



JAB



Medical Laboratory
Accreditation
Certificate

Accreditation No. RML00240

***Tokushima University
Laboratory Medical technology Section,
Tokushima University Hospital***

***2-50-1, Kuramotocho, Tokushima-shi, Tokushima,
770-8503 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, 2023

Revised (7)	December 29, 2020
Renewed (3)	April 23, 2019
Initial accreditation	July 6, 2007

Y. Iizuka, President

Japan Accreditation Board

Accreditation Certificate Appendix

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Tokushima University Laboratory Medical technology Section, Tokushima University Hospital

Tokushima University
Laboratory Medical technology Section,
Tokushima University Hospital
2-50-1, Kuramotocho, Tokushima-shi, Tokushima, 770-8503 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), Albumin)	Urine	uropaperαIII'eiken'11 gravity : refractometer bilirubin:Ictotest
Protein quantitation	Urine	μTP-AR II
Glucose quantitation	Urine	Quick auto neo GLU-HK
Sedimentary test, urine	Urine	labosteinS
2 Hematology		
a Blood test		
Peripheral blood general test*(complete blood counts)* : RBC,WBC,Hgb,PLT,Hct	Blood	CN-FREE CBC TIMEPAC DIFF TIMEPAC PEROX SHEATH FUOROCELL WNR LYSERCELL WNR SULFOLYSER CELLPAC DCL
Reticulocytes	Blood	autoRETIC capirott
Hemogram (The microscope method)	Blood	May-Giemsa's stain
Hemogram (The automatic analyser method)	Blood	DIFF TIMEPAC
b Coagulation/fibrinolysis		
Prothrombin time(PT)	Plasma	Heamos IL RecombPlastin 2G
Activated partial thromboplastin time(APTT)	Plasma	Heamos IL Synthsil
Fibrinogen (Quantitative)	Plasma	thrombo check
Fibrinogen degradation products(FDP)	Plasma	LPIA FDP-P
3 Biochemistry I		
a Hematochemistry I		
Total bilirubin	Serum	Accuras auto T-BIL
Bilirubin, indirect and direct	Serum	Accuras auto D-BIL
Total protein	Serum	Accuras auto TP
Albumin	Serum	Accuras auto ALB II
Proteins fractionation	Serum	Agarose gel electrophoresis
Urea nitrogen(BUN)	Serum	Urine
Creatinine	Serum	Urine
		Aqua auto kainos UN II Reagent
		Serotec CRE-N



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Scope of accreditation :

Item	Type of Samples		Test Method
Uric acid	Serum	Urine	Serotec UA-L
Na and Cl	Serum	Urine	Ion choice electric method
K	Serum	Urine	Ion choice electric method
Ca	Serum	Urine	Aqua auto kainos Ca Reagent
Inorganic phosphate and phosphoric acid	Serum	Urine	Detamina-L IP II
Mg	Serum		Iatoro LQ Mg rate II
Total cholesterol	Serum		Detamina L TC II
Triglyceride	Serum		Quorigent TG
HDL-cholesterol	Serum		Metaboride HDL-C
LDL-cholesterol	Serum		Quorigent LDL
Glycated albumin	Serum		Lucika GA
Glucose	Plasma		Quick auto neo GLU-HK
Hemoglobin A1c (HbA1c)	Blood		HPLC
Fe	Serum		Quick auto neo Fe
Unsaturated iron binding capacity(UIBC)	Serum		Quick auto neo UIBC
Ammonia	Blood	Plasma	fuji drychem slide NH3-W II fuji drychem slide NH3-P III
Alkaline phosphatase	Serum		Cygnus auto ALP IF
Cholinesterase	Serum		Quick auto neo Ch-E
γ -glutamyltranspeptidase(γ -GT)	Serum		Quick auto neo γ -GT JS
Lactate dehydrogenase(LD)	Serum		Serotec LD IF
Amylase	Serum	Urine	Serotec AMY-ML
Creatine kinase (CK)	Serum		Labofit CK cica Liquid CK
Asparate aminotransferase (AST)	Serum		Ltype wako AST · J2
Alanine aminotransferase (ALT)	Serum		Ltype wako ALT · J2
Blood gas analysis	Blood		electrode method algorithm
5 Immunology			
a Immunochemistry I			
C-reactive protein(CRP)	Serum		Accuras auto CRP-N
Immunoglobulin (IgG,IgA,IgM)	Serum		N-assay TIA IgG-SH,N-assay TIA IgA-SH,N-assay IgM-SH
C3	Serum		N-assay TIA C3-SH
C4	Serum		N-assay TIA C4-SH
Immunoglobulin(RF)	Serum		LZ test EIKEN RF
b Immunohematology			
Blood group (ABO type)	Blood		Ortho Biovue anti-A,anti-B,anti-D cassette
Blood group(Rho(D) factor)	Blood		Ortho Biovue anti-A,anti-B,anti-D cassette
Indirect Coombs,direct Coombs	Blood		Gamma-clone anti-IgG



