



Medical Laboratory  
Accreditation  
Certificate

Accreditation No.RML02120



**The Aichi Prefectural federation of agricultural cooperative  
for health and welfare  
Anjo Kosei Hospital Clinical Laboratory**

**28, Higashihirokute, Anjo-cho, Anjo, Aichi 446-8602 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 : December 31, 2023

Revised  
Initial accreditation

March 7, 2022  
December 13, 2019

Y. Iizuka, President

**Japan Accreditation Board**



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28, Higashihirokute, Anjo-cho, Anjo, Aichi 446-8602 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 III8S UroPaper IIIG UroPaper uIII-7
Protein quantitation	Urine	Cobas System TPUC
Glucose quantitation	Urine	Cobas System Glu-HK
Hemoglobin, feces	Feces	Nescaut TRANSFERRIN plus Nescaut HEMO plus
Sedimentary test, urine	Urine	microscopy
2 Hematology		
a Blood count / blood cell morphology test		
Peripheral blood general test*(complete blood counts)* : RBC, WBC, Hgb, PLT, Hct	Blood	Lysercell WNR Fluorocell WNR SULFOLYZER Fluorocell PLT CELLPACK DFL CELLPACK DCL
Reticulocytes	Blood	Fluorocell RET
Hemogram (The microscope method)	Blood	May-Grünwald's Stain Solution SMS-800 Gimsa's Stain Solution SGS-800 microscopy
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	Datafi APTT
Fibrinogen (Quantitative)	Plasma	Thrombocheck Fib(L)
3 Biochemistry I		
a Biochemistry		
Total bilirubin	Serum	Cobas System T-Bil E-HA
Bilirubin, indirect and direct	Serum	Cobas System D-Bil E-HA



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### Scope of accreditation :

Item	Type of Samples		Test Method
Total protein	Serum	Plasma	Cobas System TP
Albumin	Serum	Plasma	Cobas System ALB II
Urea nitrogen(BUN)	Serum	Plasma	Cobas System UN
Creatinine	Serum	Plasma	Cobas System CRE
Uric acid	Serum	Plasma	Cobas System UA II
Na and Cl	Serum	Plasma	Electrode (NA),Electrode (CL) Internal standard solution , Diluted solution , Reference electrode solution
K	Serum	Plasma	Electrode (K) Internal standard solution , Diluted solution , Reference electrode solution
Ca	Serum	Plasma	Cobas System Ca II
Inorganic phosphate and phosphoric acid	Serum	Plasma	Cobas System IP
Mg	Serum	Plasma	Cobas System Mg II
Total cholesterol	Serum	Plasma	Cobas System TC II
Triglyceride	Serum	Plasma	Cobas System TG II
HDL-cholesterol	Serum	Plasma	Cobas System HDL-C
LDL-cholesterol	Serum	Plasma	Cobas System LDL-C
Glycated albumin	Serum	Plasma	Rushika GA-L
Glucose	Blood	Plasma	Cobas System Glu-HK Glucose Buffer II
Hemoglobin A1c (HbA1c)	Blood		Eluent90A-C Eluent90CV-S Hemolysis Washing solution 90H-C
Fe	Serum	Plasma	Cobas System Fe
Unsaturated iron binding capacity (UIBC)	Serum	Plasma	Cobas System UIBC
Ammonia	Plasma	Blood	Fuji drychem slide NH3-WII
Alkaline phosphatase	Serum	Plasma	Cobas System ALP IFCC
Cholinesterase	Serum	Plasma	Cobas System Ch-E
$\gamma$ -glutamyltranspeptidase ( $\gamma$ -GT)	Serum	Plasma	Cobas System $\gamma$ -GT JS
Lactate dehydrogenase (LD)	Serum	Plasma	Cobas System LDH IFCC
Amylase	Serum	Plasma	Cobas System AMY-IF
Creatine kinase (CK)	Serum	Plasma	Cobas System CK
Aspartate aminotransferase (AST)	Serum	Plasma	Cobas System AST JS
Alanine aminotransferase (ALT)	Serum	Plasma	Cobas System ALT JS
Blood gas analysis	Blood		Calibration solution1 Calibration solution2 Rinse solution
5 Immunology			
a Immunochemistry I			
C-reactive protein (CRP)	Serum	Plasma	Cobas System CRP-HS II
Immunoglobulin (IgG, IgA, IgM)	Serum		Cobas System IgG-TIA NX Cobas System IgA-TIA NX Cobas System IgM-TIA NX
C3	Serum		Cobas System C3-TIA NX



