

Medical Laboratory
Accreditation
Certificate

Accreditation No. RML01250

Amuru Inc.
Ageo Medical Laboratory

1-23-24, Midoricho, Yashio-shi, Saitama, 340-0808 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, 2025

Revised	March 24, 2022
Renewed	March 8, 2021
Initial accreditation	March 16, 2017

Y. Iizuka, President

Japan Accreditation Board



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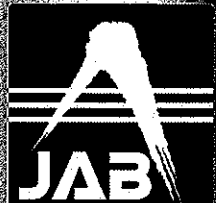


Amuru Inc. **Ageo Medical Laboratory**

Amuru Inc.
Ageo-Medical Laboratory
1-23-24, Midoricho, Yashio-shi, Saitama, 340-0808 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, Urobilin, Bilirubin, Ketones, Occult blood reaction (Urinary), Bacteria (Test paper), Sodium chloride, Leukocyte (Test paper), Albumin)	Urine	Paper of crow and snowy heron III EIKEN CHEMICAL
Hemoglobin, feces	Feces	OC-HEMODIAAUTO III EIKEN CHEMICAL
2 Hematology		
a Blood count / blood cell morphology test		
Peripheral blood general test*(complete blood counts)* : RBC, WBC, Hgb, PLT, Hct	Blood	Cell packDST, Cell packDFL, Ryser cellWNR, Ryser cellWDF, Ryser cellWPC, Fluoro cellPLT, Fluoro cellWDF, Fluoro cellWNR, Fluoro cellWPC, SLS, SYSMEX flow cytometry
Reticulocytes	Blood	Fluoro cellRET flow cytometry, Visual method SYSMEX
Eosinophils	Blood	Cell packDST, Cell packDFL, Ryser cellWNR, Ryser cellWDF, Ryser cellWPC, Fluoro cellPLT, Fluoro cellWDF, Fluoro cellWNR, Fluoro cellWPC, Phosphate buffer, SYSMEX, May Grinwald staining solution Visual method, flow cytometry,
Hemogram (The microscope method)	Blood	May Glyn Waldo dyeing liquid and Giemsa stain liquid Muto chemistry Concentration phosphoric acid buffer solution SYSMEX Visual method
Hemogram (The automatic analyser method)	Blood	Cell packDST, Cell packDFL, Ryser cellWNR, Ryser cellWDF, Ryser cellWPC, Fluoro cellPLT, Fluoro cellWDF, Fluoro cellWNR, Fluoro cellWPC, Phosphate buffer SYSMEX, May Grinwald staining solution, Giemsa dyeing Muto Kagaku, flow cytometry
b Thrombus / hemostasis related test		
Prothrombin time(PT)	Plasma	Thromborel S SYSMEX
Activated partial thromboplastin time(APTT)	Plasma	Revohem APTT (APTT reagent) Revohem 0.025M calcium chloride Solution SYSMEX



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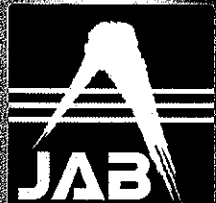
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Scope of accreditation :

