



Medical Laboratory
Accreditation
Certificate

Accreditation No.RML00150

***Kumamoto University
Kumamoto University Hospital,
Clinical Laboratory/Transfusion Medicine and Cell Therapy
/Surgical Pathology***

***1-1-1, Honjo, Chuo-ku, Kumamoto city, Kumamoto,
860-8556 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	: August 31, 2026

Revised	October 10, 2023
Renewed	September 1, 2022
Initial accreditation	August 30, 2006

Y. Iizuka, President

Japan Accreditation Board



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1-1-1, Honjo, Chuo-ku, Kumamoto city, Kumamoto, 860-8556 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	kurinitekku nobasushiyaku kasetto (siemensuherusukea · daiagunosutekusu kabusikigaisya)
Protein quantitation	Urine	maikuroTP-tesutowako2
Glucose quantitation	Urine	akuaotokainosu GLU shiyaku
Hemoglobin, feces	Feces	OC-Hemodia®auto III 'Eiken'
Sedimentary test, urine	Urine	Sternheimer Stain Solution
2 Hematology		
a Blood count / blood cell morphology test		
Peripheral blood general test*(complete blood counts)* : RBC, WBC, Hgb, PLT, Hct	Blood	SULFOLYSER
Reticulocytes	Blood	fururoseru RET
Hemogram (The microscope method)	Blood	Meigimuza
Hemogram (The automatic analyser method)	Blood	raizaseruWDF · WNR fururoseruWDF · WNR
b Thrombus / hemostasis related test		
Prothrombin time(PT)	Plasma	Coagpia PT-N thromplastin
Activated partial thromboplastin time(APTT)	Plasma	Coagpia APTT-N
Fibrinogen (Quantitative)	Plasma	Coagpia Fbg thrombin
Fibrinogen degradation products(FDP)	Plasma	erupia FDP-P
D dimer(Quantitative)	Plasma	LIPA jeneshisu Ddimer
3 Biochemistry I		
a Biochemistry		
Total bilirubin	Serum	iatoro LQ T-BIL II
Bilirubin, indirect and direct	Serum	iatoro LQ T-BIL(A)
Total protein	Serum	akuaotokainosu TP- II shiyaku
Albumin	Serum	akuaotokainosu ALB shiyaku
Proteins fractionation	Serum	sereka-VSP
Urea nitrogen(BUN)	Serum Urine	akuaotokainosu UN- II shiyaku
Creatinine	Serum Urine	akuaotokainosu CRE-IIIplus
Uric acid	Serum Urine	akuaotokainosu UA- II shiyaku
Na and Cl	Serum Urine	JEOL clinalyzer ELA-IS Internal Standard fluid
K	Serum Urine	JEOL clinalyzer ELA-IS Internal Standard fluid



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Item	Type of Samples		Test Method
	Serum	Urine	
Ca	Serum	Urine	「serotekku」 Ca-AL
Inorganic phosphate and phosphoric acid	Serum	Urine	「serotekku」 Pi-AS
Mg	Serum	Urine	「serotekku」 Mg-L
Total cholesterol	Serum		detamina L TC II
Triglyceride	Serum		detamina L TG II
HDL-cholesterol	Serum		metaborido HDL-C
LDL-cholesterol	Serum		metaborido LDL-C
Glycated albumin	Serum		rushika GA-L2
Glucose	Serum	Plasma	akuaotokainosu GLU shiyaku gurukosu BP STD
Hemoglobin A1c (HbA1c)	Blood		HSi youketu・senjoueki (L) HSi dai1eki (S) HSi dai2eki (S) HSi dai3eki (S)
Fe	Serum		kuikkuoto neo Fe
Unsaturated iron binding capacity (UIBC)	Serum		kuikkuoto neo UIBC
Ammonia	Plasma		sikarikiddo NH3(SPS-A)
Alkaline phosphatase	Serum		「serotekku」ALP-IF
Cholinesterase	Serum		kuikkuo-to neo Ch-E
γ-glutamyltranspeptidase (γ-GT)	Serum		ekudhia XL'eiken'r-GTP II
Lactate dehydrogenase (LD)	Serum		「serotekku」LD-IF
Amylase	Serum		「serotekku」AMY-EL
Creatine kinase (CK)	Serum		N-assei L CPK-S nittobo
Asparate aminotransferase (AST)	Serum		N-assei L AST nittobo
Alanine aminotransferase (ALT)	Serum		N-assei L ALT nittobo
5 Immunology			
a Immunochemistry I			
C-reactive protein (CRP)	Serum		CRP-ratekkusu X2 「seiken」 NX
Immunoglobulin (IgG, IgA, IgM, IgD)	Serum		N-assei TIA IgG-SH nittobo N-assei TIA IgA-SH nittobo N-assei TIA IgM-SH nittobo
C3	Serum		N-assei TIA C3-SH nittobo N-assei TIA C4-SH nittobo
C4	Serum		N-assei TIA C3-SH nittobo N-assei TIA C4-SH nittobo
Immunoglobulin (RF)	Serum		LZ tesuto 'eiken'RF
b Immunohematology			
Blood group (ABO type)	Blood		Ortho baiobyu kouA,kouB,kouD kasetto
Blood group (Rho (D) factor)	Blood		Ortho baiobyu kouA,kouB,kouD kasetto
Indirect Coombs, direct Coombs	Blood		ganma kurohn kouIgG
c Infectious disease I			
HBs antigen	Serum		aakitekutoHBsAg QT
HBs antibody	Serum		aakitekuto oosabu
HCV antibody (Quantitative, Qualitative)	Serum		HCV Ab・abotto
HIV-1,2 antigen and antibody simultaneous measurement	Serum		aakitekuto HIV Ag/Ab konboassei esupurainHIV Ag/Ab
Serologic test for syphilis (STS) (Qualitative)	Serum		medexie-du RPR
Serologic test for syphilis (Qualitative)	Serum		akyurasuo-to TP koutai
SARS coronavirus antigen	Secretions		ekuruusisuiyaku SARS-CoV-2 Ag