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#### Scope of accreditation :

Item	Type of Samples	Test Method	
C4	Serum	Cobas System C4-TIA NX	
Immunoglobulin (RF)	Serum	Cobas System RF X1	
b Immunohematology			
Blood group (ABO type)	Blood	affirmagen for AutoVue AntiA/AntiB/AntiD/Contol/Reverse Diluennto-Ortho BioVue System Monoclonal AntiAWako Monoclonal AntiBWako DiaCellABOA1,B	
Blood group (Rho (D) factor)	Blood	affirmagen for AutoVue AntiA/AntiB/AntiD/Contol/Reverse Diluennto-Ortho BioVue System AntiD DiaClon DiaClonRhesus Contorol	
Indirect Coombs, direct Coombs	Blood	DiaCell I+II+III DiaCell Dia ortho PEG Ortho anti-human IgG serum (rabbit) Ortho Coomb control Bio Rat Dia Liss Ortho Coombs Serum Bioclones Ortho-bioclonc anti-C3d	
c Infectious disease I			
HBs antigen	Serum	Elecsys HBsAg II	
HBs antibody	Serum	Elecsys Anti-HBs II	
HCV antibody (Quantitative, Qualitative )	Serum	Elecsys Anti-HCV II	
HIV-1,2 antigen and antibody simultaneous measurement	Serum	Elecsys HIV Duo	
HTLV-Iantibody (Qualitative)	Serum	Elecsys HTLV I/II	
Serologic test for syphilis (STS) (Qualitative)	Serum	Cobas System RPR	
Serologic test for syphilis (Qualitative)	Serum	Elecsys Syphilis	
6 Microbiology			
a Microscopic examination for stained film (general bacteria)			
Other	Others	Gram-Stain Solution neo-B&M Crystal Violet Gram-Stain Solution neo-B&M iodine Gram-Stain Solution neo-B&M carbol fuchin wako 1st Grade Acetone EtOH for pathology Ziehl's Carbol-Fuchin Solution Loffler's Kali-Methylene Blue Splution wako 1st Grade Acid Hydrochloric	
b Bacterial culture and identification / Antimicrobial sensitivity test(general bacteria)			
Bacterial culture and identification	Blood	Others	MALDI Biotyper
Anaerobic culture	Blood	Others	MALDI Biotyper
Antimicrobial sensitivity test (general bacteria)	Others		DPS192, MicroScan Walkaway



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### Scope of accreditation :

