



# Accreditation Certificate Appendix

(Page 1/9)

Accreditation No. RML02120

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

The Aichi Prefectural federation of agricultural cooperative for health and welfare Anjo Kosei Hospital Clinical Laboratory  
28, Higashihirookute, 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, Ketones, Occult blood reaction (Urinary), Albumin)	Urine	UroPaper III8S UroPaper III G UroPaper αIII-7	
Protein quantitation	Urine	Cobas System TPUC	
Glucose quantitation	Urine	Cobas System Glu-HK	
Hemoglobin, feces	Feces	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-Grinwald'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	Thrombocheck APTT-SLA	
Fibrinogen (Quantitative)	Plasma	Thrombocheck Fib(L)	
3 Biochemistry I			
a Biochemistry			
Total bilirubin	Serum	Plasma	Cobas System T-Bil E-HA
Bilirubin, indirect and direct	Serum	Plasma	Cobas System D-Bil E-HA
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





**The Aichi Prefectural federation of agricultural cooperative  
for health and welfare  
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Scope of accreditation :

Item	Type of Samples		Test Method
	Serum	Plasma	
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
C4	Serum		Cobas System C4-TIA NX
Immunoglobulin (RF)	Serum		Cobas System RF XI





# Accreditation Certificate Appendix

(Page 3/9)

Accreditation No. RML02120

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

### Scope of accreditation :

Item	Type of Samples		Test Method
<b>b Immunohematology</b>			
Blood group (ABO type)	Blood		affirmagen Anti-A/Anti-B/Anti-D /Control/Reverse Diluent-Ortho BioVue System Monoclonal Anti-A Wako Monoclonal Anti-B Wako BiotestCell-A1,B
Blood group (Rho (D) factor)	Blood		Anti-A/Anti-B/Anti-D /Control/Reverse Diluent-Ortho BioVue System Anti-D DiaClone DiaClone Rhesus Control
Indirect Coombs, direct Coombs	Blood		BioClone Anti-IgG, -C3d; polyspecific Gamma Clone Anti-IgG (Green) Anti-C3d BioClone BiotestCell-P3 BiotestCell-Di <sup>a</sup> Gamma PEG ORTHO Antibody Enhancement Solution ProClin
<b>c Infectious disease I</b>			
HBs antigen	Serum	Plasma	Elecsys HBsAg II
HBs antibody	Serum	Plasma	Elecsys Anti-HBs II
HCV antibody (Quantitative,Qualitative )	Serum	Plasma	Elecsys Anti-HCV II
HIV-1,2 antigen and antibody simultaneous measurement	Serum	Plasma	Elecsys HIV Duo
HTLV-Iantibody (Qualitative)	Serum	Plasma	Elecsys HTLV I/II
Serologic test for syphilis (STS) (Qualitative)	Serum	Plasma	Cobas System RPR
Serologic test for syphilis (Qualitative)	Serum	Plasma	Elecsys Syphilis
<b>6 Microbiology</b>			
<b>a Microscopic examination for stained film (general bacteria)</b>			
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 Spltion wako 1st Grade Acid Hydrochloric
<b>b Bacterial culture and identification / Antimicrobial sensitivity test(general bacteria)</b>			
Bacterial culture and identification	Blood	Others	MALDI Biotyper
Anaerobic culture	Blood	Others	MALDI Biotyper





# Accreditation Certificate Appendix

(Page 4/9)

Accreditation No. RML02120

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

### Scope of accreditation :

Item	Type of Samples	Test Method
Antimicrobial sensitivity test (general bacteria)	Others	DPS192ix, DxM 1096 MicroScan WalkAway, IA40MIC-i, Dry Plate' Eiken' AN53, Dry Plate' Eiken' EP31, Dry Plate' Eiken' EP32, Dry Plate' Eiken' EP34, MicroScan POS MIC 2J, MicroScan NEG MIC 3J, MicroScan NEG MIC NF 1J
<b>Non-Basic Series</b>		
11 General (urine, feces, etc.)		
a General urinalysis		
Albumin (Quantitative) (Urinary)	Urine	Cobas System U-ALB AE
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 Scatolscopy		
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, 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	Sodium 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)





# Accreditation Certificate Appendix

(Page 5/9)

