

Medical Laboratory
Accreditation
Certificate

Accreditation No. RML02620

***JA Nagano Kouseiren
Minaminagano Medical Center, Shinonoi General Hospital
Clinical Laboratory***

666-1 Ai, Shinonoi Nagano, 388-8004 Japan

meets the following criteria. On the basis of this, Japan Accreditation Board (JAB) grants accreditation to the said medical laboratory.

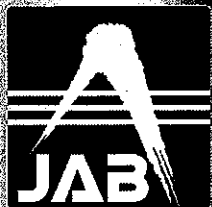
Applicable accreditation criteria	: ISO 15189 : 2012
Scope of accreditation	: As described in the appendix.
Premises covered by accreditation	: As described in the appendix.
Expiry date of accreditation	: July 31, 2025

Initial accreditation

July 16, 2021

Y. Iizuka, President

Japan Accreditation Board



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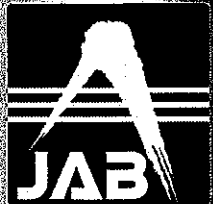
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Minaminagano Medical Center, Shinonoi General Hospital Clinical Laboratory
666-1 Ai, Shinonoi Nagano, 388-8004 Japan
Including primary sample collection in the scope of accreditation

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), Leukocyte (Test paper), Albumin)	Urine	UROPAPER α III 'EIKEN'
Protein quantitation	Urine	Punctured fluid MicroTP-AR
Glucose quantitation	Urine	Punctured fluid Quick-Auto 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 Lysercell WNR Fluorocell WNR Sulfolyser CELLPACK DFL Fluorocell PLT
Reticulocytes	Blood	CELLPACK DFL Fluorocell RET CELLPACK DCL
Eosinophils	Blood	Lysercell WNR Lysercell WDF Lysercell WPC Fluorocell WNR Fluorocell WDF Fluorocell WPC CELLPACK DCL
Hemogram (The microscope method)	Blood	May-Grunwald Stain Solution Giemsa Stain Solution Phosphate Buffer Solution(pH6.6) Methanol



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Scope of accreditation :

Item	Type of Samples	Test Method
Hemogram (The automatic analyser method)	Blood	Lysercell WNR Lysercell WDF Lysercell WPC Fluorocell WNR Fluorocell WDF Fluorocell WPC CELLPACK DCL
b Thrombus / hemostasis related test		
Prothrombin time(PT)	Plasma	Thoromborel S
Activated partial thromboplastin time(APTT)	Plasma	Revohem APTT SLA
Fibrinogen (Quantitative)	Plasma	Thorombochekku Fib(L)
Fibrinogen degradation products(FDP)	Plasma	LIASAUTO P-FDP
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	Aqua-auto KINOS TP- II
Albumin	Serum	Aqua-auto KINOS ALB
Urea nitrogen(BUN)	Serum	Quick-Auto Neo BUN
Creatinine	Serum	Cygnus Auto CRE
Uric acid	Serum	Quick-Auto Neo Ua II
Na and Cl	Serum	Ion selective electrode
K	Serum	Ion selective electrode
Ca	Serum	"Serotec" Ca-AL
Inorganic phosphate and phosphoric acid	Serum	L-type wako IP
Mg	Serum	N-assey L Mg-S
Total cholesterol	Serum	QUALIGENT CHO
Triglyceride	Serum	QUALIGENT TG
HDL-cholesterol	Serum	QUALIGENT HDL
LDL-cholesterol	Serum	QUALIGENT LDL
Glycated albumin	Serum	RUSIKA GA-L GA, RUSIKA GA-L ALB
Glucose	Serum	Quick-Auto Neo GLU-HK
Hemoglobin A1c (HbA1c)	Blood	arkray Automated glycohemoglobin analyzer ADAMS A1c HA-8190V
Fe	Serum	Quick-Auto Neo Fe
Unsaturated iron binding capacity (UIBC)	Serum	Quick-Auto Neo UIBC
Ammonia	Blood	NH ₃ - W II
Alkaline phosphatase	Serum	Quick-Auto Neo ALP-JS
Cholinesterase	Serum	Quick-Auto Neo Ch-E
γ-glutamyltranspeptidase (γ-GT)	Serum	LABOFIT γ-GT
Lactate dehydrogenase (LD)	Serum	Quick-Auto Neo LDJS
Amylase	Serum	Accurus-Auto AMY-IF
Creatine kinase (CK)	Serum	Cygnus Auto CK
Asparate aminotransferase (AST)	Serum	Quick-Auto Neo ASTJS
Alanine aminotransferase (ALT)	Serum	Quick-Auto Neo ALTJS