Item	Type of Samples	Test Method
<b>Non-Basic Series</b>		
11 General (urine, feces, etc.)		
a General urinalysis		
B-J proteins (Qualitative) (Urinary)	Urine	manual method Aceto Acid
Albumin (Quantitative) (Urinary)	Urine	Cobas System U-ALB
Osmolarity	Urine	OM-6060(depression of freezing point)
N-acetyl glucosaminidase (NAG) (Urinary)	Urine	Cobas System NAG
Urinary sediment by flow cytometry (Urinary)	Urine	UF-cellsheath UF-fluorocell CR UF-fluorocell SF
b Scatology		
Parasitic worm eggs (feces)	Feces	microscopy
Direct smear method(helminth ova and including observation of fat and intestinal absorption test)	Feces	microscopy
Parasite (feces)	Feces	microscopy
Hemoglobin and transferrin (Quantitative,Qualitative ) (feces)	Feces	Nescaut TRANSFERRIN plus Nescaut HEMO plus
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)	Others	Cobas System TPUC Cobas System Glu-HK microscopy Samsung fluid Gentian Violet Aceto Acid Truic liquid Lysercell WDF Fluorocell WDF
Test of gastric juice or duodenal juice	Others	Sodiumu Hydroxide
Test of semen	Others	microscopy
Uterus cervical mucous granulocyte elastase (Qualitative)	Others	Fagnos Elastase Dip
12 Hematology		
a General hematology, hemogram		
Erythrocyte sedimentation rate	Blood	Monosed V-S
Erythroresistant test (Giffin-Sanford test)	Blood	sodium chloride
Serum osmolality	Serum	OM-6060(depression of freezing point)
Eosinophils, nasal/sputum smear	Sputum	Others microscopy May-Grinwald's Stain Solution SMS-800 Gimsa's Stain Solution SGS-800
HemoglobinF (HbF)	Blood	ELUENT 90A-C ELUENT 90B ELUENT 90CV-S HEMOLYSIS WASHING SOLUTION 90H-C
Microbiology in blood	Blood	BD BACTEC FX system



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### Scope of accreditation :

Item	Type of Samples	Test Method
Hemogram (special stain)	Blood	microscopy α-Naphthyl Butylate Esterase Naphthol AS-D chloroacetate Esterase New Peroxidase stain kit
Myelogram	Others	microscopy
Myelogram (special stain)	Others	microscopy α-Naphthyl Butylate Esterase Naphthol AS-D chloroacetate Esterase New Peroxidase stain kit
b Thrombus / hemostasis related test I		
Antithrombin (activity)	Plasma	Berichrom ATIII
Coagulation factor inhibitor Qualitative (cross mixing test)	Plasma	Datafi APTT
Fibrin monomer	Plasma	auto LIA FM CA/CS
D dimer	Plasma	LiasAuto D-dimmer neo
c Thrombus / hemostasis related test II		
Bleeding time	Others	Duke method
13 Biochemistry I		
a Biochemistry I		
Ketones	Serum	TKB-L Kainos
Ketones, fractionation	Serum	TKB-L Kainos 3HB-L Kainos
Bicarbonate	Serum	Cobas System CO2-L
Ferritin Quantitative	Serum	Elecsys Ferritin
Procalcitonin (PCT) (Quantitative)	Serum	Elecsys BRAHMS PCT
b Biochemistry II		
Lipase	Serum	Cobas System LIPS
KL-6	Serum	Cobas System KL-6 (RD)
c Isozyme		
CK-MB	Serum	Elecsys CK-MB
d Immunochemistry		
Cardiac troponin T (TnT) (Qualitative,Quantitative)	Serum	Elecsys Troponin T hs
14 Biochemistry II		
a Endocrinology I		
Human chorionic gonadotropin (HCG) (Qualitative)	Urine	GONASTICK25
Human chorionic gonadotropin (HCG) (Quantitative)	Serum	Elecsys HCG STAT
Thyroid-stimulating hormone (TSH)	Serum	Elecsys TSH
Free triiodothyronine (FT3)	Serum	Elecsys FT3 III
Free thyroxine (FT4)	Serum	Elecsys FT4 III
C-peptide (CPR)	Serum	Elecsys C-Peptide
Insulin (IRI)	Serum	Elecsys Insulin
Parathyroid hormones (PTH)	Serum	Elecsys PTH
N-terminal pro brain natriuretic peptide (NT-proBNP)	Serum	Elecsys proBNP II
b Tumor marker		
α-fetoprotein (AFP)	Serum	Elecsys AFP
Carcinoembryonic antigen (CEA)	Serum	Elecsys CEA
CA19-9	Serum	Elecsys CA19-9



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### Scope of accreditation :

