

Medical Laboratory
Accreditation
Certificate

Accreditation No. RML00810

***National University Corporation,
Hamamatsu University School of Medicine
Clinical Laboratories, Hamamatsu University Hospital***

***1-20-1 Handayama, Higashi-ku, Hamamatsu city, Shizuoka,
431-3192 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, 2026

Revised	December 25, 2021
Renewed	April 1, 2022
Initial accreditation	March 26, 2014

Y. Iizuka, President

Japan Accreditation Board



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Appendix

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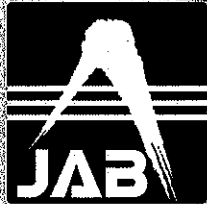
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**National University Corporation,
Hamamatsu University School of Medicine
Clinical Laboratories, Hamamatsu University Hospital**

National University Corporation, Hamamatsu University School of Medicine
Clinical Laboratories, Hamamatsu University Hospital
1-20-1 Handayama, Higashi-ku, Hamamatsu city, Shizuoka, 431-3192 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 III 'EIKEN' Uropaper αIII 'EIKEN'
Protein quantitation	Urine	AR Wako Micro TP-AR
Glucose quantitation	Urine	Quick auto Neo GLU-HK HLS
Hemoglobin, feces	Feces	OC-HEMODIA AUTO S '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 DFL CELLPACK DST CELLPACK DCL Lysercell WNR Fluorocell PLT Fluorocell WNR SULFOLYSER
Reticulocytes	Blood	CELLPACK DFL Fluorocell RET
Hemogram (The microscope method)	Blood	May-Grunwald Stain Solution Giemsa's Stain Solution
Hemogram (The automatic analyser method)	Blood	CELLPACK DST CELLPACK DCL Lysercell WNR Lysercell WDF Lysercell WPC Fluorocell WNR Fluorocell WPC Fluorocell WDF
b Thrombus / hemostasis related test		
Prothrombin time(PT)	Plasma	Coaggpia PT-N
Activated partial thromboplastin time(APTT)	Plasma	Coaggpia APTT-N
Fibrinogen (Quantitative)	Plasma	Coaggpia Fbg
3 Biochemistry I		
a Biochemistry		
Total bilirubin	Serum	Iatro LQ T-BIL II



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Scope of accreditation :

Item	Type of Samples		Test Method
Bilirubin, indirect and direct	Serum		Iatro LQ D-BIL(A)
Total protein	Serum		QUALIGENT TP-N
Albumin	Serum		QUALIGENT ALB-N
Proteins fractionation	Serum		QuickGel SP Ponceau S (M3)
Urea nitrogen(BUN)	Serum	Urine	Quick auto Neo UN HLS Quick auto Neo UN HLS
Creatinine	Serum	Urine	Cygnus Auto CRE HLS Cygnus Auto CRE HLS
Uric acid	Serum	Urine	Quick auto Neo UAII HLS Quick auto Neo UAII HLS
Na and Cl	Serum	Urine	Ion Selective Electrode Diluted(Indirect.)
K	Serum	Urine	Ion Selective Electrode Diluted(Indirect.)
Ca	Serum	Urine	Accuras Auto Ca II HLS Accuras Auto Ca II HLS
Inorganic phosphate and phosphoric acid	Serum	Urine	Accuras Auto IP HLS Accuras Auto IP HLS
Mg	Serum		Accuras Auto Mg HLS
Total cholesterol	Serum		QUALIGENT CHO
Triglyceride	Serum		QUALIGENT TG
HDL-cholesterol	Serum		QUALIGENT HDL
LDL-cholesterol	Serum		QUALIGENT LDL
Glycated albumin	Serum		Lucica GA-L
Glucose	Plasma	Blood	Electrode Method
Hemoglobin A1c (HbA1c)	Blood		HPLC Method
Fe	Serum		Quick auto Neo Fe HLS
Unsaturated iron binding capacity (UIBC)	Serum		Quick auto Neo UIBC HLS
Ammonia	Plasma		CicaLiquid NH3
Alkaline phosphatase	Serum		Cygnus Auto ALP IF HLS
Cholinesterase	Serum		Quick auto Neo Ch-E HLS
γ -glutamyltranspeptidase (γ -GT)	Serum		Quick auto Neo γ GT HLS
Lactate dehydrogenase (LD)	Serum		Cygnus Auto LD IF HLS
Amylase	Serum	Urine	Accuras Auto AMY-IF HLS Accuras Auto AMY-IF HLS
Creatine kinase (CK)	Serum		Cygnus Auto CK HLS
Asparate aminotransferase (AST)	Serum		Quick auto Neo AST JS HLS
Alanine aminotransferase (ALT)	Serum		Quick auto Neo ALT JS HLS
Blood gas analysis	Blood		Electrode Method
5 Immunology			
a Immunochemistry I			
C-reactive protein (CRP)	Serum		QUALIGENT CRP
Immunoglobulin (IgG, IgA, IgM, IgD)	Serum		N-Assay TIA IgG-SH Nittobo N-Assay TIA IgA-SH Nittobo N-Assay TIA IgM-SH Nittobo
C3	Serum		N-Assay TIA C3-SH Nittobo
C4	Serum		N-Assay TIA C4-SH Nittobo
Immunoglobulin (RF)	Serum		LZ TEST*EIKEN*RF



