

Medical Laboratory Accreditation Certificate

Accreditation No.RML00120



**Kyushu University
Department of Clinical Chemistry and Laboratory of Medicine,
and Division of Diagnostic Pathology,
Kyushu University Hospital**

**3-1-1, Maidashi, Higashi-ku, Fukuoka-shi, Fukuoka,
812-8582 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.

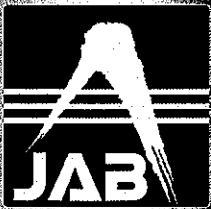
Premises covered by accreditation : As described in the appendix.

Expiry date of accreditation : March 31, 2026

Revised	March 3, 2023
Renewed	April 1, 2022
Initial accreditation	March 29, 2006

Y. Tizuka, President

Japan Accreditation Board



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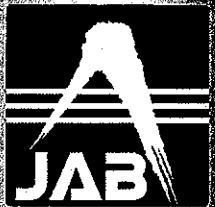
Kyushu University Department of Clinical Chemistry and Laboratory of Medicine, and Division of Diagnostic Pathology, Kyushu University Hospital

Kyushu University

Department of Clinical Chemistry and Laboratory of Medicine,
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3-1-1, Maidashi, Higashi-ku, Fukuoka-shi, Fukuoka, 812-8582 Japan
Excluding primary sample collection from 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, Urobilin, Bilirubin, Ketones, Occult blood reaction (Urinary), Bacteria (Test paper), Sodium chloride, Leukocyte (Test paper), Albumin)	Urine	uropaper αIII
Protein quantitation	Urine	AR-wako microTP-AR
Glucose quantitation	Urine	Kuorijyento GLU
Sedimentary test, urine	Urine	urinary sediment staining solution NEWURISTAIN
2 Hematology		
a Blood count / blood cell morphology test		
Peripheral blood general test* (complete blood counts)* : RBC, WBC, Hgb, PLT, Hct	Blood	ADVIA 2120i Flow cytometry assay cyanfree method (AAO method—alkylamine oxide method) laser optical method
Reticulocytes	Blood	ADVIA 2120i Flow cytometry assay
Hemogram (The microscope method)	Blood	MICROX stain (May-Gruenwald stain solution) (sysmex) , MICROX stain (Giems) (sysmex) , MICROXbuffer (May-Gruenwald + Giems) (sysmex) ,
Hemogram (The automatic analyser method)	Blood	ADVIA 2120i Flow cytometry assay
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)
Fibrinogen degradation products(FDP)	Plasma	riasauto P-FDP
D dimer(Quantitative)	Plasma	riasauto D dimer



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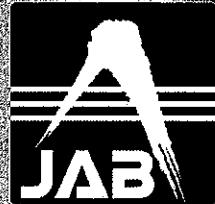
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Scope of accreditation:

