

Medical Laboratory  
Accreditation  
Certificate

Accreditation No. RML00960



**Osaka University**  
**Laboratory for Clinical Investigation, Department of Blood Transfusion, Department of Diagnostic Pathology, Clinic of Radiology, Ultrasound Diagnostic Center, Osaka University Hospital**

**2-15, Yamada-oka, Suita, Osaka, 565-0871 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	: September 30, 2027

Revised	February 18, 2023
Renewed	October 1, 2023
Initial accreditation	September 17, 2015

Y. Iizuka, President

**Japan Accreditation Board**



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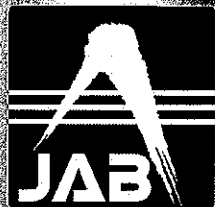


## **Osaka University Laboratory for Clinical Investigation, Department of Blood Transfusion, Department of Diagnostic Pathology, Clinic of Radiology, Ultrasound Diagnostic Center, Osaka University Hospital**

Osaka University  
Laboratory for Clinical Investigation, Department of Blood Transfusion, Department of  
Diagnostic Pathology, Clinic of Radiology, Ultrasound Diagnostic Center, Osaka University  
Hospital  
2-15, Yamada-oka, Suita, Osaka, 565-0871 Japan  
Including primary sample collection in the scope of accreditation

### Scope of accreditation :

Item	Type of Samples	Test Method
<b>Basic Series</b>		
1 General (urine, feces, etc.)		
a Qualitative (urine / feces)		
Urinary Qualitative / semi-Quantitative Examination (general substances) (Gravity, pH, Protein, Glucose, Urobilinogen, Bilirubin, Ketones, Occult blood reaction (Urinary), Bacteria (Test paper), Leukocyte (Test paper), Creatinine)	Urine	Uriflet S 11UA
Protein quantitation	Urine	Punctured fluid micro TP AR
Glucose quantitation	Urine	Punctured fluid Quickauto Neo GLU HK
Hemoglobin, feces	Feces	OC HEMODIA AUTO III 'Eiken'
Sedimentary test, urine	Urine	Labostain S
2 Hematology		
a Blood count / blood cell morphology test		
Peripheral blood general test* (complete blood counts)* : RBC, WBC, Hgb, PLT, Hct	Blood	CELLPACK DCL CELLPACK DST CELLPACK DFL SULFOLYSER Lysercell WNR Fluorocell WNR Fluorocell PLT
Reticulocytes	Blood	Fluorocell RET
Hemogram (The microscope method)	Blood	May-Grünwald Giemsa Stain
Hemogram (The automatic analyser method)	Blood	Lysercell WDF Lysercell WPC Fluorocell WDF Fluorocell WPC
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	Nanopia P-FDP



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Scope of accreditation :

Item	Type of Samples	Test Method
3 Biochemistry I		
a Biochemistry		
Total bilirubin	Serum	Total Bilirubin E HA test WAKO
Bilirubin, indirect and direct	Serum	Direct Bilirubin E HA test WAKO
Total protein	Serum	L type WAKO TP
Albumin	Serum	L type WAKO ALB-BCP
Proteins fractionation	Serum	Agarose gel
Urea nitrogen(BUN)	Serum Urine	Quickauto Neo UN
Creatinine	Serum Urine	L type WAKO CRE ·M
Uric acid	Serum Urine	Autosera S UA
Na and Cl	Serum Urine	ELA-IS buffer solution
K	Serum Urine	ELA-IS buffer solution
Ca	Serum Urine	L type WAKO Ca
Inorganic phosphate and phosphoric acid	Serum Urine	L type WAKO IP
Mg	Serum Urine	L type WAKO Mg·N
Total cholesterol	Serum	Choles test CHO
Triglyceride	Serum	Choles test TG
HDL-cholesterol	Serum	Choles test N HDL
LDL-cholesterol	Serum	Choles test LDL
Glycated albumin	Plasma	LUCICA GA-L
Glucose	Plasma	Quickauto Neo GLU-HK
Hemoglobin A1c (HbA1c)	Blood	HPLC method
Fe	Serum	L type WAKO Fe ·N
Total iron binding capacity (TIBC)	Serum	L type WAKO UIBC
Unsaturated iron binding capacity (UIBC)	Serum	L type WAKO UIBC
Ammonia	Plasma	Sikarikiddo NH3
Alkaline phosphatase	Serum	Cygnus auto Neo ALP IF
Cholinesterase	Serum	Quickauto Neo CHE
$\gamma$ -glutamyltranspeptidase ( $\gamma$ -GT)	Serum	L type WAKO $\gamma$ -GT ·J
Lactate dehydrogenase (LD)	Serum	L type WAKO LD IF
Amylase	Serum Urine	L type WAKO Amylase
Creatine kinase (CK)	Serum	L type WAKO CK
Asparate aminotransferase (AST)	Serum	L type WAKO AST ·J2
Alanine aminotransferase (ALT)	Serum	L type WAKO ALT ·J2
Blood gas analysis	Blood	ABL90FLEX PLUS
5 Immunology		
a Immunochemistry I		
C-reactive protein (CRP)	Serum	IATRO CRP-EX
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	LZ test 'Eiken' RF



