

Medical Laboratory  
Accreditation  
Certificate

Accreditation No.RML01230



**JAB**



***Hyogo Prefectural Hospitals Agency  
Department of Clinical Laboratory, Hyogo Cancer Center***

***13-70, Kitaoji-cho, Akashi-shi, Hyogo, 673-8558, 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	: February 28, 2025

Renewed (1)	February 15, 2021
Initial accreditation	February 21, 2017

Y. Iizuka, President

**Japan Accreditation Board**



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**Hyogo Prefectural Hospitals Agency  
Department of Clinical Laboratory, Hyogo Cancer Center**

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Department of Clinical Laboratory, Hyogo Cancer Center  
13-70, Kitaoji-cho, Akashi-shi, Hyogo, 673-8558, Japan  
Excluding primary sample collection from the scope of accreditation

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, Bilirubin, Ketones, Occult blood reaction (Urinary), Bacteria (Test paper), Leukocyte (Test paper))	Urine	Uriflet S 9UB
Protein quantitation	Urine	MICRO TP-AR
Glucose quantitation	Urine	quick auto neo GLU-HK
Hemoglobin, feces	Feces	OC-Hemodia auto S Eiken
Sedimentary test, urine	Urine	microscope
<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	Others Flowcytometry Peroxidase stain Colorimetric method
Reticulocytes	Blood	autoRETIC
Hemogram (The microscope method)	Blood	Others May-Giemsa stain
Hemogram (The automatic analyser method)	Blood	Others Peroxidase stain
<b>b Thrombus / hemostasis related test</b>		
Prothrombin time(PT)	Plasma	Thromborel S
Activated partial thromboplastin time(APTT)	Plasma	ThromboCheck APTT
Fibrinogen (Quantitative)	Plasma	ThromboCheck Fib
Fibrinogen degradation products(FDP)	Plasma	LPIA FDP-P
<b>3 Biochemistry I</b>		
<b>a Biochemistry</b>		
Total bilirubin	Serum	Plasma Neskoto VL T-BIL
Bilirubin, indirect and direct	Serum	Plasma Neskoto VL D-BIL
Total protein	Serum	Plasma AQUA AUTO KAINOS TP- II
Albumin	Serum	Plasma AQUA AUTO KAINOS ALB
Urea nitrogen(BUN)	Serum	Plasma AQUA AUTO KAINOS UN- II
Creatinine	Serum	Plasma AQUA AUTO KAINOS CRE-III plus
Uric acid	Serum	Plasma AQUA AUTO KAINOS UA- II
Na and Cl	Serum	Plasma TOSHIBA Ion Collect, ICT Reference Solution
K	Serum	Plasma TOSHIBA Ion Collect, ICT Reference Solution
Ca	Serum	Plasma AQUA AUTO KAINOS Ca
Inorganic phosphate and phosphoric acid	Serum	Plasma AQUA AUTO KAINOS IP-K II

# Accreditation Certificate Appendix

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## Hyogo Prefectural Hospitals Agency Department of Clinical Laboratory, Hyogo Cancer Center