Item	Type of Samples	Test Method
Fibrinogen (Quantitative)	Plasma	Thrombocheck Fib (large) SYSMEX
Fibrinogen degradation products(FDP)	Plasma	Lias, automatic P-FDP SYSMEX
3 Biochemistry I		
a Biochemistry		
Total bilirubin	Serum	General bilirubin E-HR Wako FUJIFILM Wako Pure Chemical
Bilirubin, indirect and direct	Serum	Direct bilirubin E-HR Wako FUJIFILM Wako Pure Chemical
Total protein	Serum	An aqua, automatic Kainos Laboratories TP Kainos Laboratories
Albumin	Serum	An aqua, automatic Kainos Laboratories ALB Kainos Laboratories
Urea nitrogen(BUN)	Serum	A quickstep, automatic Neo- BUN. SHINO- TEST
Creatinine	Serum	An aqua, automatic Kainos Laboratories CRE-II. Kainos Laboratories
Uric acid	Serum	A quickstep, automatic Neo- UA SHINO- TEST
Na and Cl	Serum	The dilution system ion electrode method A&T
K	Serum	The dilution system ion electrode method A&T
Ca	Serum	An aqua, automatic Kainos Laboratories Ca Kainos Laboratories
Inorganic phosphate and phosphoric acid	Serum	Oculars, automatic An IP SHINO-TEST
Mg	Serum	Magnesium - HR II FUJIFILM Wako Pure Chemical
Total cholesterol	Serum	Determiner L TC II Hitachi Chemical Diagnostics
Triglyceride	Serum	Determiner L TG II Hitachi Chemical Diagnostics
HDL-cholesterol	Serum	Metabolead HDL-C Hitachi Chemical Diagnostics
LDL-cholesterol	Serum	Metabolead LDL-C Hitachi Chemical Diagnostics
Glycated albumin	Serum	RUSHIKA GAL Asahi Chemical Industry
Glucose	Plasma Urine	Pole way A&T A quickstep, automatic Neo- GLU-HK SHINO-TEST
Hemoglobin A1c (HbA1c)	Blood	HPLC way Enzyme method BM test HbA1c JEOL
Fe	Serum	A quickstep, automatic Neo- Fe SHINO- TEST
Total iron binding capacity (TIBC)	Serum	Calculation method
Unsaturated iron binding capacity (UIBC)	Serum	A quickstep, automatic Neo- UIBC SHINO- TEST
Alkaline phosphatase	Serum	Cygnus, automatic ALP IF SHINO-TEST
Cholinesterase	Serum	A quickstep, automatic Neo- Ch-E SHINO- TEST
γ -glutamyltranspeptidase (γ -GT)	Serum	A quickstep, automatic Neo- γ -GT JS. SHINO-TEST
Lactate dehydrogenase (LD)	Serum	Cygnus, automatic LD IF SHINO-TEST
Amylase	Serum Urine	Oculars, automatic AMY-IF SHINO-TEST
Creatine kinase (CK)	Serum	Cygnus, automatic CK SHINO-TEST
Asparate aminotransferase (AST)	Serum	A quickstep, automatic Neo- AST JS. SHINO-TEST
Alanine aminotransferase (ALT)	Serum	A quickstep, automatic Neo- ALT JS. SHINO-TEST



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Scope of accreditation :

Item	Type of Samples	Test Method
5 Immunology		
a Immunochemistry I		
C-reactive protein (CRP)	Serum	LZ test' nutrition research' CRP - HG EIKEN CHEMICAL
Immunoglobulin (IgG, IgA, IgM)	Serum	N-assay TIA IgA-SH Nittobo N-assay TIA IgG-SH Nittobo N-assay TIA IgM-SH Nittobo
C3	Serum	N-assay TIA C3-SH Nittobo
C4	Serum	N-assay TIA C4-SH Nittobo
Immunoglobulin (RF)	Serum	LZ test' EIKEN CHEMICAL' RF EIKEN CHEMICAL
b Immunohematology		
Blood group (ABO type)	Blood	Column cohesion way Ortho
Blood group (Rho (D) factor)	Blood	Column cohesion way Ortho
Indirect Coombs, direct Coombs	Blood	Test tube way
c Infectious disease I		
HBs antigen	Serum	HBsAg QT · Abbott Abbott
HBs antibody	Serum	Anti-HBs · Abbott Abbott
HCV antibody (Quantitative, Qualitative)	Serum	HCV · Abbott Abbott
HIV-1,2 antigen and antibody simultaneous measurement	Serum	HIV Ag/Ab Combo assay Abbott Abbott
Serologic test for syphilis (STS) (Qualitative)	Serum	Mediace RPR KYOKUTO
Serologic test for syphilis (Qualitative)	Serum	Mediace TPLA KYOKUTO
Anti streptolysin O (ASO)	Serum	N-assay LAASO Nittobo
6 Microbiology		
a Microscopic examination for stained film (general bacteria)		
Other	Urine Sputum	Gram stain and CHIRUNERUZEN dyeing Nippon Suisan
Use a fluorescent microscope	Urine Sputum	Fluorescence way Muto
b Bacterial culture and identification / Antimicrobial sensitivity test (general bacteria)		
Bacterial culture and identification	Feces Sputum	Mass spectrography Burqa - dull tonics
Anaerobic culture	Punctured fluid Blood	Blood agaragar culture medium Becton
Antimicrobial sensitivity test (general bacteria)	Others	Inoculator Σ 192 DPS MIC192/ID (Small amount liquid dilution way) EIKEN CHEMICAL
Mycobacterial culture and Isolation (liquid medium)	Sputum Others	MGIT way Becton
Non-Basic Series		
11 General (urine, feces, etc.)		
a General urinalysis		
Albumin (Quantitative) (Urinary)	Urine Others	N-assay TIA Micro Alb Nittobo
b Scatoloscropy		
Hemoglobin (Qualitative) (feces)	Feces	OC-HEMODIAUTO III EIKEN CHEMICAL
12 Hematology		
a General hematology, hemogram		
Eosinophils, nasal/sputum smear	Secretions Sputum	Hansel Staining
Hemogram (special stain)	Blood	POD dyeing, ALP dyeing (the NAP score), Muto chemistry
b Thrombus / hemostasis related test I		
Antithrombin (activity)	Plasma	EII system, AT III SYSMEX



