

# Medical Laboratory Accreditation Certificate

Accreditation No.RML00010

BML, INC. BML General Laboratory

1361-1, Matoba, Kawagoe-shi, Saitama, 350-1101 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

: September 30, 2025

Revised Renewed Initial accreditation October 6, 2023 October 1, 2021 September 5, 2005

Y. Iizuka, President

Japan Accreditation Board



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#### BML, INC. BML General Laboratory

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BML-General Laboratory

1361-1, Matoba, Kawagoe-shi, Saitama, 350-1101 Japan

Field: Basic Series Non-Basic Series Decific program I

□ Pathology □ Physiology

Type of test: Accreditation by Flexible Scope

Element to be fixed: Test / Analyte
Flexible element: Sample and Method

Note: Details of accreditation by flexible scope ('list of activities') are available on the

laboratory's website.

Excluding primary sample collection from the scope of accreditation

Scope of accreditation:

	Test / Analyte
Basic Series	
1 Urine /	feces test
	D000 Urinary Qualitative / semi-Quantitative Examination
	D001 Urinary special substance qualitative and quantitative test
	D002 Urinary Sedimentary by microscopy
2 Hemat	ology
	D005 Blood morphology/function test
	D006 Bleeding/coagulation test
3 Bioche	mistry I
	D007 Blood chemistry test
5 Immun	ology
	D011 Immunohematology
	D012 Infectious disease
	D013 Hepatitis and relates
	D014 Autoantibody
	D015 Immunology for plasma protein



## Accreditation Certificate Appendix Accreditation

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Accreditation No. RMIL00010

#### BML, INC. BML General Laboratory

Scope of accreditation:

Deope of accreation		
	Ţest / Analyte	
6 Microbiology		
	D017 Microscopic examination for stained film	
	D018 Bacterial culture and identification	
1	D019 Antimierobial sensitivity test	
	D020 Mycobacterial culture and Isolation	
Non-Basic Series		
11 Urine /	feces test	
	D001 General urinalysis	
	D002-2 Urinary sediment by flow cytometry (Urinary)	
	D003 Scatoloscopy	
. ]	D004 Basic analysis for punctatum, sperm, sputum and others	
12 Hematology		
	D005 General hematology, hemogram	
. [1	D006 Bleeding/coagulation test	
13 Biocher	mistry I	
	D007 Blood chemistry test	
14 Biochemistry II		
	D008 Endocrinology	
	D009 Tumor marker	
	D010 Special analysis	
15 Immunology		
	D011 Immunohematology	
	D012 Immunology for infectious disease	
	D013 Hepatitis and relates	
]	D014 Autoantibody	
	D015 Immunology for plasma protein	
	D016 Cellular functional test (cellular immunity related test)	



### Accreditation Certificate Appendix

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Accreditation No. RMILooo10

BML, INC. BML General Laboratory

Scope of accreditation:

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	Test / Analyte	
16 Micro		
	D019-2 Examination for drug sensitivity test, yeastlike fungi	
	D021 Identification of mycobacteria (per series regardless of the	
(An 3) (An 3)	number of events)	
1. ( ) ( ) ( ) ( ) ( ) ( ) ( ) ( ) ( ) (	D022 Drug susceptibility test for mycobacteria	
L Vasof (	D023-2 Other microbiological tests	
17 Gene-related test / Chromosome test		
1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	a-1 Somatic cell genetic test (Hematopoietic specimens such as	
	hematological malignancies and transplants, and germline-derived	
	cells) (non-NGS)	
·	a-2 Somatic cell genetic test (Pathology specimens such as solid	
	tumors) (non-NGS)	
	b Pathogenic nucleic acid homologation (D023 Microbial nucleic	
	acid identification and quantification testing) (non-NGS)	
	c Chromosome test (non-NGS)	
	d Germline gene test (non-NGS)	
	e NGS (Insurance coverage items only, Pathogenic nucleic acid	
	homologation, Somatic cell genetic test, Chromosome test and	
	Germline gene test)	
18 Other tests		
	B0012 Specific drug treatment management fee (drug blood	
	concentration measurement)	

#### **Japan Accreditation Board**