Item	Type of Samples	Test Method
3 Biochemistry I		
a Biochemistry		
Total bilirubin	Serum	iatoroLQ T-BIL II
Bilirubin, indirect and direct	Serum	iatoroLQ D-BIL (A)
Total protein	Serum	Aqua-auto-kainos TP-II
Albumin	Serum	Aqua-auto-kainos ALB
Proteins fractionation	Serum	minicap protein 6Maxi kit sokutei sousahou
Urea nitrogen(BUN)	Serum	[Serotekku] UN-SL
Creatinine	Serum	[Serotekku] CRE-N
Uric acid	Serum	quickauto-neo UA II
Na and Cl	Serum	naibu-hyoujyun-eki-B kishaku-eki-B hikaku-denkyoku-eki
K	Serum	naibu-hyoujyun-eki-B kishaku-eki-B hikaku-denkyoku-eki
Ca	Serum	akyurasauto Ca
Inorganic phosphate and phosphoric acid	Serum	akyurasauto IP
Mg	Serum	[Serotekku] Mg-L
Total cholesterol	Serum	[Serotekku] TCHO-L
Triglyceride	Serum	[Serotekku] TG-L
HDL-cholesterol	Serum	Cholestest® N HDL
LDL-cholesterol	Serum	Cholestest® LDL
Glycated albumin	Serum	Lucica® GA-L
Glucose	Serum	Kuorijyento GLU
Hemoglobin A1c (HbA1c)	Blood	Tosoh-glycohemoglobin automatic analyzer HLC-723G9
Fe	Serum	quickauto-neo Fe
Unsaturated iron binding capacity (UIBC)	Serum	quickauto-neo UIBC
Ammonia	Plasma	sikarikiddo NH3
Alkaline phosphatase	Serum	Ltype-wako ALP IFCC
Cholinesterase	Serum	quickauto-neo ChE-E
γ-glutamyltranspeptidase (γ-GT)	Serum	sikarikiddo γ - GT J
Lactate dehydrogenase (LD)	Serum	Ltype-wako LD·IF
Amylase	Serum	akyurasauto AMY-IF
Creatine kinase (CK)	Serum	Signas-auto CK
Aspartate aminotransferase (AST)	Serum	Ltype-wako AST
Alanine aminotransferase (ALT)	Serum	Ltype-wako ALT
Blood gas analysis	Blood	rapidpoint500 measurement cartridge



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**Kyushu University
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Scope of accreditation:

Item	Type of Samples	Test Method				
5 Immunology						
a Immunochemistry I						
C-reactive protein(CRP)	Serum	CRP-latex X2	「seiken」			
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	Iatoro RF II				
b Immunohematology						
Blood group (ABO type)	Blood	Column.	Agglutination Technology,	Tube Test		
Blood group (Rho (D) factor)	Blood	Column.	Agglutination Technology,	Tube Test		
Indirect Coombs, direct Coombs	Blood	Plasma	Column.	Agglutination Technology,	Tube Test	
c Infectious disease I						
HBs antigen	Serum	LumipulsePresto	HBsAg-HQ			
HBs antibody	Serum	LumipulsePresto	HBsAb-III			
HCV antibody (Quantitative,Qualitative)	Serum	LumipulsePresto	ortho-HCV			
HIV-1,2 antigen and antibody simultaneous measurement	Serum	LumipulsePresto	HIV Ag/Ab			
HTLV-Iantibody (Qualitative)	Serum	LumipulsePresto	HTLV-I/II			
Serologic test for syphilis (STS) (Qualitative)	Serum	LASAY	auto RPR			
Serologic test for syphilis (Qualitative)	Serum	LASAY	auto TPAb			
6 Microbiology						
a Microscopic examination for stained film (general bacteria)						
Other	Sputum	Others	Gram stain(Feiba G 「NISSUI」), Acid fast stain(Ziehl-Neelsen stain)			
b Bacterial culture and identification / Antimicrobial sensitivity test(general bacteria)						
Bacterial culture and identification	Sputum	Others	culture medium, VITEK MS, Others			
Anaerobic culture	Punctured fluid	Others	Brucella HK Agar			
Antimicrobial sensitivity test (general bacteria)	Sputum	Others	VITEK2 Antimicrobial sensitivity testing card, Antimicrobial sensitivity testing dryplate 'EIKEN'			
Mycobacterial culture and Isolation (liquid medium)	Sputum	Others	BACTEC MGIT			
Mycobacterial culture and Isolation (other)	Sputum	Others	NALC-NaOH method, 2%OGAWA Agar(SP)			
Mycobacterial identification	Sputum	Others	Mycobacterium tuberculosis complex antigen kit(Capilia TB-Neo), DNA amplification assay for Mycobacterium tuberculosis complex(GENE CUBE), DNA amplification assay for Mycobacterium avium/intracellulare (GENE CUBE)			



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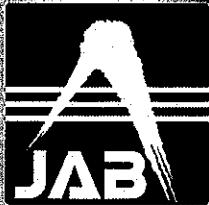
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Scope of accreditation:

