



Medical Laboratory
Accreditation
Certificate

Accreditation No. RML00970



***Incorporated School of Kurume University
Department of Clinical Laboratory Medicine,
Department of Pathology,
Kurume University Hospital***

***67, Asahi-machi, Kurume-shi, Fukuoka-ken, 830-0011
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	: December 31, 2023

Revised	May 28, 2021
Renewed	December 4, 2019
Initial accreditation	December 17, 2015

Y. Iizuka, President

Japan Accreditation Board



***Incorporated School of Kurume University
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Incorporated School of Kurume University
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67, Asahi-machi, Kurume-shi, Fukuoka-ken, 830-0011 Japan
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	CLINITEC Novus Urinalysis Cassette 10
Protein quantitation	Urine	Punctured fluid MicroTP-Wako
Glucose quantitation		GA-1172 Ltype Wako Glu2
Hemoglobin, feces	Feces	IG auto Hem
Sedimentary test, urine	Urine	New Uristain
2 Hematology		
a Blood count / blood cell morphology test		
Peripheral blood general test*(complete blood counts)* : RBC, WBC, Hgb, PLT, Hct	Blood	XN-10
Reticulocytes	Blood	XN-10
Hemogram (The microscope method)	Blood	SP-50
Hemogram (The automatic analyser method)	Blood	XN-10
b Thrombus / hemostasis related test		
Prothrombin time(PT)	Plasma	Coagpia PT-Liquid
Activated partial thromboplastin time(APTT)	Plasma	Coagpia APTT-N
Fibrinogen (Quantitative)	Plasma	Coagpia Fbg
Fibrinogen degradation products(FDP)	Plasma	Nanopia P-FDP
3 Biochemistry I		
a Biochemistry		
Total bilirubin	Serum	IatoroLQ T-BIL II
Bilirubin, indirect and direct	Serum	IatoroLQ D-BIL (A)
Total protein	Serum	Ltype Wako TP
Albumin	Serum	Ltype Wako ALB-BCP
Proteins fractionation	Serum	Urine Epalyzer2 Junior
Urea nitrogen(BUN)	Serum	Urine Ltype Wako UN ·V
Creatinine	Serum	Urine Ltype Wako CRE ·M
Uric acid	Serum	Urine Ltype Wako UA·M
Na and Cl	Serum	Urine Hitachi ionic electrode reagent
K	Serum	Urine Hitachi ionic electrode reagent



Accreditation Certificate
Appendix

(Page 2/8)

Accreditation No. RML00970

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Scope of accreditation :

Item	Type of Samples		Test Method
Ca	Serum	Urine	Ltype Wako Ca
Inorganic phosphate and phosphoric acid	Serum	Urine	Ltype Wako Inorganic phosphate
Mg	Serum	Urine	Ltype Wako Mg · N
Total cholesterol	Serum		Ltype Wako CHO · M
Triglyceride	Serum		Ltype Wako TG · M
HDL-cholesterol	Serum		Ltype Wako HDL-C · M
LDL-cholesterol	Serum		Ltype Wako LDL-C · M
Glycated albumin	Serum		Lucica GA-L
Glucose	Plasma	Urine	GA-1172
Hemoglobin A1c (HbA1c)	Blood		HA-8182
Fe	Serum		Ltype Wako Fe · N
Unsaturated iron binding capacity (UIBC)	Serum		Ltype Wako UIBC
Ammonia	Plasma		Cika Liquid NH3
Alkaline phosphatase	Serum		Ltype Wako ALP·IFCC
Cholinesterase	Serum		Ltype Wako ChE·J
γ-glutamyltranspeptidase (γ-GT)	Serum		Ltype Wako γ-GT·J
Lactate dehydrogenase (LD)	Serum		Ltype Wako LD·IF
Amylase	Serum	Urine	Ltype Wako AMY·IF
Creatine kinase (CK)	Serum		Cygnus auto CK
Aspartate aminotransferase (AST)	Serum		Ltype Wako AST·J2
Alanine aminotransferase (ALT)	Serum		Ltype Wako ALT·J2
Blood gas analysis	Blood		RAPIDPoint500
5 Immunology			
a Immunochemistry I			
C-reactive protein (CRP)	Serum		LT auto Wako CRP-HS II
Immunglobulin (IgG, IgA, IgM)	Serum		Auto Wako IgG·N Auto Wako IgA·N Auto Wako IgM·N
C3	Serum		Auto Wako C3·N
C4	Serum		Auto Wako C4·N
Immunglobulin (RF)	Serum		LT auto Wako RF
b Immunohematology			
Blood group (ABO type)	Blood		VISION, AUTOVUE Innova II Test tube method
Blood group (Rho (D) factor)	Blood		VISION, AUTOVUE Innova II Test tube method
Indirect Coombs, direct Coombs	Blood		VISION, AUTOVUE Innova II Gamma Peg Ortho anti-human IgG serum (rabbit)
c Infectious disease I			
HBs antigen	Serum		Lumipulse Presto HBsAg-HQ
HCV antibody (Quantitative, Qualitative)	Serum		Lumipulse Presto Ortho HCV
Anti streptolysin O (ASO)	Serum		LTauto Wako ASO
6 Microbiology			
a Microscopic examination for stained film (general bacteria)			
Other	Blood	Sputum	Gram stain Ziehl-Neelsen stain