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D dimer	Plasma	Lias, automatic D-dimer-NEO SYSMEX
13 Biochemistry I		
a Biochemistry I		
Ferritin Quantitative	Serum	LZ test EIKEN CHEMICAL FER EIKEN CHEMICAL
Type IV collagen	Serum	PANASSEI IV · C [Latex] Kyowa Pharma Chemical
Hyaluronate	Serum	Others Eli peer ace HA FUJIREBIO
Procalcitonin (PCT) (Quantitative)	Serum	Chemilumi BRAHMS Procalcitonin SIEMENS
b Biochemistry II		
Leucine Aminopeptidase (LAP)	Serum	A quickstep, automatic Neo- LAP SHINO- TEST
KL-6	Serum	NanopiaKL-6 Sekisui medical
c Isozyme		
Amylase Isozyme	Serum	Oculars, automatic P-AMY-IF SHINO-TEST
e Vitamin		
Vitamin B12	Serum	Chemilumi-vitamin B12 SIEMENS
Folic acid	Serum	Chemilumi-folic acid SIEMENS
14 Biochemistry II		
a Endocrinology I		
Thyroid-stimulating hormone (TSH)	Serum	ARCHITECT · TSH Abbott
Free triiodothyronine (FT3)	Serum	FT3 · Abbott Abbott
Free thyroxine (FT4)	Serum	FT4 · Abbott Abbott
C-peptide (CPR)	Serum	Urine Chemilumi C - Peptide SIEMENS
Insulin (IRI)	Serum	ARCHITECT · insulin Abbott
Parathyroid hormones (PTH)	Serum	Elecsys reagent PTH Roche
Brain natriuretic peptide (BNP)	Plasma	Chemilumi BNP SIEMENS
N-terminal pro brain natriuretic peptide (NT-proBNP)	Serum	Elecsys reagent NT - proBNP II Roche
N-terminal propeptide of type I procollagen	Serum	Elecsys reagent totalP1NP Roche
b Tumor marker		
α-fetoprotein (AFP)	Serum	AFP · Abbott Abbott
Carcinoembryonic antigen (CEA)	Serum	CEA · Abbott Abbott
CA19-9	Serum	CA19-9XR · Abbott Abbott
CA125	Serum	CA125 II · Abbott Abbott
Prostate-specific antigen (PSA)	Serum	TotalPSA · Abbott Abbott
Squamous cell cancer related antigen (SCC)	Serum	SCC · Abbott Abbott
CA15-3	Serum	CA15-3 · Abbott Abbott
CA72-4	Serum	Elecsys reagent CA 72-4 Roche
Neuron specific enolase (NSE)	Serum	Elecsys reagent NSE Roche
Cytokeratin 19 fragment	Serum	Elecsys reagent CYFRA Roche
Free PSA/Total PSA ratio	Serum	FreePSA · Abbott Abbott TotalPSA · Abbott Abbott
PIVKA-II (Quantitative)	Serum	PIVKA- II · Abbott Abbott
Elastase I	Serum	Iatro IRE1 II LSI Medience
Interleukin 2 receptor, soluble (sIL-2R)	Serum	Nanopia IL-2R Sekisui medical