Item	Type of Samples	Test Method
Non-Basic Series		
11 General (urine, feces, etc.)		
a General urinalysis		
Albumin (Quantitative) (Urinary)	Urine	TIA-ALBG
Latty acid binding protein, L-type (L-FABP) (Urinary)	Urine	Nordia L-FABP
b Scatoloscopy		
Hemoglobin and transferrin (Quantitative, Qualitative) (feces)	Feces	QuickChaser bensennketu
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)	Punctured fluid	ADVIA 2120i Flow cytometry assay microTP-AR Kuorijento GLU
12 Hematology		
a General hematology, hemogram		
Erythrocyte sedimentation rate	Blood	Photometrical capillary stopped flow kinetic analysis
HemoglobinF (HbF)	Blood	Tosoh-glycohemoglobin automatic anaizer HLC-723G9
Hemogram (special stain)	Blood	PO-K stain kit Esterase stain kit, Esterase AS-D stain kit Fe stain kit ALP stain kit
Myelogram	Others	MICROX stain (May-Gruenwald stain solution) (sysmex), MICROX stain (Giemsa) (sysmex), MICROXbuffer (May-Gruenwald + Giemsa) (sysmex),
Myelogram (special stain)	Others	PO-K stain kit Esterase stain kit, Esterase AS-D stain kit Fe stain kit ALP stain kit
b Thrombus / hemostasis related test I		
Antithrombin (activity)	Plasma	L system AT III
Plasminogen (activity)	Plasma	L system PLG
Plasmin inhibitor/plasmin complex(PIC)	Plasma	HISCL PIC
Protein C (activity)	Plasma	STA Staclot Protein C II
Protein S (activity)	Plasma	STA Staclot Protein S



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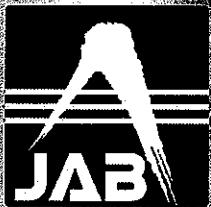
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Scope of accreditation:

Item	Type of Samples	Test Method
PIVKA-II	Serum	LumipulsePresto PIVKA-II-N
tPA/PAI-1 complex	Plasma	HISCL tPAI・C
Thrombomodulin	Plasma	HISCL TM
Thrombin anti-Thrombin complex (TAT)	Plasma	HISCL TAT
13 Biochemistry I		
a Biochemistry I		
Calcium, ionized	Blood	rapidpoint500 measurement cartridge
Zn	Serum	akyurasauto Zn
Ketones	Serum	3-HB-L kainos
Monocarboxylate	Plasma	N-assay L LAC nittobo
Bile acids	Serum	Aqua-auto-kainos TBA
Bicarbonate	Serum	daiyacolor・CO2
Ferritin Quantitative	Serum	FER-latex RX 「seiken」
Procalcitonin (PCT) (Quantitative)	Serum	Accuraceed PCT
b Biochemistry II		
Adenosine-l-converting enzyme (ACE)	Serum	ACE color
Lipase	Serum	Signas-auto LIP
KL-6	Serum	LumipulsePresto KL-6 eisai
Mac-2 binding protein glycosylated isomers	Serum	HISCL M2BPGi
c Isozyme		
Alkaline phosphatase Isozyme	Serum	quick EP BAP-IF reagent
Amylase Isozyme	Serum	akyurasauto P-AMY-IF
Lactate dehydrogenase Isozyme	Serum	Taitangel S-LD reagent (QG)
CK Isozyme	Serum	Signas-auto CK-MB MtO
d Immunochemistry		
Cardiac troponin T (TnT) (Qualitative, Quantitative)	Serum	Accuraceed Troponin T
14 Biochemistry II		
a Endocrinology I		
Human chorionic gonadotropin (HCG) (Qualitative)	Urine	Gonastick25
Human chorionic gonadotropin (HCG) (Quantitative)	Serum	AIA-PackCL βHCG
Thyroid-stimulating hormone (TSH)	Serum	Ekurusis reagent TSH v2
Free triiodothyronine (FT3)	Serum	Ekurusis reagent FT3 III
Free thyroxine (FT4)	Serum	Ekurusis reagent FT4 III
C-peptide (CPR)	Serum	AIA-PackCL C-peptide
Insulin (IRI)	Serum	AIA-PackCL Insulin
Growth hormone (GH)	Serum	AIA-PackCL GH
Follicle-stimulating hormone (FSH)	Serum	AIA-PackCL FSH
Luteinizing hormone (LH)	Serum	AIA-PackCL LH
Prolactin (PRL)	Serum	AIA-PackCL Prolactin
Progesterone	Serum	AIA-PackCL Progesterone
Parathyroid hormones (PTH)	Serum	Ekurusis reagent PTH
Brain natriuretic peptide (BNP)	Plasma	AIA-PackCL BNP
Estradiol (E2)	Serum	Ekurusis reagent E2IV