Accreditation Certificate Appendix

(Page 3/8)

Accreditation No. RML00970

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Item	Type of Samples		Test Method
b Bacterial culture and identification / Antimicrobial sensitivity test (general bacteria)			
Bacterial culture and identification	Urine	Others	MALDI Biotyper smart DxM 1096 Micro Scan Walk Away VITEK II
Anaerobic culture	Punctured fluid	Others	Brucella HK agar(RS)
Antimicrobial sensitivity test (general bacteria)	Urine	Others	DxM 1096 Micro Scan Walk Away
Mycobacterial culture and Isolation (other)	Sputum	Others	Ogawa medium
Non-Basic Series			
11 General (urine, feces, etc.)			
a General urinalysis			
Albumin (Quantitative) (Urinary)	Urine		AutoWako micro albumin
Osmolarity	Urine		OSMO STATION OM-6060
VMA(Qualitative) (Urinary)	Urine		Sato, et al:Tohoku J Exp Med 77:78,1962
N-acetyl glucosaminidase (NAG) (Urinary)	Urine		N-assayL NAG nittobo
Urinary sediment by flow cytometry (Urinary)	Urine		UF-5000
Neutrophil gelatinase-associated lipocalin (NGAL) (Urinary)	Urine		U-NGAL · Abbott
b Scatolscopy			
Parasitic worm eggs (feces)	Feces		Formalin · Ether centrifugal method MGL method
Lipid (feces)	Feces		Sudan III stain
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		Micro TP-test Wako GA-1172 Ltype Wako Glu2 Samson solution
12 Hematology			
a General hematology, hemogram			
Erythrocyte sedimentation rate	Blood		Quick eye-8
Serum osmolality	Serum		OSMO STATION OM-6060
Eosinophils, nasal/sputum smear	Others		May-Gruenwald Stain (Hand method)
b Thrombus / hemostasis related test I			
Antithrombin (activity)	Plasma		Testzym S AT III
Plasminogen (activity)	Plasma		Testzym S PLG
Plasmin inhibitor (Antiplasmin)	Plasma		Testzym S APL
Protein C (activity)	Plasma		Testzym S PC
Coagulation factor inhibitor Qualitative (cross mixing test)	Plasma		Coapresta 2000
Coagulation factor(VIII,XIII)	Plasma		Thrombocheck FACTOR VIII Factor auto II FX III -M
Fibrin monomer	Plasma		Nanopia SF
D dimer	Plasma		Nanopia D-dimer
Thrombin anti-Thrombin complex (TAT)	Plasma		HISCL TAT
c Thrombus / hemostasis related test II			
Bleeding time	Blood		Duke method



Accreditation Certificate Appendix

(Page 4/8)

