

Medical Laboratory
Accreditation
Certificate

Accreditation No. RML00970



JAB



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

67, Asahi-machi, Kurume-shi, Fukuoka, 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, 2019

This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system.

The management system requirements meet the principles of ISO 9001:2008 and are aligned with its pertinent requirements.

Revised (2)	May 15, 2018
Initial accreditation	December 17, 2015

K. Watanabe, Chairman
Medical Laboratory Accreditation Committee

Y. Mizuka, President
Japan Accreditation Board



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Including primary sample collection in the scope of accreditation

Scope of accreditation :

Basic Series	Item	Type of Samples		Test Method
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	Urine		GA-1172 Ltype Wako Glu2
	Hemoglobin, feces	Feces		IG auto Hem
	Sedimentary test, urine	Urine		New urine stain
2	Hematology			
a	Blood test			
	Peripheral blood general test*(complete blood counts)* : RBC,WBC,Hgb,PLT,Hct	Blood		XE-5000
	Reticulocytes	Blood		XE-5000
	Hemogram (The microscope method)	Blood		SP-1000i
	Hemogram (The automatic analyser method)	Blood		XE-5000
b	Coagulation/fibrinolysis			
	Prothrombin time(PT)	Plasma		Coagpia PT-N
	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	Hematochemistry I			
	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	Epalyzer 2
	Urea nitrogen(BUN)	Serum	Urine	Ltype Wako UN ·V
	Creatinine	Serum	Urine	Ltype Wako CRE ·M
	Uric acid	Serum	Urine	Ltype Wako UA ·M



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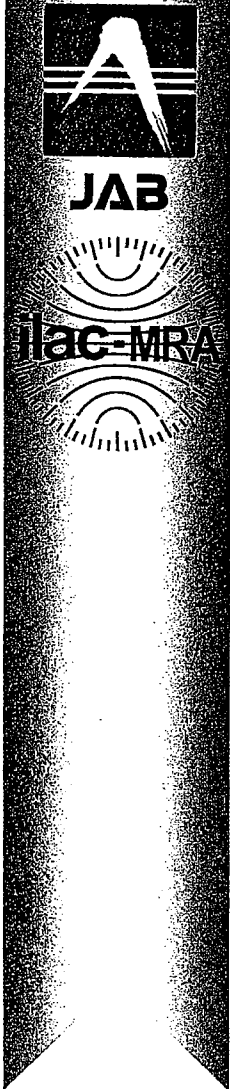
Scope of accreditation

Item	Type of Samples		Test Method
	Serum	Urine	
Na and Cl	Serum	Urine	Hitachi ionic electrode reget
K	Serum	Urine	Hitachi ionic electrode reget
Ca	Serum	Urine	Ltype Wako Ca
Inorganic phosphate and phosphoric acid	Serum	Urine	Ltype Wako Inorganic phosphate
Mg	Serum	Urine	Ltype Wako Mg
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	Serum	Urine	GA-1172
Hemoglobin A1c (HbA1c)	Serum		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·J2
Cholinesterase	Serum		Ltype Wako ChE·J
γ-glutamyltranspeptidase(γ-GT)	Serum		Ltype Wako γ-GT·J
Lactate dehydrogenase(LD)	Serum		Ltype Wako LD·J
Amylase	Serum	Urine	Ltype Wako Amylase
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
Immunoglobulin (IgG,IgA,IgM,IgD)	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
Immunoglobulin(RF)	Serum		LT auto Wako RF
b Immunohematology			
Blood group (ABO type)	Blood		AUTOVUE Innova, AUTOVUE Innova II Test tube method
Blood group(Rho(D) factor)	Blood		AUTOVUE Innova, AUTOVUE Innova II Test tube method
Indirect Coombs,direct Coombs	Blood		AUTOVUE Innova, AUTOVUE Innova II Gamma Peg Ortho anti-human IgG serum (rabbit)

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Scope of accreditation

Item	Type of Samples		Test Method
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
b Bacterial culture and identification			
Antimicrobial sensitivity test (general bacteria)			
Bacterial culture and identification	Urine	Others	Walk Away 96 plus VITEK II
Anaerobic culture	Punctured fluid	Others	Brucella HK agar(RS)
Antimicrobial sensitivity test (general bacteria)	Urine	Others	Walk Away 96 plus
Mycobacterial culture and Isolation (other)	Sputum	Others	Ogawa medium Kudou 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-assay L NAG nittobo
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		SESR-2001
Serum osmolality	Serum		OSMO STATION OM-6060
Eosinophils, nasal/sputum smear	Others		Hand method
b Coagulation, fibrinolysis I			
Antithrombin (activity)	Plasma		Test team S AT III
Plasminogen (activity)	Plasma		Test team S PLG
Plasmin inhibitor (Antiplasmin)	Plasma		Test team S APL
Protein C (activity)	Plasma		Test team S PC



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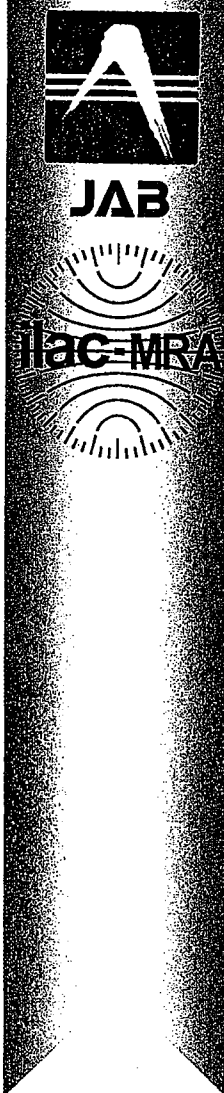
Scope of accreditation

