



JAB



Medical Laboratory
Accreditation
Certificate

Accreditation No. RML01070

***National University Corporation Gunma University
Department of Clinical Laboratory,
Clinical Investigation and Research Unit,
Gunma University Hospital***

3-39-15, Showa-machi, Maebashi, Gunma, 371-8511 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	: March 31, 2024

Renewed (1)	February 18, 2020
Initial accreditation	March 17, 2016

Y. Iizuka, President

Japan Accreditation Board

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**National University Corporation Gunma University
Department of Clinical Laboratory,
Clinical Investigation and Research Unit,
Gunma University Hospital**

National University Corporation Gunma University
Department of Clinical Laboratory, Clinical Investigation and Research Unit,
Gunma University Hospital
3-39-15, Showa-machi, Maebashi, Gunma, 371-8511 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, Bilirubin, Ketones, Occult blood reaction (Urinary), Bacteria (Test paper), Leukocyte (Test paper))	Urine	Uropaper αIII9L
Protein quantitation	Urine	Micro TP-AR
Glucose quantitation	Urine	PureautoS GLU
Hemoglobin, feces	Feces	OC-hemoCatch S
Sedimentary test, urine	Urine	The light microscopy method
2 Hematology		
a Blood test		
Peripheral blood general test*(complete blood counts)* : RBC,WBC,Hgb,PLT,Hct	Blood	CELLPACK (II) SE sheath (II) STROMATOLYSER-FB (II) STROMATOLYSER-NR STROMATOLYSER-IM SULFOLYSER
Reticulocytes	Blood	RET- SEARCH (II) CELLPACK (II) New Methylene Blue
Eosinophils		CELLPACK (II) STROMATOLYSER-4DL STROMATOLYSER-4DS May-Grunwald stain solution Giemsa stain solution
Hemogram (The microscope method)	Blood	May-Grunwald stain solution Giemsa stain solution
Hemogram (The automatic analyser method)	Blood	CELLPACK (II) STROMATOLYSER-4DL STROMATOLYSER-4DS
b Coagulation/fibrinolysis		
Prothrombin time(PT)	Plasma	Dade Innovin
Activated partial thromboplastin time(APTT)	Plasma	Thrombocheck APTT-SLA
Fibrinogen (Quantitative)	Plasma	Thrombocheck Fib (L)
Fibrinogen degradation products(FDP)	Plasma	LIASAUTO P-FDP



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Scope of accreditation :

Item	Type of Samples	Test Method
3 Biochemistry I		
a Hematochemistry I		
Total bilirubin	Serum	Iatro LQ T-BIL II
Bilirubin, indirect and direct	Serum	Iatro LQ D-BIL(A)
Total protein	Serum	Ltype Wako TP
Albumin	Serum	Ltype Wako ALB-BCP
Urea nitrogen(BUN)	Serum	「serotec」L-UN
Creatinine	Serum	Cygnus auto CRE
Uric acid	Serum	Quick auto neo UA II
Na and Cl	Serum	Hitachi ion selective electrode method. (IS,DIL,REF)
K	Serum	Hitachi ion selective electrode method. (IS,DIL,REF)
Ca	Serum	Accurass auto Ca
Inorganic phosphate and phosphoric acid	Serum	Determiner L IP II
Mg	Serum	Iatro LQ Mg rate II
Total cholesterol	Serum	Quick auto neo T-CHO II
Triglyceride	Serum	Quick auto neo TG II (A)
HDL-cholesterol	Serum	Qualigent HDL
LDL-cholesterol	Serum	Qualigent LDL
Glycated albumin	Serum	Lucica GA-L
Glucose	Serum Plasma	Quick auto neo GLU-HK, The enzyme electrode method (ARKRAY)
Hemoglobin A1c (HbA1c)	Blood	Method of HPLC (ARKRAY)
Fe	Serum	Quick auto neo Fe
Unsaturated iron binding capacity(UIBC)	Serum	Quick auto neo UIBC
Ammonia	Blood	FUJI DRY-CHEM SLIDE NH3-W II
Alkaline phosphatase	Serum	Ltype Wako ALP · J2
Cholinesterase	Serum	Quick auto neo Ch-E
γ-glutamyltranspeptidase(γ-GT)	Serum	Ltype Wako γ-GT · J
Lactate dehydrogenase(LD)	Serum	Ltype Wako LD · J
Amylase	Serum	Accurass auto AMY-IF
Creatine kinase (CK)	Serum	Cygnus auto CK
Asparate aminotransferase (AST)	Serum	Ltype Wako AST · J2
Alanine aminotransferase (ALT)	Serum	Ltype Wako ALT · J2
Blood gas analysis	Blood	Rapidpoint 405
5 Immunology		
a Immunochemistry I		
C-reactive protein(CRP)	Serum	CRP-Latex X2 「Seiken」
Immunoglobulin (IgG,IgA,IgM)	Serum	N-Assay TIA IgG-SH Nittōbō, N-Assay TIA IgA-SH Nittōbō, N-Assay TIA IgM-SH Nittōbō
C3	Serum	C3-TIA NX
C4	Serum	C4-TIA NX



