



JAB



Medical Laboratory
Accreditation
Certificate

Accreditation No.RML00170

***The University of Tokyo
Department of Clinical Laboratory,
The University of Tokyo Hospital***

7-3-1, Hongo, Bunkyo-ku, Tokyo, 113-8655 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	: January 31, 2019

This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system.

The management system requirements meet the principles of ISO 9001:2008 and are aligned with its pertinent requirements.

Revised (5)	February 24, 2016
Renewed (2)	January 15, 2015
Initial accreditation	January 19, 2007

K. Watanabe, Chairman
Medical Laboratory Accreditation Committee

H. Kume, President
Japan Accreditation Board

Accreditation Certificate Appendix

(Page 1/9)

Accreditation No. RML00170



JAB



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7-3-1, Hongo, Bunkyo-ku, Tokyo, 113-8655 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, Urobilin, Bilirubin, Ketones, Occult blood reaction (Urinary), Bacteria (Test paper), Sodium chloride, Leukocyte (Test paper), Albumin)	Urine		CLINITEC Novus cassettes PRO12 N-Multistix SG-L
Protein quantitation	Urine		Micro TP-Test Wako 2
Glucose quantitation	Urine		Serotec UGLU-L
Hemoglobin, feces	Feces		OC-Hemodia auto III Eiken
Sedimentary test, urine	Urine		LabostainS
2 Hematology			
a Blood test			
Peripheral blood general test*(complete blood counts)* : RBC,WBC,Hgb,PLT,Hct	Blood	Others	CELLPACK DST Fluorocell RET Fluorocell PLT Sulfolyser Lysercell WNR Lysercell WDF Lysercell WPC Fluorocell WPC Fluorocell WNR Fluorocell WDF
Reticulocytes	Blood		Fluorocell RET
Hemogram (The microscope method)	Blood	Others	May-Grunwald Stain Solution Giemsa Stain Solution
Hemogram (The automatic analyser method)	Blood		Lysercell WDF Fluorocell WDF
b Coagulation/fibrinolysis			
Prothrombin time(PT)	Plasma		HemosILRecombiPlasTin2G
Activated partial thromboplastin time(APTT)	Plasma		HemosILSynthASill
Fibrinogen (Quantitative)	Plasma		HemosIL Fibrinogen-C XL
Fibrinogen degradation products(FDP)	Plasma		LPIA FDP-P
D dimer(Quantitative)	Plasma		LPIA A700 DD II
3 Biochemistry I			
a Hematochemistry I			
Total bilirubin	Serum		Nescoat VL T-BIL Fuji drichem slide TBIL-PIII
Bilirubin, indirect and direct	Serum		Nescoat VL D-BIL Fuji drichem slide DBIL-PIII
Total protein	Serum		L Type Wako TP Fuji drichem slide TP-PIII
Albumin	Serum		L Type Wako ALB-BCPFuji drichem slide ALB-P
Proteins fractionation	Serum	Urine	Quick Gel SP



JAB



Accreditation Certificate Appendix

(Page 2/9)

Accreditation No. RML00170

The University of Tokyo Department of Clinical Laboratory, The University of Tokyo Hospital

Scope of accreditation :