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Item	Type of Samples		Test Method
13 Biochemistry I			
a Biochemistry I			
Phospholipid	Serum		Ltype Wako phospholipid
Zn	Serum	Urine	Accurass auto Zn
Ketones	Plasma		TKB-L reagent KAINOS
Ketones, fractionation	Plasma	Serum	3HB-L reagent KAINOS
Monocarboxylate	Plasma		DeterminerLA
Bile acids	Serum		Pure auto S TBA
Ethanol	Serum		Flex cartridge alcohol
Cu	Serum		Quick auto neo Cu
Ferritin Quantitative	Serum		LT auto Wako Ferritin
Type IVcollagen	Serum		Panassay IV・C 「Latex」
Procalcitonin (PCT) (Quantitative)	Serum		Accuraseed PCT
b Biochemistry II			
Lipase	Serum		Lipase color auto test Wako
KL-6	Serum		Lumipulse Presto KL-6
Apolipoprotein (AI, AII, B, CII, CIII, E)	Serum		ApoA- I auto・N 「Daiichi」 ApoB- I auto・N 「Daiichi」 ApoE- I auto・N 「Daiichi」
Mac-2 binding protein glycosylated isomers	Serum		HISCL M2BPGi reagent
c Isozyme			
Amylase Isozyme	Serum	Urine	Ltype Wako P-AMY・IF
CK-MB	Serum		Cygnus auto CK-MB MtO
d Immunochemistry			
Cardiac troponin T (TnT) (Qualitative, Quantitative)	Serum		Accuraseed troponin T
14 Biochemistry II			
a Endocrinology I			
Human chorionic gonadotropin (HCG) (Qualitative)	Urine		HCGtestpack・plusOBC
Human chorionic gonadotropin (HCG) (Quantitative)	Serum	Urine	ECLusys reagent HCG II STAT
Thyroid-stimulating hormone (TSH)	Serum		ECLusys reagent TSH
Free triiodothyronine (FT3)	Serum		ECLusys reagent FT3 III
Free thyroxine (FT4)	Serum		ECLusys reagent FT4 III
C-peptide (CPR)	Serum	Urine	ECLusys reagent C-peptide
Insulin (IRI)	Serum		ECLusys reagent Inslin
Growth hormone (GH)	Serum		ECLusys reagent hGH
Follicle-stimulating hormone (FSH)	Serum		ECLusys reagent FSH II
Luteinizing hormone (LH)	Serum		ECLusys reagent LH
Prolactin (PRL)	Serum		ECLusys reagent Prolactin III
Progesterone	Serum		ECLusys reagent Progesterone III
Parathyroid hormones (PTH)	Serum		ECLusys reagent PTH
Estradiol (E2)	Serum		ECLusys reagent E2IV
Cortisol	Plasma		ECLusys reagent Cortisol II
N-terminal pro brain natriuretic peptide (NT-proBNP)	Serum		Accuraseed NT-proBNP
Catecholamines	Plasma	Urine	HLC-725CA II
Renin (Quantitative)	Plasma		Accuraseed Renin(ARC)
Androsterone	Plasma		Accuraseed Aldosterone



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Item	Type of Samples	Test Method
Adrenocorticotrophic hormone (ACTH)	Plasma	ECLusys reagent ACTH
b Tumor marker		
α-fetoprotein (AFP)	Serum	ECLusys reagent AFP II
Carcinoembryonic antigen (CEA)	Serum	ECLusys reagent CEA II
CA19-9	Serum	ECLusys reagent CA19-9 II
CA125	Serum	ECLusys reagent CA125 II
Prostate-specific antigen (PSA)	Serum	ECLusys reagent PSA II
Squamous cell cancer related antigen (SCC)	Serum	ECLusys reagent SCC
CA15-3	Serum	ECLusys reagent CA15-3 II
Cytokeratin 19 fragment	Serum	ECLusys reagent CYFRA
Free PSA/Total PSA ratio	Serum	ECLusys reagent freePSA
PIVKA-II (Quantitative)	Serum	Lumipulse Presto PIVKA- II -N
α-fetoprotein lectin-affinity fraction (AFPL3%)	Serum	μTAS Wako AFP-L3
Inteleukin 2 receptor, soluble (sIL-2R)	Serum	Lumipulse Presto IL-2R
c Special analysis		
Urea breath test (UBT)	Others	UBIT tablets 100mg
15 Immunology		
a Immunohematology		
Blood group, Rh system	Blood	Ortho Anti-C BioClone Ortho Anti-c BioClone Ortho Anti-E BioClone Ortho Anti-e BioClone
Irregular antibody	Blood	VISION, AUTOVUE Innova II Gamma Peg Ortho anti-human IgG serum (rabbit)
b Immunology for infectious disease II		
Mycoplasma pneumoniae antibody (Semi-quantitative)	Serum	SERODIA-MYCO II
c Immunology for infectious disease III		
Clostridium difficile toxin A (Qualitative)	Feces	C.DIFF QUIK CHEK complete
Adenovirus antigen (Qualitative) (Feces)	Feces	DIPSTICK 'Eiken' ADENO
Rotavirus antigen (Qualitative) (Feces)	Feces	DIPSTICK 'Eiken' ROTA IP LINE DUO 「NORO・ROTA」
(1→3)-β-D-Glucan	Plasma	β-glucan test Wako
Serologic test for syphilis (STS) (Quantitative)	Serum	Rapidia auto RPR
Group A-β Streptococcal-rapid Detection (Qualitative)	Others	ImmunoAce Strep A
Influenza virus antigen (Qualitative)	Others	ImmunoAce Flu
Streptococcus pneumoniae in cerebrospinal (fluid, urinary)	Urine	IMMUNOCATCH Streptococcus pneumoniae/Legionella
Treponema pallidum antibody (Quantitative)	Serum	Lumipulse Presto TP
Norovirus antigen (Qualitative)	Feces	IP LINE DUO 「NORO・ROTA」
HTLV-I antibody	Serum	Lumipulse Presto HTLV- I /II
Endotoxin	Plasma	Endotoxin-single test Wako
Legionella pneumophila antigen (Urinary)	Urine	IMMUNOCATCH Streptococcus pneumoniae/Legionella
HIV-1,2 Antigen, antibody simultaneous measurement (Quantitative)	Serum	Lumipulse Presto HIV Ag/Ab



