



Medical Laboratory
Accreditation
Certificate

Accreditation No. RML00110

Kyoto Biseibutsu Kenkyusho

***20-1, Ohbayashicho, Kitakazan, Yamashina-ku, Kyoto-shi,
Kyoto, 607-8482 Japan***

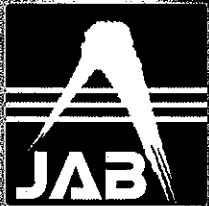
meets the following criteria. On the basis of this, Japan Accreditation Board (JAB) grants accreditation to the said medical laboratory.

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 December 4, 2021
Renewed April 1, 2022
Initial accreditation March 29, 2006

Y. Iizuka, President

Japan Accreditation Board



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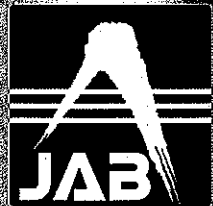
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20-1, Ohbayashicho, Kitakazan, Yamashina-ku, Kyoto-shi, Kyoto, 607-8482 Japan
Excluding primary sample collection from the scope of accreditation

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, Bilirubin, Ketones, Occult blood reaction (Urinary))	Urine	kusetukeihou, uropepa II eiken
Protein quantitation	Urine	maikuroTP-testwako
Glucose quantitation	Urine	L-typewakou Glu2
Sedimentary test, urine	Urine	Rabosutein S
2 Hematology		
a Blood count / blood cell morphology test		
Peripheral blood general test*(complete blood counts)* : RBC, WBC, Hgb, PLT, Hct	Blood	CellpackDST • CellpackDFL • FluorocellPLT • LysercellWNR • FluorocellWNR
Reticulocytes	Blood	FluorocellRET • CellpackDFL
Eosinophils	Blood	LysercellWNR • LysercellWDF • LysercellWPC • FluorocellWNR • FluorocellWDF
Hemogram (The microscope method)	Blood	Kyoukenhou
Hemogram (The automatic analyser method)	Blood	LysercellWNR • LysercellWDF • LysercellWPC • FluorocellWNR • FluorocellWDF • FluorocellWPC
b Thrombus / hemostasis related test		
Prothrombin time(PT)	Plasma	Revohem PT
Activated partial thromboplastin time(APTT)	Plasma	toronbocheckAPTPurs
Fibrinogen (Quantitative)	Plasma	toronbocheckFib(L)
Fibrinogen degradation products(FDP)	Plasma	Liasauto P-FDP
3 Biochemistry I		
a Biochemistry		
Total bilirubin	Serum	souBilirubinE-HRwako
Bilirubin, indirect and direct	Serum	chyokusetuBilirubinHR
Total protein	Serum	Sotanpaku-HR II
Albumin	Serum	Alubumin
Proteins fractionation	Serum	dennkieidouhou
Urea nitrogen(BUN)	Serum Urine	UN-L TypeC
Creatinine	Serum Urine	Sikarikido-S CRE
Uric acid	Serum Urine	datamina-C-UA
Na and Cl	Serum Urine	ISE
K	Serum Urine	ISE



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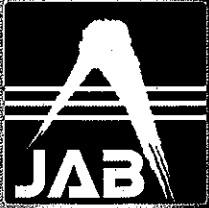
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Scope of accreditation :