Item	Type of Samples		Test Method
	Serum	Urine	
Urea nitrogen(BUN)	Serum	Urine	Serotec UA-CL Fuji drichem slide UA-PⅢ Serotec UUN-L
Creatinine	Serum	Urine	Cygnus Auto CRE HLS Fuji drichem slide CRE-PⅢ L type wako CRE · M
Uric acid	Serum	Urine	Serotec UA-CL Fuji drichem slide UA-PⅢ
Na and Cl	Serum	Urine	Internal Standard Solution - B Diluent Solution - B Reference Electrode Solution Fuji drichem slide Na K CL-P
K	Serum	Urine	Internal Standard Solution - B Diluent Solution - B Reference Electrode Solution Fuji drichem slide Na K CL-P
Ca	Serum	Urine	Qualigent CA Fuji drichem slide Ca-PⅢ HR II Calcium-HR II
Inorganic phosphate and phosphoric acid	Serum	Urine	Serotec Pi-L Serotec Upi-L
Mg	Serum	Urine	Serotec Mg-L Fuji drichem slide Mg-PⅢ Ltype wako Mg
Total cholesterol	Serum		Determiner TC II
Triglyceride	Serum		Determiner TG II
HDL-cholesterol	Serum		MetaboLead HDL-C
LDL-cholesterol	Serum		MetaboLead LDL-C
Glycated albumin	Serum		Lucica GA-L
Glucose	Plasma		An electrode method arkray Quick Auto Neo GLU-HK HLS Fuji drichem slide Glu-PⅢ
Hemoglobin A1c (HbA1c)	Blood		HPLC method (Totho Co.)
Fe	Serum		Quick Auto Neo Fe HLS
Unsaturated iron binding capacity(UIBC)	Serum		Quick Auto Neo UIBC HLS
Ammonia	Serum		Fuji drichem slide NH ₃ -P II
Alkaline phosphatase	Serum		Quick Auto Neo ALP-JS II HLS Fuji drichem slide ALP-PⅢ
Cholinesterase	Serum		Quick Auto Neo Ch-E HLS
γ-glutamyltranspeptidase(γ-GT)	Serum		Quick Auto Neo γ-GT JS-HLS Fuji drichem slide GGT-PⅢ
Lactate dehydrogenase(LD)	Serum		Quick Auto Neo LD JS-HLS Fuji drichem slide LDH-PⅢ
Amylase	Serum	Urine	Fuji drichem slide AMYL-PⅢ Serotec AML-EL
Creatine kinase (CK)	Serum		Cygnus Auto CK HLS Fuji drichem slide CPK-PⅢ
Asparate aminotransferase (AST)	Serum		Quick Auto Neo AST JS-HLS Fuji drichem slide GOT/AST-PⅢ
Alanine aminotransferase (ALT)	Serum		Quick Auto Neo ALT JS-HLS Fuji drichem slide GPT/ALT-PⅢ

Accreditation Certificate Appendix

(Page 3/9)

Accreditation No. RML00170



JAB



**The University of Tokyo
Department of Clinical Laboratory,
The University of Tokyo Hospital**

Scope of accreditation :

Item	Type of Samples		Test Method
5 Immunology			
a Immunochemistry I			
C-reactive protein(CRP)	Serum		LZ test EIKEN CRP-HG Quick Turbo CRP-NV
Immunoglobulin (IgG,IgA,IgM,IgD)	Serum	Punctured fluid	Iatro IgG Iatro IgA Iatro IgM Auto Wako IgG·N
C3	Serum		Iatro C3
C4	Serum		Iatro C4
Immunoglobulin(RF)	Serum		Iatro RF II
b Immunohematology			
Blood group (ABO type)	Blood		Micro Typing System ABD · Card (mono) Ortho BioClone antibody A Ortho BioClone antibody B
Blood group(Rho(D) factor)	Blood		Micro Typing System ABD · Card (mono) Ortho BioClone antibody D
Indirect Coombs,direct Coombs	Blood		Direct : Micro Typing System AHG Card Indirect : Micro Typing System AHG Card
c Infectious disease I			
HBs antigen	Serum	Plasma	ARCHITECT · HBsAg QT
HBs antibody	Serum	Plasma	ARCHITECT · ohSub
HCV antibody(Quantitative,Qualitative)	Serum	Plasma	ARCHITECT · HCV
HIV-1,2 antigen and antibody simultaneous measurement	Serum	Plasma	ARCHITECT · HIV Ag/Ab Comboassay
HTLV-Iantibody (Qualitative)	Serum	Plasma	ARCHITECT HTLV
Serologic test for syphilis(STS) (Qualitative)	Serum	Plasma	RPR Test“SANKO”
Serologic test for syphilis (Qualitative)	Serum	Plasma	Architect · TP Ab
Anti streptolysin O (ASO)	Serum		LPIA Ace ASO II
6 Microbiology			
a Microscopic examination for stained film (general bacteria)			
Other	Sputum	Others	Favor G "Nissui"
b Bacterial culture and identification · Antimicrobial sensitivity test(general bacteria)			
Bacterial culture and identification	Sputum	Others	Blood agar,Chocolate agar, Bact/ALERT 3D
Anaerobic culture	Sputum	Others	Blood agar,Chocolate agar, Bact/ALERT 3D
Antimicrobial sensitivity test(general bacteria)	Others		Microdilution method WalkAway
Non-Basic Series			
11 General (urine, feces, etc.)			
a General urinalysis			
Albumin (Quantitative)(Urinary)	Urine		Auto Wako micro albumin
Osmolarity	Urine		Freezing point depression method
N-acetyl glucosaminidase(NAG)(Urinary)	Urine		L type Wako NAG
Urinary sediment by flow cytometry (Urinary)	Urine		UF II sheath
b Scatolscopy			
Hemoglobin and transferrin (Quantitative,Qualitative) (feces)	Feces		OC-Hemodia auto III Eiken