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Item	Type of Samples		Test Method
d Hepatitis and relates			
HBe antigen	Serum		Lumipulse Presto HBeAg
HBe antibody	Serum		Lumipulse Presto HBeAb
HBs antigen (Qualitative, Semi-quantitative)	Serum		espline・HBsAg
HBs antibody (Quantitative)	Serum		Lumipulse Presto HBsAb-N
HBc antibody (Semi-quantitative, Quantitative)	Serum		Lumipulse Presto HBcAb-III
e Autoantibody			
Cold agglutination	Serum		Hemagglutination
Anti RNP antibody (Quantitative)	Serum		STACIA MEBLUX test RNP
Anti Sm antibody (Quantitative)	Serum		STACIA MEBLUX test Sm
Anti Jo-1 antibody (Quantitative)	Serum		STACIA MEBLUX test Jo-1
Anti centromere antibody (Quantitative)	Serum		STACIA MEBLUX test CENP-B
Serine proteinase 3-anti-neutrophil cytoplasmic antibody (PR3-ANCA)	Serum		STACIA MEBLUX test PR3-ANCA
Anti neutrophil cytoplasmic myeloperoxidase antibody (MPO-ANCA)	Serum		STACIA MEBLUX test MPO-ANCA
Anti Thyroglobulin antibody	Serum		ECLusys reagent Anti-Tg
Anti Thyroid peroxidase antibody	Serum		ECLusys reagent Anti-TPO
Anti-nuclear antibody (immunofluorescence) (Semi-Quantitative)	Serum		Fluoro HEPANA2 test
Anti SS-A/Ro antibody (Quantitative)	Serum		STACIA MEBLUX test SS-A
Anti SS-B/La antibody (Quantitative)	Serum		STACIA MEBLUX test SS-B
Anti Scl-70 antibody (Quantitative)	Serum		STACIA MEBLUX test Scl-70
Anti DNA antibody (Quantitative)	Serum		STACIA MEBLUX test dsDNA STACIA MEBLUX test ssDNA
Anti citrullinated peptide antibody (Quantitative)	Serum		STACIA MEBLUX test CCP
f Immunology for plasma protein			
β2-microglobulin	Serum	Urine	LTauto Wako β2m
Immnoelectrophoresis (Singular antiserum)	Serum	Urine	Epalyzer2 Junior
Non-specific immunoglobulin IgE (Quantitative)	Serum		Lumipulse Presto IgE
Transthyretin(Prealbumin)	Serum		Auto Wako pre albumin
16 Microbiology			
b Bacterial culture and identification / Antimicrobial sensitivity test(general bacteria)			
Drug susceptibility test for mycobacteria	Sputum	Others	Drug susceptobolity test for Mycobacteria-Vite Spectrum-SR
c Identification of nucleic acid (genetic testing)			
Staphylococcus aureus penicillin-binding protein 2' (PBP2') (Qualitative)	Others		MRSA-LA[seiken]
E. coli vero cytotoxin (Qualitative)	Others		Duopath Verotoxins
17 Gene-related / Chromosome test			
a Somatic gene test			
Preparation for HER2 gene specimen	Tissues		Dual Color in situ Hybridization
EGFR genetic testing (Plasma)	Plasma		The real-time PCR method (the cobas EGFR Mutation Test v2.0)
EGFR genetic test (other than the real-time PCR method), K-ras genetic test, EWS-FII1 genetic test, TLS-CHOP genetic test, SYT-SSX genetic test, c-kit genetic test, examination for microsatellite uneasiness (Qualitative), sentinel lymph node biopsy, BRAF genetic test, RAS genetic test, ROS1 genetic test	Tissues		The real-time PCR method (the cobas EGFR Mutation Test v2.0)



