

Medical Laboratory
Accreditation
Certificate

Accreditation No. RML01220



JAB



***Hyogo Prefectural Hospitals Agency
Department of Clinical Laboratory,
Hyogo Prefectural Amagasaki General Medical Center***

***2-17-77, Higashinaniwa-cho, Amagasaki-city, Hyogo,
660-8550, 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	: February 28, 2025

Renewed (1)	February 19, 2021
Initial accreditation	February 21, 2017

Y. Iizuka, President

Japan Accreditation Board

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Hyogo Prefectural Hospitals Agency
Department of Clinical Laboratory, Hyogo Prefectural Amagasaki General Medical Center
2-17-77, Higashinaniwa-cho, Amagasaki-city, Hyogo, 660-8550, 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	Uropaper-αIII 'Eiken'
Protein quantitation	Urine	Micro TP-Test Wako
Glucose quantitation	Urine	L-Type GLU2
Hemoglobin, feces	Feces	OC-Hemocatch S'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	Fluorocell RET
Hemogram (The microscope method)	Blood	May-Grünwald's Stain Solution, Giemsa's Solution
Hemogram (The automatic analyser method)	Blood	Fluorocell WDF
b Thrombus / hemostasis related test		
Prothrombin time(PT)	Plasma	Thromborel S
Activated partial thromboplastin time(APTT)	Plasma	Thrombocheck APTT-SLA
Fibrinogen (Quantitative)	Plasma	Coagpia Fbg Thrombin Reagent
Fibrinogen degradation products(FDP)	Plasma	Nanopia P-FDP
3 Biochemistry I		
a Biochemistry		
Total bilirubin	Serum	NescoatVL T-BIL
Bilirubin, indirect and direct	Serum	NescoatVL D-BIL
Total protein	Serum	Aqua-auto Kainos TP- II test Kit
Albumin	Serum	Aqua-auto Kainos ALB test Kit
Urea nitrogen(BUN)	Serum	Aqua-auto Kainos UNII test Kit
Creatinine	Serum	Aqua-auto Kainos CREIII plus test Kit
Uric acid	Serum	DetaminarL UA
Na and Cl	Serum	Ion selective electrode method
K	Serum	Ion selective electrode method
Ca	Serum	Aqua-auto Kainos Ca test Kit

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Scope of accreditation :

Item	Type of Samples		Test Method
Inorganic phosphate and phosphoric acid	Serum		Detaminar L IP
Mg	Serum		L-Type Mg + N
Total cholesterol	Serum		Cholestest TG
Triglyceride	Serum		Cholestest CHO
HDL cholesterol	Serum		Cholestest N HDL
LDL cholesterol	Serum		Cholestest LDL
Glucose	Plasma	Blood	L-Type GLU2, GOD hydrogen peroxide electrode method
Hemoglobin A1c (HbA1c)	Blood		Reversed-phase cation exchange chromatography
Fe	Serum		Quickauto-neo Fe
Unsaturated iron binding capacity (UIBC)	Serum		Quickauto-neo UIBC ¹¹
Ammonia	Serum		FUII DRI-CHEM NH3-W II
Alkaline phosphatase	Serum		Quickauto-neo ALP-JS II
Cholinesterase	Serum		Quickauto-neo Ch-E
γ-glutamyltranspeptidase (γ-GT)	Serum		Cicaliquid γ-GT J
Lactate dehydrogenase (LD)	Serum		L-Type LD J
Amylase	Serum		L-Type AMY
Creatine kinase (CK)	Serum		Cicaliquid CK
Aspartate aminotransferase (AST)	Serum		L-Type AST J2
Alanine aminotransferase (ALT)	Serum		L-Type ALT J2
Blood gas analysis	Blood		ABL series
5 Immunology			
a Immunochemistry I			
C-reactive protein (CRP)	Serum		N-assay LA CRP Nittobo
Immunoglobulin (IgG, IgA, IgM, IgD)	Serum		N-assay TIA IgG-SH Nittobo, N-assay TIA IgA-SH Nittobo, N-assay TIA IgM-SH Nittobo
C3	Serum		N-assay TIA C3-SH Nittobo
C4	Serum		N-assay TIA C4-SH Nittobo
Immunoglobulin (RF)	Serum		N-assay TIA RF Nittobo
b Immunohematology			
Blood group (ABO type)	Blood		Ortho BioVue anti-A, anti-B, anti-D cassettes
Blood group (Rho (D) factor)	Blood		Ortho BioVue anti-A, anti-B, anti-D cassettes
Indirect Coombs, direct Coombs	Blood		Ortho BioVue IgG cassettes, Gammaclone antiIgG C3d
c Infectious disease I			
HBs antigen	Serum		ARCHITECT HBsAg QT
HCV antibody (Quantitative, Qualitative)	Serum		ARCHITECT HCV
HIV-1,2 antigen and antibody simultaneous measurement	Serum		ARCHITECT HIV Ag/Ab Combo assay
Serologic test for syphilis (Qualitative)	Serum		ARCHITECT TP · Ab
Anti streptolysin O (ASO)	Serum		N-assay LA ASO Nittobo
6 Microbiology			
a Microscopic examination for stained film (general bacteria)			
Other	Sputum	Others	Favor G "nissui", Ziehl-neelsen stain

