

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, 2022

Revised (9)	March 29, 2021
Renewed (3)	February 7, 2018
Initial accreditation	March 29, 2006

Y. Iizuka, President

Japan Accreditation Board



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Accreditation No. RML00110

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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	kusutukeihou, uropepa II eiken	
Protein quantitation	Urine	maikuro TP-testwako	
Glucose quantitation	Urine	L-typewakou Glu2	
Sedimentary test, urine	Urine	UFII SatiSED	
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	toronbocheckPTPurs	
Activated partial thromboplastin time(APTT)	Plasma	toronbocheckAPTTPurs	
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	Ltipuwako-UN	
Creatinine	Serum	Urine	Sikarikido-S CRE
Uric acid	Serum	Urine	datamina-C-UA
Na and Cl	Serum	Urine	ISE



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Scope of accreditation :

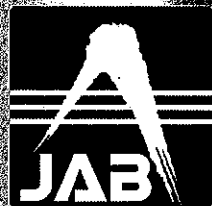
Item	Type of Samples		Test Method
	Serum	Urine	
K	Serum	Urine	ISE
Ca	Serum	Urine	Ca-AL TypeC
Inorganic phosphate and phosphoric acid	Serum	Urine	mukirin-HR II
Mg	Serum	Urine	magnesium-HR II
Total cholesterol	Serum		pyuaotoS CHO-N
Triglyceride	Serum		pyuaotoS TG-N
HDL-cholesterol	Serum		koresutest HDL
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 · J
Cholinesterase	Serum		kuikuneo Ch-E
γ-glutamyltranspeptidase (γ-GT)	Serum		Ltypewako γ-GT · J
Lactate dehydrogenase (LD)	Serum		Ltype LDH · J
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		serodiaTP · PA
Serologic test for syphilis (Qualitative)	Serum		N-Assay LAASO Nitobo
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 maikuroalubumin
Albumin (Quantitative) (Urinary)	Urine	Auto maikuroalubumin
Urinary sediment by flow cytometry (Urinary)	Urine	UF CELLSHEATH
b Scatoloscropy		
Parasitic worm eggs (feces)	Feces	siyurannhou
Parasite (feces)	Feces	Microscopy
Hemoglobin (Qualitative) (feces)	Feces	nesukoto hemo Plus
Hemoglobin and transferrin (Quantitative, Qualitative) (feces)	Feces	nesukoto hemo Plus · nesukoto toransuferin Plus
c Basic anialysis 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, Ltpewako Glu2, Samsoneki, kutusetukeihou, nonneaperutohannou, 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 I. 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-Prolaktin(FRL)
Estradiol (E2)	Serum	chemilumiACS-Estradiol-6(E2-6)



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Item	Type of Samples		Test Method
Cortisol	Serum		AkitekutoCortisol
b Tumor marker			
Carcinoembryonic antigen (CEA)	Serum		ChemilumiACS-CEA(CEA)
CA19-9	Serum		ChemilumiACS-CA19-9 II (CA19-9)
Prostate-specific antigen (PSA)	Serum		ArchtectPSAAssay
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	Serum	Garusabu,Alrekutin,Hrekutin
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
HBe 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
Immunoelectrophoresis (Anti-Human serum)	Serum	Urine	TitanzieruFEkouhitoketuseiseto
Immunoelectrophoresis (Singular antiserum)	Serum	Urine	TitanzieruFEkouhitoketuseiseto
18 Others excluding 11 to 16 class			
a Therapeutic drug monitoring			
Digoxin, Digoxin	Serum		nanopia TDM zigokisin
Theophylline	Serum		nanopia TDM teofuri
Valproic acid, Carbamazepine	Serum		nanopia TDM barupurosan, nanopia TDM karubamazepin
Phenytoin, Primidone, Ethosuximide, Phenobarbital, Zonisamide, Nitrazepam, Clonazepam, Others	Serum		nanopia TDM fenitoin, nanopia TDM fenobarbitaru
Vancomycin, Teicoplanin, Gentamicin, Tobramycin, Amikacin, Arbekacin, Voriconazole	Serum		nanopia TDM vancomycin