Item	Type of Samples		Test Method
	Serum	Urine	
Ca	Serum	Urine	Ca-AL TypeC
Inorganic phosphate and phosphoric acid	Serum	Urine	mukirin-HR II
Mg	Serum	Urine	magnesium-HR II
Total cholesterol	Serum		pyuaotoS CHO-N
Triglyceride	Serum		pyuaotoS TG-N
HDL-cholesterol	Serum		koresutest HDL
LDL-cholesterol	Serum		koresutest LDL
Glucose	Serum		Ltypewako Glu2
Hemoglobin A1c (HbA1c)	Serum		GurikohemogurobinA1c sanku HbA1c
Fe	Serum		Ltypeuwako-Fe
Total iron binding capacity (TIBC)	Serum		Calculation
Unsaturated iron binding capacity (UIBC)	Serum		Ltype-UIBC
Ammonia	Serum		ammoniatestwako
Alkaline phosphatase	Serum		Ltypewako ALP IFCC
Cholinesterase	Serum		kuikuneco Ch-E
γ -glutamyltranspeptidase (γ -GT)	Serum		Ltypewako γ -GT • J
Lactate dehydrogenase (LD)	Serum		Ltypewako LD • IF
Amylase	Serum	Urine	Ltypeamylase
Creatine kinase (CK)	Serum		Ltypewako CK
Asparate aminotransferase (AST)	Serum		N-Assay L GOT Nitobo
Alanine aminotransferase (ALT)	Serum		N-Assay L GPT Nitobo
5 Immunology			
a Immunochemistry I			
C-reactive protein (CRP)	Serum		N-Assay L CRP-S Nitobo
b Immunohematology			
Blood group (ABO type)	Blood	Serum	orthobaiovuekouA,kouB,kouDkaseto
Blood group (Rho (D) factor)	Blood		orthobaiovuekouA,kouB,kouDkaseto
Indirect Coombs, direct Coombs	Blood	Serum	orthobaiovuekumusukaseto
c Infectious disease I			
HBs antigen	Serum		Archtect HBsAg QT
HBs antibody	Serum		Archtect osabu
HCV antibody (Quantitative, Qualitative)	Serum		Architect • HCV, Lumipulse II OrthoHCV
HIV-1,2 antigen and antibody simultaneous measurement	Serum		ARCHITECT HIV Ag/Ab Combo
Serologic test for syphilis (STS) (Qualitative)	Serum		Mediacs RPR
Serologic test for syphilis (Qualitative)	Serum		serodiaTP • PA
6 Microbiology			
a Microscopic examination for stained film (general bacteria)			
Other	Others		Microscopy



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Item	Type of Samples	Test Method
Non-Basic Series		
11 General (urine, feces, etc.)		
a General urinalysis		
B-J proteins (Qualitative) (Urinary)	Urine	Putnumhou
Albumin (Qualitative) (Urinary)	Urine	Auto maikuroalbumin
Albumin (Quantitative) (Urinary)	Urine	Auto maikuroalbumin
Urinary sediment by flow cytometry (Urinary)	Urine	UF CELLSHEATH
b Scatolscopy		
Parasitic worm eggs (feces)	Feces	siyurannhou
Parasite (feces)	Feces	Microscopy
Hemoglobin (Qualitative) (feces)	Feces	NESCAUTO Hb Auto
Hemoglobin and transferrin (Quantitative, Qualitative) (feces)	Feces	NESCAUTO Hb Auto · NESCAUTO Tf Auto
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	Pyrogallolredhou, Ltypewako Glu2, Samsoneki, kutusetukeihou, nonneaperuto hannou, pandihannou, kiyoukenhou
Test of semen	Others	Microscopy
12 Hematology		
a General hematology, hemogram		
Erythrocyte sedimentation rate	Blood	wetergrenhou
Erythroresistant test (Giffin-Sanford test)	Blood	sanfodohou
Eosinophils, nasal/sputum smear	Others	Wright stain
Microbiology in blood	Blood	Giemsa stain
Hemogram (special stain)	Blood	DBA stain
Myelogram	Others	Light Giemsa stain
b Thrombus / hemostasis related test I		
Antithrombin (activity)	Plasma	N-Assay L AtIII Nitobo
13 Biochemistry I		
a Biochemistry I		
Ferritin Quantitative	Serum	KemirumiACS Ferritin II (FER)
b Biochemistry II		
Leucine Aminopeptidase (LAP)	Serum	LtaipuwakoLAP
14 Biochemistry II		
a Endocrinology I		
Human chorionic gonadotropin (HCG) (Qualitative)	Urine	GESTATE ST- II
Human chorionic gonadotropin (HCG) (Quantitative)	Urine	Siemens ImmulizuHCG II (2000)
Thyroid-stimulating hormone (TSH)	Serum	ChemilumiACS-TSHIII Urutora(TSH)
Free triiodothyronine (FT3)	Serum	ChemilumiACS-FT3 II (FT3)
Free thyroxine (FT4)	Serum	ChemilumiE-FT4(FT4)
C-peptide (CPR)	Serum	ChemilumiC-Peputaido
Insulin (IRI)	Serum	ChemilumiInsulin
Follicle-stimulating hormone (FSH)	Serum	ChemilumiACS-LH II (LH)
Luteinizing hormone (LH)	Serum	ChemilumiACS-FSH(FSH)
Prolactin (PRL)	Serum	ChemilumiACS-Prolactin(FRL)
Estradiol (E2)	Serum	chemilumiACS-Estradiol-6(E2-6)
Cortisol	Serum	AkitekutoCortisol



