



Medical Laboratory  
Accreditation  
Certificate

Accreditation No. RML01550

***Eil Inc.  
Itabashi Chuo Rinshoukensa Kenkyujo***

***2-20-10, Azusawa, Itabashi-ku, Tokyo, 174-0051, Japan***

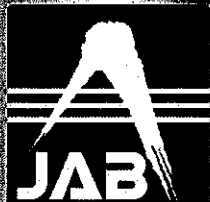
meets the following criteria. On the basis of this, Japan Accreditation Board (JAB) grants accreditation to the said medical laboratory.

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	April 23, 2023
Renewed	April 1, 2022
Initial accreditation	March 15, 2018

Y. Izuka, President

**Japan Accreditation Board**



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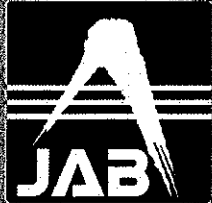


## **Eil Inc. Itabashi Chuo Rinshoukensa Kenkyujo**

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Itabashi Chuo Rinshoukensa Kenkyujo  
2-20-10, Azusawa, Itabashi-ku, Tokyo, 174-0051, Japan

### Scope of accreditation :

Item	Type of Samples	Test Method	
<b>Basic Series</b>			
<b>1 General (urine, feces, etc.)</b>			
<b>a Qualitative (urine / feces)</b>			
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 III 'EIKEN' UROPAPER α III 'EIKEN'	
Glucose quantitation	Urine	QUICK AUTO NEO GLU <sup>TM</sup> HK	
<b>2 Hematology</b>			
<b>a Blood count / blood cell morphology test</b>			
Peripheral blood general test*(complete blood counts)* : RBC, WBC, Hgb, PLT, Hct	Blood	Cell pack DST, Sulfo lyser, Lyser cell WNR, Fluor cell WNR, Cell pack DFL, Fluor cell PLT	
Reticulocytes	Blood	Cell pack DST, Cell pack DFL, Fluor cell RET	
Eosinophils	Blood	Cell pack DST, Lyser cell WDF, Fluor cell WDF, Lyser cell WNR, Fluor cell WNR	
Hemogram (The microscope method)	Blood	Others MICROX stain solution(Wright), 1/15M phosphate buffer solution, May-Gruenwald stain solution, Giemsa stain solution, Phosphate buffer solution pH 6.8(concentrated/for SP)	
Hemogram (The automatic analyser method)	Blood	Cell pack DST, Lyser cell WDF, Fluor cell WDF, Lyser cell WNR, Fluor cell WNR, Lyser cell WPC, Fluor cell WPC	
<b>b Thrombus / hemostasis related test</b>			
Prothrombin time(PT)	Plasma	Coagpia PT-N	
Activated partial thromboplastin time(APTT)	Plasma	Coagpia APTT-N	
Fibrinogen (Quantitative)	Plasma	Coagpia Fbg	
Fibrinogen degradation products(FDP)	Plasma	Nanopia P-FDP	
<b>3 Biochemistry I</b>			
<b>a Biochemistry</b>			
Total bilirubin	Serum	Plasma	Total bilirubin EA-HA test WAKO
Bilirubin, indirect and direct	Serum	Plasma	Direct bilirubin E-HA test WAKO
Total protein	Serum	Plasma	AKYURASU AUTO TP
Albumin	Serum	Plasma	AKYURASU AUTO ALB II
Proteins fractionation	Serum		Capirally Protein6 Kit



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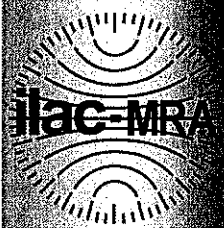
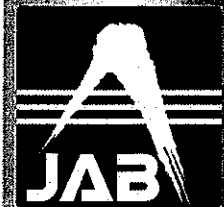
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**Eil Inc.**  
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## Scope of accreditation

