



Medical Laboratory  
Accreditation  
Certificate

Accreditation No. RML01260



***Center for Public Strategy Nagasaki University  
Department of Laboratory Medicine  
Nagasaki University Hospital***

***1-7-1 Sakamoto, Nagasaki city, 852-8501 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, 2025

Revised	June 15, 2023
Renewed	March 16, 2021
Initial accreditation	March 16, 2017

Y. Iizuka, President

**Japan Accreditation Board**



# Accreditation Certificate Appendix

(Page 1/6)

Accreditation No. RML01260

## **Center for Public Strategy Nagasaki University Department of Laboratory Medicine Nagasaki University Hospital**

Center for Public Strategy Nagasaki University  
Department of Laboratory Medicine Nagasaki University Hospital  
1-7-1 Sakamoto, Nagasaki city, 852-8501 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	Urifuretto S 11UA AUTION Sticks	
Protein quantitation	Urine	AR WAKO micro TP-AR	
Glucose quantitation	Urine	QuickAUTO 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 DST Sulfolyser Lysercell WNR Fluorocell PLT Fluorocell WNR	
Reticulocytes	Blood	Fluorocell RET	
Hemogram (The microscope method)	Blood	May-Grunwald Stain solution Giemsa Stain Solution	
Hemogram (The automatic analyser method)	Blood	Lysercell WDF Fluorocell WDF	
b Thrombus / hemostasis related test			
Prothrombin time(PT)	Plasma	Thromborel S	
Activated partial thromboplastin time(APTT)	Plasma	Revohem ATPP SLA	
Fibrinogen (Quantitative)	Plasma	Thrombocheck Fib (L)	
Fibrinogen degradation products(FDP)	Plasma	nanopia P-FDP	
3 Biochemistry I			
a Biochemistry			
Total bilirubin	Serum	Plasma	Total bilirubin E-HA test wako
Bilirubin, indirect and direct	Serum	Plasma	Direct bilirubin E-HA test wako
Total protein	Serum	Plasma	Aqua-auto Kainos TP-II
Albumin	Serum	Plasma	Aqua-auto Kainos ALB



# Accreditation Certificate Appendix

(Page 2/6)

Accreditation No. RML01260

## **Center for Public Strategy Nagasaki University Department of Laboratory Medicine Nagasaki University Hospital**

### Scope of accreditation :

Item	Type of Samples		Test Method
Proteins fractionation	Serum		Capillary electrophoresis
Urea nitrogen(BUN)	Serum	Plasma	QuickAUTO Neo BUN
Creatinine	Serum	Plasma	Cygnus Auto CRE
Uric acid	Serum	Plasma	QuickAUTO Neo UA II
Na and Cl	Serum	Plasma	Ion- Selective Electrode Method
K	Serum	Plasma	Ion- Selective Electrode Method
Ca	Serum	Plasma	Aqua-auto Kainos Ca
Inorganic phosphate and phosphoric acid	Serum	Plasma	Determinar- L IP II
Mg	Serum	Plasma	Aqua-auto Kainos Mg-II
Total cholesterol	Serum	Plasma	Determinar- L TC II
Triglyceride	Serum	Plasma	Determinar- L TG II
HDL-cholesterol	Serum	Plasma	Metabolite HDL-C
LDL-cholesterol	Serum	Plasma	Metabolite LDL-C
Glycated albumin	Serum	Plasma	Lucica GA-L
Glucose	Plasma		QuickAUTO Neo GLU-HK GOD electrode
Hemoglobin A1c (HbA1c)	Blood		Ion exchange high performance liquid chromatography
Fe	Serum	Plasma	QuickAUTO Neo Fe
Unsaturated iron binding capacity (UIBC)	Serum	Plasma	QuickAUTO Neo UIBC
Ammonia	Blood		Fuji Dri-chem slide NH3- II
Alkaline phosphatase	Serum	Plasma	L-type Wako- ALP IFCC
Cholinesterase	Serum	Plasma	「Serotec」 Che-ML
γ-glutamyltranspeptidase (γ-GT)	Serum	Plasma	L-type Wako- γGTP·J
Lactate dehydrogenase (LD)	Serum	Plasma	L-tipe Wako- LDH·IF
Amylase	Serum	Plasma	Akyurasu auto AMY-IF
Creatine kinase (CK)	Serum	Plasma	L-type Wako- CK
Asparate aminotransferase (AST)	Serum	Plasma	L-type Wako- AST·J2
Alanine aminotransferase (ALT)	Serum	Plasma	L-type Wako- ALT·J2
Blood gas analysis	Blood		Electrode Method
<b>5 Immunology</b>			
<b>a Immunochemistry I</b>			
C-reactive protein (CRP)	Serum	Plasma	CRP-Latex 「seiken」
Immunoglobulin (IgG, IgA, IgM)	Serum		N-assay TIA IgG-SH nittobo N-assay TIA IgA-SH nittobo N-assay TIA IgM-SH nittobo
C3	Serum		N-assay TIAC3-SH nittobo
C4	Serum		N-assay TIAC4-SH nittobo
Immunoglobulin (RF)	Serum		LZ test eiken RF
<b>b Immunohematology</b>			
Blood group (ABO type)	Blood		Tube test,MTS method
Blood group (Rho (D) factor)	Blood		Tube test,MTS method
Indirect Coombs, direct Coombs	Blood		Tube test,MTS method



