Quality And Accreditation Institute

Centre for International Accreditation

Certificate of Accreditation

Centre of Medical Laboratory

Mongolian National University of Medical Sciences

Mongolia-Japan Hospital, Bayanzurkh district, 12 khoroo, Botanical Garden

has been assessed and accredited in accordance with the Standard

ISO 15189:2022

"Medical Laboratories - Requirements for Quality and Competence"

In the field of

Medical Testing

This certificate remains valid for the Scope of Accreditation as specified in the annexure subject to continued compliance to the above standard & any other requirements specified by QAI.

QAI/CIA/ML/2024/0020

(Date of First Accreditation: 30 June 2024)

Valid from: ***30 June 2026***

Valid until: ***29 June 2030***

Dr. Bhupendra Kumar Rana
Chief Executive Officer

Prof. Vikram Kumar
Chair, CIA

User is advised to verify the current certificate and scope of accreditation by visiting our website: www.qai.org.in

Quality And Accreditation Institute
Centre for International Accreditation

Scope of Accreditation

Centre of Medical Laboratory
Mongolian National University of Medical Sciences
Mongolia-Japan Hospital, Bayanzurkh district, 12 khoroo,
Botanical Garden

QAI/CIA/ML/2024/0020

Date Of First Accreditation: **30 June 2024**
Valid from: **30 June 2026**
Valid until: **29 June 2030**

Accreditation Standard: ISO 15189:2022

Clinical Biochemistry			
Sl. No.	**Type of Sample Examined/ Tested**	**Specific Tests/ Examination Performed**	**Standard (Method), Principle/ Methodology or Technique Used**
1.	Serum/Plasma	ALT	Photometric
2.	Serum/Plasma	ALT	Spectrophotometer
3.	Serum/Plasma	AST	Photometric and Immunoturbidimetric assay
4.	Serum/Plasma	AST	Spectrophotometric
5.	Serum/Plasma	LDH	Photometric and Immunoturbidimetric assay
6.	Serum/Plasma	LDH	Photometric
7.	Serum/Plasma	ALP	Photometric and Immunoturbidimetric assay
8.	Serum/Plasma	ALP	Colorimetric assay
9.	Serum/Plasma	AMY	Photometric and Immunoturbidimetric assay
10.	Serum/Plasma	AMY	Enzymatic, colorimetric method
11.	Serum/Plasma	GGT	Photometric and Immunoturbidimetric assay
12.	Serum/Plasma	GGT	Enzymatic, colorimetric method
13.	Serum/Plasma	TG	Photometric and Immunoturbidimetric assay

Scope of Accreditation

Centre of Medical Laboratory
Mongolian National University of Medical Sciences
Mongolia-Japan Hospital, Bayanzurkh district, 12 khoroo,
Botanical Garden

QAI/CIA/ML/2024/0020

Date Of First Accreditation: 30 June 2024
Valid from: 30 June 2026
Valid until: 29 June 2030

Accreditation Standard: ISO 15189:2022

Clinical Biochemistry			
Sl. No.	**Type of Sample Examined/ Tested**	**Specific Tests/ Examination Performed**	**Standard (Method), Principle/ Methodology or Technique Used**
14.	Serum/Plasma	TG	Enzymatic, colorimetric method
15.	Serum/Plasma	T-CHOL	Photometric and Immunoturbidimetric assay
16.	Serum/Plasma	T-CHOL	Colorimetric method
17.	Serum/Plasma	HDL	Photometric and Immunoturbidimetric assay
18.	Serum/Plasma	HDL	Homogeneous enzymatic colorimetric assay
19.	Serum/Plasma, body fluid	GLU	Photometric and Immunoturbidimetric assay
20.	Serum/Plasma/Supernatant/CSF/ Whole blood	GLU	Enzymatic reference method
21.	Serum/Plasma	T-Bil	Photometric and Immunoturbidimetric assay
22.	Serum/Plasma	T-Bil	Colorimetric assay
23.	Serum/Plasma	D-Bil	Photometric and Immunoturbidimetric assay
24.	Serum/Plasma	D-Bil	Photometric
25.	Serum/Plasma	CK-MB	Photometric and Immunoturbidimetric assay
26.	Serum/Plasma	LDL	Photometric and Immunoturbidimetric assay

Scope of Accreditation

Centre of Medical Laboratory
Mongolian National University of Medical Sciences
Mongolia-Japan Hospital, Bayanzurkh district, 12 khoroo,
Botanical Garden

