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

Initial accreditation December 13, 2019

Y. Iizuka

Y. Iizuka, President

Japan Accreditation Board

Issue No. : RML02120-20191213

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The Aichi Prefectural federation of agricultural cooperative for health and welfare
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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, Ketones, Occult blood reaction (Urinary))	Urine		UroPaper III8S UroPaper IIIG UroPaper αIII-7
Protein quantitation	Urine		wako Micro TP-AR
Glucose quantitation	Urine		Glucose ECO buffer QuikAuto neo GLU-HK R1 QuikAuto neo GLU-HK R2
Hemoglobin, feces	Feces		Nescaut TRANSFERRIN plus Nescaut HEMO plus
Sedimentary test, urine	Urine		microscopy
2 Hematology			
a Blood test			
Peripheral blood general test*(complete blood counts)* : RBC,WBC,Hgb,PLT,Hct	Blood		STROMATOLYZER 4DL STROMATOLYZER 4DS STROMATOLYZER FBII STROMATOLYZER IM STROMATOLYZER NR SULFOLYZER CELLPACKII
Reticulocytes	Blood		STROMATOLYZER 4DL STROMATOLYZER 4DS STROMATOLYZER FBII STROMATOLYZER IM STROMATOLYZER NR SULFOLYZER CELLPACKII
Eosinophils	Blood		STROMATOLYZER 4DLSTROMATOLYZER 4DSSTROMATOLYZER FBIISTROMATOLYZER IMSTROMATOLYZER NRSULFOLYZERCELLPACKII
Hemogram (The microscope method)	Blood		May-Grinwald's Stain Solution SMS-800 Gimsa's Stain Solution SGS-800 microscopy

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Item	Type of Samples		Test Method
Hemogram (The automatic analyser method)	Blood		STROMATOLYZER 4DL STROMATOLYZER 4DS STROMATOLYZER FBII STROMATOLYZER IM STROMATOLYZER NR SULFOLYZER CELLPACKII
b Coagulation/fibrinolysis			
Prothrombin time(PT)	Plasma		Thromborel S
Activated partial thromboplastin time(APTT)	Plasma		Datafi APTT
Fibrinogen (Quantitative)	Plasma		Thrombocheck Fib(L)
3 Biochemistry I			
a Hematochemistry I			
Total bilirubin	Serum	Plasma	Total Bilirubin E-HR R1 Total Bilirubin E-HR R2
Bilirubin, indirect and direct	Serum	Plasma	Direct Bilirubin E-HR R1 Direct Bilirubin E-HR R2
Total protein	Serum	Plasma	Aquaauto Kainos TP-II reagent Reaction reagent I Aquaauto Kainos TP-II reagent Reaction reagent II Aquaauto Kainos TP-II reagent
Albumin	Serum	Plasma	Aquaauto Kainos ALB reagent Reaction reagent I Aquaauto Kainos ALB reagent Reaction reagent II Aquaauto Kainos ALB reagent
Urea nitrogen(BUN)	Serum	Plasma	L type UN · V enzyme solution A L type UN · V enzyme solution B L type Wako UN · V (LABOSPECT)
Creatinine	Serum	Plasma	Acuras auto CRE R1 Acuras auto CRE R2 Acurus auto CRE HLS
Uric acid	Serum	Plasma	Determina L UA N R1 Determina L UA N R2 Determination of L-UA LST
Na and Cl	Serum	Plasma	Electrode (NA) Electrode (CL) ELA IS buffer
K	Serum	Plasma	Electrode (K) ELA IS buffer
Ca	Serum	Plasma	Ca-AL R1 Ca-AL R2 Ca-AL
Inorganic phosphate and phosphoric acid	Serum	Plasma	Pi-CL R1 Pi-CL R2 Pi-CL
Mg	Serum	Plasma	Mg-L R1 Mg-L R2 Mg-L