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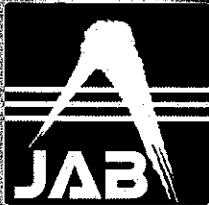
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Scope of accreditation:

Item	Type of Samples	Test Method
Cortisol	Plasma	Ekurusis reagent Cortisol II
Testosterone	Serum	Ekurusis reagent Testosterone
N-terminal pro-brain natriuretic peptide (NT-proBNP)	Serum	Ekurusis reagent NT-proBNP
Renin (Quantitative)	Serum	Accuraceed Renin
Androsterone	Serum	Accuraceed Androsterone S
Thyroglobulin	Serum	Ekurusis reagent Tg
Adrenocorticotropic hormone (ACTH)	Plasma	Ekurusis reagent ACTH
b Tumor marker		
α-fetoprotein (AFP)	Serum	Ekurusis reagent AFP II
Carcinoembryonic antigen (CEA)	Serum	Ekurusis reagent CEA II
CA19-9	Serum	Ekurusis reagent CA19-9 II
CA125	Serum	Ekurusis reagent CA125 II
Prostate-specific antigen (PSA)	Serum	Ekurusis reagent PSA II v2
Squamous cell cancer related antigen (SCC)	Serum	Ekurusis reagent SCC
CA15-3	Serum	Ekurusis reagent CA15-3 II
Neuron specific enolase (NSE)	Serum	Ekurusis reagent NSE
Cytokeratin 19 fragment	Serum	Ekurusis reagent CYFRA
Free PSA/Total PSA ratio	Serum	Ekurusis reagent free PSA v2
Progastorin releasing peptide(ProGRP)	Plasma	HISCL ProGRP
PIVKA-II (Quantitative)	Serum	Lumipulse Presto PIVKA II -N
Inteleukin 2 receptor, soluble (sIL-2R)	Serum	Lumipulse Presto IL-2R
c Special analysis		
Urea breath test (UBT)	Others	POCone U-Bit
15 Immunology		
a Immunohematology		
Irregular antibody	Serum	Column Agglutination Technology,Tube Test
Heparin induced thrombocytopenia antibody (IgG, IgM and IgA)	Plasma	Himos IL HIT -Ab(PF4 -H)
c Immunology for infectious disease III		
Escherichia coli serotyping	Feces	Antiserum for Enteropathogenic E.coli
RS virus antigen (Qualitative)	Others	Check RSV
Varicella virus antigen (in the epithelial cell)	Others	DermaQuick VZV
Clostridium difficile toxin A (Qualitative)	Feces	C.DIFF QUIK CHEK Complete
Adenovirus antigen (Qualitative) (Feces)	Feces	BD Rota/Adeno examan™ stick
Rotavirus antigen (Qualitative) (Feces)	Feces	BD Rota/Adeno examan™ stick
(1→3)-β-D-Glucan	Plasma	β-Glucan Test Wako
Serologic test for syphilis (STS) (Quantitative)	Serum	LASAY auto RPR
Influenza virus antigen (Qualitative)	Others	Fuji Dry-Chem IMMUNO AG Cartridge FluAB
Streptococcus pneumoniae capsular antigen (fluid, urinary)	Urine	Quick Chaser Streptococcus pneumoniae Legionella
Treponema pallidum antibody (Quantitative)	Serum	LASAY auto TPAb



