



COLLEGE of AMERICAN
PATHOLOGISTS

CERTIFICATE OF ACCREDITATION

**Childrens Hospital Medical Center
Outpatient Fairfield Lab
Fairfield, Ohio
Alex M. Drach, MD**

CAP Number: 1667817

AU-ID: 1192911

CLIA Number: 36D0951823

The organization named above meets all applicable standards for accreditation and is hereby accredited by the College of American Pathologists' Laboratory Accreditation Program. Reinspection should occur prior to **January 12, 2025** to maintain accreditation.

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

Kathleen G. Beavis, MD, Accreditation Committee Chair

Emily Volk, MD, FCAP, President, College of American Pathologists



February 21, 2023
CAP #: 1667817
AU-ID: 1192911

Alex M. Drach, MD
Childrens Hospital Medical Center
Outpatient Fairfield Laboratory
3050 Mack Rd
Fairfield, Ohio 45014-5379

Dear Dr. Drach:

The College of American Pathologists has determined to accredit Childrens Hospital Medical Center Outpatient Fairfield Laboratory subject to compliance with the requirement set forth below. **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 granted to this laboratory for a two-year period and may be maintained on a continuous basis provided the following requirement is met. Failure to comply with the following requirement will result in review by the Accreditation Committee and possible sanctions, up to and including revocation.

- **Submit documentation demonstrating that all staff have been trained on proper handling of PT survey specimens and results, to include understanding that results may not be referred or accepted from any other laboratory site, even within the same system, and that all evaluation, grading, and submission shall be completed only at the site at which the PT survey is performed; due March 31st, 2023**

Submit the requested documentation by March 31st, 2023 to Linda Whaley, MLS(ASCP) at CAP headquarters via email (lwhaley@cap.org) or fax (847-832-8915).

This documentation is required to ensure continuous compliance with CAP requirements and CMS regulations.

As an accredited laboratory within the CAP Laboratory Accreditation Program, you have agreed to adhere to the attached Terms of Accreditation.

Please remember CAP accreditation is not a substitute for continuous in-depth monitoring by the laboratory personnel to maintain a safe and properly functioning laboratory.

Sincerely,



Kathleen G. Beavis, MD, Accreditation Committee Chair

cc: Richard M. Scanlan, MD, Chair, Council on Accreditation
Carlos N. Machicao, MD, Great Lakes Regional Commissioner
Michael Fisher, CEO

February 21, 2023
CAP #: 1667817
AU-ID: 1192911

Alex M. Drach, MD
Childrens Hospital Medical Center
Outpatient Fairfield Laboratory
3333 Burnet Ave # ML1010
Cincinnati, OH 45229-3026

Dear Dr. Drach:

I completed my review of the findings from the College of American Pathologists (CAP) inspection of your laboratory conducted on January 12, 2023 by Ted E. Schutzbank, PhD, D(ABMM).

I reviewed the inspection report and your documentation of the correction of deficiencies and am recommending **accreditation subject to the following requirement:**

- **Submit documentation demonstrating that all staff have been trained on proper handling of PT survey specimens and results, to include understanding that results may not be referred or accepted from any other laboratory site, even within the same system, and that all evaluation, grading, and submission shall be completed only at the site at which the PT survey is performed; due March 31st, 2023**

Submit the requested documentation by March 31st, 2023 to Linda Whaley, MLS(ASCP) at CAP headquarters via email (lwhaley@cap.org) or fax (847-832-8915).

This documentation is required because to ensure continuous compliance with CAP requirements and CMS regulations. Disposition of future accreditation for your laboratory will depend on the outcome of this process.

If you have any questions please contact Linda Whaley, MLS(ASCP) at 800-323-4040 ext. 7915.

Thank you for participation in the CAP's Accreditation Programs. Our purpose is to strive for excellence in Laboratory Medicine and Pathology.

Sincerely,



Meggen A. Walsh, DO
Great Lakes Deputy Regional Commissioner
CAP Accreditation Programs

Terms of Accreditation

Accreditation by the College of American Pathologists' (CAP) Accreditation Program is contingent on compliance with the terms and obligations listed below.