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Item	Type of Samples		Test Method
Total cholesterol	Serum	Plasma	T-CHO(S)N A R1 T-CHO(S)N B R2 T-CHO(S)LABOSPECT
Triglyceride	Serum	Plasma	Determina L-TG II(M)R-1 Determina L-TG II(M)R-2 Determina L-TG II LST
HDL－cholesterol	Serum	Plasma	Metabolite HDL-C R1 Metabolite HDL-C R2 Metabolite HDL-C LST
LDL－cholesterol	Serum	Plasma	Auto analysis regent「seiken」LDL-EX(N)R1Auto analysis regent「seiken」LDL-EX(N)R2Auto analysis regent「seiken」LDL-EX(N) LaboSPECT
Glycated albumin	Serum	Plasma	RushikaGA-L ALB R1 RushikaGA-L ALB R2 RushikaGA-L GA R1 RushikaGA-L GA R2
Glucose	Blood	Plasma	Glucose bufferII QuikAuto neo GLU-HK R1 QuikAuto neo GLU-HK R2
Hemoglobin A1c (HbA1c)	Blood		Eluent90A-C Eluent90CV-S Hemolysis Washing solution 90H-C
Fe	Serum	Plasma	QuickAuto neo Fe R1 QuickAuto neo Fe R2 QuickAuto neo Fe
Unsaturated iron binding capacity(UIBC)	Serum	Plasma	QuickAuto neo UIBC R1 QuickAuto neo UIBC R2 QuickAuto neo UIBC
Ammonia	Plasma	Blood	Flex cartrige AMM Fuji drychem slide
Alkaline phosphatase	Serum	Plasma	L type Wako ALP·J2 buffer L type Wako ALP·J2 substrate L type Wako ALP ·J2
Cholinesterase	Serum	Plasma	QuickAuto neo CHE R1 QuickAuto neo CHE R2 QuickAuto neo CHE
γ－glutamyltranspeptidase(γ－GT)	Serum	Plasma	shikafit γGT R1 shikafit γGT R2 shikafit γGT
Lactate dehydrogenase(LD)	Serum	Plasma	shikafit LD R1 shikafit LD R2 shikafit LD
Amylase	Serum	Plasma	shikaliquid AMY R1 shikaliquid AMY R2 shikaliquid AMY

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Item	Type of Samples		Test Method
Creatine kinase (CK)	Serum	Plasma	shikafit LD R1 shikafit LD R2 shikafit LD
Asparate aminotransferase (AST)	Serum	Plasma	L type Wako AST·J2 sudstrate enzyme solution L type Wako AST·J2 α-KG solution L type Wako AST·J2
Alanine aminotransferase (ALT)	Serum	Plasma	L type Wako ALT·J2 sudstrate enzyme solution L type Wako ALT·J2 α-KG solution L type Wako ALT·J2
Blood gas analysis	Blood		Calibration solution1 Calibration solution2 Rinse solution
5 Immunology			
a Immunochemistry I			
C－reactive protein(CRP)	Serum	Plasma	N-Assey LA CRP-T Nittobo R1 N-Assey LA CRP-T Nittobo R2 N-Assey LA CRP-T Nittobo Quiktabo CRP
Immunoglobulin (IgG,IgA,IgM,IgE)	Serum		N-Assey TIA IgA-SH Nittobo N-Assey TIA IgA-SH Nittobo R-1 N-Assey TIA IgA-SH Nittobo R-2 N-Assey TIA IgG-SH Nittobo N-Assey TIA IgG-SH Nittobo R-1 N-Assey TIA IgG-SH Nittobo R-2 N-Assey TIA IgM-SH Nittobo N-Assey TIA IgM-SH Nittobo R-1 N-Assey TIA IgM-SH Nittobo R-2 N-Assey LA IgE-S Nittobo
C3	Serum		N-Assey TIA C3-SH Nittobo
C4	Serum		N-Assey TIA C4-SH Nittobo
Immunoglobulin(RF)	Serum		N-Assey LA RF-K Nittobo
b Immunohematology			
Blood group (ABO type)	Blood		affirmagen for AutoVue AntiA/AntiB/AntiD/Contol/Reverse Diluennto-Ortho BioVue System Monoclnal AntiAWako Monoclnal 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

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Item	Type of Samples		Test Method
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-bioclone anti-C3d
c Infectious disease I			
HBs antigen	Serum	Plasma	Lumipulse II HBsAg
HBs antibody	Serum	Plasma	Lumipulse HBsAb-N
HCV antibody(Quantitative,Qualitative)	Serum	Plasma	Lumipulse II ortho HCV
HIV－1,2 antigen and antibody simultaneous measurement	Serum	Plasma	Lumipulse HIVAg/Ab
HTLV－Iantibody (Qualitative)	Serum	Plasma	Lumipulse HTLV-I/II
Serologic test for syphilis(STS) (Qualitative)	Serum	Plasma	immuno tyikurus auto3 RPR RPRtest"sanko"
Serologic test for syphilis (Qualitative)	Serum	Plasma	immuno tyikurus auto3 TP
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 Hydorocholoric
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		IA-40 Mic-i
Non－Basic Series			
11 General (urine, feces, etc.)			
a General urinalysis			
B－J proteins(Qualitative)(Urinary)	Urine		manual method Aceto Acid
Albumin (Quantitative)(Urinary)	Urine		N-Assey TIA Micro-Alb Nittobo R1 N-Assey TIA Micro-Alb Nittobo R2
Osmolarity	Urine		OM-6060(depression of freezing point)
N－acetyl glucosaminidase(NAG)(Urinary)	Urine		N-assay L NAG Nittobo