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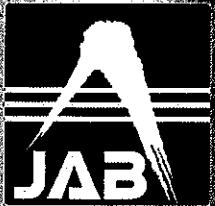
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Scope of accreditation:

Item	Type of Samples	Test Method
adenovirus antibody (Qualitative) (remove feces)	Others	Check Ad
HTLV-I antibody	Serum	Lumipulse Presto HTLV I/II
The group of Mycobacterium antigen (Qualitative)	Sputum	Mycobacterium tuberculosis complex antigen kit(Capilia TB-Neo)
Endotoxin	Plasma	Endotoxin-single Test Wako
Legionella pneumophila antigen (Urinary)	Urine	Quick Chaser Streptococcus pneumoniae/Legionella
HIV-1,2 Antigen, antibody simultaneous measurement (Quantitative)	Serum	Lumipulse Presto HIV Ag/Ab
d Hepatitis and relates		
HBc antigen	Serum	Lumipulse Presto HBcAg
HBc antibody	Serum	Lumipulse Presto HBcAb
HBs antigen (Qualitative, Semi-quantitative)	Serum	Lumipulse Presto HBsAg-HQ
HBs antibody (Qualitative)	Serum	Lumipulse Presto HBsAb-III
HBs antibody (Quantitative)	Serum	Lumipulse Presto HBsAb-III
HBc antibody (Semi-quantitative, Quantitative)	Serum	Lumipulse Presto HBcAb-III
e Autoantibody		
Anti RNP antibody (Quantitative)	Serum	UniCAP Elia U1RNP antigen-well
Anti Sm antibody (Quantitative)	Serum	UniCAP Elia Sm antigen-well
Anti Jo-1 antibody (Quantitative)	Serum	UniCAP Elia Jo-1 antigen-well
Anti centromere antibody (Quantitative)	Serum	UniCAP Elia CENP-B antigen-well
Matrix metalloproteinase-3 (MMP-3)	Serum	LZtest'eiken' MMP-3
Serine proteinase 3-anti-neutrophil cytoplasmic antibody (PR3-ANCA)	Serum	STACIA MEBLuxTMtest PR3-ANCA
Anti neutrophil cytoplasmic myeloperoxidase antibody (MPO-ANCA)	Serum	STACIA MEBLuxTMtest MPO-ANCA
Anti Thyroglobulin antibody	Serum	Ekurusis reagent TgAb
Anti Thyroid peroxidase antibody	Serum	Ekurusis reagent TPOAb
Anti TSH receptor antibody (TRAb)	Serum	Ekurusis reagent TRAb
Anti-nuclear antibody antibody (fluorescent treponemal antibody) (Quantitative)	Serum	Antinuclear antibody Kit IIFT HEp20-10 EUROIMMUN
Anti SS-A/Ro antibody (Quantitative)	Serum	UniCAP Elia SS-A/Ro antigen-well
Anti SS-B/La antibody (Quantitative)	Serum	UniCAP Elia SS-B/La antigen-well
Anti Scl-70 antibody (Quantitative)	Serum	anti-Scl-70antibody kit ELIA Scl-70s
Anti DNA antibody (Quantitative)	Serum	UniCAP Elia dsDNA antigen-well
Anti citrullinated peptide antibody (Quantitative)	Serum	STACIA MEBLuxTMtest CCP
IgG4	Serum	N-Assay LA IgG4 Nittobo
f Immunology for plasma protein		
CH50	Serum	complement activity-HA test wako
TARC	Serum	HISCL TARC
β 2-microglobulin	Serum	Urine N-assay LA β 2-MG-H II
Non-specific immunoglobulin IgE (Quantitative)	Serum	IgE-latex 「seiken」
Specific immunoglobulin IgE (Semi-Quantitative Qualitative) / (Quantitative)	Serum	UniCAP Specific-IgE
16 Microbiology		
b Bacterial culture and identification / Antimicrobial sensitivity test(general bacteria)		
Examination for drug sensitivity test, yeastlike fungi	Blood	Others Yeast Antimicrobial sensitivity testing Kit ASTY