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Scope of accreditation :

Item	Type of Samples		Test Method
	Sputum	Others	
Use a fluorescent microscope	Sputum	Others	Fluorescent stain
b Bacterial culture and identification / Antimicrobial sensitivity test (general bacteria)		"	"
Bacterial culture and identification	Sputum	Others	Sheep blood agar, Chocolate agar, Other agar, ID test HN-20 "nissul"
Anaerobic culture	Punctured fluid	Others	Brucella HK agar, BB _E agar, Rap ID ANA II
Antimicrobial sensitivity test (general bacteria)	Blood	Others	WalkAway40Plus (PC31J, NENC1J, NNFC1J, MF7J, MF4J)
Mycobacterial culture and Isolation (liquid medium)	Sputum	Others	MGIT
Mycobacterial culture and Isolation (other)	Sputum	Others	Ogawa Agar
Non-Basic Series			
11 General (urine, feces, etc.)			
a General urinalysis			
Albumin (Quantitative) (Urinary)	Urine		N-assay TIA Micro Alb Nittobo
Osmolarity	Urine		Freezing point depression method
Urinary sediment by flow cytometry (Urinary)	Urine		UF1000i
b Scatoloscropy			
Parasitic worm eggs (feces)	Feces		MGL method
Direct smear method (helminth ova and including observation of fat and intestinal absorption test)	Feces		Thin blood film method
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-AR2, SULFOLYSER, Fluorocell WDF
12 Hematology			
a General hematology, hemogram			
Erythrocyte sedimentation rate	Blood		Rate method
Serum osmolality	Serum		Freezing point depression method
HemoglobinF (HbF)	Blood		Reversed-phase cation exchange chromatography
Myelogram	Others		May-Grünwald's Stain Solution, Giemsa's Solution
Myelogram (special stain)	Others		new PO-k stain kit, PAS stain kit, Esterase stain kit, Esterase AS-D stain kit, Fe stain kit
Malignant tumor cell	Blood	Others	Flowcytometry
b Thrombus / hemostasis related test I			
Antithrombin (activity)	Plasma		Testzym S AtIII
D dimer	Plasma		Nanopia D-dimer
c Thrombus / hemostasis related test II			
Platelet aggregation	Plasma		PRP313M
13 Biochemistry I			
a Biochemistry I			
Ethanol	Serum		Emit II Ethyl Alcohol Assay
Ferritin Quantitative	Serum		LZ test 'eiken' FER

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Scope of accreditation :

