

CENTERS FOR MEDICARE & MEDICAID SERVICES
CLINICAL LABORATORY IMPROVEMENT AMENDMENTS
CERTIFICATE OF PROVIDER-PERFORMED MICROSCOPY PROCEDURES

LABORATORY NAME AND ADDRESS
AKRON CHILDREN'S HOSPITAL PATH
AND LAB MED AT AKRON
ONE PERKINS SQUARE
AKRON, OH 44308-1063

CLIA ID NUMBER
36D0656120

EFFECTIVE DATE
09/01/2018

LABORATORY DIRECTOR
SIHE W WANG Ph.D.

EXPIRATION DATE
08/31/2020

Pursuant to Section 353 of the Public Health Services Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures.

This certificate shall be valid until the expiration date above, but is subject to revocation, suspension, limitation, or other sanctions for violation of the Act or the regulations promulgated thereunder.



Karen W. Dyer, Director
Division of Laboratory Services
Survey and Certification Group
Center for Clinical Standards and Quality

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- If this is a Certificate of Registration, it represents only the enrollment of the laboratory in the CLIA program and does not indicate a Federal certification of compliance with other CLIA requirements. The laboratory is permitted to begin testing upon receipt of this certificate, but is not determined to be in compliance until a survey is successfully completed.
- If this is a Certificate for Provider-Performed Microscopy Procedures, it certifies the laboratory to perform only those laboratory procedures that have been specified as provider-performed microscopy procedures and, if applicable, examinations or procedures that have been approved as waived tests by the Department of Health and Human Services.
- If this is a Certificate of Waiver, it certifies the laboratory to perform only examinations or procedures that have been approved as waived tests by the Department of Health and Human Services.

FOR MORE INFORMATION ABOUT CLIA, VISIT OUR WEBSITE AT WWW.CMS.GOV/CLIA
OR CONTACT YOUR LOCAL STATE AGENCY. PLEASE SEE THE REVERSE FOR
YOUR STATE AGENCY'S ADDRESS AND PHONE NUMBER.
PLEASE CONTACT YOUR STATE AGENCY FOR ANY CHANGES TO YOUR CURRENT CERTIFICATE.



Department
of Health

Mike DeWine, Governor
Jon Husted, Lt. Governor

Amy Acton, M.D., MPH, Director

CLIA #36D0656120
September 23, 2019

Akron Children's Hospital
Attn: Ms. Debra Butler MT(ASCP), Laboratory POCT Coordinator
One Perkins Square, 5th Floor Lab
Akron, OH 44308

RE: Akron Children's Hospital Path and Lab Med at Akron
Dr. Jennifer Baccon, M.D., CLIA Laboratory Director
One Perkins Square
Akron, OH 44308-1063

Dear Ms. Butler:

This letter is to confirm your CLIA file has been updated to document the above new Director for your laboratory.

We received notification that the Director of your CLIA laboratory has changed. The Clinical Laboratory Improvement Amendments of 1988 (CLIA), as published in the 42 CFR, Part 493, requires the laboratory to have a qualified:

- **Director** (all laboratories),
- **Clinical Consultant** (Waived and PPMP excluded)
- **Technical Consultant** (Moderate Complexity), for each specialty/sub-specialty in which testing is performed **and/or**,
- **Technical Supervisor** (High complexity only) for each specialty/sub-specialty in which testing is performed, and
- **General Supervisor** (High complexity only)

You will not receive a new CLIA certificate until the end of the current CLIA certificate period. This letter and any attached forms are your documentation of the change.

CLIA also requires the notification of any change in Director (all laboratories), Clinical Consultant (Waived and PPMP excluded) or supervisor (High complexity only) **within 30 days of the change**. See the new CLIA regulations at www.cms.gov/CLIA.

Please verify that all the above CLIA required qualified personnel cover function areas for your laboratory. **Future changes must be provided to us with the name and documentation of education/training for the new personnel within 30 days of the change. Mail documentation/requests to:**

OHIO DEPARTMENT OF HEALTH
CLIA LABORATORY PROGRAM
246 NORTH HIGH STREET, 2nd FLOOR
COLUMBUS, OHIO 43215

246 North High Street
Columbus, Ohio 43215 U.S.A.

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www.odh.ohio.gov