



# 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, 2027

Revised  
Renewed  
Initial accreditation

March 2, 2023  
August 1, 2023  
July 6, 2007

Y. Iizuka, President

**Japan Accreditation Board**



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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
<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, Urobilin, Bilirubin, Ketones, Occult blood reaction (Urinary), Bacteria (Test paper), Sodium chloride, Leukocyte (Test paper), Albumin)	Urine	uropaper@III'eiken'II 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 count / blood cell morphology 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 capiroott
Hemogram (The microscope method)	Blood	May-Gieamsa's stain
Hemogram (The automatic analyser method)	Blood	DIFF TIMEPAC .LYSARCELL WDF
b Thrombus / hemostasis related test		
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 Biochemistry		
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



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### Scope of accreditation :

Item	Type of Samples	Test Method
Proteins fractionation	Serum	Agarose gel electrophoresis
Urea nitrogen(BUN)	Serum	Aqua auto kainos UN II Reagent
Creatinine	Serum	Serotec CREA-N
Utic acid	Serum	Serotec UA-L
Na and Cl	Serum	Ion choice electric method
K	Serum	Ion choice electric method
Ca	Serum	Aqua auto kainos Ca Reagent
Inorganic phosphate and phosphoric acid	Serum	Detamina-L IP II
Mg	Serum	Iatoro I.Q 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-PIII
Alkaline phosphatase	Serum	Cygnus auto ALP IF
Cholinesterase	Serum	Quick auto neo Ch-E
$\gamma$ -glutamyltranspeptidase ( $\gamma$ -GT)	Serum	Quick auto neo $\gamma$ -GT JS
Lactate dehydrogenase (LD)	Serum	Serotec LD IF
Amylase	Serum	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 1		
C-reactive protein (CRP)	Serum	Accuras auto CRP-N
Immunoglobulin (IgG, IgA, IgM, IgD)	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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### Scope of accreditation :

Item	Type of Samples	Test Method
① 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-I antibody (Qualitative)	Serum	LUMIPULSE PRESTO HTLV- I / II
Serologic test for syphilis (STS) (Qualitative)	Serum	Accuris auto RPR
Serologic test for syphilis (Qualitative)	Serum	Lumipulse Presto TP
Anti streptolysin O (ASO)	Serum	I.Z 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	Serotech 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 Scatology		
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, Kanizinsokusyntouhuyuhou
Hemoglobin (Qualitative) (feces)	Feces	OC-hemodiaautoSeiken



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### Scope of accreditation :

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: $\mu$ TP-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-Gieamsa's stain
b Thrombus / hemostasis related test 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 Thrombus / hemostasis related test II		
Bleeding time	Others	Duke method
Platelet aggregation	Plasma	[MCM]ADP,Collagen Reagent horn
13 Biochemistry I		
a Biochemistry I		
Phospholipid	Serum	Detamina L PL
Zn	Serum	Accuris 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 Biochemistry II		
Leucine Aminopeptidase (LAP)	Serum	Serotec LAP-R
Lipase	Serum	Cygnus auto LIP
KL-6	Serum	LUMIPLUSE PRESTO KL-6
c Isozyme		
Amylase Isozyme	Serum	setotec AMISO-ML
CK-MB	Serum	L type wako CK-MB mass
d Immunochemistry		
Cardiac troponin I	Serum	Lumipulse high sensitive Troponin I



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### Scope of accreditation :

Item	Type of Samples	Test Method
14 Biochemistry II		
a Endocrinology I		
Human chorionic gonadotropin, $\beta$ -subunit (HCG- $\beta$ )	Serum	E TESUTO 「TOSOH」 II ( $\beta$ -HCG)
Thyroid-stimulating hormone (TSH)	Serum	LUMIPLUSE PRESTO TSH IFCC
Free triiodothyronine (FT3)	Serum	LUMIPLUSE PRESTO FT3
Free thyroxine (FT4)	Serum	LUMIPLUSE PRESTO FT4
C-peptide (CPR)	Serum	E TESUTO 「TOSOH」 II (C-PEPUCHIDO)
Insulin (IRI)	Serum	E TESUTO 「TOSOH」 II (IRI)
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 II)
Testosterone	Serum	E TESUTO 「TOSOH」 II (TESOTOSUTERONN)
N-terminal pro brain natriuretic peptide (NT-proBNP)	Serum	ARCHITECT Alere NT-proBNP • Abbott
Adrenocorticotropic hormone (ACTH)	Plasma	E TESUTO 「TOSOH」 II (ACTH)
b Tumor marker		
$\alpha$ -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 • MPVIA • Screen
c Immunology for infectious disease III		
Escherichia coli,serotyping	Others	byougendaiyoukinmenekikessci「seiken」
Clostridium difficile toxin A (Qualitative)	Feces	C DIFF QUIK CHEK complete
(1→3)- $\beta$ -D-Glucan	Plasma	$\beta$ -Glucan TEST WAKO
Serologic test for syphilis (STS) (Quantitative)	Serum	Accuras auto RPR
Treponema pallidum antibody (Semi-quantitative)	Serum	SERODIA TP



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### **Tokushima University Laboratory Medical technology Section, Tokushima 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	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, SAITOMEGARO IgM[SEIKENN], 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 KURAMIIJA IgA, PEPUTAIDO KURAMIIJA IgG
d Hepatitis and relates		
HBe antigen	Serum	Lumipulse Presto HBeAg
HBe antibody	Serum	Lumipulse Presto HBeAb
HBc antibody (Semi-quantitative, Quantitative)	Serum	Lumipulse Presto HBcAb-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 HEPPANA TESUTO
Anti IgG4	Serum	N-assay LA IgG4
f Immunology for plasma protein		
CH50	Serum	Hotaika HA test wako
β2-microglobulin	Serum	LUMIPLUS PRESTO β2-M
Non-specific immunoglobulin IgE (Quantitative)	Serum	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
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)		
E. coli vero cytotoxin (Qualitative)	Others	dyuopas vero toxin
17 Gene-related / Chromosome test		
b Identification of pathogen nucleic acid		
Mycobacteria DNA	Others	DDH Mycobacteria, MALDI Biotype
DNA amplification assay for Mycobacteria tuberculosis complex	Others	GENECUBE(PCR reaction)
Mycobacterium avium / intracellulare DNA	Others	GENECUBE(PCR reaction)



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

### Scope of accreditation

Item	Type of Samples	Test Method
18 Others excluding 11 to 16 class a Therapeutic drug monitoring		
Lithium	Serum	Espa Li II
Vancomycin, Teicoplanin, Gentamicin, Tobramycin, Amikacin, Arbekacin, Voriconazole	Serum	Nanopia TDM teicoplanin Nanopia TDM Vancomycin
Cyclosporin, Tacrolimus hydrat, Everolimus, Mycophenolate mofetil	Serum	ECLusys Cyclosporine, ECLusys Tacrolimus
Methotrexate	Serum	Nanopia TDM methotrexate

# Japan Accreditation Board