Accreditation No. RML02120

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

### Scope of accreditation :

Item	Type of Samples		Test Method
	Sputum	Others	
Eosinophils, nasal/sputum smear	Sputum	Others	microscopy May-Grinwald's Stain Solution SMS-800 Gimsa's Stain Solution SGS-800
Microbiology in blood	Blood		microscopy May-Grinwald's Stain Solution SMS-800 Gimsa's Stain Solution SGS-800
Hemogram (special stain)	Blood		microscopy $\alpha$ -Naphthyl Butylate Esterase Naphthol AS-D chloroacetate Esterase New Peroxidase stain kit
Myelogram	Others		microscopy
Myelogram (special stain)	Others		microscopy $\alpha$ -Naphthyl Butylate Esterase Naphthol AS-D chloroacetate Esterase New Peroxidase stain kit
<b>b Thrombus / hemostasis related test I</b>			
Antithrombin (activity)	Plasma		Berichrom ATIII
Coagulation factor inhibitor Qualitative (cross mixing test)	Plasma		Thrombocheck APTT-SLA
D dimer	Plasma		LiasAuto D-dimmer neo
<b>c Thrombus / hemostasis related test II</b>			
Bleeding time	Others		Duke method
<b>13 Biochemistry I</b>			
<b>a Biochemistry I</b>			
Ketones	Serum	Plasma	TKB-L Kainos
Ketones, fractionation	Serum	Plasma	TKB-L Kainos 3HB-L Kainos
Bicarbonate	Serum	Plasma	Cobas System CO2-L
Ferritin Quantitative	Serum	Plasma	Elecsys Ferritin
<b>b Biochemistry II</b>			
Lipase	Serum	Plasma	Cobas System LIPS
KL-6	Serum	Plasma	Cobas System KL-6 (RD)
<b>c Isozyme</b>			
CK-MB	Serum	Plasma	Elecsys CK-MB
<b>d Immunochemistry</b>			
Cardiac troponin T (TnT) (Qualitative, Quantitative)	Serum	Plasma	Elecsys Troponin T hs
<b>14 Biochemistry II</b>			
<b>a Endocrinology I</b>			
Human chorionic gonadotropin (HCG) (Qualitative)	Urine		GONASTICK25
Human chorionic gonadotropin (HCG) (Quantitative)	Serum	Plasma	Elecsys HCG STAT
Thyroid-stimulating hormone (TSH)	Serum	Plasma	Elecsys TSH
Free triiodothyronine (FT3)	Serum	Plasma	Elecsys FT3 III
Free thyroxine (FT4)	Serum	Plasma	Elecsys FT4 III
C-peptide (CPR)	Serum	Plasma	Elecsys C-Peptide
Insulin (IRI)	Serum	Plasma	Elecsys Insulin
Parathyroid hormones (PTH)	Serum	Plasma	Elecsys PTH
N-terminal pro brain natriuretic peptide (NT-proBNP)	Serum	Plasma	Elecsys proBNP II





# Accreditation Certificate Appendix

(Page 6/9)

Accreditation No. RML02120

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### Scope of accreditation :

Item	Type of Samples		Test Method
<b>b Tumor marker</b>			
α-fetoprotein (AFP)	Serum	Plasma	Elecsys AFP
Carcinoembryonic antigen (CEA)	Serum	Plasma	Elecsys CEA
CA19-9	Serum	Plasma	Elecsys CA19-9
CA125	Serum	Plasma	Elecsys CA125 II
Prostate-specific antigen (PSA)	Serum	Plasma	Elecsys total PSA
PIVKA-II (Quantitative)	Serum	Plasma	Alinity PIVKA-II
<b>c Special analysis</b>			
Urea breath test (UBT)	Others		POC one
<b>15 Immunology</b>			
<b>a Immunohematology</b>			
Irregular antibody	Blood		0.8% CELLSCREEN J Alba 0.8% RESOLVE Panel C Anti-IgG Ortho BioVue System BiotestCell-P3 BiotestCell-Di <sup>a</sup> Gamma PEG Gamma Clone Anti-IgG (Green)
<b>c Immunology for infectious disease III</b>			
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		TECHLAB C.DIFF QUIK CHEK コンプリートキット
Adenovirus antigen (Qualitative) (Feces)	Feces		Rapidtesta rota-adeno 2
Helicobacter pylori (Qualitative)			Christensen urea agar
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
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		Ribotest Legionella
Denguevirus antigen, antibody simultaneous measurement (Qualitative)	Serum		Bioline Dengue Duo
SARS-CoV-2 antigen	Others		Elecsys SARS-CoV-2 Ag
<b>e Autoantibody</b>			
Matrix metalloproteinase-3 (MMP-3)	Serum	Plasma	Cobas System MMP-3
Anti TSH receptor antibody (TRAb)	Serum		Elecsys Anti-TSHR
<b>f Immunology for plasma protein</b>			
β <sub>2</sub> -microglobulin	Serum	Urine	Cobas System BMG
Haptoglobin (Typing)	Serum	Plasma	Cobas System HAPT II