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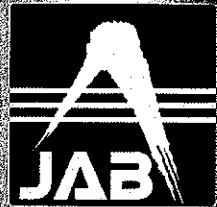
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Transfusion, Department of Diagnostic Pathology, Clinic of  
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**Scope of accreditation :**

Item	Type of Samples		Test Method
<b>b Immunohematology</b>			
Blood group (ABO type)	Blood		Hemagglutination, Gel Column Agglomeration
Blood group (Rho (D) factor)	Blood		Hemagglutination, Gel Column Agglomeration
Indirect Coombs, direct Coombs	Blood		Hemagglutination
<b>c Infectious disease I</b>			
HBs antigen	Serum		LUMIPULSE PRESTO HBsAg-HQ
HBs antibody	Serum		Alinity Anti-HBs Abbott
HCV antibody (Quantitative, Qualitative)	Serum		Alinity HCV Ab Abbott
HIV-1,2 antigen and antibody simultaneous measurement	Serum		Alinity HIV Ag/Ab Combo assay Abbott
Serologic test for syphilis (STS) (Qualitative)	Serum		RPR Test 'Sanko'
Serologic test for syphilis (Qualitative)	Serum		Alinity TPAb Abbott ESPLINE TP
<b>6 Microbiology</b>			
<b>a Microscopic examination for stained film (general bacteria)</b>			
Other	Sputum	Secretions	Gram stain neo-B&M
Use a fluorescent microscope	Sputum	Secretions	Acridine Stain
<b>b Bacterial culture and identification / Antimicrobial sensitivity test (general bacteria)</b>			
Bacterial culture and identification	Sputum	Blood	TSA II 5%SB/Difco™ Desoxycholate Agar/Sabouraud agar
Anaerobic culture	Blood	Punctured fluid	ABHK/BBE agar
Antimicrobial sensitivity test (general bacteria)	Blood	Punctured fluid	Micro Scan Panel
Mycobacterial culture and Isolation (liquid medium)	Sputum	Secretions	BBL™ MGIT™ Mycobacteria Growth Indicator Tube
Mycobacterial culture and Isolation (other)	Sputum	Secretions	2% Vite medium
Mycobacterial identification	Sputum	Secretions	MALDI-TOF-MS
<b>Non-Basic Series</b>			
<b>11 General (urine, feces, etc.)</b>			
<b>a General urinalysis</b>			
Albumin (Quantitative) (Urinary)	Urine		TAC-2 test Albumin U
Osmolarity	Urine		Freezing point method
N-acetyl glucosaminidase (NAG) (Urinary)	Urine		L type WAKO NAG
Fibrinogen degradation products (FDP) (Urinary)	Urine		LPIA FDP-U
Urinary sediment by flow cytometry (Urinary)	Urine		UF-CELLSHEATH UF-Fluorocell CR UF-Fluorocell SF UF-CELLPACK CR UF-CELLPACK SF
Neutrophil gelatinase-associated lipocalin (NGAL) (Urinary)	Urine		U-NGAL·Abbott