QAI/CIA/ML/2024/0020

Date Of First Accreditation: **30 June 2024**
Valid from: **30 June 2026**
Valid until: **29 June 2030**

Accreditation Standard: ISO 15189:2022

Clinical Biochemistry			
Sl. No.	**Type of Sample Examined/ Tested**	**Specific Tests/ Examination Performed**	**Standard (Method), Principle/ Methodology or Technique Used**
27.	Serum/Plasma	LDL	Enzymatic colorimetric assay
28.	Serum/Plasma, body fluid	TP	Photometric and Immunoturbidimetric assay
29.	Serum/Plasma, supernatant, CSF, urine	TP	Colorimetric assay
30.	Serum/Plasma, body fluid	ALB	Photometric and Immunoturbidimetric
31.	Serum/Plasma	ALB	Colorimetric
32.	Serum/Plasma	Ca	Photometric and Immunoturbidimetric
33.	Serum/Plasma	Ca	Photometric
34.	Serum/Plasma	PO3	Photometric and Immunoturbidimetric
35.	Serum/Plasma	PO3	Photometric
36.	Serum/Plasma	Fe	Colorimetric assay
37.	Serum/Plasma	CREA-P	Photometric and Immunoturbidimetric
38.	Serum/Plasma	CREJ	Colorimetric assay
39.	Plasma, CSF	LACT	Colorimetric assay

Scope of Accreditation

Centre of Medical Laboratory
Mongolian National University of Medical Sciences
Mongolia-Japan Hospital, Bayanzurkh district, 12 khoroo,
Botanical Garden

QAI/CIA/ML/2024/0020

Date Of First Accreditation: 30 June 2024
Valid from: 30 June 2026
Valid until: 29 June 2030

Accreditation Standard: ISO 15189:2022

Clinical Biochemistry			
Sl. No.	**Type of Sample Examined/ Tested**	**Specific Tests/ Examination Performed**	**Standard (Method), Principle/ Methodology or Technique Used**
40.	Serum/Plasma	LIPASE	Photometric and Immunoturbidimetric
41.	Serum/Plasma	LIPASE	Enzymatic colorimetric assay
42.	Serum/Plasma	Mg	Photometric and Immunoturbidimetric
43.	Serum/Plasma	Mg	Colorimetric method
44.	Serum/Plasma	P-AMY	Photometric and Immunoturbidimetric
45.	Serum/Plasma	P-AMY	Enzymatic colorimetric method
46.	Serum/Plasma	UREA	Photometric and Immunoturbidimetric
47.	Serum/Plasma	UREA	Photometric method
48.	Serum/Plasma	UA	Photometric and Immunoturbidimetric
49.	Serum/Plasma	UA	Enzymatic colorimetric
50.	Serum/Plasma	Na	Ion-specific electrode
51.	Serum/Plasma	K	Ion-specific electrode
52.	Serum/Plasma	Cl	Ion-specific electrode

Scope of Accreditation

Centre of Medical Laboratory
Mongolian National University of Medical Sciences
Mongolia-Japan Hospital, Bayanzurkh district, 12 khoroo,
Botanical Garden

QAI/CIA/ML/2024/0020

Date Of First Accreditation: **30 June 2024**
Valid from: **30 June 2026**
Valid until: **29 June 2030**

Accreditation Standard: ISO 15189:2022

Clinical Biochemistry			
Sl. No.	**Type of Sample Examined/ Tested**	**Specific Tests/ Examination Performed**	**Standard (Method), Principle/ Methodology or Technique Used**
53.	Serum/Plasma	CK	Photometric assay
54.	Serum/Plasma	IG A	Immunoturbidimetric assay
55.	Serum/Plasma	IG G	Immunoturbidimetric assay
56.	Serum/Plasma	IG M	Immunoturbidimetric assay
57.	Serum/Plasma	RF	Immunoturbidimetric assay
58.	Serum/Plasma	RF	Photometric and Immunoturbidimetric
59.	Serum/Plasma	CRP	Immunoturbidimetric assay
60.	Serum/Plasma	CRP	Immunoturbidimetric assay
61.	Serum/Plasma	HBA1C	Turbidimetric immunoassay (TINIA)
62.	Serum/Plasma	ASLO	Immunoturbidimetric assay
63.	Serum/Plasma	ASLO	Photometric and Immunoturbidimetric assay
64.	Serum/Plasma	FERR	Photometric and Immunoturbidimetric assay

Scope of Accreditation

Centre of Medical Laboratory
Mongolian National University of Medical Sciences
Mongolia-Japan Hospital, Bayanzurkh district, 12 khoroo,
Botanical Garden