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Item	Type of Samples		Test Method
6 Microbiology			
a Microscopic examination for stained film (general bacteria)			
Other	Sputum	Urine	feibaG
Use a fluorescent microscope	Sputum	Urine	feibaG
b Bacterial culture and identification / Antimicrobial sensitivity test (general bacteria)			
Bacterial culture and identification kenkiseikindouteikit rapid ID32Aapi	Sputum	Urine	baitarumedeia tori • soiketsuekikantenbaichi (hitsuji) No.2
Anaerobic culture	Punctured fluid	Secretions	MicroScan PC3.1J
Antimicrobial sensitivity test (general bacteria)	Sputum	Urine	IA-40MIC-I, DPS192ix
Non-Basic Series			
11 General (urine, feces, etc.)			
a General urinalysis			
Albumin (Quantitative) (Urinary)	Urine		N-assei TIA Micro Alb
Osmolarity	Urine		ARKRAY OSMO STATION OM-6050
N-acetyl glucosaminidase (NAG) (Urinary)	Urine		N-assei L NAG nittobo
Urinary sediment by flow cytometry (Urinary)	Urine		UF-CELLSHATH
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)	Others		maikuroTP-tesutowako2 akuaotokainosu GLU shiyaku raizasel WDF
12 Hematology			
a General hematology, hemogram			
Erythrocyte sedimentation rate	Blood		Roller 20PN
Serum osmolality	Serum		Weisberg no shintouatusiki
b Thrombus / hemostasis related test I			
Antithrombin (activity)	Plasma		testoteam S AtIII
Plasminogen (activity)	Plasma		testoteam S PLG
Plasmin inhibitor (Antiplasmin)	Plasma		testoteam S APL
Plasmin inhibitor/plasmin complex (PIC)	Plasma		riasuauto PIC
Protein C (activity)	Plasma		testoteam S PC
PIVKA II	Serum		rumiparusu PIVKA II
Fibrin monomer	Plasma		nanopi SF
Thrombin anti-Thrombin complex (TAT)	Plasma		HISCL TAT
13 Biochemistry I			
a Biochemistry I			
Zn	Serum		akyurasuoto Zn
Ketones	Plasma		TKB-L shiyakukainosu
Ketones, fractionation	Plasma		TKB-L shiyakukainosu 3HB-L shiyakukainosu
Monocarboxylate	Plasma		detamina LA detamina PA
Bile acids	Serum		akuaotokainosu TBA shiyaku