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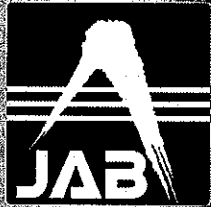
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## **Osaka University Laboratory for Clinical Investigation, Department of Blood Transfusion, Department of Diagnostic Pathology, Clinic of Radiology, Ultrasound Diagnostic Center, Osaka University Hospital**

### Scope of accreditation :

Item	Type of Samples	Test Method
<b>b Scatoloscropy</b>		
Parasitic worm eggs (feces)	Feces	Formol ether concentration
Direct smear method(helminth ova and including observation of fat and intestinal absorption test)	Feces	Non stain method Sugar Floatation SudanIII stain solution
Parasite (feces)	Feces	Direct observation method
Hemoglobin and transferrin (Quantitative,Qualitative ) (feces)	Feces	OC-HEMODIA AUTOIII 'Eiken'
<b>c Basic analysis for punctatum, sperm, sputum and others</b>		
Test of cerebrospinal fluid (protein quantification, glucose quantification, chlorine quantification, cell numbers, cell classify)	Punctured fluid	MicroTp-AR Quickauto Neo GLU-HK ELA-IS buffer solution Samson solution Fluorocell WNR
<b>12 Hematology</b>		
<b>a General hematology, hemogram</b>		
Erythrocyte sedimentation rate	Blood	Ves-matic 30
Serum osmolality	Serum	Freezing point method
Hemogram (special stain)	Blood	ALP stain
Myelogram	Punctured fluid	May-Grünwald Giemsa Stain
Myelogram (special stain)	Punctured fluid	DAB stain solution PAS stain solution $\alpha$ -Naphthyl Butylate Esterase stain solution Naphthol AS-D chloroacetate Esterase stain solution Fe stain solution
<b>b Thrombus / hemostasis related test I</b>		
Antithrombin (activity)	Plasma	Revohem AT
Plasminogen (activity)	Plasma	Testteam S PLG
Plasmin inhibitor(Antiplasmin)	Plasma	Testteam S APL
Protein C (activity)	Plasma	Testteam S PC
Fibrin monomer complex detection (Qualitative)	Plasma	FM test
Coagulation factor (II,V, VII, VIII,IX, X,XI,XII,XIII)	Plasma	Factor II deficiency plasma , Thromborel S Factor V deficiency plasma , Thromborel S Factor VII deficiency plasma , Thromborel S Factor VIII deficiency plasma , DataFi APTT(FS) Factor IX deficiency plasma , DataFi APTT(FS) Factor X deficiency plasm , Thromborel S Factor XI deficiency plasm , DataFi APTT(FS) Factor XII deficiency plasm , DataFi APTT(FS) Berichrom FXIII
Thrombomodulin	Plasma	HISCL TM



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Item	Type of Samples		Test Method
D dimer	Plasma		LPIA Ace D-D dimer II
Coagulation factor inhibitor	Plasma		Bethesda modified Factor VIII Poor Plasma, Datafi APTT(FS) Factor IX Poor Plasma, Datafi APT(FS)
Thrombin anti-Thrombin complex (TAT)	Plasma		HISCL TAT
c Thrombus / hemostasis related test II			
Clot retraction	Plasma		Clot Retraction Time
Platelet aggregation	Plasma		[MCM] ADP MCM Collagen H Ristomycin monosulfate
Platelet adhesiveness	Plasma		Collagen Beads method
13 Biochemistry I			
a Biochemistry I			
Creatinine	Urine		Aqua-auto Kainos CR
Free cholesterol	Serum		L type WAKO Free Cholesterol
Phospholipid	Serum		L type WAKO Phospholipid
Zn	Serum		Akyurasauto Zn
Ketones, fractionation	Plasma		TKB-L Kainos 3HB-L Kainos
1,5-Anhydro-D-glucitol (1,5AG)	Serum		Lana 1.5AG auto
Monocarboxylate	Plasma	Serum	Detaminer LA, Detaminer PA
Bile acids	Serum		Aqua-auto Kainos TBA
Cu	Serum		Quickauto Neo Cu
Ferritin Quantitative	Serum		Lumipulse Presto FER
Lipoprotein (a)	Serum		Lp(a)-HA test WAKO (II)
Procalcitonin (PCT) (Quantitative)	Plasma		BRAHMS PCT
Infliximab (Qualitative)	Serum		Infliximab qualitative test Remicheck Q
b Biochemistry II			
Leucine Aminopeptidase (LAP)	Serum		IATRO LQ LAP Rate II
Lipase	Serum	Plasma	Lipase Colorauto test WAKO
Aldolase	Serum		Clinimate ALD
KL-6	Serum		LUMIPULSE PRESTO KL-6
Cystatine C	Serum		LZ test 'Eiken' Cystatin-C
Apolipoprotein (AI, AII, B, CII, CIII, E)	Serum		ApoA- I auto N [Daiichi] ApoA- II auto N [Daiichi] ApoB auto N [Daiichi] ApoC- II auto N [Daiichi] ApoC- III auto N [Daiichi] ApoE auto N [Daiichi]
Mac-2 binding protein glycosylated isomers	Serum		HISCL M2BPGi
presepsin	Plasma		STACIA CLEIA Presepsin
Leucine - rich alpha 2 glycoprotein (LRG)	Serum		Nanopia LRG