Item	Type of Samples		Test Method
	Serum	Urine	
Urea nitrogen(BUN)	Serum	Urine	QUICK AUTO NEO BUN
Creatinine	Serum	Urine	AQUAAUTO KAINOSU CRE-II
Uric acid	Serum	Urine	QUICK AUTO NEO UAI
Na and Cl	Serum	Urine	Electrode method
K	Serum	Urine	Electrode method
Ca	Serum	Urine	AQUAAUTO KAINOSU Ca
Inorganic phosphate and phosphoric acid	Serum	Urine	AKYURASU AUTO IP
Mg	Serum	Urine	AQUAAUTO KAINOSU Mg-II
Total cholesterol	Serum	Plasma	Determiner L TC II
Triglyceride	Serum	Plasma	Determiner L TG II
HDL-cholesterol	Serum	Plasma	Metabolead HDL-C
LDL-cholesterol	Serum	Plasma	Metabolead LDL-C
Glycated albumin	Serum	Plasma	RUSIKA GA-L
Glucose	Serum	Plasma	QUICK AUTO NEO GLU-HK
Hemoglobin A1c (HbA1c)	Blood		NORUDIA N HbA1c
Fe	Serum	Plasma	QUICK AUTO NEO Fe
Total iron binding capacity (TIBC)	Serum	Plasma	operation(Fe+UIBC)
Unsaturated iron binding capacity (UIBC)	Serum	Plasma	QUICK AUTO NEO UIBC
Alkaline phosphatase	Serum	Plasma	CYGNUS AUTO NEO ALP IF
Cholinesterase	Serum	Plasma	QUICK AUTO NEO ch-E
γ-glutamyltranspeptidase (γ-GT)	Serum	Plasma	QUICK AUTO NEO γ-GT
Lactate dehydrogenase (LD)	Serum	Plasma	CYGNUS AUTO NEO LD IF
Amylase	Serum	Urine	AKYURASU AUTO AMY-IF
Creatine kinase (CK)	Serum	Plasma	CYGNUS AUTO CK
Asparate aminotransferase (AST)	Serum	Plasma	QUICK AUTO NEO AST
Alanine aminotransferase (ALT)	Serum	Plasma	QUICK AUTO NEO ALT
<b>5 Immunology</b>			
<b>a Immunochemistry I</b>			
C-reactive protein (CRP)	Serum	Plasma	LZ test'EIKEN'CRP-HG
Immunoglobulin (IgG, IgA, IgM, IgD)	Serum	Plasma	N-assay TIA IgG-SH Nittobo, N-assay TIA IgA-SH Nittobo, N-assay TIA IgM-SH Nittobo
C3	Serum	Plasma	N-assay TIA C3-SH Nittobo
C4	Serum	Plasma	N-assay TIA C4-SH Nittobo
Immunoglobulin (RF)	Serum	Plasma	LZ test'EIKEN'RF
<b>b Immunohematology</b>			
Blood group (ABO type)	Blood		IMMUCOR KOU A Monoclo,IMMUCOR KOU B Monoclo
Blood group (Rho (D) factor)	Blood		IMMUCOR gamma clone KOU D(IgG/IgM)
<b>c Infectious disease I</b>			
HBs antigen	Serum	Plasma	Alinity HBsAg QT·Abbott
HBs antibody	Serum	Plasma	Alinity OSABU·Abbott
HCV antibody (Quantitative, Qualitative)	Serum	Plasma	Alinity HCV·Abbott
HIV-1,2 antigen and antibody simultaneous measurement	Serum	Plasma	Alinity HIV Ag/Ab Combo assay·Abbott



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## *Eil Inc.* *Itabashi Chuo Rinshoukensa Kenkyujo*

