



Medical Laboratory Accreditation Certificate

Accreditation No. RMIL01260

Center for Public Strategy Nagasaki University Department of Laboratory Medicine Nagasaki University Hospital

1-7-1 Sakamoto, Nagasaki city, 852-8501 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 : 2022

Scope of accreditation

· As described in the appendix.

Premises covered by accreditation : As described in the appendix.

Expiry date of accreditation

: March 31, 2029

Revised Renewed Initial accreditation

December 17, 2024 April 1, 2025 March 16, 2017

Japan Accreditation Board





Accreditation Certificate (Page 1/3) Appendix Accreditation No. RML01260

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Field: Basic Series

■ Non-Basic Series

□ Specific 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 intranet.

Including primary sample collection in 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 | | |
| D003 Feces test | | |
| 2 Hematology | | |
| D005 Blood morphology/function test | | |
| D006 Bleeding/coagulation test | | |
| 3 Biochemistry I | | |
| D007 Blood chemistry test | | |
| 5 Immunology | | |
| D011 Immunohematology | | |
| D012 Infectious disease | | |
| D013 Hepatitis and relates | | |
| D014 Autoantibody | | |
| D015 Immunology for plasma protein | | |





Accreditation Certificate (Page 2/3) Appendix Accreditation No. RML01260

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| Scope | of accreditation: | |
|-------|-------------------|--|
| | | |

| Test / Analyte | | | |
|---|--|--|--|
| 6 Microbiology | | | |
| D017 Microscopic examination for stained film | | | |
| D018 Bacterial culture and identification | | | |
| D019 Antimicrobial 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) | | | |
| 12 Hematology | | | |
| D005 General hematology, hemogram | | | |
| D006 Bleeding/coagulation test | | | |
| 13 Biochemistry I | | | |
| D007 Blood chemistry test | | | |
| 14 Biochemistry II | | | |
| D008 Endocrinology | | | |
| D009 Tumor marker | | | |
| 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) | | | |
| 16 Microbiology | | | |
| D017 Microscopic examination for stained film | | | |
| D019-2 Examination for drug sensitivity test, yeastlike fungi | | | |
| D021 Identification of mycobacteria (per series regardless of the | | | |
| number of events) | | | |
| D022 Drug susceptibility test for mycobacteria | | | |
| D023-2 Other microbiological tests | | | |
| 17 Gene-related test / Chromosome test | | | |
| a-1 Somatic cell genetic test (Hematopoietic specimens such as | | | |
| hematological malignancies and transplants, and germline-derived | | | |
| cells) (non-NGS) | | | |
| b Pathogenic nucleic acid homologation (D023 Microbial nucleic acid | | | |
| identification and quantification testing) (non-NGS) | | | |





Accreditation Certificate Appendix

(Page 3/3)

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Scope of accreditation:

| scope of accreatation . | |
|------------------------------------|----|
| Test / Analyte | |
| Physiology | |
| 101 Physiology | |
| a Respiratory function test | |
| D200 Spirography | |
| D202 Closing volume | |
| D203 DLCO | |
| b Circulatory function test | |
| D208 Electrocardiogram | |
| D210 Holter Electrocardiogram | |
| d Electroencephalography | |
| D235 Electroencephalography (PS, H | V) |

Japan Accreditation Board