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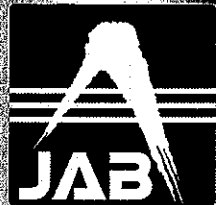
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Hospital**

**Scope of accreditation :**

Item	Type of Samples	Test Method	
<b>c Isozyme</b>			
Amylase Isozyme	Serum	L type WAKO P-AMY	
CK-MB	Plasma	ARCHITECT CK-MB ST	
<b>d Immunochemistry</b>			
Cardiac troponin I	Plasma	ARCHITECT high sensitive TnI ST	
Cardiac troponin T (TnT) (Qualitative, Quantitative)	Serum	Accuraseed troponinT	
<b>e Vitamin</b>			
Vitamin B12	Serum	ADVIA Centaur VB12	
Folic acid	Serum	ADVIA Centaur FOL	
<b>14 Biochemistry II</b>			
<b>a Endocrinology I</b>			
Human chorionic gonadotropin (HCG) (Quantitative)	Serum	Urine	Elecsys HCG II STAT
Thyroid-stimulating hormone (TSH)	Serum		AIA-PackCL TSH Immunoreaction Reagent
Free triiodothyronine (FT3)	Serum		AIA-PackCL FT3 Immunoreaction Reagent
Free thyroxine (FT4)	Serum		AIA-PackCL FT4 Immunoreaction Reagent
C-peptide (CPR)	Serum	Urine	Lumipulse Presto C-peptide, LUMIPULSE C-peptide
Insulin (IRI)	Serum		Lumipulse Presto Insulin
Growth hormone (GH)	Serum		Elecsys hGH
Follicle-stimulating hormone (FSH)	Serum		Lumipulse Presto FSH
Luteinizing hormone (LH)	Serum		Lumipulse Presto LH
Prolactin (PRL)	Serum		ADVIA Centaur PRL
Parathyroid hormones (PTH)	Serum		AIA-PackCL PTH Immunoreaction Reagent
Brain natriuretic peptide (BNP)	Plasma		AIA-PackCL BNP Immunoreaction Reagent
Estradiol (E2)	Serum		Lumipulse Presto E2-N
Cortisol	Serum		Accuraseed Cortisol(B)
Testosterone	Serum		Lumipulse Presto Testosterone
N-terminal pro brain natriuretic peptide (NT-proBNP)	Serum		Elecsys NT-proBNP II v2
Dehydroepiandrosterone sulfate (DHEA-S)	Serum		ADVIA Centaur DHEAS
Renin (Quantitative)	Serum		Accuraseed Renin (ARC)
aldosterone	Serum		Accuraseed Aldosterone S
Thyroglobulin	Serum		LUMIPULSE Presto iTACT Tg
Adrenocorticotrophic hormone (ACTH)	Plasma		Elecsys ACTH
Interleukin-6 (IL-6)	Serum		Elecsys IL-6
<b>b Tumor marker</b>			
α-fetoprotein (AFP)	Serum		Lumipulse Presto AFP
Carcinoembryonic antigen (CEA)	Serum		Lumipulse Presto CEA
CA19-9	Serum		Lumipulse Presto CA19-9
CA125	Serum		Lumipulse Presto CA125 II
Prostate-specific antigen (PSA)	Serum		AIA-PackCL PSA Immunoreaction Reagent