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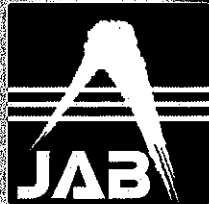
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Accreditation No. RML00810

National University Corporation, Hamamatsu University School of Medicine Clinical Laboratories, Hamamatsu University Hospital

Scope of accreditation :

Item	Type of Samples	Test Method
c Infectious disease I		
HBs antigen	Serum	HISCL HBsAg Assay Kit
HBs antibody	Serum	HISCL Anti-HBs Assay Kit
HCV antibody (Quantitative, Qualitative)	Serum	HISCL Anti-HCV Assay Kit
Serologic test for syphilis (STS) (Qualitative)	Serum	Mediace RPR
6 Microbiology		
a Microscopic examination for stained film (general bacteria)		
Other	Punctured fluid	Secretions bami M Gram strain kit
Use a fluorescent microscope	Sputum	Punctured fluid auramine O strain
b Bacterial culture and identification / Antimicrobial sensitivity test (general bacteria)		
Bacterial culture and identification	Punctured fluid	Secretions MALDI Biotyper
Anaerobic culture	Punctured fluid	Secretions Brusera HK Agar
Antimicrobial sensitivity test (general bacteria)	Punctured fluid	Secretions MicroScan WalkAway
Non-Basic Series		
11 General (urine, feces, etc.)		
a General urinalysis		
Urinary sediment by flow cytometry (Urinary)	Urine	UF- CELLPACK SF UF- CELLPACK CR UF- Fluorocell SF UF- Fluorocell CR UF- CELL SHEATH
b Scatolscopy		
Parasitic worm eggs (feces)	Feces	Formalin-Ether method
Direct smear method (helminth ova and including observation of fat and intestinal absorption test)	Feces	Sudan III Stain Solution
c Basic analysis for punctatum, sperm, sputum and others		
Test of cerebrospinal fluid (protein quantification, glucose quantification, cell numbers, cell classify)	Punctured fluid	AR Wako Micro TP-AR Electrode Method Sumson's Solution
12 Hematology		
a General hematology, hemogram		
Erythrocyte sedimentation rate	Blood	Monitor 40
HemoglobinF (HbF)	Blood	HPLC Method
Myelogram	Others	Wright's eosin methylene blue solution Giemsa's Stain Solution
Myelogram (special stain)	Others	Peroxidase Staining Kit Esterase Staining Kit Esterase AS-D Staining Kit PAS Staining Kit Fe Staining Kit
b Thrombus / hemostasis related test I		
Antithrombin (activity)	Plasma	Testzym S AtIII
Plasminogen (activity)	Plasma	Testzym S PLG
Fibrin monomer	Plasma	Nanopia SF



