

The College of American Pathologists
certifies that the laboratory named below

**Cleveland Clinic
Amherst FHC Lab
Lorain, Ohio
Megan O. Nakashima, MD**

CAP Number: 8869359
AU-ID: 1743601
CLIA Number: 36D0333551

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 April 1, 2022 to maintain accreditation.

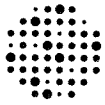
Accreditation does not automatically survive a change in director, ownership,
or location and assumes that all interim requirements are met.



Chair, Accreditation Committee



President, College of American Pathologists



COLLEGE of AMERICAN
PATHOLOGISTS

CAP #: 8869359
AU-ID: 1743601
October 8, 2020

Megan O. Nakashima, MD
Cleveland Clinic
Amherst FHC Lab
Lab
5172 Leavitt Rd
Lorain, Ohio 44053-2384

Dear Dr. Nakashima:

I have completed my review of the findings from the College of American Pathologists (CAP) inspection of your laboratory conducted on August 24, 2020 by Elizabeth J. Hood, MBA, BS, MT(AMT).

The documentation provided demonstrates the correction of all deficiencies cited during the inspection.

I recommend accreditation for your laboratory.

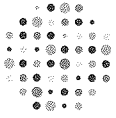
Congratulations on the excellent services that your laboratory is providing for your community and the efforts that you have made towards accreditation. We value your participation in the CAP's Accreditation Programs.

Sincerely,

Victor Y. Cabanas, MD
Great Lakes Regional Commissioner
CAP Accreditation Programs

DEFREC

325 Waukegan Road
Northfield IL 60093
800-323-4040 | cap.org



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PATHOLOGISTS

CAP#: 8869359
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October 8, 2020

Megan O. Nakashima, MD
Cleveland Clinic
Amherst FHC Lab
Lab
5172 Leavitt Rd
Lorain, Ohio 44053-2384

Dear Dr. Nakashima:

The College of American Pathologists (CAP) is pleased to advise you that the medical laboratory you direct, Cleveland Clinic Amherst FHC Lab, in Lorain, Ohio, has successfully met the Laboratory Accreditation Program Standards for Accreditation in the area(s) listed on the attached sheet. **Please retain this letter and list of accredited services in your records, as this is your official notification of accreditation.**

Your Certificate of Accreditation is enclosed. Accreditation is valid for two years and is maintained through continuous compliance with the Terms of Accreditation contained in the attached document.

The Accreditation Committee congratulates you and your entire staff on this achievement as together you provide excellence in laboratory medicine services. This is a significant accomplishment and I encourage you to share the inspection results with your organization's leadership.

Please remember CAP accreditation is not a substitute for the laboratory personnel's continuous in-depth monitoring and maintenance of a safe and properly functioning laboratory. We look forward to working with you in the future and commend your commitment to the highest level of laboratory accreditation for the patients you serve.

Sincerely,

Michael B. Datto, MD, PhD, Accreditation Committee Chair

cc: Walter H. Henricks, MD, Chair, Commission on Laboratory Accreditation

Terms of Accreditation

A laboratory that is College of American Pathologists (CAP) accredited must:

- Provide a trained inspection team comparable in size and scope to that required for its own inspection at least once during the two-year accreditation period, if requested by the regional and/or state commissioner.
- Participate annually in a CAP-accepted proficiency testing (PT) program, if applicable.
- Promptly notify the CAP:
 - Of any changes in the following: directorship, location, ownership, name, insolvency, or bankruptcy within 30 days of the change, *
 - Of any changes in the laboratory's test menu prior to beginning that testing or the laboratory permanently or temporarily discontinues some or all testing,
 - If the laboratory discovers laboratory personnel actions that appear to violate federal, state, or local laws that regulate laboratories.
- Have a written procedure for employees to communicate concerns about quality and safety to management and for management to investigate employee complaints. Incorporate corrective or preventive actions into the laboratory Quality Management Plan.
- Cooperate in any CAP investigation or inspection and promptly notify the CAP if the laboratory becomes the subject of:
 - An investigation by a government entity (including federal, state, local, or foreign),
 - A validation inspection,
 - Adverse media attention.
- Authorize the CAP to release its inspection and PT data and other information required by law to the appropriate regulatory or oversight agencies such as the Centers for Medicare & Medicaid Services (CMS), Department of Veterans Affairs, Department of Defense, The Joint Commission, Healthcare Facilities Accreditation Program / American Osteopathic Association, United Network for Organ Sharing, or state/provincial agencies.
- Make available on a reasonable basis the laboratory's annual PT results upon request of any person, and if the laboratory is subject to US Clinical Laboratory Improvement Amendments (CLIA) regulations,
 - Allow CMS or its agent to perform a validation or complaint inspection at any time during the laboratory's hours of operation and permit CMS to monitor the correction of any deficiencies found through such an inspection,
 - Obtain a CLIA Certificate of Accreditation and pay all applicable fees as a CLIA-certified laboratory if it will use CAP accreditation to meet CLIA certification requirements.
- Submit a completed Self-Inspection Verification Form in the interim year.
- Submit only documentation and other materials to CAP that have been de-identified of all protected health information (PHI) in accordance with the requirements of the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations unless the laboratory must submit PHI to CAP to respond to a deficiency or patient complaint.
- Accept and adhere to the *Certification Mark Terms of Use/Agreement for CAP Accredited Mark and Design*, if the laboratory is/or will use the CAP Certification Mark of accreditation. The agreement may be downloaded and printed from the CAP web site.
- Refrain from copying or distributing the CAP Checklists or any content thereof except for use by inspectors in conducting a CAP inspection and by the laboratory in preparing for such an inspection.