QAI/CIA/ML/2024/0020

Date Of First Accreditation: 30 June 2024
Valid from: 30 June 2026
Valid until: 29 June 2030

Accreditation Standard: ISO 15189:2022

Immunology			
Sl. No.	**Type of Sample Examined/ Tested**	**Specific Tests/ Examination Performed**	**Standard (Method), Principle/ Methodology or Technique Used**
1.	Serum/Plasma	AFP	Sandwich- chemiluminescence immunoassay
2.	Serum/Plasma	CA19-9	Indirect sandwich chemiluminescence immunoassay
3.	Serum/Plasma	TSH	Sandwich- chemiluminescence immunoassay
4.	Serum/Plasma	FT3	Competitive chemiluminescence immunoassay
5.	Serum/Plasma	FT4	Competitive chemiluminescence immunoassay
6.	Serum/Plasma	PSA	Indirect chemiluminescence immunoassay
7.	Serum/Plasma	CA125	Indirect chemiluminescence immunoassay
8.	Serum/Plasma	CEA	Indirect chemiluminescence immunoassay
9.	Serum	PIVKA	Sandwich chemiluminescence immunoassay
10.	Serum/Plasma	Insulin	Indirect chemiluminescence
11.	Serum/Plasma	C-peptide	Sandwich chemiluminescence immunoassay

Scope of Accreditation

Centre of Medical Laboratory
Mongolian National University of Medical Sciences
Mongolia-Japan Hospital, Bayanzurkh district, 12 khoroo,
Botanical Garden

QAI/CIA/ML/2024/0020

Date Of First Accreditation: **30 June 2024**
Valid from: **30 June 2026**
Valid until: **29 June 2030**

Accreditation Standard: ISO 15189:2022

Immunology			
Sl. No.	**Type of Sample Examined/ Tested**	**Specific Tests/ Examination Performed**	**Standard (Method), Principle/ Methodology or Technique Used**
12.	Serum/Plasma	Anti-CCP	Indirect chemiluminescence immunoassay
13.	Serum/Plasma	CA 72-4	Indirect chemiluminescence immunoassay
14.	Serum/Plasma	CA 15-3	Indirect chemiluminescence immunoassay
15.	Serum/Plasma	Anti-TG	Indirect chemiluminescence immunoassay
16.	Serum/Plasma	Anti-TPO	Indirect chemiluminescence immunoassay
17.	Serum/Plasma	Total T3	Competitive chemiluminescence immunoassay
18.	Serum/Plasma	Total T4	Competitive chemiluminescence immunoassay
19.	Serum/Plasma	Anti-TSHR	Indirect chemiluminescence immunoassay
20.	Serum/Plasma	25-OH Vitamin D	Indirect chemiluminescence immunoassay
21.	Serum/Plasma	LH	Sandwich CLIA
22.	Serum/Plasma	FSH	Sandwich CLIA

Scope of Accreditation

Centre of Medical Laboratory
Mongolian National University of Medical Sciences
Mongolia-Japan Hospital, Bayanzurkh district, 12 khoroo,
Botanical Garden

QAI/CIA/ML/2024/0020

Date Of First Accreditation: 30 June 2024
Valid from: 30 June 2026
Valid until: 29 June 2030

Accreditation Standard: ISO 15189:2022

Immunology			
Sl. No.	**Type of Sample Examined/ Tested**	**Specific Tests/ Examination Performed**	**Standard (Method), Principle/ Methodology or Technique Used**
23.	Serum/Plasma	Prolactin	Sandwich CLIA
24.	Serum/Plasma	Progesterone	Competitive CLIA
25.	Serum/Plasma	Estradiol	Competitive CLIA
26.	Serum/Plasma	Testosterone	Competitive CLIA
27.	Serum/Plasma	Anti-dsDNA IgG	Indirect chemiluminescence immunoassay
28.	Serum/Plasma	ANA Screen	Indirect chemiluminescence immunoassay
29.	Serum/Plasma	PCT	Sandwich chemiluminescence immunoassay
30.	Serum/Plasma	PCT	Enzyme linked fluorescent assay
31.	Serum/Plasma	NT-proBNP	sandwich chemiluminescence immunoassay
32.	Serum/Plasma	Hs-cTnI	Indirect chemiluminescence immunoassay
33.	Serum/Plasma	Hs-cTnI	Enzyme linked fluorescent assay

Scope of Accreditation

Centre of Medical Laboratory
Mongolian National University of Medical Sciences
Mongolia-Japan Hospital, Bayanzurkh district, 12 khoroo,
Botanical Garden