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Scope of accreditation :

Item	Type of Samples		Test Method
Blood gas analysis	Blood		RADIOMETER blood-gas analyzer ABL800 FLEX
5 Immunology			
a Immunochemistry I			
C-reactive protein(CRP)	Serum		N-assey LA CRP-T NITTOBO
Immunoglobulin (IgG, IgA, IgM)	Serum		N-assey TIA NITTOBO
C3	Serum		N-assey TIA NITTOBOC3-SH
C4	Serum		N-assey TIA NITTOBOC4-SH
Immunoglobulin (RF)	Serum		N-assey LA RF-K NITTOBO
b Immunohematology			
Blood group (ABO type)	Blood	Plasma	Gel column sgglutination technology, Tube tests
Blood group (Rho (D) factor)	Blood		Gel column sgglutination technology, Tube tests
Indirect Coombs, direct Coombs	Blood	Plasma	Gel column sgglutination technology, Tube tests
c Infectious disease I			
HBs antigen	Serum		ARCHITECT HBsAg QT
HBs antibody	Serum		ARCHITECT Anti-Hbs
HCV antibody (Quantitative, Qualitative)	Serum		ARCHITECT HCV
HIV-1,2 antigen and antibody simultaneous measurement	Serum		ARCHITECT HIV Ag-Ab combo assey
HTLV-Iantibody (Qualitative)	Serum		ARCHITECT r HTLV- I / II Reagentkit
Serologic test for syphilis (STS) (Qualitative)	Serum		RPRtestsankou
Serologic test for syphilis (Qualitative)	Serum		ARCHITECT Syphilis TP
6 Microbiology			
a Microscopic examination for stained film (general bacteria)			
Other	Sputum	Others	Gram stain(neo-B&M WAKO)
Use a fluorescent microscope	Sputum	Others	Acridine orange stain
b Bacterial culture and identification / Antimicrobial sensitivity test(general bacteria)			
Bacterial culture and identification	Sputum	Others	Sheep blood agar VITEK2
Simple method culture	Sputum	Feces	X-MRSA agar
Anaerobic culture	Punctured fluid	Others	BHK agar(RS)
Antimicrobial sensitivity test (general bacteria)	Sputum	Others	VITEK2, RAISUS ANY
Mycobacterial culture and Isolation (other)	Sputum	Others	Kyokuto 2%Ogawa agar(SP)
Non-Basic Series			
11 General (urine, feces, etc.)			
a General urinalysis			
Albumin (Quantitative) (Urinary)	Urine		"Serotec" TIA-ALB G
Osmolarity	Urine	Serum	OSMO STATION OM-6060
Iuteinizing hormone (Qualitative) (Urinary)	Urine		L CHECK FT
b Scatolscopy			
Parasitic worm eggs (feces)	Feces		Method of Ooshima
Direct smear method(helminth ova)	Feces		Microscopic method
c Basic analysis for punctatum, sperm, sputum and others			
Test of cerebrospinal fluid (protein quantification, glucose quantification, cell numbers, cell classify)	Punctured fluid		micro TP test wako, Quickneo auto glucose, Samson solution
Test of semen	Others		Microscopic method



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Scope of accreditation :