### Scope of accreditation :

Item	Type of Samples		Test Method
Mg	Serum	Plasma	AQUA AUTO KAINOS Mg- II
Total cholesterol	Serum	Plasma	detaminaL TC II
Triglyceride	Serum	Plasma	detaminaL TG II
HDL-cholesterol	Serum	Plasma	Metaboredo HDL-C
LDL-cholesterol	Serum	Plasma	Metaboredo LDL-C
Glucose	Serum	Plasma	quick auto neo GLU-HK
Hemoglobin A1c (HbA1c)	Blood		TOSOH Automatic Glycohemoglobin Analyzer (G9)
Fe	Serum	Plasma	quick auto neo Fe
Unsaturated iron binding capacity (UIBC)	Serum	Plasma	quick auto neo UIBC
Ammonia	Blood		FUJI DRI-CHEM slide NH <sub>3</sub> -W II
Alkaline phosphatase	Serum	Plasma	quick auto neo ALP-JS II
Cholinesterase	Serum	Plasma	quick auto neo Ch-E
γ-glutamyltranspeptidase (γ-GT)	Serum	Plasma	CicaLiquid γ-GT J
Lactate dehydrogenase (LD)	Serum	Plasma	L type WAKO LD · J
Amylase	Serum	Plasma	akyuras auto AMY-IF
Creatine kinase (CK)	Serum	Plasma	CicaLiquid CK
Aspartate aminotransferase (AST)	Serum	Plasma	L type WAKO AST · J2
Alanine aminotransferase (ALT)	Serum	Plasma	L type WAKO ALT · J2
Blood gas analysis	Blood		ABL 90 FLEX sensor cassette
<b>5 Immunology</b>			
<b>a Immunochemistry I</b>			
C-reactive protein (CRP)	Serum	Plasma	N-ASSAY LA CRP · S NITTOBO
Immunoglobulin (IgG, IgA, IgM, IgD)	Serum	Plasma	N-ASSAY TIA IgG, IgA, IgM · SH NITTOBO
<b>b Immunohematology</b>			
Blood group (ABO type)	Blood		Immucor CMT
Blood group (Rho (D) factor)	Blood		Immucor CMT
Indirect Coombs, direct Coombs	Blood		Direct: Aiti-Human IgG Serum
<b>c Infectious disease I</b>			
HBs antigen	Serum	Blood	HBsAg QT Ab b ott
HBs antibody	Serum	Plasma	ohSub Abbott
HCV antibody (Quantitative, Qualitative)	Serum	Plasma	HCV Ab b ott
HIV-1,2 antigen and antibody simultaneous measurement	Serum	Plasma	HIV Ag/Ab Comboassay Abbott
Serologic test for syphilis (STS) (Qualitative)	Serum	Plasma	Rapi Deer auto RPR
Serologic test for syphilis (Qualitative)	Serum	Plasma	TPAb Ab b ott
<b>6 Microbiology</b>			
<b>a Microscopic examination for stained film (general bacteria)</b>			
Other	Sputum	Others	Gram stain(Bami M) Acid-fast bacterium stain(Ziehl-Neelsen stain)
Use a fluorescent microscope	Sputum	Others	Fluorescent stain(Trant stain)



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**Hyogo Prefectural Hospitals Agency  
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Scope of accreditation :

Item	Type of Samples		Test Method
b Bacterial culture and identification / Antimicrobial sensitivity test (general bacteria)			
Bacterial culture and identification	Sputum	Others	Sheep Blood agar, Chocolate agar, Other mediums, BBL CRYSTAL Identification reagent, ID Test HN20 Rapid Nissui, Walk Away 40 SI
Anaerobic culture	Punctured fluid	Tissues	ABHK agar / BBE agar
Antimicrobial sensitivity test (general bacteria)	Sputum	Others	Walk Away 40 SI
<b>Non-Basic Series</b>			
<b>11 General (urine, feces, etc.)</b>			
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		MICRO TP-AR Calculating board method quick auto neo GLU-HK
<b>12 Hematology</b>			
a General hematology, hemogram			
Erythrocyte sedimentation rate	Blood		Venocject II Erythrocyte Sedimentation Rate System
Hemogram (special stain)	Blood		Peroxidase stain EST stain
Myelogram	Others		May-Giemsa stain
Myelogram (special stain)	Others		Peroxidase stain Fe stain EST stain PAS stain
Malignant tumor cell	Blood	Others	Flowcytometry
b Thrombus / hemostasis related test I			
Antithrombin (activity)	Plasma		Revohem AT
D dimer	Plasma		LPIA GENESIS D-dimer
<b>13 Biochemistry I</b>			
a Biochemistry I			
Ferritin Quantitative	Serum	Plasma	LUMIPULSE Ferritin-N
Procalcitonin (PCT) (Semi-quantitative)	Blood		Rapid chip PCT
b Biochemistry II			
Leucine Aminopeptidase (LAP)	Serum	Plasma	L type WAKO LAP
Lipase	Serum	Plasma	CygnusAuto LIP
KL-6	Serum	Plasma	LUMIPULSE KL6
Cystatine C	Serum	Plasma	Neskoto GC CystatineC
c Isozyme			
CK-MB	Serum	Plasma	CicaLiquid CK-MB
d Immunochemistry			
Cardiac troponin T (TnT) (Qualitative, Quantitative)	Blood		TROP T Sensitive
<b>14 Biochemistry II</b>			
a Endocrinology I			
Human chorionic gonadotropin (HCG) (Qualitative)	Urine		Clear View EASY HCG
Thyroid-stimulating hormone (TSH)	Serum	Plasma	LUMIPULSE TSH-III