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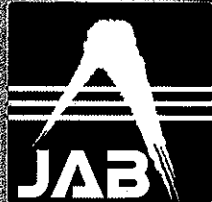
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Item	Type of Samples	Test Method
c Special analysis		
Urea breath test (UBT)	Others	IR (infrared/spectroscopic analysis) law Otsuka
15 Immunology		
a Immunohematology		
Blood group, Rh system	Blood	Monoclonal anti E, anti e, anti C, anti c, anti D and Rh control Column cohesion way Test tube way Ortho
Irregular antibody	Blood	Ortho® biotechnology view™ screening J Resolve® panel B and resolve® panel C. Ortho
b Immunology for infectious disease II		
Antistreptokinase(ASK) (Semi-quantitative)	Serum	SERODIA-ASK FUJIREBIO
Mycoplasma pneumoniae antibody (Semi-quantitative)	Serum	SERODIA · MYCO II FUJIREBIO
c Immunology for infectious disease III		
Clostridium difficile toxin A (Qualitative)	Feces	C.DIFF QUIK CHEK Complete Alere Medical
Adenovirus antigen (Qualitative) (Feces)	Feces	Dip stick EIKEN CHEMICAL adenovirus EIKEN CHEMICAL
Rotavirus antigen (Qualitative) (Feces)	Feces	Dip stick EIKEN CHEMICAL Rota EIKEN CHEMICAL
Helicobacter pylori antibody	Serum	H. Pylori-Latex "Seiken" Denka
Serologic test for syphilis (STS) (Semi-quantitative)	Serum	RPR test "SANKO" SEKISUI medical
Streptococcus pneumoniae capsular antigen (fluid, urinary)	Urine	BinaxNOW Pneumococcus Alere Medical
Treponema pallidum antibody (Semi-quantitative)	Serum	SERODIA-TP FUJIREBIO
Norovirus antigen (Qualitative)	Feces	Immuno Catch Noro EIKEN CHEMICAL
Legionella pneumophila antigen (Urinary)	Urine	Immuno Catch Legionella EIKEN CHEMICAL
d Hepatitis and relates		
HBe antigen	Serum	HBeAg · Abbott Abbott
HBe antibody	Serum	HBeAb · Abbott Abbott
HBc-IgM antibody	Serum	HBc-M · Abbott Abbott
HA-IgM antibody	Serum	HAVAB-M · Abbott Abbott
HBs antigen (Qualitative, Semi-quantitative)	Serum	HBsAg QT · Abbott Abbott
HBs antibody (Qualitative)	Serum	Anti-HBs · Abbott Abbott
HBc antibody (Semi-quantitative, Quantitative)	Serum	HBc · Abbott Abbott
e Autoantibody		
Matrix metalloproteinase-3 (MMP-3)	Serum	PANAKURIA MMP-3 [Latex] Kyowa Pharma Chemical
Anti Thyroglobulin antibody (Semi-quantitative)	Serum	SERODIA · ATG FUJIREBIO
Anti-thyroid microsomal antibody, semiquantitative (Semi-Quantitative/Qualitative)	Serum	SERODIA · AMC FUJIREBIO
f Immunology for plasma protein		
CH50	Serum	Auto CH50-L "Seiken" II Denka
β2-microglobulin	Serum Urine	LZ Test 'EIKEN' β2-M EIKEN CHEMICAL
Non-specific immunoglobulin IgE (Quantitative)	Serum	Siemens · Immulyze the total IgE III SIEMENS
Specific immunoglobulin IgE (Semi-Quantitative/Qualitative) / (Quantitative)	Serum	Siemens · Immulyze ARASUTATTO IgE II SIEMENS
16 Microbiology		
b Bacterial culture and identification / Antimicrobial sensitivity test(general bacteria)		
Examination for drug sensitivity test, yeastlike fungi	Others	Antifungal susceptibility ASTY colorimetric microdilution test Kyokuto



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Scope of accreditation :

Item	Type of Samples	Test Method
17 Gene-related / Chromosome test		
b. Identification of pathogen nucleic acid		
DNA amplification assay for Mycobacteria tuberculosis complex	Urine Sputum	TaqManPCR way Roche
Mycobacterium avium / intracellulare DNA	Urine Sputum	TaqManPCR way Roche
Quantification of HBV nucleic acid (Quantitative)	Serum	Cobas TaqMan HBV [auto] v.2.0 Roche
HCV DNA (Quantitative)	Serum	Cobas TaqMan HCV [auto] v.2.0 Roche
SARS-CoV-2 RNA	Others	TaKara SARS-CoV-2 Direct PCR Detection Kit TRCReady SARS-CoV-2 i Tosoh
18 Others excluding 11 to 16 class		
a Therapeutic drug monitoring		
Digitoxin, Digoxin	Serum	ARCHITECT · Digoxin ST Abbott
Theophylline	Serum	ARCHITECT · Theophylline ST Abbott
Valproic acid, Carbamazepine	Serum	ARCHITECT · Valproic Acid ST Abbott
Phenytoin, Primidone, Ethosuximide, Phenobarbital, Zonisamide, Nitrazepam, Clonazepam, Others	Serum	ARCHITECT · Phenobarbital ST Abbott ARCHITECT · Phenytoin ST Abbott
Vancomycin, Teicoplanin, Gentamicin, Tobramycin, Amikacin, Arbekacin, Voriconazole	Serum	ARCHITECT · Vancomycin ST Abbott

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