Item	Type of Samples		Test Method
Coagulation factor inhibitor Qualitative (cross mixing test)	Plasma		Coapresta 2000
Coagulation factor(II, V, VII, VIII, IX, X, XI, XII, XIII)	Plasma		Thromb check FACTOR VIII Factor auto II FX III-M
Fibrin monomer	Plasma		Nanopia SF
D dimer	Plasma		Nanopia Ddimer
Thrombin anti-Thrombin complex (TAT)	Plasma		PATHFAST TAT
c Coagulation, fibrinolysis II			
Bleeding time	Blood		Duke method
13 Biochemistry I			
a Hematochemistry I			
Phospholipid	Serum		Ltype Wako phospholipid
Zn	Serum	Urine	Accurass auto Zn
Ketones	Plasma		Total ketone bodies KAINOS
Ketones, fractionation	Plasma	Serum	3-HB KAINOS
Monocarboxylate	Plasma		DetaminaLA
Bile acids	Serum		Pure auto S TBA
Ethanol	Serum		Flex cartridge alcohol
Cu	Serum		Quick auto neo Cu
Ferritin Quantitative	Serum		Ltype Wako ferritin
Type IV collagen	Serum		Panassay IV-C [Latex]
Procalcitonin (PCT) (Quantitative)	Serum		SphereLight brahms PCT
b Hematochemistry 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]
c Isozyme			
Amylase Isozyme	Serum	Urine	Ltype Wako P-AMY
CK-MB	Serum		Cygnus auto CK-MB MtO
d Immunochemistry			
Cardiac troponin T (TnT) (Qualitative, Quantitative)	Serum		SphereLight troponin T
14 Biochemistry II			
a Endocrinology I			
Human chorionic gonadotropin(HCG)(Qualitative)	Urine		HCGtestpack plusOBC
Human chorionic gonadotropin(HCG)(Quantitative)	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 II
C-peptide (CPR)	Serum		ECLusys reagent C-peptide
Insulin (IRI)	Serum		ECLusys reagent Inslin
Growth hormone (GH)	Serum		ECLusys reagent hGH

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Item	Type of Samples		Test Method
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
Estradiol (E2)	Serum		ECLusys reagent E2IV
N-terminal pro brain natriuretic peptide (NT-proBNP)	Serum		SphereLight proBNP
Catecholamines	Plasma	Urine	HLC-725CA II
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 eisai
α-fetoprotein lectin-affinity fraction (AFPL3%)	Serum		μTAS Wako AFP-L3
Inteleukin 2 receptor,soluble (sIL-2R)	Serum		STACIA CLEIA IL-2R
c Special analysis			
Urea breath test (UBT)	Others		UBIT tablets 100mg
15 Immunology			
a Immunohematology			
Blood group, Rh system	Blood		Anti-C antibody·neo 「KOKUSAI」 Anti-c antibody·neo 「KOKUSAI」 Anti-E antibody·neo 「KOKUSAI」 Anti-e antibody·neo 「KOKUSAI」
Irregular antibody	Blood		AUTOVUE Innova, 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
(1→3)-β-D-Glucan	Plasma		β-glcان test Wako
Serologic test for syphilis(STS)(Quantitative)	Serum		Rapidia auto RPR

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Item	Type of Samples	Test Method
Group A, B Streptococcal-rapid Detection (Qualitative)	Others	Immuno ace Strep A
Influenza virus antigen (Qualitative)	Others	Immuno ace Flu
Staphylococcus aureus penicillin-binding protein 2 (PBP2) (Qualitative)	Others	MRSA-LA [seiken]
Streptococcus pneumoniae in cerebrospinal fluid, urinary)	Urine	BinxNOW Streptococcus pneumoniae
E. coli verotoxin (Qualitative)	Others	Duopath Verotoxins
Treponema pallidum antibody (Quantitative)	Serum	Lumipulse Presto TP
Norovirus antigen (Qualitative)	Feces	GEtest immunochromato-Noro [Nissui]
HTLV-I antibody	Serum	Lumipulse Presto HTLV- I / II
Endotoxin	Plasma	Endotoxin-single test Wako
Legionella pneumophila antigen (Urinary)	Urine	BinaxNOW Legionella pneumophila
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	esplain 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 regent Anti-Tg
Anti Thyroid peroxidase antibody	Serum	ECLusys regent Anti-TPO
anti-nuclear antibody (immunofluorescence) (Semi-Quantitative)	Serum	Fluoro HEPANA 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
Immunolectrophoresis	Serum Urine	Epalyzer 2
Non-specific immunoglobulin IgE (Quantitative)	Serum	Lumipulse Presto IgE
Transthyretin (Prealbumin)	Serum	Auto Wako pre albumin

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Scope of accreditation:

Item	Type of Samples		Test Method
16 Microbiology			
b Bacterial culture and identification Antimicrobial sensitivity test (general bacteria)			
Drug susceptibility test for mycobacteria	Sputum	Others	Well pack S
c Identification of nucleic acid (genetic testing)			
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
17 Others excluding 11 to 16 class			
b Therapeutic Drug Monitoring			
Digitoxin, Digoxin	Serum		Flex cartridge Digoxin (N) DGNA
Theophylline	Serum		Flex cartridge Theophylline (N) THEO
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 Emit Primidone assay 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	Blood		Nanopia eTDM Methotrexate



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Item	Type of Samples	Test Method
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-1550
d Electroencephalography		
Electroencephalography (PS, HV)		Neurofax EEG-1200

Japan Accreditation Board