# Accreditation Certificate Appendix

(Page 3/6)

Accreditation No. RML01260

## **Center for Public Strategy Nagasaki University Department of Laboratory Medicine Nagasaki University Hospital**

### Scope of accreditation :

Item	Type of Samples		Test Method
<b>c Infectious disease I</b>			
HBs antigen	Serum	Plasma	Alinity HBsAg QT · Abbott
HCV antibody (Quantitative, Qualitative)	Serum	Plasma	Alinity HCVAb · Abbott
HIV-1,2 antigen and antibody simultaneous measurement	Serum	Plasma	Alinity HIV Ag/Ab Combo · Abbott
HTLV-I antibody (Qualitative)	Serum	Plasma	Alinity HTLV · Abbott
<b>6 Microbiology</b>			
<b>a Microscopic examination for stained film (general bacteria)</b>			
Other	Sputum	Blood	Gram stain, Ziehl-Neelsen stain
<b>b Bacterial culture and identification / Antimicrobial sensitivity test (general bacteria)</b>			
Bacterial culture and identification	Sputum	Blood	MALDI-TOF Mass spectrometry
Anaerobic culture	Secretions	Feces	Anaerobic Culture
Antimicrobial sensitivity test (general bacteria)	Sputum	Secretions	Antimicrobial Susceptibility Test (Phoenix M50)
Mycobacterial culture and Isolation (liquid medium)	Sputum	Punctured fluid	BD BACTEC MGIT 960
Mycobacterial culture and Isolation (other)	Sputum	Punctured fluid	Ogawa KY medium
Mycobacterial identification	Sputum	Punctured fluid	Mass spectrometry
<b>Non-Basic Series</b>			
<b>11 General (urine, feces, etc.)</b>			
<b>a General urinalysis</b>			
Albumin (Quantitative) (Urinary)	Urine		「Serotec」 TIA-ALBG
Osmolarity	Urine		Freezing Point Method
N-acetyl glucosaminidase (NAG) (Urinary)	Urine		N-assay NAG nittobo
Urinary sediment by flow cytometry (Urinary)	Urine	Punctured fluid	Flow-cytometry
<b>12 Hematology</b>			
<b>a General hematology, hemogram</b>			
Erythrocyte sedimentation rate	Blood		Modified Westergren Method
Serum osmolality	Serum		Freezing Point Method
Terminal deoxynucleotidyl transferase (TdT) (High-sensitive)	Blood		Flow cytometry assay
Myelogram	Others		May-Grunwald Stain solution Giemsa Stain Solution
Malignant tumor cell	Blood	Others	Flow cytometry assay
<b>b Thrombus / hemostasis related test I</b>			
Antithrombin (activity)	Plasma		Revohem AT
Coagulation factor (VIII, IX)	Plasma		Thrombocheck factor VIII Thrombocheck factor IX Revohem APTT SLA
Fibrin monomer	Plasma		auto LIA FM
D dimer	Plasma		nanopia D dimer
<b>13 Biochemistry I</b>			
<b>a Biochemistry I</b>			
Ferritin Quantitative	Serum	Plasma	Elecsys Ferritin (S300)
Procalcitonin (PCT) (Quantitative)	Serum	Plasma	Elecsys Ferritin (S300)



**Center for Public Strategy Nagasaki University**  
**Department of Laboratory Medicine**  
**Nagasaki University Hospital**

Scope of accreditation :