Accreditation Certificate Appendix

(Page 4/9)

Accreditation No. RML00170



JAB



The University of Tokyo Department of Clinical Laboratory, The University of Tokyo Hospital

Scope of accreditation :

Item	Type of Samples		Test Method
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)	Secretions	Others	Micro TP-Test Wako 2 Auto Wako micro albumin Serotec UGLU-L Samson's solution Internal standard liquid
Test of semen	Secretions		Turk's solution
12 Hematology			
a General hematology, hemogram			
Erythrocyte sedimentation rate	Blood		Westergren-based methods
Erythroresistant test (Giffin-Sanford test)	Blood		Parpart test kit
Erythroresistant test (Parpart test)	Serum		Freezing point depression method
Myelogram	Others		May-Grunwald Stain Solution Giemsa Stain Solution
Myelogram (special stain)	Others		Fe stain kit Esterase stain kit Esterase ASD stain kit PAS stain kit New PO-K stain kit
b Coagulation, fibrinolysis I			
Antithrombin (activity)	Plasma		Hemos IL Liquid Antithrombin
Plasmin inhibitor/plasmin complex(PIC)	Plasma		LPIA-A700 PPI II
Protein C (activity)	Plasma		Hemos IL ProteinC
Protein S (Qualitative)	Plasma		Hemos IL ProteinS
Coagulation factor inhibitor Qualitative (cross mixing test)	Plasma		HemosILSynthASill
Coagulation factor(VII, VIII, IX, XIII)	Plasma		Factor VIIdeficient Plasma Factor VIIIdeficient Plasma Factor IXdeficient Plasma LPIA-A700 FX III
D dimer	Plasma		LPIA A700 DD II
Coagulation factor inhibitor	Plasma		HemosILSynthASill
Thrombin anti-Thrombin complex (TAT)	Plasma		STACIACLEIA TAT
c Coagulation, fibrinolysis II			
Bleeding time	Blood		Duke Method
Platelet aggregation	Plasma		PA-200 (KOWA Co.)
Platelet adhesiveness	Blood		ISK SYRINGE PUMP
Hepaplastin test	Plasma		HepatoComplex
13 Biochemistry I			
a Hematochemistry I			
Free fatty acid	Serum		Autosera NEFA
Ketones	Serum		3HB-L Test Kit Kainos
Monocarboxylate	Blood		Determiner LA Determiner PA
Ferritin Quantitative	Serum		LZ test EIKEN FER
Blood gas analysis	Blood		PH Electrode method CO2 Electrode method O2 Electrode method
Procalcitonin (PCT) (Quantitative)	Serum	Plasma	ECLUSys Brahms PCT
b Hematochemistry II			
Lipase	Serum		Liquitec lipase color II
KL-6	Serum	Plasma	Lumipulse Presto KL-6 Eizai
c Isozyme			
Alkaline phosphatase Isozyme	Serum		Quick Gel ALP