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Item	Type of Samples		Test Method
Immunoglobulin(RF)	Serum		N Latex RF Kit
c Infectious disease I			
HBs antigen	Serum		ARCHITECT · HBsAg QT
HBs antibody	Serum		ARCHITECT · AUSAB · Abbott
HCV antibody(Quantitative,Qualitative)	Serum		ARCHITECT · Anti-HCV
HIV-1,2 antigen and antibody simultaneous measurement	Serum		ARCHITECT · HIVAg/Ab Combo assay
HTLV-Iantibody (Qualitative)	Serum		LUMIPULSE Presto HTLV- I / II
Serologic test for syphilis(STS) (Qualitative)	Serum		RPR Test sanko
Serologic test for syphilis (Qualitative)	Serum		ARCHITECT · Syphilis TP · Abbott
Anti streptolysin O (ASO)	Serum		N Latex ASL
6 Microbiology			
a Microscopic examination for stained film (general bacteria)			
Other	Sputum	Urine	feibaG
Use a fluorescent microscope	Sputum	Others	Auramine-RhodamineB
b Bacterial culture and identification · Antimicrobial sensitivity test(general bacteria)			
Bacterial culture and identification	Sputum	Urine	poamedhia hitujikanten baiti
Anaerobic culture	Feces	Secretions	nissuipureto henpou GAM kantenbaiti
Antimicrobial sensitivity test(general bacteria)	Urine	Sputum	MicroScan Pos Combo Panel 1J
Mycobacterial culture and Isolation(liquid medium)			BACTEC MGIT960
Mycobacterial culture and Isolation(other)	Sputum	Others	kudou PD baiti (pura)
Non-Basic Series			
11 General (urine, feces, etc.)			
a General urinalysis			
B-J proteins(Qualitative)(Urinary)	Urine		The Putnum method
Urobilinogen(Quantitative) (Urinary)	Urine		Uropaper αIII9L
Albumin (Quantitative)(Urinary)	Urine		Auto wako microalbumin
Osmolarity	Urine		Freezing point depressing method
N-acetyl glucosaminidase(NAG)(Urinary)	Urine		Ltype Wako NAG
Fibrinogen degradation products(FDP) (Urinary)	Urine		Latex Test BL-2 Blood · Urine FDP
Urinary sediment by flow cytometry (Urinary)	Urine		sysmex UF-1000i
Neutrophil Gelatinase – Associated Lipocalin(NGAL)(Urinary)	Urine		ARCHITECT Urine NGAL · Abott
b Scatolscopy			
Parasitic worm eggs (feces)	Feces		The MGL method
Direct smear method(helminth ova and including observation of fat and intestinal absorption test)	Feces		smear method
Parasite (feces)	Feces		The light microscopy method
Hemoglobin (Qualitative) (feces)	Feces		OC-hemoCatch S
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		MicroTP-AR, Pureauto S GLU, Fuchs Rosenthal calculation
Cerebrospinal fluid smear dyeing specimen (bacteria, stain)	Punctured fluid		feibaG



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Scope of accreditation :