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Scope of accreditation :

Item	Type of Samples		Test Method
<b>16 Microbiology</b>			
<b>b Bacterial culture and identification / Antimicrobial sensitivity test (general bacteria)</b>			
Examination for drug sensitivity test, yeastlike fungi	Others		Drug sensitivity test kit for yeastlike fungi ASTY
<b>c Identification of nucleic acid (genetic testing)</b>			
E. coli vero cytotoxin (Qualitative)	Others		Capillia VT
<b>17 Gene-related / Chromosome test</b>			
<b>a Somatic gene test</b>			
Preparation for HER2 gene specimen	Tissues		Hisutora HER2 FISH KIT
K-ras genetic test	Tissues		KRAS Mutation Test v2 (LSR)
<b>b Identification of pathogen nucleic acid</b>			
DNA amplification assay for Mycobacteria tuberculosis complex			Smartgene Myco test cartridge
Mycoplasma DNA	Others		Smartgene Myco test cartridge
Simultaneous detection of multiple items of viral and bacterial nucleic acids	Others		FilmArray
Clostridioides difficile toxin B gene detection	Feces		Xpert C.difficile
SARS-CoV-2 DNA	Others		FilmArray Respiratory Panel 2.1
<b>18 Others excluding 11 to 16 class</b>			
<b>a Therapeutic drug monitoring</b>			
Digitoxin, Digoxin	Serum	Plasma	Elecsys Digoxin
Valproic acid, Carbamazepine	Serum	Plasma	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 hydrate	Blood		Elecsys Cyclosporine Elecsys Tacrolimus
Methotrexate	Plasma		Alinity Methotrexate
<b>Pathology</b>			
<b>31 Preparation</b>			
<b>a Preparation for histodiagnosis</b>			
Organize slices	Tissues		New Hematoxylin sokution Pure eosin solution EtOH for pathology 95NP EtOH for pathology 100NP
CELL BLOCK	Others		New Hematoxylin sokution Pure eosin solution EtOH for pathology 95NP EtOH for pathology 100NP





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Scope of accreditation :

Item	Type of Samples		Test Method
c Preparation for immunological stain (histodiagnosis)			
Estrogen receptor	Tissues		VENTANA ultraView confirm ER(SP1)
Progesterone receptor	Tissues		VENTANA ultraView confirm PGR(1E2)
Human epidermal growth factor receptor-2	Tissues		VENTANA ultraView pathway HER2(4B5)
CD30	Tissues		VENTANA OptiView CD30(Ber-H2)
Others	Tissues		ultraView DAB Universal kit
d Preparation for rapid pathologic daiagnosis			
Preparation for operative rapid pathologic daiagnosis	Tissues		New Hematoxylin sokution Pure eosin solution EtOH for pathology 95NP EtOH for pathology 100NP
Preparation for operative rapid cytodiagnosis	Tissues		Papanicolaou stain sokution EA-50 Papanicolaou stain sokution OG-6 Gill's Hematoxylin V EtOH for pathology 95NP EtOH for pathology 100NP
e Cytodiagnosis			
Gynecology	Tissues		Papanicolaou stain sokution EA-50 Papanicolaou stain sokution 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 sokution EA-50 Papanicolaou stain sokution 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





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Scope of accreditation :

Item	Type of Samples	Test Method
<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
Holter Electrocardiogram		SUZUKEN Cardy 303 pico+ , 305 pico
c Ultrasonography		
Cardiac ultrasonography		VividE95 , Affiniti , EPIQ Elite , EPIQ CVX
Abdominal ultrasonography		LOGIQE9 , Aplio i800
Body surface ultrasonography		LOGIQE9 , Aplio i800
Vascular ultrasonography		LOGIQE9 , Aplio i800
d Electroencephalography		
Electroencephalography (PS, HV)		EEG-1200 , EEG-1214
Electromyography (SEP, VEP, ERA, ABR audiometry)		MEB-2306, MEB-9204