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Amylase Isozyme	Serum		Serotec AMISO-EL
Lactate dehydrogenase Isozyme	Serum		Titan Gel S-LD
CK Isozyme	Serum		Cygnus Auto CK-MB MtO HLS
d Immunochemistry			
Myoglobin (Quantitative)	Serum	Urine	Mb-latex CN 「seiken」
14 Biochemistry II			
a Endocrinology I			
Human chorionic gonadotropin(HCG)(Quantitative)	Serum	Urine	ST E Test TOSOH II HCG II
Human chorionic gonadotropin, β -subunit(HCG- β)	Serum	Plasma	ST AIA-PACK β HCG II
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)	Plasma	Urine	SphereLight CPR(B)
Insulin (IRI)	Plasma		SphereLight IRI(II)
Follicle-stimulating hormone (FSH)	Serum	Plasma	ST AIA-PACK FSH
Luteinizing hormone (LH)	Serum	Plasma	ST AIA-PACK LH II
Prolactin (PRL)	Serum	Plasma	ST AIA-PACK PRL
Progesterone	Serum	Plasma	ST AIA-PACK PROG
Parathyroid hormones (PTH)	Serum	Plasma	ECLusys PTH
Brain natriuretic peptide (BNP)	Plasma		ST E Test TOSOH II BNP
Estradiol (E2)	Serum	Plasma	Lumipulse Presto E2-N
Cortisol	Serum	Plasma	ECLusys Cortisol
Adrenocorticotrophic hormone (ACTH)	Plasma		ECLusys ACTH
b Tumor marker			
α -fetoprotein (AFP)	Serum	Plasma	ST AIA-PACK AFP
Carcinoembryonic antigen (CEA)	Serum	Plasma	ST AIA-PACK CEA
CA19-9	Serum	Plasma	Lumipulse Presto CA19-9
CA125	Serum	Plasma	Lumipulse Presto CA125 II
Prostate-specific antigen (PSA)	Serum	Plasma	ST AIA-PACK PSA II
CA15-3	Serum	Plasma	Lumipulse Presto CA15-3
Cytokeratin 19 fragment	Serum	Plasma	Lumipulse Presto CYFRA
PIVKA-II(Quantitative)	Serum		μ Tas Wako PIVKA II
Elastase 1	Serum		Iatro IRE1 II
α -fetoprotein lectin-affinity fraction (AFPL3%)	Serum		μ Tas Wako AFP-L3
Inteleukin 2 receptor,soluble (sIL-2R)	Serum	Plasma	SIEMENS IMMULYZE IL-2R II
15 Immunology			
a Immunohematology			
Blood group, Rh system	Blood		Ortho Anti-C BioClone Ortho Anti-c Bioclone Ortho Anti-E Bioclone Ortho Anti-e Bioclone
Blood group, ABO subgroups	Blood		Lectin: Ortho anti-A1, anti-H lectin Antigen dilution titer: Ortho anti-A or B Bioclone Adsorption/Elution test:Ortho DT Elution solution-II anti A or B hemagglutinin titer: ID-DiaCell ABO Irregular antibody: ID-DiaPanel A or B transferase: Galserve AB kit A, B or H substance in saliva :Ortho antiA BioClone, Ortho antiB BioClone, anti-H lectin

Accreditation Certificate Appendix

(Page 6/9)

Accreditation No. RML00170



JAB



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The University of Tokyo Hospital**

Scope of accreditation :