QAI/CIA/ML/2024/0020

Date Of First Accreditation: **30 June 2024**
Valid from: **30 June 2026**
Valid until: **29 June 2030**

Accreditation Standard: ISO 15189:2022

Immunology			
Sl. No.	**Type of Sample Examined/ Tested**	**Specific Tests/ Examination Performed**	**Standard (Method), Principle/ Methodology or Technique Used**
34.	Plasma	D-Dimer	Enzyme linked fluorescent assay
35.	Serum/Plasma	Cyfra21-1	Two-step enzyme immunoassay sandwich method with a final fluorescent
36.	Serum/Plasma	Anti-CCP	Indirect chemiluminescence immunoassay

Scope of Accreditation

Centre of Medical Laboratory
Mongolian National University of Medical Sciences
Mongolia-Japan Hospital, Bayanzurkh district, 12 khoroo,
Botanical Garden

QAI/CIA/ML/2024/0020

Date Of First Accreditation: 30 June 2024
Valid from: 30 June 2026
Valid until: 29 June 2030

Accreditation Standard: ISO 15189:2022

Clinical Pathology			
Sl. No.	**Type of Sample Examined/ Tested**	**Specific Tests/ Examination Performed**	**Standard (Method), Principle/ Methodology or Technique Used**
1.	Urine	RBC	Fluorescent flow cytometry
2.	Urine	NL RBC	Fluorescent flow cytometry
3.	Urine	WBC	Fluorescent flow cytometry
4.	Urine	WBC Clumps	Fluorescent flow cytometry
5.	Urine	EC	Fluorescent flow cytometry
6.	Urine	Squa.EC	Fluorescent flow cytometry
7.	Urine	Non-SEC	Fluorescent flow cytometry
8.	Urine	Tran.EC	Fluorescent flow cytometry
9.	Urine	RTEC	Fluorescent flow cytometry
10.	Urine	CAST	Fluorescent flow cytometry
11.	Urine	Hy. CAST	Fluorescent flow cytometry
12.	Urine	Path. CAST	Fluorescent flow cytometry
13.	Urine	BACT	Fluorescent flow cytometry
14.	Urine	X'TAL	Fluorescent flow cytometry
15.	Urine	YLC	Fluorescent flow cytometry
16.	Urine	Sperm	Fluorescent flow cytometry

Scope of Accreditation

Centre of Medical Laboratory
Mongolian National University of Medical Sciences
Mongolia-Japan Hospital, Bayanzurkh district, 12 khoroo,
Botanical Garden

QAI/CIA/ML/2024/0020

Date Of First Accreditation: 30 June 2024
Valid from: 30 June 2026
Valid until: 29 June 2030

Accreditation Standard: ISO 15189:2022

Clinical Pathology			
Sl. No.	**Type of Sample Examined/ Tested**	**Specific Tests/ Examination Performed**	**Standard (Method), Principle/ Methodology or Technique Used**
17.	Urine	Mucus	Fluorescent flow cytometry
18.	Urine	URO	Azo coupling method
19.	Urine	BLD	Peroxidase-like reaction of the haemoglobin
20.	Urine	PRO	Protein error of pH indicator
21.	Urine	GLU	Enzymatic method (GOD, POD)
22.	Urine	KET	Alkali nitroprusside method
23.	Urine	BIL	Azo coupling method
24.	Urine	NIT	Griess method
25.	Urine	LEU	Leukocyte esterase activity
26.	Urine	pH	pH indicator method
27.	Urine	CRE	Benedict-Behre method
28.	Urine	ALB	Protein error of pH indicator
29.	Urine	S.G	Refractometer method

Scope of Accreditation

Centre of Medical Laboratory
Mongolian National University of Medical Sciences
Mongolia-Japan Hospital, Bayanzurkh district, 12 khoroo,
Botanical Garden

QAI/CIA/ML/2024/0020

Date Of First Accreditation: **30 June 2024**
Valid from: **30 June 2026**
Valid until: **29 June 2030**