### Scope of accreditation

Item	Type of Samples		Test Method
Serologic test for syphilis (STS) (Qualitative)	Serum	Plasma	Mediate RPR(M)
Serologic test for syphilis (Qualitative)	Serum	Plasma	Mediate TPLA(M)
Anti-streptolysin O (ASO)	Serum	Plasma	LZ test'EIKEN'ASO'
<b>6. Microbiology</b>			
a Microscopic examination for stained film (general bacteria)			
Other	Sputum	Urine	Gram stain, india ink method, Gimenez stain, Ziehl-Neelsen stain
b Bacterial culture and identification / Antimicrobial sensitivity test (general bacteria)			
Bacterial culture and identification	Sputum	Urine	HCCA-portioned, TWIN PLATE9, TWIN PLATE4, BTB ager, Pourmedia chocolate ager, GAM Semisolid agar medium
Simple method culture	Urine	Secretions	Trichomonas-RY semisolid agar medium
Anaerobic culture	Blood	Others	HCCA-portioned, Brucella HK ager (Rabbit), GAM Semisolid agar medium
Antimicrobial sensitivity test (general bacteria)	Sputum	Urine	Dry Plate 192 (EP01, EP02, EP04)
<b>Non-Basic Series</b>			
<b>11 General (urine, feces, etc.)</b>			
a General urinalysis			
Albumin (Quantitative) (Urinary)	Urine		N-assay TIA Micro Alb (Nittobo)
N-acetyl glucosaminidase (NAG) (Urinary)	Urine		N-assay L NAG Nittobo
Latty acid binding protein, L-type (L-FABP) (Urinary)	Urine		NORUDIA L-FABP
b Scatolscopy			
Hemoglobin (Qualitative) (feces)	Feces		OC-HEMODIA AUTO III 'EIKEN'
<b>12 Hematology</b>			
a General hematology, hemogram			
Erythrocyte sedimentation rate	Blood		Westergren method
Eosinophils, nasal/sputum smear	Others	Sputum	May-Grünwald's eosin methyleneblue solution, Giemsa's azure eosin methyleneblue solution, 1/15M phosphate buffer solution
Microbiology in blood	Others	Blood	Giemsa stain (Giemsa's azure eosin methylene blue solution), methanol
Hemogram (special stain)	Others		peroxidase stain: DAB stain kit, esterase stain: esterase stain kit, esterase AS-D stain kit, alkaline phosphatase (ALP) stain: ALP stain kit, PAS (Periodic acid-Schiff) stain: PAS stain kit, acid phosphatase (ACP) stain: ACP stain kit, iron stain: Berlin blue stain
Myelogram	Others		May-Grünwald's eosin methylene blue solution, Giemsa's azure eosin methylene blue solution, 1/15M phosphate buffer solution