Accreditation Certificate Appendix

(Page 7/8)

Accreditation No. RML00970

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Scope of accreditation :

Item	Type of Samples		Test Method
b Identification of pathogen nucleic acid			
DNA amplification assay for Mycobacteria tuberculosis complex	Sputum	Others	Cobas TaqMan MTB
Mycobacterium avium / intracellulare DNA	Sputum	Others	Cobas TaqMan MAI
Quantification of HBV nucleic acid (Quantitative)	Plasma		cobas6800/8800 System HBV
HCV DNA (Quantitative)	Serum		cobas6800/8800 System HCV
18 Others excluding 11 to 16 class			
a Therapeutic drug monitoring			
Digitoxin, Digoxin	Serum		Flex cartridge Digoxin (N) DGNA
Valproic acid, Carbamazepine	Serum		Flex cartridge Valproic acid VALP Flex cartridge Carbamazepine (N) CRBM
Phenytoin, Primidone, Ethosuximide, Phenobarbital, Zonisamide, Nitrazepam, Clonazepam, Others	Serum		Flex cartridge Phenytoin (N) PTN Flex cartridge Phenobarbital (N) PHNO
Lithium	Serum		Flex cartridge Lithium LI
Vancomycin, Teicoplanin, Gentamicin, Tobramycin, Amikacin, Arbekacin, Voriconazole	Serum		Flex cartridge Vancomycin (N) VANC Nanopia TDM Teicoplanin Nanopia TDM Arbekacin
Cyclosporin, Tacrolimus hydrat, Everolimus, Mycophenolate mofetil	Blood		Flex cartridge Cyclosporin CSA ECLusys reagent Tacrorimus
Methotrexate	Serum		Nanopia eTDM Methotrexate
Pathology			
31 Preparation			
a Preparation for histodiagnosis			
Organize slices	Tissues		Hematoxylin & Eosin stain
CELL BLOCK	Punctured fluid		Hematoxylin & Eosin stain
c Preparation for immunological stain (histodiagnosis)			
Estrogen receptor	Tissues		Immunohistochemistry
Progesterone receptor	Tissues		Immunohistochemistry
Human epidermal growth factor receptor-2	Tissues		Immunohistochemistry
Anaplastic lymphoid kinase fusion protein	Tissues		Immunohistochemistry
d Preparation for rapid pathologic daiagnosis			
Preparation for operative rapid pathologic daiagnosis	Tissues		Hematoxylin & Eosin stain
Preparation for operative rapid cytodiagnosis	Punctured fluid		Papanicolaou stain, Diff-Quik stain
e Cytodiagnosis			
Gynecology	Others		Papanicolaou stain
Fine needle aspiration cytology, Body cavity washing	Punctured fluid		Papanicolaou stain, May-Gruenwald Stain



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Item	Type of Samples	Test Method
32 Pathological diagnosis		
a Pathological diagnosis		
Histology	Tissues	Hematoxylin & Eosin stain
Cytology	Others	Papanicolaou stain
Physiology		
101 Physiology		
a Respiratory function test (Spirography)		
Slow vital capacity		CHESTAC-8900 CHESTAC-9900
Forced vital capacity		CHESTAC-8900 CHESTAC-9900
b Electrocardiogram		
At least 12 leads including limb monopole lead and the chest leads		cardiofax V ECG-2450
d Electroencephalography		
Electroencephalography (PS, HV)		Neurofax EEG-1260