



JAB



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

Renewed (1)	December 4, 2019
Initial accreditation	December 17, 2015

Y. Iizuka, President

Japan Accreditation Board

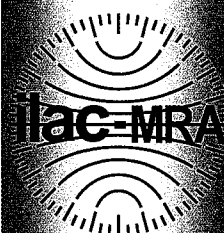
Accreditation Certificate Appendix

(Page 1/8)

Accreditation No. RML00970



JAB



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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), 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 Uristain
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
Na and Cl	Serum	Urine Hitachi ionic electrode reagent
K	Serum	Urine Hitachi ionic electrode reagent

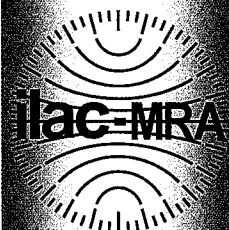
Accreditation Certificate Appendix

(Page 2/8)

Accreditation No. RML00970



JAB



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Scope of accreditation :

Item	Type of Samples		Test Method
	Serum	Urine	
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 · 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		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

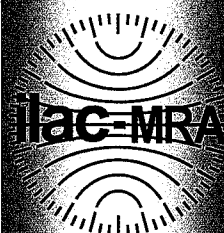
Accreditation Certificate Appendix

(Page 3/8)

Accreditation No. RML00970



JAB



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Item	Type of Samples		Test Method
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	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
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
d Examination of malignant tumor tissue			
EGFR genetic test (other than the real-time PCR method)	Tissues		The real-time PCR method (the cobas EGFR Mutation Test v2.0)
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		Testzym S ATIII
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 (II, V, VII, VIII, IX, X, XI, XII, 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

Accreditation Certificate Appendix

(Page 4/8)

Accreditation No. RML00970



JAB



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Item	Type of Samples	Test Method
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	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 Hematochemistry II		
Lipase	Serum	Lipase color auto test Wako
KL-6	Serum	Lumipulse Presto KL-6
Apolipoprotein (AI,AII,B,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
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
Estradiol (E2)	Serum	ECLusys reagent E2IV
Cortisol	Plasma	ECLusys reagent Cortisol II

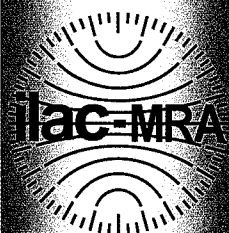
Accreditation Certificate Appendix

(Page 5/8)

Accreditation No. RML00970



JAB



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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
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

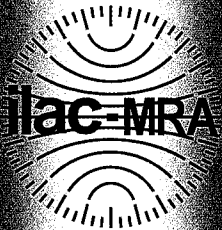
Accreditation Certificate Appendix

(Page 6/8)

Accreditation No. RML00970



JAB



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Item	Type of Samples		Test Method
Staphylococcus aureus penicillin-binding protein 2'(PBP2') (Qualitative)	Others		MRSA-LA「seiken」
Streptococcus pneumoniae in cerebrospinal (fluid, urinary)	Urine		BinaxNOW Streptococcus pneumoniae
E. coli vero cytotoxin (Qualitative)	Others		Duopath Verotoxins
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		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		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 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
Immnoelectrophoresis	Serum	Urine	Epalyzer 2
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

Accreditation Certificate Appendix

(Page 7/8)

Accreditation No. RML00970



JAB



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Scope of accreditation :

Item	Type of Samples		Test Method
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			
Digoxin	Serum		Flex cartridge Digoxin (N) DGNA
Valproic acid, Carbamazepine	Serum		Flex cartridge Valproic acid VALP Flex cartridge Carbamazepine (N) CRBM
Phenytoin, Phenobarbital	Serum		Flex cartridge Phenytoin (N) PTN Flex cartridge Phenobarbital (N) PHNO
Lithium	Serum		Flex cartridge Lithium LI
Vancomycin, Teicoplanin, Arbekacin	Serum		Flex cartridge Vancomycin (N) VANC Nanopia TDM Teicoplanin Nanopia TDM Arbekacin
Cyclosporin, Tacrolimus hydrat,	Blood		Flex cartridge Cyclosporin CSA ECLusys reagent Tacrorimus
Methotrexate	Serum		Nanopia eTDM Methotrexate
Pathology			
31 Preparation			
a Preparation for histodiagnosis			
Preparation for histodiagnosis	Tissues		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
CELL BLOCK	Punctured fluid		Hematoxylin & Eosin stain

Accreditation Certificate
Appendix

(Page 8/8)

Accreditation No. RML00970



JAB



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Scope of accreditation :

Item	Type of Samples	Test Method
f Preparation for HER2 gene specimen for ALK fused gene specimen		
Preparation for HER2 gene specimen	Tissues	Dual Color in situ Hybridization
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-1550
d Electroencephalography		
Electroencephalography (PS, HV)		Neurofax EEG-1200

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