



COLLEGE of AMERICAN
PATHOLOGISTS



The College of American Pathologists
certifies that the laboratory named below

**Lurie Childrens
Infectious Disease Lab
Chicago, Illinois
Xiaotian Zheng, PhD**

CAP Number: 7183915

AU-ID: 1401897

CLIA Number: 14D0665386

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 31, 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#: 7183915
AU-ID: 1401897
December 11, 2019

Xiaotian Zheng, PhD
Lurie Childrens
Infectious Disease Lab
2515 N Clark St Ste 3012
Chicago, Illinois 60614-2720

Dear Dr. Zheng:

The College of American Pathologists (CAP) is pleased to advise you that the medical laboratory you direct, Lurie Childrens Infectious Disease Lab, in Chicago, Illinois, 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.

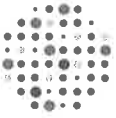
Please remember CAP accreditation is not a substitute for the laboratory personnel's continuous in-depth monitoring and maintenance of a safe and properly functioning laboratory. We look forward to working with you in the future and commend your commitment to the highest level of laboratory accreditation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

Sincerely,

A handwritten signature in black ink, appearing to read "M. Datto", with the name "DATTO" printed in a smaller font directly below the signature.

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

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



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CAP #: 7183915
AU-ID: 1401897
December 11, 2019

Xiaotian Zheng, PhD
Lurie Childrens
Infectious Disease Lab
2515 N Clark St Ste 3012
Chicago, Illinois 60614-2720

Dear Dr. Zheng:

I have completed my review of the findings from the College of American Pathologists (CAP) inspection of your laboratory conducted on November 22, 2019 by Dinesh Rakheja, MD.

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,

Leonard I. Boral, MD, MBA
Mid-Central Regional Commissioner
CAP Accreditation Programs



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).

Lurie Childrens
Infectious Disease Lab

LAP Number: 7183915

AU ID: 1401897

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

All Common

Director Assessment

Director/Organizational Assessment

Laboratory General

Molecular Microbiology

This accreditation is valid for the period ending January 31, 2022.

Lurie Childrens
Infectious Disease Lab

LAP Number: 7183915
AU ID: 1401897
Reference Number: 14D0665386

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

**Laboratory Accreditation Programs
List of Deficiencies**

LAP Number: 7183915
Accreditation Unit (AU): Lurie Childrens-Infectious Disease Lab
Address: 2515 N Clark St Ste 3012
Chicago, IL 60614-2720

Director: Zheng, Xiaotian, PhD
AU Inspection Date: 11/22/2019
Inspection Type: Routine
Team Leader: Rakheja, Dinesh, MD
Number of Deficiencies: 1

Laboratory Accreditation Programs

List of Deficiencies

AU ID: 1401897
Accreditation Unit (AU): Lurie Childrens-Infectious Disease Lab

SU ID: 1650041
Section Unit (SU): Infectious Disease Laboratory
SU Inspection Date: 11/22/2019

Checklist	Requirement ID	Phase	Requirement
All Common	COM.40000	II	For each nonwaived test, there is an evaluation of the test method validation or verification study (accuracy, precision, etc.) signed by the laboratory director, or designee meeting CAP director qualifications, prior to use in patient testing to confirm the acceptability of the data and approve each nonwaived test for clinical use.

List of Deficiencies

AU ID: 1401897
Accreditation Unit (AU): Lurie Childrens-Infectious Disease Lab
SU ID: 1629733
Section Unit (SU): Lab General
SU Inspection Date: 11/22/2019

Checklist	Requirement ID	Phase	Requirement
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There were no deficiencies from the inspection of this section.



COLLEGE of AMERICAN
PATHOLOGISTS

MEMORANDUM

TO: Xiaotian Zheng, PhD

FROM: Joe Schramm
Director, Enterprise Communications

DATE: December 11, 2019

RE: News Release and Certification Mark for Your Accredited Laboratory
CAP #: 7183915
AU ID: 1401897

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
December 11, 2019

Contact: *Tailor to your organization*

**LURIE CHILDRENS
INFECTIOUS DISEASE LAB
RECEIVES ACCREDITATION FROM
COLLEGE OF AMERICAN PATHOLOGISTS**

The Accreditation Committee of the College of American Pathologists (CAP) has awarded accreditation to Lurie Childrens Infectious Disease Lab, Chicago, Illinois based on results of a recent on-site inspection as part of the CAP's Accreditation Programs.

The facility's director, Xiaotian Zheng, PhD, was advised of this national recognition and congratulated for the excellence of the services being provided. Lurie Childrens Infectious Disease 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