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**Hyogo Prefectural Hospitals Agency  
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Item	Type of Samples		Test Method
Free triiodothyronine (FT3)	Serum	Plasma	LUMIPULSE FT3-III
Free thyroxine (FT4)	Serum	Plasma	LUMIPULSE FT4-N
Brain natriuretic peptide (BNP)	Plasma		LUMIPULSE BNP
Cortisol	Serum	Plasma	Cortisol · Abbott
<b>b Tumor marker</b>			
α-fetoprotein (AFP)	Serum	Plasma	LUMIPULSE AFP-N
Carcinoembryonic antigen (CEA)	Serum	Plasma	CEA · Abbott
CA19-9	Serum	Plasma	CA19-9XR · Abbott
CA125	Serum	Plasma	CA125 · Abbott
Prostate-specific antigen (PSA)	Serum	Plasma	Total PSA · Abbott
Squamous cell cancer related antigen (SCC)	Serum	Plasma	SCC · Abbott
CA15-3	Serum	Plasma	CA15-3 · Abbott
Cytokeratin 19 fragment	Serum		Shifura Abbott
Free PSA/Total PSA ratio	Serum		Free PSA · Abbott
Progesterin releasing peptide (ProGRP)	Plasma		ProGRP · Abbott
PIVKA-II (Quantitative)	Serum		LUMIPULSE PIVKA II -N
<b>c Special analysis</b>			
Urea breath test (UBT)	Others		Analysis of Expired Gas
<b>15 Immunology</b>			
<b>a Immunohematology</b>			
Blood group, Rh system	Blood		Ortho Bio Clone Rh blood group
Irregular antibody	Plasma		Immucor Capture R Ready-Screen III
<b>c Immunology for infectious disease III</b>			
Escherichia coli, serotyping	Feces	Others	Enteropathogenic E.coli Serotyping Seiken
Varicella virus antigen (in the epithelial cell)	Others		Derma quik VZV
Clostridium difficile toxin A (Qualitative)	Feces		C.DIFF QUIK CHECK Complete
(1→3)-β-D-Glucan	Plasma		β Glucan Test WAKO
Group A-β Streptococcal-rapid Detection (Qualitative)	Others		Immuno card EX Strep A
Influenza virus antigen (Qualitative)	Others		Immuno Ace Ful
Streptococcus pneumoniae capsular antigen (fluid, urinary)	Urine		Immuno Catch Streptococcus pneumoniae
Norovirus antigen (Qualitative)	Feces		Quick Navi™ Noro2
adenovirus antibody (Qualitative) (remove feces)	Others		Immuno Ace Adeno
Endotoxin	Plasma		Endotoxin · single test WAKO
Legionella pneumophila antigen (Urinary)	Urine		Immuno Catch Legionella
<b>d Hepatitis and relates</b>			
HBe antigen	Serum	Plasma	LUMIPULSE I HBeAg
HBe antibody	Serum	Plasma	LUMIPULSE HBeAb-N
HBe antibody (Semi-quantitative, Quantitative)	Plasma	Plasma	HBe · Abbott
<b>f Immunology for plasma protein</b>			
Transthyretin (Prealbumin)	Serum	Plasma	N-Assay TIA Prealbumin Nittobo
<b>g Cellular functional test (cellular immunity related test)</b>			
T and B lymphocyte subpopulation	Blood	Others	Flowcytometry
CCR4 protein	Blood	Others	Flowcytometry