Item	Type of Samples		Test Method
Glyco transferase associated with ABO blood typ	Serum	Plasma	A or B transferase: Galserve AB kit
Irregular antibody	Serum	Plasma	Micro typing system IgG card or NaCl/Enzyme card
Anti platelet antibody	Serum		Anti-PLT・MPHA・Screen or Panel
b Immunology for infectious disease II			
Mycoplasma antigen (Qualitative) (Immunochromatography method)	Secretions		Ribo test [®] Mycoplasma
c Immunology for infectious disease III			
RS virus antigen (Qualitative)	Secretions		ImunoAceRSV
Rotavirus antigen(Qualitative) (Feces)	Feces		Imunocard ST Rota virus
(1→3)-β-D-Glucan	Plasma		β-Glucan Test WAKO
Serologic test for syphilis(STS) (Semi-quantitative)	Serum	Plasma	RPR Test“SANKO”
Group A-β Streptococcal-rapid Detection(Qualitative)	Secretions		Clearview EZ Strep A
Influenza virus antigen (Qualitative)	Secretions		Imunoace Flu
Staphylococcus aureus penicillin-binding protein 2'(PBP2') (Qualitative)	Others		MRSA-LA 「Seiken」
Streptococcus pneumoniae capular antigen (fluid,urinary)	Urine		Binax NOW Streptococcus pneumoniae
E. coli vero cytotoxin (Qualitative)	Others		Duopath [®] Verotoxins
human metapneumovirus (hMPV) antigen (Qualitative)	Secretions		Check hHMP
adenovirus antibody (Qualitative) (remove feces)	Secretions		Check AD
Capsule antigen of Streptococcus pneumoniae (Qualitative)	Secretions		RAPIRUN [®] S.pneumoniae HS
The group of Mycobacterium antigen (Qualitative)	Others		Capilia [®] TB
Legionella pneumophila antigen (Urinary)	Urine		Binax NOW Legionella
d Hepatitis and relates			
HBe antigen	Serum	Plasma	ARCHITECT・HBeAg
HBe antibody	Serum	Plasma	ARCHITECT・HBeAb
HBe antibody (Semi-quantitative, Quantitative)	Serum	Plasma	ARCHITECT・HBe II
e Autoantibody			
Cold agglutination	Serum		Hemagglutination
Donath-Landsteiner test	Blood	Serum	Hemolytic reaction
Anti RNP antibody (Quantitative)	Serum		EliA U1RNP
Anti Sm antibody (Quantitative)	Serum		EliA SmDp
Anti centromere antibody (Quantitative)	Serum		EliA Mitochondria M2
Matrix metalloproteinase-3 (MMP-3)	Serum		PANACLEAR MMP-3「Latex」
Serine proteinase 3-anti-neutrophil cytoplasmic antibody (PR3-ANCA)	Serum		EliA PR3s-ANCA
Anti neutrophil cytoplasmic myeloperoxidase antibody (MPO-ANCA)	Serum		EliA MPOs-ANCA
Anti TSH receptor antibody(TRAb)	Serum		ECLUSys Anti-TSHR
anti-nuclear antibody(immunofluorescence) (Semi-Quantitative)	Serum		Fluoro HEPANA Test
Anti SS-A/Ro antibody (Quantitative)	Serum		EliA SS-A/Ro
Anti SS-B/La antibody (Quantitative)	Serum		EliA SS-B/La
Anti DNA antibody (Quantitative)	Serum		EliA dsDNA EliA ssDNA
f Immunology for plasma protein			
CH50	Serum		Hotaika-HA test Wako
Bence Jones protein, quaritative (Urinary)	Urine		Titan Gel IFE Agarose Set
α1-microglobulin	Urine		LZ test Eiken α1-M
Immnoelectrophoresis	Serum		Titan Gel IFE Agarose Set

Accreditation Certificate Appendix

(Page 7/9)

Accreditation No. RML00170



JAB



***The University of Tokyo
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Scope of accreditation :

Item	Type of Samples		Test Method
Haptoglobin (Typing)	Serum		N-assay TIA HP Nittobo
Transthyretin(Prealbumin)	Serum		N-assay TIA Prealbumin Nittobo
g Cellular functional test(cellular immunity related test)			
T and B lymphocyte subpopulation	Blood	Others	Monoclonal Antibody
T lymphocyte subpopulation	Blood	Others	Monoclonal Antibody
16 Microbiology			
b Bacterial culture and identification· Antimicrobial sensitivity test(general bacteria)			
Examination for drug sensitivity test, yeastlike fungi	Others		Kouboyou shinkin FPEIKEN'
Mycobacterial culture and Isolation (liquid medium)	Sputum	Others	BACTEC MIGIT 960 BACTEC FX40
Drug susceptibility test for mycobacteria	Others		Vite Spectrum SR PZA Broth BrothMIC NTM
c Identification of nucleic acid (genetic testing)			
Mycobacteria DNA	Others		DDH Mycobacteria 'Kyokuto'
DNA amplification assay for Mycobacteria tuberculosis complex	Sputum	Others	cobas TaqMan 48
Mycobacterium avium · intracellulare DNA	Sputum	Others	cobas TaqMan 48
17 Others excluding 11 to 16 class			
d Genetic test			
Gene diagnosis of hematopoietic organ tumor	Blood	Others	PCR Super Mix High Fidelity
Specific program I			
21 Specified health checkup testing (health checkup for metabolic syndrome)			
a Basic Series			
Triglyceride	Serum		Determiner TG II
HDL-cholesterol	Serum		MetaboLead HDL-C
LDL-cholesterol	Serum		MetaboLead LDL-C
Creatinine	Serum		Cygnus Auto CRE HLS Fuji drichem slide CRE-PIII
Glucose	Plasma		An electrode method arkray
Hemoglobin A1c(HbA1c)	Blood		HPLC method (Totho Co.)
Uric Acid	Serum		Serotec UA-CL Fuji drichem slide UA-PIII
AST	Serum		Quick Auto Neo AST JS-HLS Fuji drichem slide GOT/AST-PIII
ALT	Serum		Quick Auto Neo ALT JS-HLS Fuji drichem slide GPT/ALT-PIII
γ-GT	Serum		Quick Auto Neo γ-GT JS-HLS Fuji drichem slide GGT-PIII
Urine Glucose qualitative	Urine		Serotec UGLU-L
Urine Protein qualitative	Urine		Micro TP-Test Wako 2