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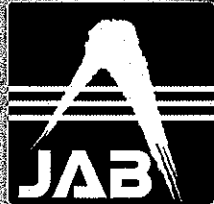
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**Laboratory for Clinical Investigation, Department of Blood Transfusion, Department of Diagnostic Pathology, Clinic of Radiology, Ultrasound Diagnostic Center, Osaka University Hospital**

**Scope of accreditation :**

Item	Type of Samples	Test Method
Squamous cell cancer related antigen (SCC) CA15-3	Serum	AIA-PackCL SCC Immunoreaction Reagent Lumipulse Presto CA15-3
Neuron specific enolase (NSE)	Serum	Elecsys NSE
Cytokeratin 19 fragment	Serum	Lumipulse Presto CYFRA
Free PSA/Total PSA ratio	Serum	AIA-PackCL free PSA Immunoreaction Reagent
Progastrin releasing peptide(ProGRP)	Plasma	Lumipulse Presto ProGRP
PIVKA-II (Quantitative)	Serum	Lumipulse Presto PIVKA II-N Eisai
Elastase 1	Serum	IATRO IRE1 II
$\alpha$ -fetoprotein lectin-affinity fraction (AFPL3%)	Serum	$\mu$ TASWako AFP-L3
Carcinoembryonic antigen (CEA) (Semi-quantitative) (Nipple discharge)	Secretions	Lanamammo Card CEA
Inteleukin 2 receptor, soluble (sIL-2R)	Serum	Nanopia IL-2R
<b>c Special analysis</b>		
Branched-chain amino acids and tyrosine molar ratio (BTR)	Serum	DIACOLOR·LUIQID BTR
Urea breath test (UBT)	Others	POCone
<b>15 Immunology</b>		
<b>a Immunohematology</b>		
Blood group, Rh system	Blood	Hemagglutination
Blood group, ABO subgroups	Blood	Hemagglutination
Irregular antibody	Blood	Hemagglutination, Gel Column Agglomeration
Anti platelet antibody	Blood	Flow PRA
<b>b Immunology for infectious disease II</b>		
Mycoplasma antigen (Qualitative) (Immunochromatography method)	Secretions	RIBOTEST Mycoplasma
Mycoplasma pneumoniae antibody (Semi-quantitative)	Serum	Serodia-MYCO 2
<b>c Immunology for infectious disease III</b>		
RS virus antigen (Qualitative)	Secretions	Immuno Ace RSV Neo
Chlamydia trachomatis antigen (Qualitative)	Secretions	Urine Clearview Chlamydia
Clostridium difficile toxin A (Qualitative)	Feces	C.DIFF QUIK CHEK Complete
Rotavirus antigen (Qualitative) (Feces)	Feces	Quickchaser Rota/Adeno
Helicobacter pylori antigen (Qualitative)	Feces	Testmate Pylori Antigen ELA
Cryptococcus neoformans antigen (Semi-quantitative)	Serum	Punctured fluid Serodirect 'Eiken' cryptococcus
Cryptococcus neoformans antigen (Qualitative)	Serum	Punctured fluid Serodirect 'Eiken' cryptococcus
(1 $\rightarrow$ 3)- $\beta$ -D-Glucan	Plasma	$\beta$ -D-Glucan Test Wako
Serologic test for syphilis (STS) (Semi-quantitative)	Serum	RPR test "Sanko"
Toxoplasma gondii antibody	Serum	Access Toxo IgG
Toxoplasma gondii IgM antibody	Serum	Access Toxo IgM (II)
Influenza virus antigen (Qualitative)	Secretions	Espline Influenza A&B-N
Streptococcus pneumoniae capsular antigen (fluid, urinary)	Urine	BinaxNOW Streptococcus pneumoniae
Treponema pallidum antibody (Semi-quantitative)	Serum	Serodia TP·PA
Norovirus antigen (Qualitative)	Feces	Immunocatch—Noro
human metapneumovirus (hMPV) antigen (Qualitative)	Secretions	Check hMPV
adenovirus antibody (Qualitative) (remove feces)	Secretions	Immuno Ace Adeno