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Item	Type of Samples	Test Method
c Infectious disease I		
HBs antigen	Serum	Lumipulse Presto HBsAg-HQ Lumipulse HBsAg-HQ
HBs antibody	Serum	Lumipulse Presto HBsAb-III Lumipulse HBsAb-N
HCV antibody(Quantitative,Qualitative)	Serum	Lumipulse Presto HCV Lumipulse HCV
HIV-1,2 antigen and antibody simultaneous measurement	Serum	Lumipulse Presto HIV Ag/Ab
HTLV-Iantibody (Qualitative)	Serum	LUMIPULSE PRESTO HTLV- I / II
Serologic test for syphilis(STS) (Qualitative)	Serum	Accuras auto RPR
Serologic test for syphilis (Qualitative)	Serum	Lumipulse Presto TP
Anti streptolysin O (ASO)	Serum	LZ test EIKEN ASO
6 Microbiology		
a Microscopic examination for stained film (general bacteria)		
Other	Others	gram stain (B&M) (AEROSPRAY 7322) Ziehl-Neelsen stain (AEROSPRAY 7722)
b Bacterial culture and identification · Antimicrobial sensitivity test(general bacteria)		
Bacterial culture and identification	Others	MALDI Biotyper, BACTEC FX, VITEK 2 blue ,Rap ID ANA II , ID test · HN-20 rapid
Anaerobic culture	Others	Rsp ID ANA II , MALDI Biotyper
Antimicrobial sensitivity test(general bacteria)	Others	DPS192iX, RAISUS ANY , KB Disk
Mycobacterial culture and Isolation(liquid medium)	Others	BACTEC MGIT 320
Mycobacterial culture and Isolation(other)	Others	Ogawa medium
Mycobacterial identification	Others	DDH Mycobacteria, MALDI Biotyper
Non-Basic Series		
11 General (urine, feces, etc.)		
a General urinalysis		
Albumin (Quantitative)(Urinary)	Urine	Serotec TIA-ALBG
Osmolarity	Urine	freezing point depressing method
N-acetyl glucosaminidase(NAG)(Urinary)	Urine	Ltype wako NAG
Urinary sediment by flow cytometry (Urinary)	Urine	UF II PACK-SED UF II PACK-BAC UF II SERCH-SED UF II SERCH-BAC
b Scatolscopy		
Parasitic worm eggs (feces)	Feces	horumarin · eruhou, syotouensinfuyuhou
Direct smear method(helminth ova and including observation of fat and intestinal absorption test)	Feces	Direct smear method, Kanizinsokusyotouhuyuhou
Hemoglobin (Qualitative) (feces)	Feces	OC-hemodiaautoSeikenn