Item	Type of Samples		Test Method
<b>b Biochemistry II</b>			
KL-6	Serum	Plasma	STACIA CLEIA KL-6
<b>c Isozyme</b>			
Amylase Isozyme	Serum	Plasma	Akyurasu auto P-AMY-IF
CK-MB	Serum	Plasma	L-Type Wako-CKMB
<b>d Immunochemistry</b>			
Cardiac troponin T (TnT) (Qualitative, Quantitative)	Serum	Plasma	Elecsys TnT hs (S300)
<b>14 Biochemistry II</b>			
<b>a Endocrinology I</b>			
Human chorionic gonadotropin, $\beta$ -subunit (HCG- $\beta$ )	Serum	Plasma	Elecsys HCG+ $\beta$ II (S300)
Thyroid-stimulating hormone (TSH)	Serum	Plasma	Elecsys TSH (S300)
Free triiodothyronine (FT3)	Serum	Plasma	Elecsys FT3 III (S300)
Free thyroxine (FT4)	Serum	Plasma	Elecsys FT4 III (S300)
C-peptide (CPR)	Serum	Plasma	Elecsys CPR (S100)
Insulin (IRI)	Serum	Plasma	Elecsys Insurin (S100)
Follicle-stimulating hormone (FSH)	Serum	Plasma	Elecsys FSH II (S300)
Luteinizing hormone (LH)	Serum	Plasma	Elecsys LH (S300)
Prolactin (PRL)	Serum	Plasma	Elecsys PRL III (S300)
Progesterone	Serum	Plasma	Elecsys Progesterone III (S300)
Parathyroid hormones (PTH)	Plasma		Elecsys PTH (S300)
Estradiol (E2)	Serum	Plasma	Elecsys E2 IV (S300)
Cortisol	Serum	Plasma	Elecsys Cortisol II (S300)
N-terminal pro brain natriuretic peptide (NT-proBNP)	Serum	Plasma	Elecsys NT-proBNP II (S300)
Thyroglobulin	Serum	Plasma	Elecsys Tg II (S300)
<b>b Tumor marker</b>			
$\alpha$ -fetoprotein (AFP)	Serum	Plasma	Elecsys AFP II (S300)
Carcinoembryonic antigen (CEA)	Serum	Plasma	Elecsys CEA II (S300)
CA19-9	Serum	Plasma	Elecsys CA19-9 II (S300)
CA125	Serum	Plasma	Elecsys CA125 II (S300)
Prostate-specific antigen (PSA)	Serum	Plasma	Elecsys PSA II (S300)
Free PSA/Total PSA ratio	Serum	Plasma	Elecsys free PSA
PIVKA-II (Quantitative)	Serum	Plasma	STACIA CLEIA PIVKA- II
Interleukin 2 receptor, soluble (sIL-2R)	Serum	Plasma	STACIA CLEIA IL-2R
<b>c Special analysis</b>			
Urea breath test (UBT)	Others		Infrared Spectroscopy
<b>15 Immunology</b>			
<b>a Immunohematology</b>			
Blood group, ABO subgroups	Blood		Tube test
Irregular antibody	Blood		Tube test, MTS method
<b>b Immunology for infectious disease II</b>			
Mycoplasma antigen (Qualitative) (Immunochromatography method)	Secretions		Ribotest® Mycoplasma



# Accreditation Certificate Appendix

(Page 5/6)

Accreditation No. RML01260

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### Scope of accreditation :