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Item	Type of Samples		Test Method
b Scatoloscopy			
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		Micro TP-AR2Quick Auto neo GLU-HKmicroscopySamsung fluidGentian VioletAceto AcidTruic liquid
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
d Examination of malignant tumor tissue			
EGFR genetic test (other than the real－time PCR method), K－ras genetic test, EWS－FlI1 genetic test, TLS－CHOP genetic test, SYT－SSX genetic test, c－kit genetic test, examination for microsatellite uneasiness (Qulitative), sentinel lymph node biopsy, BRAF genetic test, RAS genetic test	Tissues		Cobas EGFR Mutation Detection Assays kit v2.0
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
Hemogram (special stain)	Blood		microscopy α-Naphthyl Butylate Esterase Napthol AS-D chloroacetate Esterase New Peroxidase stain kit
Myelogram	Others		microscopy
Myelogram (special stain)	Others		microscopy α-Naphthyl Butylate Esterase Napthol AS-D chloroacetate Esterase New Peroxidase stain kit

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Item	Type of Samples		Test Method
b Coagulation, fibrinolysis 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 Coagulation, fibrinolysis II			
Bleeding time	Others		Duke method
13 Biochemistry I			
a Hematochemistry I			
Ketones	Serum	Plasma	TKB-L Kainos
Ketones, fractionation	Serum	Plasma	TKB-L Kainos 3HB-L Kainos
Bicarbonate	Serum	Plasma	Flex cartridge ECO2
Ferritin Quantitative	Serum	Plasma	N-assay LA FER-S Nittobo
Procalcitonin (PCT) (Quantitative)	Serum	Plasma	LumipulseG B・R・A・H・M・S PCT
b Hematochemistry II			
Lipase	Serum	Plasma	Nescort VL II LIP
KL－6	Serum	Plasma	Lumipulse KL-6
c Isozyme			
CK－MB	Serum	Plasma	ST AIA-PACK CK-MB
d Immunochemistry			
Cardiac troponin I	Serum	Plasma	ST AIA-PACK cTnl 3rd-Gen
14 Biochemistry II			
a Endocrinology I			
Human chorionic gonadotropin(HCG)(Qualitative)	Urine		GONASTICK25
Human chorionic gonadotropin(HCG)(Quantitative)	Serum	Plasma	ST AIA-PACK HCGII
Thyroid－stimulating hormone (TSH)	Serum	Plasma	ST AIA-PACK TSH
Free triiodothyronine(FT3)	Serum	Plasma	ST AIA-PACK iFT3
Free thyroxine(FT4)	Serum	Plasma	ST AIA-PACK FT4
C－peptide (CPR)	Serum	Plasma	ST AIA-PACK C-PeptideII
Insulin (IRI)	Serum	Plasma	ST AIA-PACK IRI
Parathyroid hormones (PTH)	Serum	Plasma	ST AIA-PACK Intact PTH
Brain natriuretic peptide (BNP)	Plasma	Serum	ST AIA-PACK BNP
b Tumor marker			
α－fetoprotein (AFP)	Serum	Plasma	LumipulseG AFP-N
Carcinoembryonic antigen (CEA)	Serum	Plasma	LumipulseG CEA
CA19－9	Serum	Plasma	LumipulseG CA19-9-N
CA125	Serum	Plasma	LumipulseG CA125II
Prostate－specific antigen (PSA)	Serum	Plasma	ST AIA-PACK PSA
PIVKA－II(Quantitative)	Serum	Plasma	Lumipulse PIVKAII-N
c Special analysis			
Urea breath test (UBT)	Others		POC one