*If subject to US CLIA regulations, also notify the Centers for Medicare and Medicaid Services (CMS).

Cleveland Clinic
Amherst FHC Lab

LAP Number: 8869359

AU ID: 1743601

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

All Common
Bacteriology
Chemistry
Coagulation
Director Assessment
Director/Organizational Assessment
Hematology
Laboratory General
Special Chemistry
Urinalysis

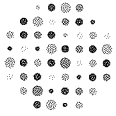
This accreditation is valid for the period ending April 1, 2022.

Cleveland Clinic
Amherst FHC Lab

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AU ID: 1743601
Reference Number: 36D0333551

The Laboratory Accreditation Program currently has the subspecialty information listed below on file for your laboratory. This information is used for reporting to regulatory agencies.

General Immunology
Hematology
Routine Chemistry
Urinalysis



COLLEGE of AMERICAN PATHOLOGISTS

MEMORANDUM

TO: Megan O. Nakashima, MD

FROM: Joe Schramm
Director, Enterprise Communications

DATE: October 8, 2020

RE: News Release and Certification Mark for Your Accredited Laboratory
CAP #: 8869359
AU ID: 1743601

News Release. Congratulations on your recent accreditation from the College of American Pathologists (CAP). The CAP encourages you to share this news and consider the following news release distribution options:

1. Share **internally** with your organization's:
 - a. Communications/public relations (PR) department,
 - b. Newsletter,
 - c. Patient magazine,
 - d. Web site, and
 - e. Social Media outlets.

2. Share **externally*** with:
 - a. Local newspaper(s),
 - b. Television station(s), and
 - c. Community newsletters and publications.

***Note:** Your internal communications/PR department may want to manage external distribution.

If you would like to tailor the release, for example, with a quote from your organization's chief executive officer, please contact me at media@cap.org for an electronic version.

Certification Mark. You may use the CAP Certification Mark to promote your CAP Accreditation via your:

1. Web site,
2. Advertisements,
3. Posters, Fliers, and Announcements, and
4. Displays in patient and others areas of your organization.

To obtain access to the Certification Mark:

1. Log into "e-LAB Solutions™/CAP Accreditation/CAP Accreditation Certification Mark" at cap.org, or
2. E-mail contactcenter@cap.org to have the Certification Mark files sent electronically.

If you have any questions, please contact me at 800-323-4040 ext. 7445, 847-832-7445 or jschramm@cap.org. Thank you for making the commitment to quality and patient safety as a CAP-accredited site.

To tailor this release for your organization contact media@cap.org for an electronic version

For Immediate Release

October 8, 2020

Contact: *Tailor to your organization*

**CLEVELAND CLINIC
AMHERST FHC LAB
RECEIVES ACCREDITATION FROM
COLLEGE OF AMERICAN PATHOLOGISTS**

The Accreditation Committee of the College of American Pathologists (CAP) has awarded accreditation to Cleveland Clinic Amherst FHC Lab, Lorain, Ohio based on results of a recent on-site inspection as part of the CAP's Accreditation Programs.

The facility's director, Megan O. Nakashima, MD, was advised of this national recognition and congratulated for the excellence of the services being provided. Cleveland Clinic Amherst FHC Lab is one of more than 8,000 CAP-accredited facilities worldwide.

"Insert quote from Laboratory Director here," said Dr. X.

Organization's Chief Executive Officer (or other leader), upon learning of the laboratory's accreditation, said: "Insert quote here."

The U.S. federal government recognizes the CAP Laboratory Accreditation Program, begun in the early 1960s, as being equal-to or more-stringent-than the government's own inspection program.

During the CAP accreditation process, designed to ensure the highest standard of care for all laboratory patients, inspectors examine the laboratory's records and quality control of procedures for the preceding two years. CAP inspectors also examine laboratory staff qualifications, equipment, facilities, safety program and record, and overall management.

About the College of American Pathologists

As the world's largest organization of board-certified pathologists and leading provider of laboratory accreditation and proficiency testing programs, the College of American Pathologists (CAP) serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide. For more information, [READ THE CAP ANNUAL REPORT](#) at cap.org