Item	Type of Samples	Test Method
Uterus cervical mucous granulocyte elastase (Qualitative)	Others	Fagnoselastase dip
12 Hematology		
a General hematology, hemogram		
Erythrocyte sedimentation rate	Blood	Smart Rate20
Eosinophils, nasal/sputum smear	Others	May-Grunwald Stain Solution Giemsa Stain Solution Phosphate Buffer Solution(pH6.6) Methanol
Hemogram (special stain)	Blood	DAB stain kit Esterase stain kit Esterase AS-D stain kit ALP stain kit
Myelogram	Punctured fluid	May-Grunwald Stain Solution Giemsa Stain Solution Phosphate Buffer Solution(pH6.6) Methanol
Myelogram (special stain)	Punctured fluid	DAB stain kit Esterase stain kit Esterase AS-D stain kit Fe stain kit
b Thrombus / hemostasis related test I		
Antithrombin (activity)	Plasma	Revohem AT
D dimer	Plasma	LIASAUTO D-Dimer NEO
c Thrombus / hemostasis related test II		
Bleeding time	Blood	Duke method
13 Biochemistry I		
a Biochemistry I		
Zn	Serum	Acurus Auto Zn
Cu	Serum	Quick-Auto Neo CU7070-R-1,R-2
Ferritin Quantitative	Serum	ARCHITECT Ferritin
Procalcitonin (PCT) (Quantitative)	Serum	ARCHITECT BRAHMSPCT
b Biochemistry II		
Lipase	Serum	Cygnus Auto LIPHls
KL-6	Serum	Nanopia KL-6
Cystatine C	Serum	N-assey LA Cystatine C NITTOBO
c Isozyme		
CK-MB	Serum	Cygnus Auto CK-MB MtO
d Immunochemistry		
Cardiac troponin I	Serum	ARCHITECT HsTnl
14 Biochemistry II		
a Endocrinology I		
Human chorionic gonadotropin (HCG) (Qualitative)	Urine	G CHECK CA · N
Human chorionic gonadotropin, β-subunit (HCG-β)	Serum	ARCHITECT hCG
Thyroid-stimulating hormone (TSH)	Serum	Elecsys TSH
Triiodothyronine (T3)	Serum	Elecsys T3
Thyroxine (T4)	Serum	Elecsys T4
Free triiodothyronine (FT3)	Serum	Elecsys FT3 III



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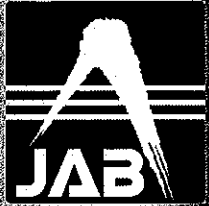
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Item	Type of Samples		Test Method
Free thyroxine (FT4)	Serum		Elecsys FT4-III
Insulin (IRI)	Serum		ARCHITECT Insulin
Follicle-stimulating hormone (FSH)	Serum		ARCHITECT FSH Assay
Luteinizing hormone (LH)	Serum		ARCHITECT LH II Assay
Prolactin (PRL)	Serum		ARCHITECT Prolactin Assay
Progesterone	Serum		ARCHITECT Progesterone Assay
Brain natriuretic peptide (BNP)	Plasma		ARCHITECT BNP-JP Assay
Estradiol (E2)	Serum		ARCHITECT Estradiol II
b Tumor marker			
α -fetoprotein (AFP)	Serum		ARCHITECT AFP
Carcinoembryonic antigen (CEA)	Serum		ARCHITECT CEA
CA19-9	Serum		ARCHITECT CA19-9
CA125	Serum		ARCHITECT CA125
Prostate-specific antigen (PSA)	Serum		ARCHITECT PSA
Squamous cell cancer related antigen (SCC)	Serum		ARCHITECT SCC
Cytokeratin 19 fragment	Serum		ARCHITECT CYFRA21-1
c Special analysis			
Urea breath test (UBT)	Others		POCone
15 Immunology			
a Immunohematology			
Blood group, Rh system	Blood		Gel column agglutination technology
Irregular antibody	Plasma		Gel column agglutination technology, Tube tests
c Immunology for infectious disease III			
RS virus antigen (Qualitative)	Others		Quicknavi RSV2
Adenovirus antigen (Qualitative) (Feces)	Feces		BD Rota/Adeno Exar Man stick
Rotavirus antigen (Qualitative) (Feces)	Feces		BD Rota/Adeno Exar Man stick
(1 \rightarrow 3)- β -D-Glucan	Plasma		β -GLLAL
Group A- β Streptococcal-rapid Detection (Qualitative)	Others		Rapidtesta Strep A
Influenza virus antigen (Qualitative)	Others		Quicknavi Flu2
Streptococcus pneumoniae capsular antigen (urinary)	Urine		Immunocatch Streptococcus pneumoniae
adenovirus antibody (Qualitative) (remove feces)	Others		Quicknavi Adeno2
Endotoxin	Plasma		ETXLAL
Legionella pneumophila antigen (Urinary)	Urine		Immunocatch Legionella pneumophila
d Hepatitis and relates			
HBs antibody (Quantitative)	Serum		ARCHITECT Anti-Anti-HBs
f Immunology for plasma protein			
β 2-microglobulin	Serum	Urine	BMG-Latex X1 "SEIKEN"
16 Microbiology			
c Identification of nucleic acid (genetic testing)			
E. coli vero cytotoxin (Qualitative)	Feces		Capilia VT
17 Gene-related / Chromosome test			
b Identification of pathogen nucleic acid			
DNA amplification assay for Mycobacteria tuberculosis complex	Sputum	Others	TRC method
Mycobacterium avium / intracellulare DNA	Sputum	Others	TRC method
Mycoplasma DNA	Others		TRC method
SARA-CoV-2 RNA	Others		Loopamp SARS-CoV-2 Detection Kit