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## **Osaka University Laboratory for Clinical Investigation, Department of Blood Transfusion, Department of Diagnostic Pathology, Clinic of Radiology, Ultrasound Diagnostic Center, Osaka University Hospital**

### Scope of accreditation :

Item	Type of Samples		Test Method
Virus antibody in immunoglobulin class (Herpesvirus, Rubella virus, Cytomegalovirus, EB virus, Measles virus, Mumps virus, Human parvoviral-B19, Varicella / Herpes virus)	Serum		Access Rubella IgG Access Rubella IgM
HTLV-I antibody	Serum		Alinity HTLV Abbott
Endotoxin	Plasma		Endotoxin Test Wako
Legionella pneumophila antigen (Urinary)	Urine		BinaxNOW Legionella
HIV-1 antibody (Western blot method)	Serum		NEW LAV BLOT 1
HIV-2 antibody (Western blot method)	Serum		NEW LAV BLOT 2
<b>d Hepatitis and relates</b>			
HBe antigen	Serum		Alinity HBeAg Abbott
HBe antibody	Serum		Alinity HBeAb Abbott
HBc-IgM antibody	Serum		Alinity HBc-M Abbott
HA-IgM antibody	Serum		Alinity HAVAB-M Abbott
HBs antibody (Quantitative)	Serum		Alinity Anti-HBs Abbott
HBc antibody (Semi-quantitative, Quantitative)	Serum		Alinity HBc Abbott
<b>e Autoantibody</b>			
Cold agglutination	Blood		Hemagglutination
Anti cardiolipin $\beta$ 2 glycoprotein I (Anti CL $\beta$ 2GPI) Complex antibody	Plasma		Anti CL $\beta$ 2GP I kit <sup>†</sup> Yamasa JEIA
Matrix metalloproteinase-3 (MMP-3)	Serum		Panaclear MMP-3 (Latex)
Lupus anticoagulant (Quantitative)	Plasma		LA test [Gradipore]
Anti Thyroglobulin antibody	Serum		AIA-PackCL TgAb Immunoreaction Reagent
Anti Thyroid peroxidase antibody	Serum		AIA-PackCL TPOAb Immunoreaction Reagent
Anti TSH receptor antibody (TRAb)	Serum		AIA-PackCL TRAb Immunoreaction Reagent
<b>f Immunology for plasma protein</b>			
CH50	Serum		Complement titer-HA test WAKO
TARC	Serum		HISCL TARC
Serum amyloid A protein (SAA)	Serum		LZ test 'Eiken' hSAA
Ceruloplasmin	Serum		N-antiserum Ceruloplasmin
$\beta$ 2-microglobulin	Serum	Urine	LZ test 'Eiken' $\beta$ 2-M
Retinol binding protein (RBP)	Serum		N-antiserum RBP
Non-specific immunoglobulin IgE (Quantitative)	Serum		Lumipulse Presto IgE
Transferrin (Tf)	Serum		N-antiserum Transferrin
Haptoglobin (Typing)	Serum		N-assay TIA Hp Nittobo
Transthyretin(Prealbumin)	Serum		N-antiserum Prealbumin
<b>g Cellular functional test (cellular immunity related test)</b>			
T and B lymphocyte subpopulation	Blood		BD Multi tet 6color TBNK
T lymphocyte subpopulation	Blood		BD Multi tet 6color TBNK
<b>16 Microbiology</b>			
<b>b Bacterial culture and identification / Antimicrobial sensitivity test(general bacteria)</b>			
Examination for drug sensitivity test, yeastlike fungi	Blood	Punctured fluid	ASTY
Drug susceptibility test for mycobacteria	Sputum	Secretions	BrothMIC NTM



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### Scope of accreditation :

