantitative)	Serum		LASAY auto RPR
Influenza virus antigen (Qualitative)	Others		Fuji Dry-Chem IMMUNO AG Cartridge FluAB
Streptococcus pneumoniae capular antigen (fluid, urinary)	Urine		Quick Chaser Streptococcus pneumoniae/Legionella
Treponema pallidum antibody (Quantitative)	Serum		LASAY auto TPAb
adenovirus antibody (Qualitative) (remove feces)	Others		Check Ad
HTLV-I antibody	Serum		Lumipulse Presto HTLV I / II
The group of Mycobacterium antigen (Qualitative)	Sputum	Others	Mycobacterium tuberculosis complex antigen kit(Capilia TB-Neo)
Endotoxin	Plasma		Endotoxin-single Test Wako
Legionella pneumophila antigen (Urinary)	Urine		Quick Chaser Streptococcus pneumoniae/Legionella
HIV-1,2 Antigen, antibody simultaneous measurement (Quantitative)	Serum		Lumipulse Presto HIV Ag/Ab
d Hepatitis and relates			
HBe antigen	Serum		Lumipulse Presto HBeAg
HBe antibody	Serum		Lumipulse Presto HBeAb
HBs antigen (Qualitative, Semi-quantitative)	Serum		Lumipulse Presto HBsAg-HQ
HBs antibody (Qualitative)	Serum		Lumipulse Presto HBsAb-III
HBs antibody (Quantitative)	Serum		Lumipulse Presto HBsAb-III
HBe antibody (Semi-quantitative, Quantitative)	Serum		Lumipulse Presto HBeAb-III
e Autoantibody			
Anti RNP antibody (Quantitative)	Serum		UniCAP Elia UIRNP antigen-well
Anti Sm antibody (Quantitative)	Serum		UniCAP Elia Sm antigen-well
Anti Jo-1 antibody (Quantitative)	Serum		UniCAP Elia Jo-1 antigen-well
Anti centromere antibody (Quantitative)	Serum		UniCAP Elia CENP-B antigen-well
Matrix metalloproteinase-3 (MMP-3)	Serum		LZtest'eiken' MMP-3



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Scope of accreditation :

Item	Type of Samples		Test Method
Serine proteinase 3-anti-neutrophil cytoplasmic antibody (PR3-ANCA)	Serum		STACIA MEBLuxTMtest PR3-ANCA
Anti neutrophil cytoplasmic myeloperoxidase antibody (MPO-ANCA)	Serum		STACIA MEBLuxTMtest MPO-ANCA
Anti Thyroglobulin antibody	Serum		Ekurusis reagent TgAb
Anti Thyroid peroxidase antibody	Serum		Ekurusis reagent TPOAb
Anti TSH receptor antibody (TRAb)	Serum		Ekurusis reagent TRAb
Anti-nuclear antibody antibody (fluorescent treponemal antibody) (Quantitative)	Serum		Premmune Hep20-10FANA 「cosmic」
Anti SS-A/Ro antibody (Quantitative)	Serum		UniCAP Elia SS-A/Ro antigen-well
Anti SS-B/La antibody (Quantitative)	Serum		UniCAP Elia SS-B/La antigen-well
Anti Scl-70 antibody (Quantitative)	Serum		anti-Scl-70antibody kit ELIA Scl-70s
Anti DNA antibody (Quantitative)	Serum		UniCAP Elia dsDNA antigen-well
Anti citrullinated peptide antibody (Quantitative)	Serum		STACIA MEBLuxTMtestCCP
IgG4	Serum		N-Assay LA IgG4 Nittobo
f Immunology for plasma protein			
CH50	Serum		complement activity-HA test wako
TARC	Serum		HISCL TARC
β2-microglobulin	Serum	Urine	N-assay LA β2-MG-HII
Non-specific immunoglobulin IgE (Quantitative)	Serum		IgE-latex 「seiken」
Specific immunoglobulin IgE (Semi-Quantitative Qualitative) / (Quantitative)	Serum		UniCAP Specific-IgE
16 Microbiology			
b Bacterial culture and identification / Antimicrobial sensitivity test(general bacteria)			
Examination for drug sensitivity test, yeastlike fungi	Blood	Others	Yeast Antimicrobial sensitivity testing Kit ASTY
c Identification of nucleic acid (genetic testing)			
E. coli vero cytotoxin (Qualitative)	Feces		Duopath Verotoxins
17 Gene-related / Chromosome test			
b Identification of pathogen nucleic acid			
DNA amplification assay for Mycobacteria tuberculosis complex	Sputum	Others	DNA amplification assay for Mycobacterium tuberculosis complex(GENE CUBE)
Mycobacterium avium / intracellulare DNA	Sputum	Others	DNA amplification assay for Mycobacterium avium/intracellulare (GENE CUBE)
Quantification of HBV nucleic acid (Quantitative)	Serum		Cobas 6800/8800 system HBV
DNA amplification assay for SARS Coronavirus	Others	Sputum	Cobas SARS-CoV-2 & FluA/B
d Germline gene test			
UDP uridine diphosphate glucuronosyltransferase	Blood		Quenching Probe(i-densy IS-5320)
Pathology			
31 Preparation			
a Preparation for histodiagnosis			
Organize slices	Tissues		Hematoxylin-Eosin Stain
CELL BLOCK	Others		Paraffin-agar sandwich method
c Preparation for immunological stain (histodiagnosis)			
Estrogen receptor	Tissues		Ventana ultraView confirm ER(SPI) ultraView DAB universal kit Roche Bench Marke ULTRA



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Scope of accreditation :

Item	Type of Samples		Test Method
Progesterone receptor	Tissues		Ventana ultraView confirm PgR(1E2) ultraView DAB universal kit Roche Bench Marke ULTRA
Human epidermal growth factor receptor-2	Tissues		Ventana ultraView Pathway HER2(4B5) ultraView DAB universal kit Roche Bench Marke ULTRA
Anaplastic lymphoid kinase fusion protein	Tissues		Ventana OptiView ALK(D5F3) Ventana OptiView DAB universal kit Roche Bench Marke ULTRA
Others	Tissues		I-VIEW DAB universal kit OptiView DAB universal kit ultraView DAB universal kit Roche Bench Marke ULTRA Bond Polymer Refine kit Leica BOND
d Preparation for rapid pathologic daiagnosis			
Preparation for operative rapid pathologic daiagnosis	Tissues		Hematoxylin-Eosin Stain
Preparation for operative rapid cytodiagnosis	Others		Papanicolaou stain ,Hemacolor stain
e Cytodiagnosis			
Gynecology	Others		Papanicolaou stain
Fine needle aspiration cytology,Body cavity washing	Punctured fluid	Others	Papanicolaou stain, May Giemsa stain
32 Pathological diagnosis			
a Pathological diagnosis			
Histology	Tissues		Hematoxylin-Eosin Stain
Cytology	Punctured fluid	Others	Papanicolaou stain, May Giemsa stain, Hemacolor stain
Physiology			
101 Physiology			
a Respiratory function test (Spirography)			
Slow vital capacity			CHESTAC-9900,CHESTAC-8900, CHESTGRAPH HI-301U
Forced vital capacity			CHESTAC-9900,CHESTAC-8900, CHESTGRAPH HI-301U
Functional Residual Capacity			CHESTAC-9900
Closing volume			CHESTAC-9900
DLCO (diffusing capacity of CO)			CHESTAC-9900
b Electrocardiogram			
At least 12 leads including limb monopole lead and the chest leads			ECG-2550
d Electroencephalography			
Electroencephalography (PS, HV)			BEG-1200

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