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Item	Type of Samples	Test 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	cell numbers:Fuchs Rosenthal specific flow cytometry gravity:refractometer Protein:μTP-AR Glucose:Quick auto neo GLU-HK
12 Hematology		
a General hematology, hemogram		
Erythrocyte sedimentation rate	Blood	Westergren
Serum osmolality	Serum	freezing point depressing method
HemoglobinF(HbF)	Blood	HPLC
Myelogram	Others	May-Giemsa's stain
b Coagulation, fibrinolysis I		
Antithrombin (activity)	Plasma	Chromorate ATIII(C) II
Plasminogen (activity)	Plasma	Chromorate PLG(C) II
Plasmin inhibitor/plasmin complex(PIC)	Plasma	LPIA ace PPI II
Coagulation factor(II, V, VII, VIII, IX, X, XI, XII, XIII)	Plasma	HemosIL RecombiPlastin 2G, HemosIL Synthsil APTT, HemosIL Factor II, V, VII, X, VIII, IX, XI, XII
D dimer	Plasma	LPIA ace D-dimer
Coagulation factor inhibitor	Plasma	HemosIL Synthsil APTT, HemosIL Factor VIII, IX
Thrombin anti-Thrombin complex (TAT)	Plasma	STACIA CLEIA TAT
c Coagulation, fibrinolysis II		
Bleeding time	Others	Duke method
Platelet aggregation	Plasma	「MCM」ADP, Collagen Reagent horm
13 Biochemistry I		
a Hematochemistry I		
Phospholipid	Serum	Detamina L PL
Zn	Serum	Accuras auto Zn
Monocarboxylate	Plasma	Detamina LA, Detamina PA
Bile acids	Serum	Aqua auto kinos TBA reagent
Cu	Serum	Quick auto neo Cu
Ferritin Quantitative	Serum	Iatoro Ferritin
b Hematochemistry II		
Leucine Aminopeptidase (LAP)	Serum	Serotec LAP-R
Lipase	Serum	Cygnus auto LIP
KL-6	Serum	LUMIPLUSE PRESTO KL-6
c Isozyme		
Alkaline phosphatase, bone (High-sensitive)	Serum	Quick EP BAP-IF reagent
Amylase Isozyme	Serum	setotec AMISO-ML
Lactate dehydrogenase Isozyme	Serum	Titan gel S-LD reagent(QG)
CK-MB	Serum	L type wako CK-MB mass



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Item	Type of Samples	Test Method
d Immunochemistry		
Cardiac troponin I	Serum	Lumipulse high sensitive Troponin I
14 Biochemistry II		
a Endocrinology I		
Human chorionic gonadotropin, β -subunit(HCG- β)	Serum	E TESUTO 「TOSOH」 II (β -HCG)
Thyroid-stimulating hormone (TSH)	Serum	LUMIPLUSE PRESTO TSH
Free triiodothyronine(FT3)	Serum	LUMIPLUSE PRESTO FT3
Free thyroxine(FT4)	Serum	LUMIPLUSE PRESTO FT4
C-peptide (CPR)	Serum	Urine
Insulin (IRI)	Serum	E TESUTO 「TOSOH」 II (C-PEPUCHIDO)
Growth hormone (GH)	Serum	E TESUTO 「TOSOH」 II (HGH)
Follicle-stimulating hormone (FSH)	Serum	ECLusys FSH
Luteinizing hormone (LH)	Serum	ECLusys LH
Prolactin (PRL)	Serum	ECLusys PURORAKUCHINN
Progesterone	Serum	E TESUTO 「TOSOH」 II (PUROGESUTERONN)
Brain natriuretic peptide (BNP)	Plasma	E TESUTO 「TOSOH」 II (BNP)
Estradiol (E2)	Serum	ECLusys ESUTORAJIOURU
Cortisol	Serum	E TESUTO 「TOSOH」 II (KORUCHIZOURU)
Testosterone	Serum	E TESUTO 「TOSOH」 II (TESUTOSUTERONN)
Adrenocorticotrophic hormone (ACTH)	Plasma	E TESUTO 「TOSOH」 II (ACTH)
b Tumor marker		
α -fetoprotein (AFP)	Serum	LUMIPLUSE PRESTO AFP
Carcinoembryonic antigen (CEA)	Serum	LUMIPLUSE PRESTO CEA
CA19-9	Serum	LUMIPLUSE PRESTO CA19-9
CA125	Serum	ECLusys CA125
Prostate-specific antigen (PSA)	Serum	ECLusys PSA
Squamous cell cancer related antigen (SCC)	Serum	ARCHITECT・SCC
CA15-3	Serum	E TESUTO 「TOSOH」 II (CA15-3)
Cytokeratin 19 fragment	Serum	LUMIPLUSE PRESTO CYFRA
PIVKA-II(Quantitative)	Serum	LUMIPLUSE PRESTO PIVKA II
Inteleukin 2 receptor,soluble (sIL-2R)	Serum	Nanopia IL-2R
15 Immunology		
a Immunohematology		
Blood group, Rh system	Blood	anti-C,anti-c,anti-E,anti-e
Blood group, ABO subgroups	Blood	GalserveAB
Glyco transferase associated with ABO blood typ	Plasma	GalserveAB
Irregular antibody	Blood	Ortho Biovue anti-IgG cassette
Anti platelet antibody	Serum	anti-PLT・MPHA・Screen
c Immunology for infectious disease III		
Escherichia coli,serotyping	Others	byougendaityoukinmenekikessei 「seiken」
Candida albicans antigen (Qualitative)	Serum	Canditec
Clostridium difficile toxin A (Qualitative)	Feces	C.DIFF QUIK CHEK complete
(1 \rightarrow 3)- β -D-Glucan	Plasma	β -Glucan TEST WAKO
Serologic test for syphilis(STS)(Quantitative)	Serum	Accuras auto RPR