Accreditation Certificate Appendix

(Page 8/9)

Accreditation No. RML00170



JAB



**The University of Tokyo
Department of Clinical Laboratory,
The University of Tokyo Hospital**

Scope of accreditation :

Item	Type of Samples		Test Method
b Additional Series			
Red Blood Cell	Blood		CELLPACK DST Fluorocell RET Fluorocell PLT Sulfolyser Lysercell WNR Lysercell WDF Lysercell WPC Fluorocell WPC Fluorocell WNR Fluorocell WDF
Hemoglobin	Blood		Sulfolyser
Hematocrit	Blood		
Pathology			
31 Preparation			
a Preparation for histodiagnosis			
Preparation for histodiagnosis	Tissues		Hematoxylin-Eosin stain
b Preparation for electron microscope			
Preparation for electron microscope	Tissues		electron stain
c Preparation for immunological stain (histodiagnosis)			
Estrogen receptor	Tissues		Ventana I-VIEW CONFIRM anti-ER (SP1) I-VIEW DAB Universal Kit
Progesterone receptor	Tissues		Ventana I-VIEW CONFIRM anti-PgR(1E2) I-VIEW DAB Universal Kit
Human epidermal growth factor receptor-2	Tissues		Ventana I-VIEW PATHWAY anti-HER2(4B5) I-VIEW DAB Universal Kit
Epidermal growth factor receptor protein	Tissues		Histofine Mouse Anti Human Epidermal Growth Factor Receptor (EGFR) Monoclonal Antibody I-VIEW DAB Universal Kit
Others	Tissues		Ventana I-VIEW DAB Universal Kit
d Preparation for rapid pathologic daiagnosis			
Preparation for operative rapid pathologic daiagnosis	Tissues		Hematoxylin-Eosin stain
Preparation for operative rapid cytodiagnosis	Punctured fluid		Papanicolaou stain
e Cytodiagnosis			
Gynecology	Others		Papanicolaou stain
Fine needle aspiration cytology,Body cavity washing	Punctured fluid		Papanicolaou stain Giemsa stain PAS stain
Others	Urine	Sputum	Papanicolaou stain Giemsa stain PAS stain
f Preparation for HER2 gene specimen ,Preparation for ALK fused gene specimen			
Preparation for HER2 gene specimen	Tissues		Ventana INFORM HER2 Dual ISH Kit
Preparation for ALK fused gene specimen	Tissues		Vysis ALK Break Apart FISH Probe Kit
32 Pathological diagnosis			
a Pathological diagnosis			
Histology	Tissues		Diagnosis
Cytology	Others		Diagnosis

Accreditation Certificate
Appendix

(Page 9/9)

Accreditation No. RML00170



JAB



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Department of Clinical Laboratory,
The University of Tokyo Hospital

Scope of accreditation :

Item	Type of Samples	Test Method
Physiology		
101 Physiology		
a Spirography		
Slow vital capacity		FUDAC-77
Forced vital capacity		FUDAC-77 AS-407
b Electrocardiogram		
At least 12 leads including limb monopole lead and the chest leads		FCP-7541 FM-190
c Ultrasonography		
Ultrasonography		Aplio300 iE33xMATRIX VividE9 SSH-880CV XarioSSA-660A Vscan
d Electroencephalography		
Electroencephalography		EEG-1218

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