Item	Type of Samples		Test Method
<b>c Immunology for infectious disease III</b>			
E. coli O157 antigen (Qualitative)	Feces		Capilia O157
RS virus antigen (Qualitative)	Secretions		Check RSV
Candida albicans antigen (Qualitative)	Serum		Cica Fungi Test Candida
Clostridium difficile toxin A (Qualitative)	Feces		C.DIFF QUIK CHEK COMPLETE
Adenovirus antigen (Qualitative) (Feces)	Feces		Rapidtesta Rota·Adeno II
Rotavirus antigen (Qualitative) (Feces)	Feces		Rapidtesta Rota·Adeno II
Cryptococcus neoformans antigen (Qualitative)	Serum		Serodirect 'EIKEN' Cryptococcus
Aspergillus antigen	Serum		Aspergillus galactomannan enzym immunoassay
(1→3)-β-D-Glucan	Serum		Fungitec G Test ES " Nissui "
Serologic test for syphilis (STS) (Quantitative)	Serum		LASAY Auto RPR
Group A-β Streptococcal-rapid Detection (Qualitative)	Secretions		Rapid test StrepA
Influenza virus antigen (Qualitative)	Secretions		Fuji drychem immuno AG FluAB
Streptococcus pneumoniae capsular antigen (fluid, urinary)	Urine		BinaxNOW Strep pneumoniae urinary test
Treponema pallidum antibody (Quantitative)	Serum		Akyurasu auto TPAb
Norovirus antigen (Qualitative)	Feces		Quick navi- Noro2
human metapneumovirus (hMPV) antigen (Qualitative)	Secretions		Check hMPV
adenovirus antibody (Qualitative) (remove feces)	Secretions		Immunoace Adeno
Legionella pneumophila antigen (Urinary)	Urine		RIBOTEST Legionella
<b>d Hepatitis and relates</b>			
HBe antigen	Serum	Plasma	Alinity HBeAg · Abbott
HBe antibody	Serum	Plasma	Alinity HBeAb · Abbott
HBs antibody (Quantitative)	Serum	Plasma	Alinity AUSAB · Abbott
HBe antibody (Semi-quantitative, Quantitative)	Serum	Plasma	Alinity HBe · Abbott
<b>e Autoantibody</b>			
Matrix metalloproteinase-3 (MMP-3)	Serum	Plasma	Panakuria MMP-3 Latex
Serine proteinase 3-anti-neutrophil cytoplasmic antibody (PR3-ANCA)	Serum		STACIA MEBLux TEST PR3-ANCA
Anti neutrophil cytoplasmic myeloperoxidase antibody (MPO-ANCA)	Serum		STACIA MEBLux TEST MPO-ANCA
Anti-nuclear antibody (immunofluorescence) (Semi-Quantitative)	Serum		FLUORO HEP-2 ANA TEST
Anti SS-A/Ro antibody (Quantitative)	Serum		STACIA MEBLux TEST SS-A
Anti SS-B/La antibody (Quantitative)	Serum		STACIA MEBLux TEST SS-B
Anti citrullinated peptide antibody (Quantitative)	Serum		STACIA MEBLux TEST CCP
<b>f Immunology for plasma protein</b>			
CH50	Serum		Auto CH50-L 「seiken」 II
Bence Jones protein, quantitative (Urinary)	Urine		QuickGel IFE kit
β2-microglobulin	Serum	Urine	BMG-latexX1 「Seiken」
Retinol binding protein (RBP)	Serum		N-assay LA RBP nittobo
Immoelectrophoresis (Singular antiserum)	Serum		QuickGel IFE kit
Non-specific immunoglobulin IgE (Quantitative)	Serum		IgE-latex 「Seiken」
Transferrin (Tf)	Serum	Plasma	N-assay TIA TF-H nittobo
Haptoglobin (Typing)	Serum	Plasma	N-assay TIA Hp nittobo
Transthyretin(Prealbumin)	Serum	Plasma	N-assay TIA prealbumin nittobo



# Accreditation Certificate Appendix

(Page 6/6)

Accreditation No. RML01260

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### Scope of accreditation :

Item	Type of Samples		Test Method
<b>g Cellular functional test (cellular immunity related test)</b>			
B-Cell Surface immunoglobulin	Blood		Flow cytometry assay
T and B lymphocyte subpopulation	Blood		Flow cytometry assay
T lymphocyte subpopulation	Blood		Flow cytometry assay
<b>16 Microbiology</b>			
<b>b Bacterial culture and identification / Antimicrobial sensitivity test (general bacteria)</b>			
Examination for drug sensitivity test, yeastlike fungi	Sputum	Feces	Antimicrobial Susceptibility Test (Yeast)
Drug susceptibility test for mycobacteria	Sputum	Punctured fluid	Brothmic MTB/NTM
<b>c Identification of nucleic acid (genetic testing)</b>			
E. coli vero cytotoxin (Qualitative)	Feces		OrthoVT1/VT2
<b>17 Gene-related / Chromosome test</b>			
<b>a Somatic gene test</b>			
Major BCR-ABL1 mRNA	Blood		ipsogen BCR-ABL1 Mber IS-MMR Dx Kit
<b>b Identification of pathogen nucleic acid</b>			
DNA amplification assay for Mycobacteria tuberculosis complex	Sputum	Punctured fluid	COBAS TaqMan MTB Test
Mycobacterium avium / intracellulare DNA	Sputum	Punctured fluid	COBAS TaqMan MAI Test
<b>Physiology</b>			
<b>101 Physiology</b>			
<b>a Respiratory function test (Spirography)</b>			
Slow vital capacity			CHESTAC-8900DN TOKUGATA
Forced vital capacity			CHESTAC-8900DN TOKUGATA
Functional Residual Capacity			CHESTAC-8900DN TOKUGATA
Closing volume			CHESTAC-8900DN TOKUGATA
DLCO (diffusing capacity of CO)			CHESTAC-8900DN TOKUGATA
<b>b Electrocardiogram</b>			
At least 12 leads including limb monopole lead and the chest leads			FCP-7541、VS-3000TE
Holter Electrocardiogram			FM-190、FM-800、SCM-8000
<b>d Electroencephalography</b>			
Electroencephalography (PS, HV)			COMET CMXL-E

# Japan Accreditation Board

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