Item	Type of Samples	Test Method
Procalcitonin (PCT) (Quantitative)	Serum	ECLusys reagent Brahms PCT
b Biochemistry III		
Leucine Aminopeptidase (LAP)	Serum	Cicafit LAP
KL-6	Serum	Lumipulse KL-6 eisa
Cystatine C	Serum	CystatinC-latex seiken
c Isozyme		
CK-MB	Serum	L-Type CK-Mbmass
d Immunochemistry		
Cardiac troponin I	Serum	ARCHITECT troponin I ST
Cardiac troponin T (TnT) (Qualitative, Quantitative)	Serum	ECLusys reagent troponin T hs STAT
14 Biochemistry II		
a Endocrinology I		
Human chorionic gonadotropin (HCG) (Qualitative)	Urine	Immunochromato method
Human chorionic gonadotropin, β -subunit (HCG- β)	Serum	Urine ARCHITECT β HCG
Thyroid-stimulating hormone (TSH)	Serum	ARCHITECT TSH
Free triiodothyronine (FT3)	Serum	ARCHITECT free T3 Abbott
Free thyroxine (FT4)	Serum	ARCHITECT free T4 Abbott
Insulin (IRI)	Serum	ARCHITECT Insulin
Growth hormone (GH)	Serum	ECLusys reagent hGH
Follicle-stimulating hormone (FSH)	Serum	ARCHITECT FSH
Luteinizing hormone (LH)	Serum	ARCHITECT LH II
Prolactin (PRL)	Serum	ARCHITECT Prolactin
Parathyroid hormones (PTH)	Serum	ARCHITECT Intact PTH
Brain natriuretic peptide (BNP)	Plasma	ARCHITECT BNP-JP
Cortisol	Serum	Urine ARCHITECT Cortisol
N-terminal pro brain natriuretic peptide (NT-proBNP)	Serum	ECLusys reagent NT-proBNP II
b Tumor marker		
α -fetoprotein (AFP)	Serum	ARCHITECT AFP EX
Carcinoembryonic antigen (CEA)	Serum	ARCHITECT CEA
CA19-9	Serum	ARCHITECT CA19-9XR
CA125	Serum	ARCHITECT CA125
Prostate-specific antigen (PSA)	Serum	ARCHITECT PSA
Squamous cell cancer related antigen (SCC)	Serum	ARCHITECT SCC
CA15-3	Serum	ARCHITECT CA15-3
Cytokeratin 19 fragment	Serum	ARCHITECT CYFRA
PIVKA-II (Quantitative)	Serum	Lumipulse G PIVKA II -N
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	Plasma	Ortho biovue IgG cas s tte s
b Immunology for infectious disease II		
Mycoplasma antigen (Qualitative) (Immunochromatography method)	Others	Ribotest Mycoplasma
Mycoplasma pneumoniae antibody (Semi-quantitative)	Serum	SERODIA - MYCO II

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Scope of accreditation :

Item	Type of Samples	Test Method
c Immunology for infectious disease III		
E. coli O157 antigen (Qualitative)	Feces	Capilia O157
E. coli O157 antibody (Qualitative)	Serum	O157 check 'LPS-antibody'
Escherichia coli serotyping	Feces	Enteropathogenic Escherichia coli Immune serum'seiken'
RS virus antigen (Qualitative)	Others	ImmunoAce RSV Neo
Clostridium difficile toxin A (Qualitative)	Feces	GE test immunochromato-CD GDH/TOX 'Nissui'
Adenovirus antigen (Qualitative) (Feces)	Feces	Rapid Testa Rota/Adeno II
Rotavirus antigen (Qualitative) (Feces)	Feces	Rapid Testa Rota/Adeno II
Helicobacter pylori antigen (Qualitative)	Feces	Testmate Rapid p y lori antigen
(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	Strep A testpack plus OBC
Influenza virus antigen (Qualitative)	Others	ImmunoAce Flu
Streptococcus pneumoniae in cerebrospinal (fluid, urinary)	Urine	Immuncatch Streptococcus pneumoniae
Norovirus antigen (Qualitative)	Feces	Rapid Testa noro
human metapneumovirus (hMPV) antigen (Qualitative)	Others	ImmunoAce hMPV
adenovirus antibody (Qualitative) (remove feces)	Others	ImmunoAce Adeno
HTLV-I antibody	Serum	ARCHITECT HTLV
The group of Mycobacterium antigen (Qualitative)	Others	Capilia TB-Neo
Endotoxin	Plasma	Endotoxin Single test Wako
Legionella pneumophila antigen (Urinary)	Urine	Ribotest Legionella
d Hepatitis and relates		
HBe antigen	Serum	ARCHITECT HBeAg
HBe antibody	Serum	ARCHITECT HBeAb
HBs antibody (Quantitative)	Serum	ARCHITECT Anti-HBsAbbott
HBc antibody (Semi-quantitative, Quantitative)	Serum	ARCHITECT Anti-HBc II
e Autoantibody		
Anti TSH receptor antibody (TRAb)	Serum	ECLusys reagent TRAb
f Immunology for plasma protein		
Serum amyloid A protein (SAA)	Serum	LZ test 'eiken' SAA
β2-microglobulin	Serum	Lumipulse G β2M - N
Non-specific immunoglobulin IgE (Quantitative)	Serum	Lumipulse G IgE
Transthyretin(Prealbumin)	Serum	N-assay TIA Transthyretin Nittobo
g Cellular functional test (cellular immunity related test)		
T and B lymphocyte subpopulation	Blood	BD Multitest 6-color TBNK
CCR4 protein	Blood	Flowcytometry
16 Microbiology		
b Bacterial culture and identification / Antimicrobial sensitivity test(general bacteria)		
Examination for drug sensitivity test, yeastlike fungi	Blood	Antifungal Susceptibility Testing of Yeasts
c Identification of nucleic acid (genetic testing)		
E. coli vero cytotoxin (Qualitative)	Others	Duopath Verotoxins