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Scope of accreditation :

Item	Type of Samples	Test Method
b Tumor marker		
Carcinoembryonic antigen (CEA)	Serum	ChemilumACS-CEA(CEA)
CA19-9	Serum	ChemilumiACS-CA19-9 II (CA19-9)
Prostate-specific antigen (PSA)	Serum	ArchtectPSA Assay
PIVKA-II (Quantitative)	Serum	PIVKA-II • Abbott
15 Immunology		
a Immunohematology		
Blood group, Rh system	Blood	BaiokuronRhketuekikatayoukouE, BaiokuronRhketuekikatayoukouC, BaiokuronRhketuekikatayoukouE, BaiokuronRhketuekikatayoukouC
Blood group, ABO subgroups	Blood	Garusabu, A1 rekitin, Hrekitin
Irregular antibody	Serum	ResolovePanelA, ResolovePanelB
c Immunology for infectious disease III		
Adenovirus antigen (Qualitative) (Feces)	Feces	Dipstick Eiken Adeno
Rotavirus antigen (Qualitative) (Feces)	Feces	Dipstick Eiken Rota
Serologic test for syphilis (STS) (Quantitative)	Serum	MediesuRPR
Treponema pallidum antibody (Semi-quantitative)	Serum	serodia TP/PA
d Hepatitis and relates		
HBe antigen	Serum	Lumipulse I HBeAg
HBe antibody	Serum	Lumipulse HBeAb-N
HBs antigen (Qualitative, Semi-quantitative)	Serum	Maiseru II HBsAg
HBs antibody (Qualitative)	Serum	Maiseru II • anti-HBs
HBs antibody (Quantitative)	Serum	Archtect osabu
HBc antibody (Semi-quantitative, Quantitative)	Serum	Lumipulse HBcAb-N
f Immunology for plasma protein		
C-reactive protein (CRP) (Qualitative)	Serum	N-Assay LA CRP-S Nitobo
Immnoelectrophoresis (Anti-Human serum)	Serum	Urine
Immnoelectrophoresis (Singular antiserum)	Serum	Urine
TitanzieruFEkouhitoketuseiseto		
TitanzieruFEkouhitoketuseiseto		
18 Others excluding 11 to 16 class		
a Therapeutic drug monitoring		
Digitoxin, Digoxin	Serum	nanopia TDM zigokisin
Theophylline	Serum	nanopia TDM teofuri
Valproic acid, Carbamazepin	Serum	nanopia TDM barupurosan, nanopia TDM karubamazepin
Phenytoin, Primidone, Ethosuximide, Phenobarbital, Zonisamide, Nitrazepam, Clonazepam, Others	Serum	nanopia TDM fenitoin, nanopia TDM fenobarubitaru
Vancomycin, Teicoplanin, Gentamicin, Tobramycin, Amikacin, Arbekacin, Voriconazole	Serum	nanopia TDM vancomycin