Item	Type of Samples	Test Method
12 Hematology		
a General hematology, hemogram		
Erythrocyte sedimentation rate	Blood	VES-MATIC 30
Erythroresistant test (Parpart test)	Serum	Freezing point depressing method
Hemogram (special stain)	Blood	DAB Stain Kit Esterase Stain Kit Esterase AS-D Stain Kit Fe Stain Kit PAS Stain Kit ALP Stain Kit ACP Stain Kit
Myelogram	Others	May-Grunwald stain solution Giemsa stain solution
Myelogram (special stain)	Others	DAB Stain Kit Esterase Stain Kit Esterase AS-D Stain Kit Fe Stain Kit PAS Stain Kit ALP Stain Kit ACP Stain Kit
b Coagulation, fibrinolysis I		
Antithrombin (activity)	Plasma	ERUSHISUTEMU · ATIII
Plasminogen (activity)	Plasma	ERUSHISUTEMU · PLG
Plasmin inhibitor/plasmin complex(PIC)	Plasma	HISCL PIC Assay Kit
Protein C (activity)	Plasma	Berichrom Protein C
Coagulation factor inhibitor Qualitative (cross mixing test)	Plasma	Thrombocheck APTT-SLA
Coagulation factor(II, V, VII, VIII, IX, X, XI, XII)	Plasma	FACTOR II DEFICIENT FACTOR V DEFICIENT FACTOR VII DEFICIENT FACTOR VIII DEFICIENT FACTOR IX DEFICIENT FACTOR X DEFICIENT FACTOR XI DEFICIENT FACTOR XII DEFICIENT Dade Innovin ACTIN
D dimer	Plasma	LIASAUTO D-Dimer NEO
Coagulation factor inhibitor	Plasma	Thrombocheck APTT-SLA FACTOR VIII DEFICIENT FACTOR IX DEFICIENT
Thrombin anti-Thrombin complex (TAT)	Plasma	HISCL TAT Assay Kit
13 Biochemistry I		
a Hematochemistry I		
Zn	Serum	Accurass auto Zn
Monocarboxylate	Blood	Determiner LA, Determiner PA

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Item	Type of Samples	Test Method
Bile acids	Serum	Pure auto S TBA
Cu	Serum	Quick auto neo Cu
Ferritin Quantitative	Serum	E Test 「TOSOH」 II (Ferritin)
Procalcitonin (PCT) (Quantitative)	Serum	μ-TAS Wako PCT
b Hematochemistry II		
Adenosine deaminase(ADA)	Serum	Reagent for autoanalyzers 「Seiken」 ADA(II)
Adenosine-I-converting enzyme(ACE)	Serum	ACE Color
Leucine Aminopeptidase (LAP)	Serum	Ltype Wako LAP
Lipase	Serum	Cygnus auto LIP
KL-6	Serum	LUMIPULSE Presto KL-6 Eisai
c Isozyme		
Alkaline phosphatase Isozyme	Serum	Quick ALP (QG)
Amylase Isozyme	Serum	Accurass auto P-AMY-IF
Lactate dehydrogenase Isozyme	Serum	TITAN gel S-LD reagent (QG)
CK Isozyme	Serum	TITAN gel CK (QG)
CK-MB	Serum	Cygnus auto CK-MB MtO
d Immunochemistry		
Cardiac troponin I	Plasma	Flex cartridge Troponin I V
Myoglobin (Quantitative)	Plasma	Flex cartridge Myoglobin MYO
14 Biochemistry II		
a Endocrinology I		
Human chorionic gonadotropin(HCG)(Qualitative)	Urine	immunochromatography
Human chorionic gonadotropin(HCG)(Quantitative)	Serum	ELECSYS HCG+β II
Thyroid-stimulating hormone (TSH)	Serum	ARCHITECT • TSH
Triiodothyronine (T3)	Serum	ARCHITECT TT3 • Abbott
Thyroxine (T4)	Serum	ARCHITECT TT4 • Abbott
Free triiodothyronine(FT3)	Serum	ARCHITECT FT3 • Abbott
Free thyroxine(FT4)	Serum	ARCHITECT FT4 • Abbott
C-peptide (CPR)	Serum Urine	E Test 「TOSOH」 II (C-peptide II)
Insulin (IRI)	Serum	E Test 「TOSOH」 II (IRI)
Growth hormone (GH)	Serum	E Test 「TOSOH」 II (HGH)
Follicle-stimulating hormone (FSH)	Serum	ARCHITECT • FSH
Luteinizing hormone (LH)	Serum	ARCHITECT • LH II
Prolactin (PRL)	Serum	ARCHITECT • Prolactin
Progesterone	Serum	E Test「TOSOH」 II (Progesterone III)
Parathyroid hormones (PTH)	Serum Plasma	ELECSYS PTH
Brain natriuretic peptide (BNP)	Plasma	E Test 「TOSOH」 II (BNP)
Estradiol (E2)	Serum	E Test 「TOSOH」 II (hsE2) set
Cortisol	Serum	ELECSYS Cortisol II