Item	Type of Samples	Test Method
CA125	Serum Plasma	Elecsys CA125 II
Prostate-specific antigen (PSA)	Serum Plasma	Elecsys total PSA
PIVKA-II (Quantitative)	Serum Plasma	Alinity PIVKA-II
c Special analysis		
Urea breath test (UBT)	Others	POC one
15 Immunology		
a Immunohematology		
Irregular antibody	Blood	0.8%CellScreen J 0.8% resolve Panel C System Anti-IgG-Ortho BioVue System DiaCell I+II+III DiaCell Dia ortho PEG Ortho anti-human IgG serum (rabbit) Ortho Coomb control
b Immunology for infectious disease II		
Mycoplasma antigen (Qualitative) (Immunochromatography method)	Secretions Others	Prorast Myco
c Immunology for infectious disease III		
Escherichia coli,serotyping	Others	Antiserum for Enteropathogenic Escherichia coli
Herpes simplex virus specific antigen (Genitals)	Others	PrimeCheck HSV TypeS
RS virus antigen (Qualitative)	Others	BD Veritor system RSV
Clostridium difficile toxin A (Qualitative)	Feces	C.DIFF QUIK CHEK complete
Adenovirus antigen (Qualitative) (Feces)	Feces	Rapidtesta rota-adeno 2
Rotavirus antigen (Qualitative) (Feces)	Feces	Rapidtesta rota-adeno 2
(1→3)-β-D-Glucan	Plasma	β-glucan Testwako β-glucan Sample Pretreatment solution
Serologic test for syphilis (STS) (Quantitative)	Serum Plasma	Cobas System RPR
Group A-β Streptococcal-rapid Detection (Qualitative)	Feces	BD Veritor system StrepA
Influenza virus antigen (Qualitative)	Others	BD Veritor system Flu
Streptococcus pneumoniae in cerebrospinal (fluid, urinary)	Urine Others	Immocatch-Streptococcus pneumoniae
Treponema pallidum antibody (Quantitative)	Serum Plasma	Elecsys Syphilis
Norovirus antigen (Qualitative)	Feces	Immocatch-noro-virus plus
human metapneumovirus (hMPV) antigen (Qualitative)	Others	Prorast hMPV
adenovirus antibody (Qualitative) (remove feces)	Others	BD Veritor system Adeno
Legionella pneumophila antigen (Urinary)	Urine	Immocatch-Legionella
Denguevirus antibody	Serum	Bioline Dengue Duo
SARS-CoV-2 antigen	Others	espline SARS-CoV-2
e Autoantibody		
Matrix metalloproteinase-3 (MMP-3)	Serum Plasma	Cobas System MMP-3
Anti TSH receptor antibody (TRAb)	Serum	Elecsys Anti-TSHR
f Immunology for plasma protein		
β2-microglobulin	Serum Urine	Cobas System BMG
Haptoglobin (Typing)	Serum Plasma	Cobas System HAPT II
16 Microbiology		
b Bacterial culture and identification / Antimicrobial sensitivity test(general bacteria)		
Examination for drug sensitivity test, yeastlike fungi	Others	Drug sensitivity test kit for yeastlike fungi ASTY



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### Scope of accreditation :