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Ferritin Semi-Quantitative	Serum	FER-ratekkusu X2 「seiken」 CN
Procalcitonin (PCT) (Quantitative)	Serum	ekuruusisusiyaku Puraamusu PCT
b Biochemistry II		
Lipase	Serum	shigunasuoto LIP
KL-6	Serum	nanopi KL-6
c Isozyme		
Amylase Isozyme	Serum	「serotekku」 AMISO-EL
CK-MB	Serum	N-assei L CK-MB nittobo
d Immunochemistry		
Cardiac troponin T (TnT) (Qualitative, Quantitative)	Serum	ekuruusisusiyaku hs-toroponinT
Myoglobin (Quantitative)	Serum	Mb-ratekkusu CN 「seiken」
14 Biochemistry II		
a Endocrinology I		
Human chorionic gonadotropin (HCG) (Semi-quantitative)	Serum	ekuruusisusiyaku HCG II STAT v2
Human chorionic gonadotropin, β -subunit (HCG- β)	Serum	ekuruusisusiyaku HCG HCG+ β II
Thyroid-stimulating hormone (TSH)	Serum	ARCHITECT · TSH
Free triiodothyronine (FT3)	Serum	ARCHITECT · FT3
Free thyroxine (FT4)	Serum	ARCHITECT · FT4
C-peptide (CPR)	Serum	ekuruusisusiyaku C-pepuchido
Insulin (IRI)	Serum	ekuruusisusiyaku insurin
Growth hormone (GH)	Serum	ekuruusisusiyak hGH
Follicle-stimulating hormone (FSH)	Serum	ekuruusisusiyak FSH II
Luteinizing hormone (LH)	Serum	ekuruusisusiyak LH
Prolactin (PRL)	Serum	ekuruusisusiyak purorakutin
Progesterone	Serum	ekuruusisusiyaku purogesuteron
Brain natriuretic peptide (BNP)	Plasma	aakitekuto BNP
Estradiol (E2)	Serum	ekuruusisusiyaku E2
Cortisol	Serum	ekuruusisusiyaku korutizooru
Adrenocorticotrophic hormone (ACTH)	Plasma	ekuruusisu [®] siyak ACTH
IL-6	Serum	ekuruusisusiyaku IL-6
b Tumor marker		
α -fetoprotein (AFP)	Serum	ekuruusisusiyaku AFP II
Carcinoembryonic antigen (CEA)	Serum	ekuruusisusiyaku CEA
CA19-9	Serum	ekuruusisusiyaku CA19-9
CA125	Serum	ekuruusisusiyaku CA125
Prostate-specific antigen (PSA)	Serum	ekuruusisusiyaku PSA
Squamous cell cancer related antigen (SCC)	Serum	aakitekuto SCC
CA15-3	Serum	ekuruusisusiyaku CA15-3
Cytokeratin 19 fragment	Serum	ekuruusisusiyaku sifura
Progastorin releasing peptide(ProGRP)	Serum	Lumiparus ProGRP
PIVKA-II (Quantitative)	Serum	rumiparusu PIVKA II
Interleukin 2 receptor, soluble (sIL-2R)	Serum	staisia CLEIA IL-2R
c Special analysis		
Urea breath test (UBT)	Others	nyousokokisikenhou



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15 Immunology		
a Immunohematology		
Blood group, Rh system	Blood	kouCkoutai neo kokusai
Blood group, ABO subgroups	Blood	garusabu AB
Irregular antibody	Blood	Ortho baiobu kumus/nyutorarukasetto
b Immunology for infectious disease II		
Mycoplasma antigen (Qualitative) (Immunochromatography method)	Others	Libotest mycoplasma
c Immunology for infectious disease III		
RS virus antigen (Qualitative)	Others	ImunoAce RSV
(1→3)-β-D-Glucan	Plasma	βgurukanshinguruM30tesutowako
Influenza virus antigen (Qualitative)	Others	ImunoAce Flu
Streptococcus pneumoniae capsular antigen (fluid, urinary)	Urine	BinaxNOW Streptococcus pneumoniae
adenovirus antibody (Qualitative) (remove feces)	Others	ImunoAce Adeno
HTLV-I antibody (Semi-quantitative)	Serum	rumiparusu HTLV- I / II
Legionella pneumophila antigen (Urinary)	Urine	Libotest Legionella
d Hepatitis and relates		
HBe antigen	Serum	aakitekuto HBeAg
HBe antibody	Serum	aakitekuto HBeAb
HBe antibody (Semi-quantitative, Quantitative)	Serum	aakitekuto HB c
IFN-λ3	Serum	HISCL IFN-λ3
e Autoantibody		
Anti RNP antibody (Quantitative)	Serum	STACIA MEBLUX tesuto RNP
Anti Sm antibody (Quantitative)	Serum	STACIA MEBLUX tesuto Sm
Anti Jo-1 antibody (Quantitative)	Serum	STACIA MEBLUX tesuto Jo-1
Anti centromere antibody (Quantitative)	Serum	STACIA MEBLUX tesuto CENP-B
Anti-nuclear antibody (immunofluorescence is excluded)	Serum	STACIA MEBLUX tesuto ANA
Anti SS-A/Ro antibody (Quantitative)	Serum	STACIA MEBLUX tesuto SS-A
Anti SS-B/La antibody (Quantitative)	Serum	STACIA MEBLUX tesuto SS-B
Anti Scl-70 antibody (Quantitative)	Serum	STACIA MEBLUX tesuto Scl-70
Anti DNA antibody (Quantitative)	Serum	STACIA MEBLUX tesuto ds-DNA STACIA MEBLUX tesuto ss-DNA
f Immunology for plasma protein		
CH50	Serum	hotaika-HA tesutowako
TARC	Serum	HISCL TARC siyaku
Serum amyloid A protein (SAA)	Serum	LZ tesuto'eiken' hSAA
β2-microglobulin	Serum Urine	BMG-ratekkusu X1 「seiken」
Immunoelectrophoresis (Singular antiserum)	Serum	QuickGel IFE agarose set
Non-specific immunoglobulin IgE (Quantitative)	Serum	N assei LA IgE-S
Transthyretin(Prealbumin)	Serum	N-assay TIA Prealbmin nittobo
g Cellular functional test (cellular immunity related test)		
T and B lymphocyte subpopulation	Blood	saitosutattoCD45 – FITC / CD56 – RD1/CD19-ECD/CD3-PC5
T lymphocyte subpopulation	Blood	saitosutattoCD45 – FITC / CD4 – RD1/CD8-ECD/CD3-PC5
Red blood cell surface antigen	Blood	FITC mouse kouhito CD55