Item	Type of Samples		Test Method
17 Gene-related /Chromosome test			
a Somatic gene test			
Gene diagnosis of hematopoietic organ tumor	Blood		i-densy Pack Multitype UNIVERSAL i-densy Pack UNIVERSAL
Major BCR-ABL1 mRNA	Blood		ipsogen BCR-ABL1 Mbc IS-MMR DX
Cytokeratin-19 (KRT19) mRNA	Others		LYNOAMP CK19
b Identification of pathogen nucleic acid			
Cytomegalovirus DNA	Plasma		cobas 6800/8800 system CMV
Quantification of HBV nucleic acid (Quantitative)	Serum		cobas 6800/8800 system HBV
HCV DNA (Quantitative)	Serum		cobas 6800/8800 system HCV
18 Others excluding 11 to 16 class			
a Therapeutic drug monitoring			
Digitoxin, Digoxin	Plasma		ARCHITECT iDigoxin
Theophylline	Plasma		cobas Theophylline II
Valproic acid, Carbamazepine	Plasma		cobas Valproic acid II cobas Carbamazepine III
Phenytoin, Primidone, Ethosuximide, Phenobarbital, Zonisamide, Nitrazepam, Clonazepam, Others	Plasma		cobas Phenytoin II cobas Phenobarbital II
Lithium	Plasma		cobas Lithium
Vancomycin, Teicoplanin, Gentamicin, Tobramycin, Amikacin, Arbekacin, Voriconazole	Plasma		cobas Vancomycin III Nanopia TDM Teicoplanin cobas Tobramycin II Emit@2000 Gentamicin Plus Assay
Cyclosporin, Tacrolimus hydrat, Everolimus, Mycophenolate mofetil	Blood		Cyclosporine • Abbott Tacrolimus • Abbott Nanopia TDM Everolimus
Methotrexate	Plasma		Nanopia eTDM Methotrexate
<b>Pathology</b>			
31 Preparation			
a Preparation for histodiagnosis			
Organize slices	Tissues	Others	HE Stain
CELL BLOCK	Tissues	Others	HE Stain
c Preparation for immunological stain (histodiagnosis)			
Estrogen receptor	Tissues	Others	VENTANA
Progesterone receptor	Tissues	Others	VENTANA
Human epidermal growth factor receptor-2	Tissues	Others	VENTANA
Anaplastic lymphoid kinase fusion protein	Tissues	Others	VENTANA
CD30	Tissues	Others	VENTANA
PD-L1	Tissues	Others	DAKO
Others	Tissues	Others	DAKO, VENTANA, IMMUNO- FLUORESCENCE



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Scope of accreditation :

Item	Type of Samples		Test Method
d Preparation for rapid pathologic diagnosis			
Preparation for operative rapid pathologic diagnosis	Tissues	Others	HE Stain
Preparation for operative rapid cytodiagnosis	Others		Papanicolaou Stain
e Cytodiagnosis			
Gynecology	Others		Papanicolaou Stain
Fine needle aspiration cytology, Body cavity washing	Punctured fluid	Others	Papanicolaou Stain
Others	Others		Papanicolaou Stain
32 Pathological diagnosis			
a Pathological diagnosis			
Histology	Tissues	Others	HE Stain
Cytology	Punctured fluid	Others	Papanicolaou Stain
<b>Physiology</b>			
101 Physiology			
a Respiratory function test (Spirography)			
Slow vital capacity			Auto Spirometer System 7w
Forced vital capacity			Auto Spirometer System 7w
Functional Residual Capacity			Auto Spirometer System 21
Closing volume			Auto Spirometer System 21
DLCO (diffusing capacity of CO)			Auto Spirometer System 21
b Electrocardiogram			
At least 12 leads including limb monopole lead and the chest leads			ECG-2550
Stress Electrocardiogram			ECG-2550
Holter Electrocardiogram			RAC-2503, RAC-2512, RAC-3203
c Ultrasonography			
Cardiac ultrasonography			Vivid E95, Vivid E9, EPIQ 7C
Abdominal ultrasonography			Aplio i800, Aplio 500, Aplio 400, LOGIQ S8
Body surface ultrasonography			Aplio i800, Aplio 500, Aplio 400
Vascular ultrasonography			Aplio i800, Aplio 500, Aplio 400
d Electroencephalography			
Electroencephalography (PS, HV)			EEG-1200

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