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COLLEGE of AMERICAN PATHOLOGISTS

CAP ACCREDITED
COLLEGE of AMERICAN PATHOLOGISTS

The College of American Pathologists
certifies that the laboratory named below

BML Inc
Main Laboratory
Saitama, Japan
Nobuki Arai, MD

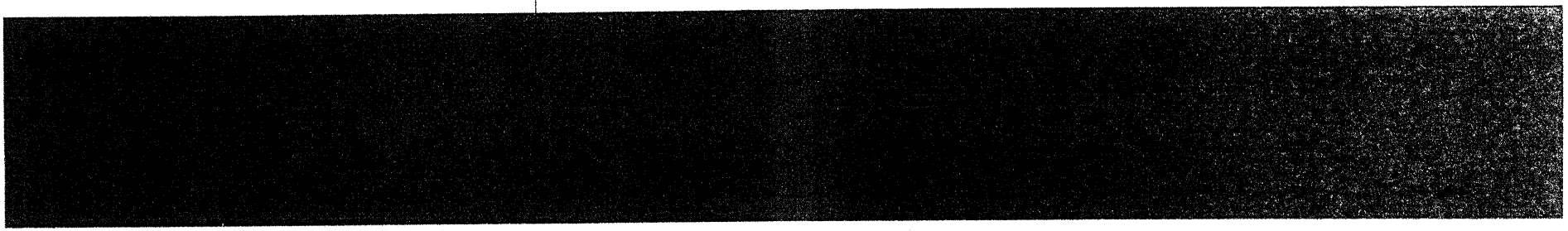
CAP Number: 2710401
AU-ID: 1189254

has met all applicable standards for accreditation and is hereby accredited by the College of American Pathologists' Laboratory Accreditation Program. Reinspection should occur prior to January 27, 2022 to maintain accreditation.

Accreditation does not automatically survive a change in director, ownership, or location and assumes that all interim requirements are met.

Chair, Accreditation Committee

President, College of American Pathologists



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BML Inc
Main Laboratory

LAP Number: 2710401
AU ID: 1189254

The above Laboratory is accredited by the College of American Pathologists Laboratory Accreditation Program for the following services:

All Common
Bacteriology
Body Fluid Analysis
Chemistry
Clinical Biochemical Genetics
Coagulation
Conventional Cytogenetics
Director Assessment
Director/Organizational Assessment
Flow Cytometry
Hematology
HLA Flow Cytometry
HLA Molecular
HLA Serology
Immunohematology
Immunology
In Situ Hybridization
Inherited Genetics
Laboratory General
Molecular Microbiology
Molecular Oncology - Hematologic I
Molecular Oncology - Solid Tumor
Mycobacteriology
Mycology
Parasitology
Special Chemistry
Toxicology
Urinalysis
Virology

This accreditation is valid for the period ending January 27, 2022.

PLEASE RETAIN THIS DOCUMENT IN YOUR RECORDS.

COLLEGE of AMERICAN PATHOLOGISTS
Laboratory Quality Solutions

CAP Accreditation Programs Instructions for Responding to Deficiencies

The copy of the Inspector Summation Report (ISR) provided at the conclusion of your inspection is the official listing of deficiencies. The CAP will not send an additional report of deficiencies cited. Responses are due to the CAP **within 30 calendar days** from the date of the inspection. **Failure to meet response deadlines or adhere to the following instructions will delay the accreditation process and may affect the laboratory's/facility's accreditation decision.**

How to Respond

- Each deficiency requires a **separate Deficiency Response Sheet.**
- **Phase I deficiencies require a written response indicating corrective action taken.**
- **Phase II deficiencies require a written response and supporting documentation demonstrating compliance. The response should explain the purpose of the documentation submitted. (Note: If the same supporting documentation will be used for multiple responses, attach a copy to each deficiency.)**

Examples of appropriate documentation include, but are not limited to:

- New or revised policies and procedures with evidence of review and approval.
- Sections (or underlined portions) of policies/procedures that pertain to a deficiency.
- QC, calibration, maintenance records, and instrument printouts.
- Log sheets, including recorded data. **Blank logs are unacceptable.**
- Purchase orders, work orders, photos, diagrams, and floor plans.
- Evidence of staff review or retraining on new, revised, or existing procedures.
- International laboratories must submit responses to deficiencies in English. Supporting documentation to a deficiency may be submitted in the native language, provided that the key elements, including title and major headings, are in English.

Helpful Hints

- Include the checklist requirement number on supporting documentation.
- Ensure all documentation is single-sided.
- Do not use staples, page protectors, or binders. (Paper clips are preferred.)
- Underline appropriate details of the response.
- Deficiencies noted as "Corrected On-Site" do not require a written response unless requested by the CAP.
- Recommendations do not require a written response unless requested by the CAP.
- Retain copies of all documentation submitted for your laboratory/facility records.

Note: Electronic versions of the enclosed Deficiency Response sheet and the Deficiency Response Signature Page are available on the CAP website—e-LAB Solutions Suite > CAP Accreditation Resources > Accreditation Forms and Instructions > Instructions for Deficiency Response

When to Challenge a Deficiency

If your laboratory was in compliance at the time of inspection, the laboratory may state its intention to challenge the cited deficiency. Comments, such as I wish to challenge this deficiency; Laboratory Challenge, etc, must be noted clearly on the deficiency response sheet, with an explanation for the challenge. Attach required documentation supporting the claim, including records of ongoing compliance dated prior to the inspection. Supporting documentation is required for both Phase I and Phase II deficiencies when challenging.

What to Send to the CAP

- Send the Deficiency Response Signature Page, signed by the director, attesting that he/she has reviewed and approved the responses.
- Include Deficiency Response Sheets with attached supporting documentation for each deficiency.

HIPAA Compliance

- Documentation submitted to the CAP must not include any protected health information (PHI).
- Any patient information must be de-identified in accordance with the requirements under HIPAA. See 45 CFR §164.514(b)(2).

Please note that accreditation is a continual process. A laboratory/facility will remain accredited until otherwise notified. Accreditation does not necessarily terminate on the date of the accreditation certificate. Should you need further documentation of your laboratory's/facility's accreditation status, please email accred@cap.org.

Mail to:
Technical Specialist
CAP Accreditation Programs
College of American Pathologists
325 Waukegan Rd.
Northfield, IL
60093-2750

Any Questions?

- CALL the CAP technical specialists at 800-323-4040 ext. 6065
- SEND an email to accred@cap.org
- VISIT cap.org

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