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Item	Type of Samples	Test Method
Testosterone	Serum	ELECSYS Testosterone II
Thyroglobulin	Serum	ELECSYS Tg II
Adrenocorticotrophic hormone (ACTH)	Plasma	ELECSYS ACTH
b Tumor marker		
α-fetoprotein (AFP)	Serum	ELECSYS AFP II
Carcinoembryonic antigen (CEA)	Serum	ELECSYS CEA II
CA19-9	Serum	ELECSYS CA19-9 II
CA125	Serum	ELECSYS CA125 II
Prostate-specific antigen (PSA)	Serum	E Test 「TOSOH」 II (PSA II)
Squamous cell cancer related antigen (SCC)	Serum	ARCHITECT · SCC
CA15-3	Serum	ELECSYS CA15-3 II
Neuron specific enolase (NSE)	Serum	ELECSYS NSE
Cytokeratin 19 fragment	Serum	ELECSYS CYFRA
PIVKA-II(Quantitative)	Serum	LUMIPULSE Presto PIVKA II -N
α-fetoprotein lectin-affinity fraction (AFPL3%)	Serum	μ-TAS Wako AFP-L3
Interleukin 2 receptor,soluble (sIL-2R)	Serum	CELLFREE N IL-2 R
c Special analysis		
Urea breath test (UBT)	Others	POCone
15 Immunology		
b Immunology for infectious disease II		
Antistreptokinase(ASK) (Semi-quantitative)	Serum	SERODIA-ASK
Mycoplasma antigen (Qualitative)(Immunochromatography method)	Secretions	kuikkucyeisa Auto Myco
Mycoplasma pneumoniae antibody (Qualitative)	Serum	ImmunoCard Mycoplasma Test
Mycoplasma pneumoniae antibody (Semi-quantitative)	Serum	SERODIA-MYCO II
c Immunology for infectious disease III		
RS virus antigen (Qualitative)	Secretions	BD berita TM sisutemu RSV
Clostridium difficile toxin A (Qualitative)	Feces	X/Pect tokisinA/B
Adenovirus antigen (Qualitative) (Feces)	Feces	papiddotesuta rota-adeno II
Rotavirus antigen(Qualitative) (Feces)	Feces	papiddotesuta rota-adeno II
Helicobacter pylori antibody (Qualitative · Semi-quantitative)	Urine	rapiranH.pirori koutai suthikku
(1→3)-β-D-Glucan	Plasma	β-Glucan TESTWako
Serologic test for syphilis(STS) (Semi-quantitative)	Serum	RPR TEST" Sanko"
Group A-β Streptococcal-rapid Detection(Qualitative)	Secretions	BD berita TM sisutemu Strep A
Influenza virus antigen (Qualitative)	Secretions	BD berita TM sisutemu Flu
Streptococcus pneumoniae capular antigen (fluid,urinary)	Urine	imunokyacchi haienkyuukin
E. coli vero cytotoxin (Qualitative)	Feces	dhuopasu berotokisin
Treponema pallidum antibody (Semi-quantitative)	Serum	SERODIA TP·PA
Norovirus antigen (Qualitative)	Feces	quick navi-noro2
adenovirus antibody (Qualitative) (remove feces)	Secretions	BD berita TM sisutemu Adeno
Endotoxin	Plasma	Endotoxin singleTESTWako
Legionella pneumophila antigen (Urinary)	Urine	imunokyacchi rezionera
Denguevirus antibody	Serum	ByoLine Dengu Duo Ns1Ag+IgG/IgM
d Hepatitis and relates		
HBe antigen	Serum	ARCHITECT · HBeAg