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## Hyogo Prefectural Hospitals Agency Department of Clinical Laboratory, Hyogo Cancer Center

### Scope of accreditation :

Item	Type of Samples	Test Method
16 Microbiology		
c Identification of nucleic acid (genetic testing)		
E. coli vero cytotoxin (Qualitative)	Feces Others	Duopath Verotoxins
17 Gene-related / Chromosome test		
a Somatic gene test		
Preparation for HER2 gene specimen	Tissues	Path Vision HER2 DNA Probe Kit
Preparation for ALK fused gene specimen	Tissues	Vysis ALK Break Apart FISH Probe Kit
EGFR genetic testing (Plasma)	Plasma	cobas EGFR mutation detection kit
EGFR genetic test (other than the real-time PCR method), examination for microsatellite uneasiness (Qualitative)	Tissues Others	cobas EGFR mutation detection kit MSI Test Kit(FALCO)
d Germline gene test		
UDP uridine diphosphate glucuronosyltransferase	Blood	i-densy Pack UGT1A1(*28/*6)
18 Others excluding 11 to 16 class		
a Therapeutic drug monitoring		
Vancomycin, Teicoplanin, Gentamicin, Tobramycin, Amikacin, Arbekacin, Voriconazole	Serum	ARCHITECT VancomycinST
Cyclosporin, Tacrolimus hydrat, Everolimus, Mycophenolate mofetil	Blood	ARCHITECT Cyclosporin Tacrolimus Abbott
Methotrexate	Serum	Nanopia eTDM Methotrexate
<b>Pathology</b>		
31 Preparation		
a Preparation for histodiagnosis		
Organize slices	Tissues	Hematoxylin eosin stain
CELL BLOCK	Tissues	Hematoxylin eosin stain
c Preparation for immunological stain (histodiagnosis)		
Estrogen receptor	Tissues	I-VIEW Con farm ER(SP1)
Progesterone receptor	Tissues	I-VIEW Con farm PGR(1E2)
Human epidermal growth factor receptor-2	Tissues	I-VIEW Pasuwe HER2(4B5)
CD30	Tissues	Bentana OptiView
PD-L1	Tissues	DAKO Autostainer Link
Others	Tissues	I-VIEW DAB Universal Kit ultraView DAB Universal Kit OptiView DAB Universal Kit BOND Polymer Refine Kit
d Preparation for rapid pathologic daiagnosis		
Preparation for operative rapid pathologic daiagnosis	Tissues	Hematoxylin eosin stain
Preparation for operative rapid cytodiagnosis	Others	Papanicolaou stain, Giemsa stain



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Item	Type of Samples	Test Method
e Cytodiagnosis		
Gynecology	Others	Papanicolaou stain, Giemsa stain
Fine needle aspiration cytology, Body cavity washing	Punctured fluid	Papanicolaou stain, Giemsa stain
32 Pathological diagnosis		
a Pathological diagnosis		
Histology	Tissues	Diagnosis by the pathologist
Cytology	Others	Diagnosis by the pathologist
Physiology		
101 Physiology		
a Respiratory function test (Spirography)		
Slow vital capacity		FUDAC7 SP790COPD
Forced vital capacity		FUDAC7 SP790COPD
Functional Residual Capacity		FUDAC7
DLCO (diffusing capacity of CO)		FUDAC7
b Electrocardiogram		
At least 12 leads including limb monopole lead and the chest leads		FCP-7541 FCP-8321 (Fukuda Denshi)
Stress Electrocardiogram		FCP-7541
Holter Electrocardiogram		FM-180-SCM-6600
c Ultrasonography		
Cardiac ultrasonography		iE 33 (PHILIPS) EPIQ Elite(philipS)
Vascular ultrasonography		Vivid S6 (GE) EPIQ Elite(philipS)

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