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Item	Type of Samples		Test Method
Myelogram (special stain)	Others		peroxidase stain:DAB stain kit, esterase stain:esterase stain kit,esterase AS-D stain kit, alkaline phosphatase(ALP) stain :ALP stain kit, PAS(Periodic acid-Schiff) stain: PAS stain kit, acid phosphatase(ACP) stain:ACP stain kit, iron stain:Berlin blue stain
<b>b Thrombus/hemostasis related test I</b>			
Antithrombin (activity)	Plasma		TestzymS ATIII
Plasmin inhibitor/plasmin complex(PIC)	Plasma		RIAS AUTO-PIC
Coagulation factor inhibitor Qualitative (cross mixing test)	Plasma		Coagpia APTT-N
D dimer	Plasma		Nanopia D dimer
Thrombin anti-Thrombin complex (TAT)	Plasma		Nanopia TAT
<b>13 Biochemistry I</b>			
<b>a Biochemistry I</b>			
Phospholipid	Serum	Plasma	L-type WAKO phospholipid
Zn	Serum	Plasma	AKYURASU AUTO Zn
1,5-Anhydro-D-glucitol (1,5AG)	Serum	Plasma	Determiner L 1.5-AG
Bile acids	Serum		AQUA AUTO KAINOSU TBA
Total carnitine	Serum	Plasma	T-Carnitine KAINOSU
Free carnitine	Serum	Plasma	F-Carnitine KAINOSU
Ferritin Quantitative	Serum	Plasma	LZ test 'EIKEN' FER
Remnant like particles (RLP) Cholesterol	Serum		MetaboLead RemL-C
Procalcitonin (PCT) (Quantitative)	Serum	Plasma	Chemilumi BRAHMS procalcitonin(Atellica)
<b>b Biochemistry II</b>			
Leucine Aminopeptidase (LAP)	Serum	Plasma	QUICK AUTO NEO LAP
Lipase	Serum	Plasma	Cygnus Auto LIP
KL-6	Serum	Plasma	Nanopia KL-6
Cystatine C	Serum	Plasma	LZ test 'EIKEN' Cystatine C
<b>c Vitamin</b>			
Vitamin B12	Serum	Plasma	Chemilumi vitaminB12(Atellica)
Folic acid	Serum		Chemilumi folate(Atellica)
<b>14 Biochemistry II</b>			
<b>a Endocrinology I</b>			
Thyroid-stimulating hormone (TSH)	Serum	Plasma	Chemilumi TSH III ultra(Atellica)
Triiodothyronine (T3)	Serum		Chemilumi E-T3(Atellica)
Thyroxine (T4)	Serum		Chemilumi T4(Atellica)
Free triiodothyronine (FT3)	Serum		Chemilumi FT3(Atellica)
Free thyroxine (FT4)	Serum	Plasma	Chemilumi E-FT4(Atellica)
C-peptide (CPR)	Serum	Urine	Chemilumi C-peptide(Atellica)
Insulin (IRI)	Serum	Plasma	Alinity insulin



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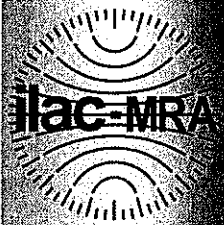
Item	Type of Samples	Test Method
Follicle-stimulating hormone (FSH)	Serum	Chemilumi FSH(Atellica)
Luteinizing hormone (LH)	Serum	Chemilumi LH(Atellica)
Prolactin (PRL)	Serum	Chemilumi prolactin(Atellica)
Parathyroid hormones (PTH)	Serum Plasma	Chemilumi intact PTH
Brain natriuretic peptide (BNP)	Plasma	AIA-packCL BNP
Estradiol (E2)	Serum Plasma	Chemilumi E-estradiol-6(Atellica)
Cortisol	Serum	Chemilumi cortisol II(Atellica)
Atrial natriuretic peptide (ANP)	Plasma	AIA-packCL ANP
N-terminal pro-brain natriuretic peptide (NT-proBNP)	Serum Plasma	Flex cartridge NT-pro BNP mono V
Thyroglobulin	Serum Plasma	AIA-packCL thyroglobulin
Adrenocorticotrophic hormone (ACTH)	Plasma	AIA-packCL ACTH
<b>b Tumor marker</b>		
α-fetoprotein (AFP)	Serum Plasma	Alinity AFP·Abbott
Carcinoembryonic antigen (CEA)	Serum Plasma	Alinity CEA·Abbott
CA19-9	Serum Plasma	Alinity CA19-9 XR·Abbott
CA125	Serum Plasma	Alinity CA125 II·Abbott
Prostate-specific antigen (PSA)	Serum Plasma	Alinity Total PSA·Abbott
Squamous cell cancer related antigen (SCC)	Serum Plasma	Alinity SCC·Abbott
CA15-3	Serum Plasma	Alinity CA15-3·Abbott
Cytokeratin 19 fragment	Serum Plasma	Alinity CYFRA·Abbott
Free PSA/Total PSA ratio	Serum	Alinity Free PSA·Abbott
Progastorin releasing peptide(ProGRP)	Plasma	Alinity ProGRP·Abbott
PIVKA-II (Quantitative)	Serum Plasma	Alinity PIVKA - II·Abbott
Inteleukin 2 receptor, soluble (sIL-2R)	Serum Plasma	SIEMANS IMMULYZE IL-2R II 2000
<b>c Special analysis</b>		
Urea breath test (UBT)	Others	Infrared spectroscopy(Ubit tablets 100mg)
<b>15 Immunology</b>		
<b>c Immunology for infectious disease III</b>		
Escherichia coli,serotyping	Feces Tissues	pathogenic E-coli antiserum「SEIKEN」
Virus antigen (Quantitative) (Rubella virus)	Serum	Rumpia Latex RUBELLA
Clostridium difficile toxin A (Qualitative)	Feces	IMMUNOCHROMATO-CD GDH/TOX
(1→3)-β-D-Glucan	Plasma	β-Glucan Test WAKO
<b>d Hepatitis and relates</b>		
HBe antigen	Serum Plasma	Alinity HBeAg·Abbott
HBe antibody	Serum Plasma	Alinity HBeAb·Abbott
HBe-IgM antibody	Serum Plasma	Alinity HBe-M·Abbott
HBs antigen (Qualitative, Semi-quantitative)	Serum Plasma	Alinity HBsAg QT·Abbott
HBs antibody (Qualitative)	Serum Plasma	Alinity OSABU·Abbott
HBs antibody (Quantitative)	Serum Plasma	Alinity OSABU·Abbott
HBe antibody (Semi-quantitative, Quantitative)	Serum Plasma	Alinity HBe·Abbott
<b>e Autoantibody</b>		
Anti RNP antibody (Quantitative)	Serum Plasma	EliA(U1RNP)