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Item	Type of Samples		Test Method
16 Microbiology			
b Bacterial culture and identification / Antimicrobial sensitivity test(general bacteria)			
Examination for drug sensitivity test, yeastlike fungi	Sputum	Urine	ASTY
ketsuekibaiyoupaneru	Blood		FilmArray ketsuekibaiyoupaneru
17 Gene-related / Chromosome test			
a Somatic gene test			
Preparation for HER2 gene specimen	Tissues		Dual Color in situ Hybridization method
b Identification of pathogen nucleic acid			
Nucleic acid identification of MRSA	Others		GeneXpert
Quantification of HBV nucleic acid (Quantitative)	Serum		cobas 6800/8800 system HBV
HCV DNA (Quantitative)	Serum		cobas 6800/8800 system HCV
PCR test for SARS-CoV-2	Secretions	Sputum	Takara SARS-CoV-2 direct kensyutukit
PCR test for SARS-CoV-2	Secretions		SmartGene SARS-CoV-2
PCR test for SARS-CoV-2	Secretions		FilmArray kokyukipanel2.1
PCR test for SARS-CoV-2	Secretions		XpertXpressSARS-Co-2 「sefeido」
Pathology			
31 Preparation			
a Preparation for histodiagnosis			
Organize slices	Tissues		Hematoxylin eosin stain
c Preparation for immunological stain (histodiagnosis)			
Estrogen receptor	Tissues		polymer method
Progesterone receptor	Tissues		polymer method
Human epidermal growth factor receptor-2	Tissues		polymer method
CD30	Tissues		polymer method
Others	Tissues		polymer method
d Preparation for rapid pathologic daiagnosis			
Preparation for operative rapid pathologic daiagnosis	Tissues		Rapid hematoxylin eosin stain
Preparation for operative rapid cytodiagnosis	Others		Rapid papanicolaou stain, Diff-Quik stain
e Cytodiagnosis			
Gynecology	Others		Papanicolaou stain
Fine needle aspiration cytology,Body cavity washing	Others		Papanicolaou stain, May-giemsa stain, PAS stain
32 Pathological diagnosis			
a Pathological diagnosis			
Histology	Tissues		Hematoxylin eosin stain
Cytology	Others		Papanicolaou stain, May-giemsa stain, PAS stain



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Item	Type of Samples	Test Method
Physiology		
101 Physiology		
a Respiratory function test (Spirography)		
Slow vital capacity	/	CHESTAC-9900
Forced vital capacity	/	CHESTAC-9900
Functional Residual Capacity	/	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
Holter Electrocardiogram	/	RAC-2512、RAC-3502 DSC-5500、DSC-5300
c Ultrasonography		
Cardiac ultrasonography	/	Aplio(TM) 500 Platinum Series EPIQ 7G Vivid i Vivid E95 ARIETTA850
Vascular ultrasonography	/	Aplio(TM) 500 Platinum Series ARIETTA850
d Electroencephalography		
Electroencephalography (PS, HV)	/	EEG 1218
Electromyography (SEP, VEP, ERA, ABR audiometry, others)	/	MEB9404