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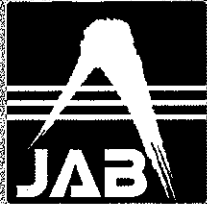
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Scope of accreditation :

Item	Type of Samples		Test Method
D dimer	Plasma		Nanopia D-dimer
c Thrombus / hemostasis related test II			
Bleeding time	Plasma		Duke method
13 Biochemistry I			
a Biochemistry I			
Zn	Serum		Accuras Auto Zn HLS
Ferritin Quantitative	Serum		LZ TEST 'EIKEN' FER
Procalcitonin (PCT) (Quantitative)	Serum		Elecsys BRAHMS PCT
b Biochemistry II			
KL-6	Serum		Nanopia KL-6
c Isozyme			
Alkaline phosphatase Isozyme	Serum		QuickGel ALP Quick EP BAP-IF
Amylase Isozyme	Serum		Accuras Auto P-AMY-IF HLS
Lactate dehydrogenase Isozyme	Serum		QuickGel LD Titan Gel S-LD Reagent
CK-MB	Serum		Cygnus Auto CK-MB MtO HLS
d Immunochemistry			
Cardiac troponin T (TnT) (Qualitative, Quantitative)	Serum	Plasma	Elecsys TroponinT hs STAT
14 Biochemistry II			
a Endocrinology I			
Human chorionic gonadotropin (HCG) (Qualitative)	Urine		TestPack +Plus with OBC
Thyroid-stimulating hormone (TSH)	Serum		Elecsys TSH
Free triiodothyronine (FT3)	Serum		Elecsys FT3 III
Free thyroxine (FT4)	Serum		Elecsys FT4 II
C-peptide (CPR)	Serum	Urine	Elecsys C-Peptide
Insulin (IRI)	Serum		Elecsys Insulin
Growth hormone (GH)	Serum		Elecsys hGH
Follicle-stimulating hormone (FSH)	Serum		Elecsys FSH
Luteinizing hormone (LH)	Serum		Elecsys LH
Prolactin (PRL)	Serum		Elecsys Prolactin II
Progesterone	Serum		Elecsys Progesterone III
Parathyroid hormones (PTH)	Serum		Elecsys PTH
Estradiol (E2)	Serum		Elecsys Estradiol IV
Cortisol	Serum		Elecsys Cortisol II
Testosterone	Serum		Elecsys Testosterone II
N-terminal pro brain natriuretic peptide (NT-proBNP)	Serum		Elecsys proBNP II
Thyroglobulin	Serum		Elecsys TG II
Adrenocorticotrophic hormone (ACTH)	Plasma		Elecsys ACTH
b Tumor marker			
α-fetoprotein (AFP)	Serum		Elecsys AFP
Carcinoembryonic antigen (CEA)	Serum		Elecsys CEA
CA19-9	Serum		Elecsys CA 19-9
CA125	Serum		Elecsys CA 125 II
Prostate-specific antigen (PSA)	Serum		Elecsys total PSA
CA15-3	Serum		Elecsys CA 15-3