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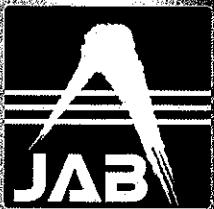
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Scope of accreditation:

Item	Type of Samples	Test Method
c Identification of nucleic acid (genetic testing) E. coli vero cytotoxin (Qualitative)	Feces	Duopath Verotoxins
17 Gene-related / Chromosome test		
b Identification of pathogen nucleic acid Nucleic acid identification of MRSA	Blood	Xpert MRSA/SA Blood Culture
DNA amplification assay for Mycobacteria tuberculosis complex	Sputum	Others DNA amplification assay for Mycobacterium tuberculosis complex(GENE CUBE)
Mycobacterium avium / intracellulare DNA	Sputum	Others DNA amplification assay for Mycobacterium avium/intracellulare (GENE CUBE)
Simultaneous detection of bacterial nucleic acid drug resistance genes	Blood	BioFire BCID2 Panel
Quantification of HBV nucleic acid (Quantitative)	Serum	Cobas 6800/8800 system HBV
DNA amplification assay for SARS Coronavirus	Others	Sputum Cobas SARS-CoV-2 & Flu A/B
d Germline gene test UDP uridine diphosphate glucuronosyltransferase	Blood	Quenching Probe(i-densy IS-5320)
Pathology		
31 Preparation a Preparation for histodiagnosis Organize slices	Tissues	Hematoxylin-Eosin Stain
CELL BLOCK	Others	Paraffin-agar sandwich method
c Preparation for immunological stain (histodiagnosis) Estrogen receptor	Tissues	Ventana ultraView confirm ER(SP1) ultraView DAB universal kit Roche Bench Marke ULTRA
Progesterone receptor	Tissues	Ventana ultraView confirm PgR(1E2) ultraView DAB universal kit Roche Bench Marke ULTRA
Human epidermal growth factor receptor-2	Tissues	Ventana ultraView Pathway HER2(4B5) ultraView DAB universal kit Roche Bench Marke ULTRA
Anaplastic lymphoid kinase fusion protein	Tissues	Ventana OptiView ALK(D5F3) Ventana OptiView DAB universal kit Roche Bench Marke ULTRA
Others	Tissues	OptiView DAB universal kit ultraView DAB universal kit ultraView RED research kit Roche Bench Marke ULTRA Bond Polymer Refine kit Leica BOND
d Preparation for rapid pathologic diagnosis Preparation for operative rapid pathologic diagnosis	Tissues	Hematoxylin-Eosin Stain
Preparation for operative rapid cytodiagnosis	Others	Papanicolaou stain ,Hemacolor stain
e Cytodiagnosis Gynecology	Others	Papanicolaou stain
Fine needle aspiration cytology,Body cavity washing	Punctured fluid	Papanicolaou stain, May Giemsa stain



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Scope of accreditation:

Item	Type of Samples	Test Method
32 Pathological diagnosis		
a Pathological diagnosis		
Histology	Tissues	Hematoxylin-Eosin Stain
Cytology	Punctured fluid	Papanicolaou stain, May Giemsa stain, Hemacolor stain
Physiology		
101 Physiology		
a Respiratory function test (Spirography)		
Slow vital capacity		CHESTAC-9900, CHESTAC-8900, CHESTGRAPH HI-301U
Forced vital capacity		CHESTAC-9900, CHESTAC-8900, CHESTGRAPH HI-301U
Functional Residual Capacity		CHESTAC-9900
Closing volume		CHESTAC-9900
DLCO (diffusing capacity of CO)		CHESTAC-9900
b Electrocardiogram		
At least 12 leads including limb monopole lead and the chest leads		ECG-2550
d Electroencephalography		
Electroencephalography (PS, HV)		EEG-1200

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