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Scope of accreditation :

Item	Type of Samples		Test Method
18 Others excluding 11 to 16 class			
a Therapeutic drug monitoring			
Digoxin	Serum		ARCHITECT Digoxin ST assey
Theophylline	Serum		ARCHITECT Theophylline ST
Valproic acid, Carbamazepine	Serum		ARCHITECT Valproic acid assey
Phenytoin, Primidone, Ethosuximide, Phenobarbital, Zonisamide, Nitrazepam, Clonazepam, Others	Serum		ARCHITECT Phenytoin ST
Vancomycin, Teicoplanin, Gentamicin, Tobramycin, Amikacin, Arbekacin, Voriconazole	Serum		ARCHITECT Vancomycin ST assey
Pathology			
31 Preparation			
a Preparation for histodiagnosis			
Organize slices	Tissues	Others	Hematoxylin-eosin stain
CELL BLOCK	Punctured fluid	Others	Hematoxylin-eosin stain
c Preparation for immunological stain (histodiagnosis)			
Others	Others	Others	Ventana I-VIEW DAB Universal Kit DAKO Envision
d Preparation for rapid pathologic daiagnosis			
Preparation for operative rapid pathologic daiagnosis	Tissues	Tissues	Hematoxylin-eosin stain
Preparation for operative rapid cytodiagnosis	Others	Others	Papanicolaou stain
e Cytodiagnosis			
Gynecology	Others	Others	Papanicolaou stain
Fine needle aspiration cytology, Body cavity washing	Punctured fluid	Others	Papanicolaou stain
Others	Others	Others	Papanicolaou stain
32 Pathological diagnosis			
a Pathological diagnosis			
Histology	Tissues	Others	Hematoxylin-eosin stain
Cytology	Others	Others	Papanicolaou stain



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Scope of accreditation :

Item	Type of Samples	Test Method
Physiology		
101 Physiology		
a Respiratory function test (Spirography)		
Slow vital capacity		CHESTAC-8800(CHEST)
Forced vital capacity		CHESTAC-8800, DISCOM-21FXIII CHESTGRAPH Jr HI-101(CHEST)
Functional Residual Capacity		CHESTAC-8800(CHEST)
DLCO (diffusing capacity of CO)		CHESTAC-8800(CHEST)
b Electrocardiogram		
At least 12 leads including limb monopole lead and the chest leads		ECG-1550(NIHON KOHDEN) ECG-1350(NIHON KOHDEN)
Stress Electrocardiogram		ECG-1550(NIHON KOHDEN)
Holter Electrocardiogram		RAC-5103, RAC-3103, DSC-3200(NIHON KOHDEN)
c Ultrasonography		
Cardiac ultrasonography		ARTIDA(CANON) HD15, EPIQ Elite(Philips)
Abdominal ultrasonography		Aplio400(CANON)EPIQ Elite(Philips)
Body surface ultrasonography		Aplio400(CANON)EPIQ Elite(Philips) EUB-7500(HITACHI)
Vascular ultrasonography		HD15, EPIQ Elite(Philips)
d Electroencephalography		
Electroencephalography (PS, HV)		EEG-1218(NIHON KOHDEN)

Japan Accreditation Board