A laboratory that is accredited by CAP or that has applied for accreditation must:

- 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),
 - The subject of a validation inspection, or
 - The subject of adverse media attention.
- Promptly notify the CAP if the laboratory discovers actions by laboratory personnel 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
- Provide a trained inspection team comparable in size and scope to that required for its own inspection. if requested by the regional and/or state commissioner at least once during the two-year accreditation period.
- Participate annually in a CAP-accepted proficiency testing program, if applicable.
- Promptly notify the CAP and, if subject to US CLIA regulations, the Centers for Medicare and Medicaid Services (CMS), in writing 30 days prior to any changes in the following: directorship, location, ownership, name, insolvency or bankruptcy.
- Promptly notify the CAP when there is a change in the laboratory's test menu prior to beginning that testing or the laboratory permanently or temporarily discontinues some or all testing.
- Authorize the CAP to release its inspection and proficiency testing data and other information required by law to the appropriate regulatory or oversight agencies such as CMS, Department of Veterans Affairs, Department of Defense, Joint Commission, HFAP(AOA), UNOS, or state/provincial agencies.
- If the laboratory is subject to US CLIA regulations:
 - Make available on a reasonable basis the laboratory's annual PT results upon request of any person.
 - 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.
- 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.
- 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 in order to respond to a deficiency or patient complaint.
- 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.

- Laboratories participating in the Laboratory Accreditation Program are required to pay for CAP Annual Accreditation Fees based on the applicable Discipline/Sub-Discipline of the lab. Those fees are set based on complexity points, test volume points, base fee and specialty fees that apply at the time of the billing month for the site. Find further information about specific fees by emailing accred@cap.org.
- Laboratories participating in any CAP Specialty Programs, including Reproductive Laboratory Accreditation, Forensic Drug Testing Accreditation, Biorepository Accreditation, System Inspection Option, are required to pay for these Annual Accreditation Fees that apply at the time of the billing month for the site.
- International Laboratories are subject to pay business class airfare for any United States-based inspector that inspects on-site.

Childrens Hospital Medical Center
Outpatient Fairfield Lab

LAP Number: 1667817
AU ID: 1192911

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

- All Common
- Chemistry
- Coagulation
- Director Assessment
- Immunology
- Laboratory General
- Urinalysis

This accreditation is valid for the period ending January 12, 2025.

Childrens Hospital Medical Center
Outpatient Fairfield Lab

LAP Number: 1667817
AU ID: 1192911
Reference Number: 36D0951823

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.

- Endocrinology
- General Immunology
- Hematology
- Routine Chemistry
- Urinalysis

Laboratory Accreditation Programs
List of Deficiencies

LAP Number: 1667817
Accreditation Unit (AU): Childrens Hospital Medical Center-Outpatient Fairfield Lab
Address: 3050 Mack Rd
Fairfield, OH 45014-5379

Director: Drach, Alex M., MD
AU Inspection Date: 01/12/2023
Inspection Type: Routine
Team Leader: Schutzbank, Ted E., PhD, D(ABMM)
Number of Deficiencies: 2

AU ID: 1192911
Accreditation Unit (AU): Childrens Hospital Medical Center-Outpatient Fairfield Lab

SU ID: 1392499
Section Unit (SU): Lab General
SU Inspection Date: 01/12/2023

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

Laboratory Accreditation Programs
List of Deficiencies

AU ID: 1192911
Accreditation Unit (AU): Childrens Hospital Medical Center-Outpatient Fairfield Lab

SU ID: 1395913
Section Unit (SU): Outpatient Laboratory - Fairfield
SU Inspection Date: 01/12/2023

Checklist	Requirement ID	Phase	Requirement
All Common	COM.01700	II	There is ongoing evaluation of proficiency testing (PT) and alternative performance assessment results by the laboratory director or designee with appropriate corrective action taken for each unacceptable result.
	COM.01800	II	There is no interlaboratory communication about proficiency testing specimens and results until after the deadline for submission of data to the proficiency testing provider.