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Item	Type of Samples	Test Method
E. coli vero cytotoxin (Qualitative)	Others	dyuopas verotoxin
Treponema pallidum antibody (Semi-quantitative)	Serum	SERODIA TP
Virus antibody in immunoglobulin class (Herpesvirus, Rubella virus, Cytomegalovirus, Measles virus, Mumps virus, Varicella · Herpes virus)	Serum	UIRUSU KOUTAI EIA[SEIKENN]RUBERA IgG, UIRUSU KOUTAI EIA[SEIKENN]RUBERA IgM, UIRUSU KOUTAI EIA[SEIKENN]MASINN IgG, MASINN IgM[SEIKENN], UIRUSU KOUTAI EIA[SEIKENN]MUNNPUSU IgG, UIRUSU KOUTAI EIA[SEIKENN]MUNNPUSU IgM, UIRUSU KOUTAI EIA[SEIKENN]SAITOMEGARO IgG, UIRUSU KOUTAI EIA[SEIKENN]SAITOMEGARO IgM, UIRUSU KOUTAI EIA[SEIKENN]SUITOU IgG, UIRUSU KOUTAI EIA[SEIKENN]SUITOU IgM, UIRUSU KOUTAI EIA[SEIKENN]HERUPESU IgG, HERUPESU IgM[SEIKENN]
HTLV-I antibody (Semi-quantitative)	Serum	SERODIA HTLV- I
Chlamydia trachomatis antibody in immunoglobulin class	Serum	PEPUTAIDO KURAMIJIA IgA, PEPUTAIDO KURAMIJIA IgG
HIV-1 antibody (Western blot method)	Serum	HIV-WEB (RABUBUROTTO1)
HIV-2 antibody (Western blot method)	Serum	HIV-WEB (RABUBUROTTO2)
d Hepatitis and relates		
HBe antigen	Serum	Lumipulse Presto HBeAg
HBe antibody	Serum	Lumipulse Presto HBeAb
HBe antibody (Semi-quantitative, Quantitative)	Serum	Lumipulse Presto HBeAb-III
e Autoantibody		
Matrix metalloproteinase-3 (MMP-3)	Serum	Panakuria MMP-3 latex
Anti TSH receptor antibody (TRAb)	Serum	E TESUTO 「TOSOH」 II (TRAB)
anti-nuclear antibody (immunofluorescence) (Semi-Quantitative)	Serum	FURUORO HEPANA TESUTO
f Immunology for plasma protein		
CH50	Serum	Hotaika HA test wako
β2-microglobulin	Serum	Urine
Non-specific immunoglobulin IgE (Quantitative)	Serum	LUMIPLUS PRESTO β2-M E TESUTO 「TOSOH」 II (IgE II)
g Cellular functional test (cellular immunity related test)		
T and B lymphocyte subpopulation	Blood	cytostat tetraCHROME CD45-FITC/CD56-RD1/CD19-ECD/CD3-PC5
T lymphocyte subpopulation	Blood	cytostat tetraCHROME CD45-FITC/CD4-RD1/CD8-ECD/CD3-PC5



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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	Others	RAISUS ANY
Drug susceptibility test for mycobacteria	Others	bit spectrum-SR 、 BrothMIC NTM
c Identification of nucleic acid (genetic testing)		
Mycobacteria DNA	Others	DDH Mycobacteria, MALDI Biotyper
DNA amplification assay for Mycobacteria tuberculosis complex	Others	GENECUBE (PCR reaction)
Mycobacterium avium • intracellulare DNA	Others	GENECUBE (PCR reaction)
17 Others excluding 11 to 16 class		
b Therapeutic Drug Monitoring		
Lithium	Serum	Espa Li II
Teicoplanin, Vancomycym	Serum	Nanopia TDM teicoplanin Nanopia TDM Vancomycym
Cyclosporin, Tacrolimus hydrat	Blood	ECLusys Cyclosporine, ECLusys Tacrolimus
Methotrexate	Serum	Nanopia TDM methotrexate

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