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Item	Type of Samples	Test Method
HBe antibody	Serum	ARCHITECT • Anti-HBe
HA antibody	Serum	ARCHITECT • Anti-HAV IgG
HA-IgM antibody	Serum	ARCHITECT • Anti-HAV IgM
HBe antibody (Semi-quantitative, Quantitative)	Serum	ARCHITECT • Anti-HBe II
e Autoantibody		
Anti RNP antibody (Quantitative)	Serum	MESACUP-2 TEST RNP
Anti Sm antibody (Quantitative)	Serum	MESACUP-3 TEST Sm
Anti mitochondrial antibody (Quantitative)	Serum	MESACUP-2 TEST mitochondria M2
Matrix metalloproteinase-3 (MMP-3)	Serum	Panaclear MMP-3 「Latex」
Lupus anticoagulant (Qualitative)	Plasma	LA test 「Gradipore」
Anti Thyroglobulin antibody (Semi-quantitative)	Serum	SERODIA-ATG
Anti-thyroid microsomal antibody, semiquantitative (Semi-QuantitativeQualitative)	Serum	SERODIA-AMC
Anti TSH receptor antibody(TRAb)	Serum	ELECSYS TRAB
anti-nuclear antibody(immunofluorescence) (Semi-Quantitative)	Serum	Fluoro HEPANA TEST (F series)
Anti SS-A/Ro antibody (Quantitative)	Serum	MESACUP-2 TEST SS-A
Anti SS-B/La antibody (Quantitative)	Serum	MESACUP-3 TEST SS-B
Anti Scl-70 antibody (Quantitative)	Serum	MESACUP-3 TEST Scl-70
Anti DNA antibody (Quantitative)	Serum	MESACUP DNA-II TEST 「ds」
Anti citrullinated peptide antibody (Quantitative)	Serum	MESACUP-2 TEST CCP
f Immunology for plasma protein		
CH50	Serum	Auto CH50-L
β2-microglobulin	Serum	Urine LZ test Eiken β2-MG
Retinol binding protein (RBP)	Serum	N-Assay LA RBP Nittōbō
Immunoelectrophoresis	Serum	Urine Quick Gel IFE kit
Non-specific immunoglobulin IgE (Quantitative)	Serum	E Test 「TOSOH」 II (IgE II)
Specific immunoglobulin IgE (Semi-Quantitative Qualitative) • (Quantitative)	Serum	ImmunoCAP specific IgE
Transferrin (Tf)	Serum	N-Assay TIA Tf-H Nittōbō
Haptoglobin (Typing)	Serum	N-Antiserum to Human Haptoglobin
Transthyretin(Prealbumin)	Serum	Auto Wako Prealbumin
g Cellular functional test(cellular immunity related test)		
T and B lymphocyte subpopulation	Blood	BD Multitest CD3/CD16+CD56/CD45/CD19
T lymphocyte subpopulation	Blood	BD Multitest CD3/CD8/CD45/CD4
16 Microbiology		
b Bacterial culture and identification • Antimicrobial sensitivity test(general bacteria)		
Drug susceptibility test for mycobacteria	Others	BACTEC MGIT960
c Identification of nucleic acid (genetic testing)		
DNA amplification assay for Mycobacteria tuberculosis complex	Sputum	Tissues Cobasu TaqMan MTB
Mycobacterium avium • intracellulare DNA	Sputum	Tissues Cobasu TaqMan MAI
Quantification of HBV nucleic acid (Quantitative)	Serum	Cobasu TaqMan
HCV DNA (Quantitative)	Serum	Cobasu TaqMan
HIV-1 DNA (Quantitative)	Plasma	Cobasu TaqMan

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Scope of accreditation :

Item	Type of Samples	Test Method
17 Others excluding 11 to 16 class		
b Therapeutic Drug Monitoring		
Digoxin	Serum	Nanopia TDM Digoxin
Theophylline	Serum	Nanopia TDM Theophylline
Valproic acid, Carbamazepine	Serum	Nanopia TDM Valproic acid, Nanopia TDM Carbamazepine
Phenytoin, Phenobarbital	Serum	Nanopia TDM Phenytoin, Nanopia TDM Phenobarbital
Lithium	Serum	Flex cartridge Lithium Li
Vancomycin, Teicoplanin, Gentamicin, Tobramycin,	Serum	Flex cartridge Vancomycin (N) VANC, Nanopia TDM Teicoplanin, Flex cartridge Gentamicin (N) GENT, Flex cartridge Tobramycin (N) TOBR
Cyclosporin, Tacrolimus hydrat	Blood	Flex cartridge Cyclosporin CSA, Flex cartridge Tacrolimus
Methotrexate	Serum	Nanopia eTDM Methotrexate
Physiology		
101 Physiology		
a Respiratory function test (Spirography)		
Slow vital capacity		CHESTAC-9800 CHESTGRAPH HI-105
Forced vital capacity		CHESTAC-9800 CHESTGRAPH HI-105
Functional Residual Capacity		CHESTAC-9800
DLCO (diffusing capacity of CO)		CHESTAC-9800
b Electrocardiogram		
At least 12 leads including limb monopole lead and the chest leads		Cardiofax G Cardiofax V
Stress Electrocardiogram		Cardiofax G Cardiofax V Q-stress
Holter Electrocardiogram		RAC-2512 RAC-3502 RAC-2103 DSC-5500
c Ultrasonography		
Cardiac ultrasonography		IE 33 Vivid 7 Vivid i Aplio 400 ARTIDA
Vascular ultrasonography		Aplio 400 LOGIQ S8

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Scope of accreditation :

Item	Type of Samples	Test Method
Electroencephalography		
Electroencephalography (PS, HV)		Neurofax EEG-1218 Neurofax EEG-1218 Neurofax EEG-1214 Neurofax EEG-1214
Electromyography (SEP, VEP, ERA, ABR audiometry, others)		Neuropack S1 Ec lipse

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