Item	Type of Samples	Test Method	
c Identification of nucleic acid (genetic testing) E. coli vero cytotoxin (Qualitative)	Others	Capillia VT	
17 Gene-related / Chromosome test			
a Somatic gene test Preparation for HER2 gene specimen	Tissues	Hisutora HER2 FISH KIT	
EGFR genetic test (other than the real-time PCR method), K-ras genetic test, EWS-F111 genetic test, TLS-CHOP genetic test, SYT-SSX genetic test, c-kit genetic test, examination for microsatellite uneasiness (Qualitative), sentinel lymph node biopsy, BRAF genetic test, RAS genetic test, ROS1 genetic test	Tissues	Cobas EGFR Mutation Detection Assays kit v2.0	
b Identification of pathogen nucleic acid Mycoplasma DNA	Others	Loopamp Mycoplasma pneumoniae detection kit D	
SARS-CoV-2 DNA	Others	Loopamp SARS-CoV-2 detect-kit	
18 Others excluding 11 to 16 class			
a Therapeutic drug monitoring Digitoxin, Digoxin Valproic acid, Carbamazepine	Serum	Plasma	Elecsys Digoxin Cobas System VALP II Cobas System CARB IV
Phenytoin, Phenobarbital	Serum	Plasma	Cobas System PHNY II Cobas System PHNO II
Lithium	Serum		Cobas System LI
Vancomycin	Serum	Plasma	Cobas System VANC III
Cyclosporin, Tacrolimus hydrat	Blood		Elecsys Cyclosporine Elecsys Tacrolimus
Methotrexate	Plasma		Alinity Methotrexate
<b>Pathology</b>			
31 Preparation			
a Preparation for histodiagnosis Organize slices	Tissues	New Hematoxylin solution Pure eosin solution EtOH for pathology 95NP EtOH for pathology 100NP	
CELL BLOCK	Others	New Hematoxylin solution Pure eosin solution EtOH for pathology 95NP EtOH for pathology 100NP	
c Preparation for immunological stain (histodiagnosis)			
Estrogen receptor	Tissues	VENTANA I-View confirm ER(SP1)	
Progesterone receptor	Tissues	VENTANA I-View confirm PGR(1E2)	



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**Scope of accreditation :**

Item	Type of Samples		Test Method
Human epidermal growth factor receptor-2	Tissues		VENTANA pathway HER2(4B5)
CD30	Tissues		VENTANA OptiView CD30(Ber-H2)
Others	Tissues		VENTANA I-View DAB kit
d Preparation for rapid pathologic diagnosis			
Preparation for operative rapid pathologic diagnosis	Tissues		New Hematoxylin solution Pure eosin solution EtOH for pathology 95NP EtOH for pathology 100NP
Preparation for operative rapid cytodiagnosis	Tissues		Papanicolaou stain solution EA-50 Papanicolaou stain solution OG-6 Gill's Hematoxylin V EtOH for pathology 95NP EtOH for pathology 100NP
e Cytodiagnosis			
Gynecology	Tissues		Papanicolaou stain solution EA-50 Papanicolaou stain solution OG-6 Gill's Hematoxylin V EtOH for pathology 95NP EtOH for pathology 100NP
Fine needle aspiration cytology, Body cavity washing	Punctured fluid	Others	Papanicolaou stain solution EA-50 Papanicolaou stain solution OG-6 Gill's Hematoxylin V EtOH for pathology 95NP EtOH for pathology 100NP
32 Pathological diagnosis			
a Pathological diagnosis			
Histology	Tissues		Hematoxylin eosin stain
Cytology	Secretions	Sputum	Papanicolaou stain
<b>Physiology</b>			
101 Physiology			
a Respiratory function test (Spirography)			
Slow vital capacity			CHESTAC-8900DN
Forced vital capacity			CHESTAC-8900DN
Functional Residual Capacity			CHESTAC-8900DN
DLCO (diffusing capacity of CO)			CHESTAC-8900DN
b Electrocardiogram			
At least 12 leads including limb monopole lead and the chest leads			cardiofax G ECG-2550 cardiofax V ECG-1450 cardiofax V ECG-1550
Stress Electrocardiogram			cardiofax G ECG-2550 cardiofax V ECG-1550
Holter Electrocardiogram			SUZUKEN Cardy 303 pico+



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## Scope of accreditation :

Item	Type of Samples	Test Method
c Ultrasonography		
Cardiac ultrasonography	/	VividE95 , VividE9 , EPIQ Elite
Abdominal ultrasonography	/	LOGIQE9
Body surface ultrasonography	/	LOGIQE9
Vascular ultrasonography	/	LOGIQE9
d Electroencephalography		
Electroencephalography (PS, HV)	/	EEG-1200 , EEG-1214
Electromyography (SEP, VEP, ERA, ABR audiotometry, others)	/	MEB-2306, MEB-9204

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