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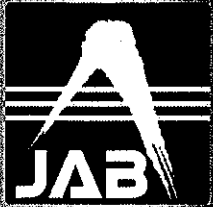
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### Scope of accreditation

Item	Type of Samples		Test Method
Anti-Sm antibody (Quantitative)	Serum	Plasma	EliA SmDp
Anti-Jo-1 antibody (Quantitative)	Serum	Plasma	EliA(Jo-1)
Anti-centromere antibody (Quantitative)	Serum	Plasma	EliA(CENP-B)
Matrix metalloproteinase-3 (MMP-3)	Serum	Plasma	LZ test 'EIKEN' MMP-3
Serine proteinase-3-anti-neutrophil cytoplasmic antibody (PR3-ANCA)	Serum	Plasma	EliA PR3s-ANCA
Anti neutrophil cytoplasmic myeloperoxidase antibody (MPO-ANCA)	Serum	Plasma	EliA MPOs-ANCA
Anti Thyroglobulin antibody	Serum	Plasma	Chemilumi anti-thyroglobulin antibody (Atellica)
Anti Thyroid peroxidase antibody	Serum	Plasma	Chemilumi anti-thyroid peroxidase antibody (Atellica)
Anti TSH receptor antibody (TRAb)	Serum	Plasma	AIA-packCL TRAb
Anti-nuclear antibody (immunofluorescence is excluded)	Serum	Plasma	EliA CTD Screen
Anti SS-A/Ro antibody (Quantitative)	Serum	Plasma	EliA(SS-A/Ro)
Anti SS-B/La antibody (Quantitative)	Serum	Plasma	EliA(SS-B/La)
Anti Scl-70 antibody (Quantitative)	Serum	Plasma	EliA Scl-70s
Anti DNA antibody (Quantitative)	Serum	Plasma	EliA(dsDNA)
Anti citrullinated peptide antibody (Quantitative)	Serum	Plasma	EliA(CCP)
<b>f Immunology for plasma protein</b>			
$\beta$ 2-microglobulin	Serum	Urine	LZ test 'EIKEN' $\beta$ 2-M
Interferon-gamma release assay specifically stimulated by latent tuberculosis infection	Plasma		QuantiFERON TB Gold plus
Non-specific immunoglobulin IgE (Quantitative)	Serum	Plasma	ImmunoCAP Total IgE
Specific immunoglobulin IgE (Semi-Quantitative) / (Quantitative)	Serum	Plasma	ImmunoCAP Specific IgE
Transferrin (Prealbumin)	Serum	Plasma	N-assay TIA prealbumin Nittobo
<b>17 Gene-related / Chromosome test</b>			
<b>b Identification of pathogen nucleic acid</b>			
DNA amplification assay for Mycobacteria tuberculosis complex	Sputum	Urine	GENECUBE MTB
Mycobacterium avium / intracellulare DNA	Sputum	Urine	GENECUBE MAI
Quantification of HBV nucleic acid (Quantitative)	Serum	Plasma	AccuGene m-HBV
HCV DNA (Quantitative)	Serum	Plasma	AccuGene m-HCV
<b>18 Others excluding 11 to 16 class</b>			
<b>a Therapeutic drug monitoring</b>			
Digoxin	Serum	Plasma	Flex cartridge Digoxin(N)DGNA
Theophylline	Serum	Plasma	Flex cartridge Theophylline THEO
Valproic acid, Carbamazepine	Serum	Plasma	Flex cartridge Valproic acid VALP Flex cartridge Carbamazepine(N)CRBM
Phenytoin, Phenobarbital	Serum	Plasma	Flex cartridge Phenobarbital(N)PHNO Flex cartridge Phenytoin(N)PTN
Lithium	Serum	Plasma	Flex cartridge Lithium LI
Vancomycin	Serum	Plasma	Flex cartridge Vancomycin(N)VANC
Cyclosporin, Tacrolimus hydrate	Blood		Flex cartridge Cyclosporine CSA Flex cartridge Tacrolimus TAC