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Item	Type of Samples		Test Method
PIVKA-II (Quantitative)	Serum		HISCL PIVKA-II Assay Kit
α -fetoprotein lectin-affinity fraction (AFPL3%)	Serum		μ TASWako AFP-L3
Interleukin 2 receptor, soluble (sIL-2R)	Serum		Nanopia IL-2R
15 Immunology			
b Immunology for infectious disease II			
Mycoplasma antigen (Qualitative) (Immunochromatography method)	Others		ImunoAce Mycoplasma
c Immunology for infectious disease III			
RS virus antigen (Qualitative)	Others		ImunoAce RSV Neo
Clostridium difficile toxin A (Qualitative)	Feces		C.DIFF QUIK COMPLETE
Adenovirus antigen (Qualitative) (Feces)	Feces		Quickchaser Rota/Adeno
Rotavirus antigen (Qualitative) (Feces)	Feces		Quickchaser Rota/Adeno
(1 \rightarrow 3)- β -D-Glucan	Plasma		β -glucan test wako
Serologic test for syphilis (STS) (Quantitative)	Serum		Mediace RPR
Group A- β Streptococcal-rapid Detection (Qualitative)	Others		ImunoAce Strep A
Influenza virus antigen (Qualitative)	Others		ImunoAce Flu
Streptococcus pneumoniae capsular antigen (fluid, urinary)	Urine		BinaxNOW Streptococcus pneumoniae
Treponema pallidum antibody (Quantitative)	Serum		HISCL Anti-Tp Assay Kit
human metapneumovirus (hMPV) antigen (Qualitative)	Others		ImunoAce hMPV
adenovirus antibody (Qualitative) (remove feces)	Others		ImunoAce Adeno
HTLV-I antibody	Serum		HISCL Anti-HTLV-I Assay Kit
Endotoxin	Plasma		endotoxin-single test wako
Legionella pneumophila antigen (Urinary)	Urine		BinaxNOW Legionella pneumophila
HIV-1,2 Antigen, antibody simultaneous measurement (Quantitative)	Serum		HISCL HIV Ag+Ab Assay Kit
d Hepatitis and relates			
HBe antigen	Serum		HISCL HBeAg Assay Kit
HBe antibody	Serum		HISCL Anti-HBe Assay Kit
HBe antibody (Semi-quantitative, Quantitative)	Serum		HISCL Anti-HBe Assay Kit
e Autoantibody			
Matrix metalloproteinase-3 (MMP-3)	Serum		PANACLEAR MMP-3 [Latex]
Anti TSH receptor antibody (TRAb)	Serum		Elecsys Anti-TSHR
f Immunology for plasma protein			
CH50	Serum		Autokit CH50
β 2-microglobulin	Serum	Urine	LZ TEST'EIKEN' β 2-M LZ TEST'EIKEN' β 2-M
Non-specific immunoglobulin IgE (Quantitative)	Serum		Elecsys IgE II
Transferrin(Prealbumin)	Serum		N-Assay TIA Prealbumin Nittobo
16 Microbiology			
b Bacterial culture and identification / Antimicrobial sensitivity test(general bacteria)			
Examination for drug sensitivity test, yeastlike fungi	Blood	Punctured fluid	ASTY
c Identification of nucleic acid (genetic testing)			
E. coli vero cytotoxin (Qualitative)	Others		Duopath Verotxins



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Scope of accreditation :

Item	Type of Samples		Test Method
17 Gene-related / Chromosome test			
b Identification of pathogen nucleic acid			
DNA amplification assay for Mycobacteria tuberculosis complex	Sputum	Punctured fluid	cobas TaqMan MTB
Mycobacterium avium / intracellulare DNA	Sputum	Punctured fluid	cobas TaqMan MAI
18 Others excluding 11 to 16 class			
a Therapeutic drug monitoring			
Digitoxin, Digoxin	Serum		Nanopia TDM DIGXN
Valproic acid, Carbamazepine	Serum		Nanopia TDM VALP Nanopia TDM CRBM
Phenytoin, Primidone, Ethosuximide, Phenobarbital, Zonisamide, Nitrazepam, Clonazepam, Others	Serum		Nanopia TDM PTN Nanopia TDM PHNO
Vancomycin, Teicoplanin, Gentamicin, Tobramycin, Amikacin, Arbekacin, Voriconazole	Serum		Nanopia TDM VANC
Cyclosporin, Tacrolimus hydrate, Everolimus, Mycophenolate mofetil	Blood		CEDIA CSA
Physiology			
101 Physiology			
a Respiratory function test (Spirography)			
Slow vital capacity			DISCOM-21 FXIII CHESTAC-8900
Forced vital capacity			DISCOM-21 FXIII CHESTAC-8900
Functional Residual Capacity			CHESTAC-8900
DLCO (diffusing capacity of CO)			CHESTAC-8900
b Electrocardiogram			
At least 12 leads including limb monopole lead and the chest leads			ECG-2550
c Ultrasonography			
Cardiac ultrasonography			EPIQ 7, Vivid E95
Abdominal ultrasonography			Aprio i700, prosound F75
d Electroencephalography			
Electroencephalography (PS, HV)			Digital EEG Neurofax EEG-1218

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