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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	Others	PCR, Fragment analysis, HRM analysis, Direct sequence, digital PCR
WT1 mRNA	Blood		Self-prepared reagent
b Identification of pathogen nucleic acid			
Nucleic acid identification of MRSA	Blood		Genecube mecA
DNA amplification assay for Mycobacteria tuberculosis complex	Sputum	Others	Genecube MTB
Mycobacterium avium / intracellulare DNA	Sputum	Others	Genecube MAC
Quantification of HBV nucleic acid (Quantitative)	Serum		Cobas TaqMan HBV
HCV DNA (Quantitative)	Serum		Cobas TaqMan HCV
18 Others excluding 11 to 16 class			
a Therapeutic drug monitoring			
Digitoxin, Digoxin	Serum		ARCHITECT Digoxin
Theophylline	Serum		ARCHITECT Theophylline
Valproic acid, Carbamazepine	Serum		ARCHITECT Sodium valproate STARCHITECT Carbamazepine ST
Phenytoin, Primidone, Ethosuximide, Phenobarbital, Zonisamide, Nitrazepam, Clonazepam, Others	Serum		ARCHITECT Phenytoin ARCHITECT Phenobarbital ST
Vancomycin, Teicoplanin, Gentamicin, Tobramycin, Amikacin, Arbekacin, Voriconazole	Serum		ARCHITECT Vancomycin ST Nanopia TDM Teicoplanin
Cyclosporin, Tacrolimus hydrate, Everolimus, Mycophenolate mofetil	Blood		ECLusys Cyclosporin ECLusys Tacrolimus hydrate
Methotrexate	Serum		ARCHITECT Methotrexate

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Scope of accreditation :

Item	Type of Samples	Test Method
Pathology		
31 Preparation		
a Preparation for histodiagnosis		
Organize slices	Tissues	Hematoxylin and Eosin stain
CELL BLOCK	Others	Hematoxylin and Eosin stain
c Preparation for immunological stain (histodiagnosis)		
Estrogen receptor	Tissues	CONFIRM anti-ER (SP1), BENCHMARK XT
Progesterone receptor	Tissues	CONFIRM anti-PgR (1E2), BENCHMARK XT
Human epidermal growth factor receptor-2	Tissues	PATHWAY anti-HER2 (4B5), BENCHMARK XT
Others	Tissues	ultraView DAB Universal Kit, Bond Polymer Refine Detection
d Preparation for rapid pathologic daiagnosis		
Preparation for operative rapid pathologic daiagnosis	Tissues	Hematoxylin and Eosin stain
Preparation for operative rapid cytodiagnosis	Others	Papanicolaou stain, Giemsa stain
e Cytodiagnosis		
Gynecology	Others	Papanicolaou stain
Fine needle aspiration cytology, Body cavity washing	Others	Papanicolaou stain, Giemsa stain
Others	Others	Papanicolaou stain, Giemsa stain
32 Pathological diagnosis		
a Pathological diagnosis		
Histology	Tissues	Diagnosis by the pathologist
Cytology	Others	Diagnosis by the pathologist

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