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Scope of accreditation

Item	Type of Samples		Test Method
<b>Specific program I</b>			
21 Specified health checkup testing (health checkup for metabolic syndrome)			
a Basic Series			
Triglyceride	Serum	Plasma	Determiner L TG II
HDL-cholesterol	Serum	Plasma	Metabolead HDL-C
LDL-cholesterol	Serum	Plasma	Metabolead LDL-C
Creatinine	Serum		AQUA AUTO KAINOSU CRE-II
Glucose	Serum	Plasma	QUICK AUTO NEO GLU-HK
Hemoglobin A1c (HbA1c)	Blood		NORUDIA N HbA1c
Uric Acid	Serum		QUICK AUTO NEO UAH
AST	Serum	Plasma	QUICK AUTO NEO AST
ALT	Serum	Plasma	QUICK AUTO NEO ALT
γ-GT	Serum	Plasma	QUICK AUTO NEO γ-GT
Urine Glucose qualitative	Urine		URO PAPER III 'EIKEN'
Urine Protein qualitative	Urine		URO PAPER III 'EIKEN'
b Additional Series			
Red Blood Cell	Blood		Cell pack DST
Hemoglobin	Blood		Cell pack DST, Sulfo lyser
Hematocrit	Blood		Cell pack DST
<b>Pathology</b>			
31 Preparation			
a Preparation for histodiagnosis			
Organize slices	Tissues		hematoxylin eosin(HE) Stain etc.
c Preparation for immunological stain (histodiagnosis)			
Estrogen receptor	Tissues		Immunostaining(Ventana ultra View confirm ER(SP1))
Progesterone receptor	Tissues		Immunostaining(Ventana ultra View confirm PGR(1E2))
Others	Tissues		Immunostaining(Ventana ultra View)
e Cytodiagnosis			
Gynecology	Others		Papanicolaou stain (Auto)
Fine needle aspiration cytology, Body cavity washing	Urine	Sputum	Papanicolaou stain (Auto)
32 Pathological diagnosis			
a Pathological diagnosis			
Histology	Tissues		hematoxylin eosin(HE) Stain etc.
Cytology	Others	Urine	Papanicolaou stain (Auto) etc.