

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***

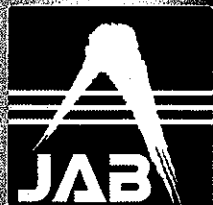
meets the following criteria. On the basis of this, Japan Accreditation Board (JAB) grants accreditation to the said medical laboratory.

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	March 7, 2023
Renewed	April 1, 2022
Initial accreditation	March 26, 2014


Y. Iizuka, President

Japan Accreditation Board



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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	Coagpia PT-Liquid
Activated partial thromboplastin time(APTT)	Plasma	Coagpia APTT-N
Fibrinogen (Quantitative)	Plasma	Coagpia 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	Quick auto Neo UN HLS
Creatinine	Serum	Quick auto Neo UN HLS
Uric acid	Serum	Cygnus Auto CRE HLS
Na and Cl	Serum	Cygnus Auto CRE HLS
K	Serum	Quick auto Neo UAII HLS
Ca	Serum	Quick auto Neo UAII HLS
Inorganic phosphate and phosphoric acid	Serum	Ion Selective Electrode Diluted(Indirect.)
Mg	Serum	Ion Selective Electrode Diluted(Indirect.)
Total cholesterol	Serum	Accuras Auto Ca II HLS
Triglyceride	Serum	Accuras Auto Ca II HLS
HDL-cholesterol	Serum	Accuras Auto IP HLS
LDL-cholesterol	Serum	Accuras Auto IP HLS
Glycated albumin	Serum	Accuras Auto Mg HLS
Glucose	Plasma	QUALIGENT CHO
Hemoglobin A1c (HbA1c)	Blood	QUALIGENT TG
Fe	Serum	QUALIGENT HDL
Unsaturated iron binding capacity (UIBC)	Serum	QUALIGENT LDL
Ammonia	Plasma	Lucica GA-L
Alkaline phosphatase	Serum	Electrode Method
Cholinesterase	Serum	HPLC Method
γ -glutamyltranspeptidase (γ -GT)	Serum	Quick auto Neo Fe HLS
Lactate dehydrogenase (LD)	Serum	Quick auto Neo UIBC HLS
Amylase	Serum	CicaLiquid NH3
Creatine kinase (CK)	Serum	Cygnus Auto ALP IF HLS
Aspartate aminotransferase (AST)	Serum	Quick auto Neo Ch-E HLS
Alanine aminotransferase (ALT)	Serum	Quick auto Neo γ GT HLS
Blood gas analysis	Blood	Cygnus Auto LD IF HLS
5 Immunology		
a Immunochemistry I		
C-reactive protein (CRP)	Serum	Accuras Auto AMY-IF HLS
Immunoglobulin (IgG, IgA, IgM, IgD)	Serum	Accuras Auto AMY-IF HLS
C3	Serum	Cygnus Auto CK HLS
C4	Serum	Quick auto Neo AST JS HLS
Immunoglobulin (RF)	Serum	Quick auto Neo ALT JS HLS



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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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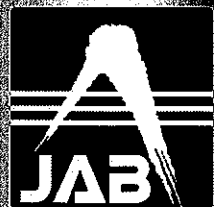
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Scope of accreditation :

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		
Lipase	Serum	Cygnus Auto LIP
KL-6	Serum	Nanopia KL-6
Cystatine C	Serum	Norudia Cystatine C
Mac-2 binding protein glycosylated isomers	Serum	HISCL M2BPGi Assay Kit
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 FT3III
Free thyroxine (FT4)	Serum	Elecsys FT4III
C-peptide (CPR)	Serum	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
Somatomedin-C	Serum	Elecsys IGF-1
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



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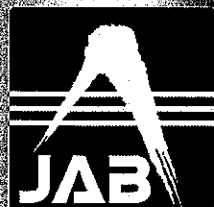
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Scope of accreditation :

Item	Type of Samples	Test Method
CA19-9	Serum	Elecsys CA 19-9
CA125	Serum	Elecsys CA 125 II
Prostate-specific antigen (PSA)	Serum	Elecsys total PSA
Squamous cell cancer related antigen (SCC)	Serum	Elecsys SCC
CA15-3	Serum	Elecsys CA 15-3
Neuron-specific enolase (NSE)	Serum	Elecsys NSE
Cytokeratin 19/fragment	Serum	Elecsys CYFRA
PIVKA-II (Quantitative)	Serum	HISCL PIVKA-II Assay Kit
α -fetoprotein lectin-affinity fraction (AFPL3%)	Serum	μ TAS Wako 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	Mediate 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
Transthyretin(Prealbumin)	Serum	N-Assay TIA Prealbumin Nittobo
g Cellular functional test (cellular immunity related test)		
T lymphocyte subpopulation	Blood	AQIOS Lysing Reagent Kit



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Scope of accreditation :

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	Blood	Punctured fluid
c Identification of nucleic acid (genetic testing)		
E. coli verotoxin (Qualitative)	Others	Duopath Verotoxins
17 Gene-related / Chromosome test		
b Identification of pathogen nucleic acid		
DNA amplification assay for Mycobacteria tuberculosis complex	Sputum	Punctured fluid
Mycobacterium avium / intracellulare DNA	Sputum	Punctured fluid
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)		Neurofax EEG-1278

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