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Item	Type of Samples		Test Method
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
Mycoplasma antigen (Qulitative)(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		QuickNavi-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	immuno tyikurus auto3 RPR RPRtest"sanko"
Group A－β Streptococcal－rapid Detection(Qualitative)	Feces		BD Belitier system StrepA
Influenza virus antigen (Qualitative)	Others		BD Belitier system Flu
Streptococcus pneumoniae in cerebrospinal (fluid,urinary)	Urine	Others	Immmocatch-Streptococcus pneumoniae
E. coli vero cytotoxin (Qualitative)	Others		Capillia VT
Treponema pallidum antibody (Quantitative)	Serum	Plasma	immuno tyikurus auto3 TP
Norovirus antigen (Qualitative)	Feces		Immmocatch-noro-virus plus
human metapneumovirus (hMPV) antigen (Qualitative)	Others		Prorast hMPV
adenovirus antibody (Qualitative) (remove feces)	Others		QuickNavi-adeno
Legionella pneumophila antigen (Urinary)	Urine		Immmocatch-Legionella
Denguevirus antibody	Serum		Bioline Dengue Duo
d Hepatitis and relates			
HBe antigen	Serum	Plasma	Lumipulse I HBeAg
HBe antibody	Serum	Plasma	Lumipulse HBeAg
HBc－IgM antibody	Serum	Plasma	Lumipulse II HBeAg
HA－IgM antibody	Serum	Plasma	Lumipulse II HAV IgM
HBc antibody (Semi－quantitative, Quantitative)	Serum	Plasma	Lumipulse HBcAb-N
e Autoantibody			
Matrix metalloproteinase－3 (MMP－3)	Serum	Plasma	PanaclearMMP-3「Latex」
Anti TSH receptor antibody(TRAb)	Serum	Plasma	ST E test「TOSOH」II(TRAb)Immune reaction reagent set
f Immunology for plasma protein			
CH50	Serum		Hotaika-HA-test WAKO-2
β2－microglobulin	Serum	Urine	N-assay LA B2-BM-H Nittobo

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Scope of accreditation :

Item	Type of Samples		Test Method
Non－specific immunoglobulin IgE (Quantitative)	Serum		N-assay LA IgE-S Nittobo
Haptoglobin (Typing)	Serum	Plasma	N-assay TIA Hp Nittobo R1N-assay TIA Hp Nittobo R2
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
c Identification of nucleic acid (genetic testing)			
DNA amplification assay for Mycobacteria tuberculosis complex	Others		Loopamp Mycobacterium tuberculosis complex detection kit
Mycoplasma DNA	Others		Loopamp Mycoplasma pneumoniae detection kit D
17 Others excluding 11 to 16 class			
b Therapeutic Drug Monitoring			
Digoxin	Serum	Plasma	Flex reagent cartridge Digoxin
Theophylline	Serum	Plasma	Flex reagent cartridge Theophylline
Valproic acid, Carbamazepine	Serum	Plasma	Flex reagent cartridge Carbamazepine Flex reagent cartridge Valproic acid
Phenytoin, Phenobarbital	Serum	Plasma	Flex reagent cartridge Phenobarbital Flex reagent cartridge Phenytoin
Vancomycin	Serum	Plasma	Flex reagent cartridge Vancomycin
Cyclosporin, Tacrolimus hydrat	Serum	Plasma	Flex reagent cartridge Cyclosporin Flex reagent cartridge Tacrolimus hydrat
Methotrexate	Plasma		Emit Methotrexate Assay
Pathology			
31 Preparation			
a Preparation for histodiagnosis			
Preparation for histodiagnosis	Tissues		New Hematoxylin sokution 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)
Human epidermal growth factor receptor－2	Tissues		VENTANA pathway HER2(4B5)
Epidermal growth facter receptor protein	Tissues		Cobas EGFR Mutation Detection Assays kit v2.0
Others	Tissues		VENTANA I-View DAB 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

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Item	Type of Samples		Test Method
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
CELL BLOCK	Others		New Hematoxylin sokution Pure eosin solution EtOH for pathology 95NP EtOH for pathology 100NP
32 Pathological diagnosis			
a Pathological diagnosis			
Histology	Tissues		Hematoxylin eosin stain
Cytology	Secretions	Sputum	Papanicolaou stain
Physiology			
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
Stress Electrocardiogram			cardiofax G ECG-2550 cardiofax V ECG-1450
Holter Electrocardiogram			SUZUKEN Cardy 303 pico
c Ultrasonography			
Cardiac ultrasonography			VividE95 , VividE9 , VividS6
Abdominal ultrasonography			LOGIQE9
Body surface ultrasonography			LOGIQE9
Vascular ultrasonography			LOGIQE9

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Item	Type of Samples		Test Method
d Electroencephalography			
Electroencephalography (PS, HV)			EEG-1200 , EEG-1214
Electromyography (SEP, VEP, ERA, ABR audiometry, others)			MEB-2306

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