Accreditation Standard: ISO 15189:2022

Microbiology & Serology			
Sl. No.	**Type of Sample Examined/ Tested**	**Specific Tests/ Examination Performed**	**Standard (Method), Principle/ Methodology or Technique Used**
1.	Swab (wound, cervical, throat, pharynx…), urine, sputum, pus and body fluid	Bacterial and fungal culture, Antimicrobial Susceptibility Testing	Aerobic culture, morphological and biochemical tests, supplemented as needed by specialized tests such as serotyping and antibiotic inhibition patterns
2.	Feces	H.pylori Ag strip test	Rapid test/Immunochromatography
3.	Cervical and vaginal swab	Gram stain	Manual, Microscope, Nugent score
4.	Feces	Rota/Adeno Ag strip test	Rapid test/Immunochromatography
5.	Serum, Plasma	HBsAg	2 step sandwich- chemiluminescence immunoassay
6.	Serum, Plasma, whole blood	HBsAg	Rapid test/Immunochromatography
7.	Serum, Plasma	Anti-HBs	1 step sandwich- chemiluminescence immunoassay
8.	Serum, Plasma	Anti-HBs	Indirect chemiluminescence immunoassay
9.	Serum, Plasma	Anti-HCV	2 step sandwich- chemiluminescence immunoassay
10.	Serum, Plasma, whole blood	Anti-HCV	Rapid test /Immunochromatography

Scope of Accreditation

Centre of Medical Laboratory
Mongolian National University of Medical Sciences
Mongolia-Japan Hospital, Bayanzurkh district, 12 khoroo,
Botanical Garden

QAI/CIA/ML/2024/0020

Date Of First Accreditation: **30 June 2024**
Valid from: **30 June 2026**
Valid until: **29 June 2030**

Accreditation Standard: ISO 15189:2022

Microbiology & Serology			
Sl. No.	**Type of Sample Examined/ Tested**	**Specific Tests/ Examination Performed**	**Standard (Method), Principle/ Methodology or Technique Used**
11.	Serum, Plasma	HIV Ag+Ab	2 step sandwich- chemiluminescence immunoassay
12.	Serum, Plasma, whole blood	HIV Ag+Ab	Rapid test /Immunochromatography
13.	Serum, Plasma	Anti-TP	2 step sandwich- chemiluminescence immunoassay
14.	Serum, Plasma, whole blood	Syphilis Ab	Rapid test /Immunochromatography/

Scope of Accreditation

Centre of Medical Laboratory
Mongolian National University of Medical Sciences
Mongolia-Japan Hospital, Bayanzurkh district, 12 khoroo,
Botanical Garden

QAI/CIA/ML/2024/0020

Date Of First Accreditation: 30 June 2024
Valid from: 30 June 2026
Valid until: 29 June 2030

Accreditation Standard: ISO 15189:2022

Haematology & Immunohaematology			
Sl. No.	**Type of Sample Examined/ Tested**	**Specific Tests/ Examination Performed**	**Standard (Method), Principle/ Methodology or Technique Used**
1.	Whole blood	White blood cell count	Fluorescence flow cytometry
2.	Whole blood	Red blood cell count	Electrical impedance
3.	Whole blood	Haemoglobin concentration	Photometric analysis (SLS-haemoglobin method)
4.	Whole blood	Haematocrit	Calculated from RBC and MCV
5.	Whole blood	Mean corpuscular volume	Electrical impedance
6.	Whole blood	Mean corpuscular haemoglobin	Calculated from HGB and RBC
7.	Whole blood	Mean corpuscular haemoglobin concentration	Calculated from HGB and HCT
8.	Whole blood	Platelet count	Fluorescence flow cytometry and electrical impedance
9.	Whole blood	Erythrocytes sedimentation rate	Photometric method for measuring the aggregation of RBCs within a specified time
10.	Whole blood	Blood type	The tube method, manual
11.	Whole blood	Rh factor	The tube method, manual

Scope of Accreditation

Centre of Medical Laboratory
Mongolian National University of Medical Sciences
Mongolia-Japan Hospital, Bayanzurkh district, 12 khoroo,
Botanical Garden

QAI/CIA/ML/2024/0020

Date Of First Accreditation: **30 June 2024**
Valid from: **30 June 2026**
Valid until: **29 June 2030**

Accreditation Standard: ISO 15189:2022

Cytopathology			
Sl. No.	**Type of Sample Examined/ Tested**	**Specific Tests/ Examination Performed**	**Standard (Method), Principle/ Methodology or Technique Used**
1.	Cytopathology (gynaecological and non-gynaecological)	Fixation, Pap staining, cover slipping	Light microscopy with interpretation

Histopathology			
Sl. No.	**Type of Sample Examined/ Tested**	**Specific Tests/ Examination Performed**	**Standard (Method), Principle/ Methodology or Technique Used**
1.	Histopathology (small, medium, large tissue samples and post mortem examination)	Grossing, decalcification, processing, paraffin-embedding, microtomy and H&E staining	Light microscopy with interpretation