

CENTERS FOR MEDICARE & MEDICAID SERVICES  
CLINICAL LABORATORY IMPROVEMENT AMENDMENTS

CERTIFICATE OF ACCREDITATION

LABORATORY NAME AND ADDRESS

LUTHERAN HOSPITAL LABORATORY  
1730 W 25TH STREET  
CLEVELAND, OH 44113

CLIA ID NUMBER

36D0336529

EFFECTIVE DATE

02/09/2015

EXPIRATION DATE

02/08/2017

LABORATORY DIRECTOR

SHALINI MOHINDRA M.D.

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

437 Certs2\_011315

If you currently hold a Certificate of Compliance or Certificate of Accreditation, below is a list of the laboratory specialties/subspecialties you are certified to perform and their effective date:

<u>LAB CERTIFICATION (CODE)</u>	<u>EFFECTIVE DATE</u>
BACTERIOLOGY (110)	02/20/1996
PARASITOLOGY (130)	02/20/1996
GENERAL IMMUNOLOGY (220)	02/20/1996
ROUTINE CHEMISTRY (310)	10/11/1995
URINALYSIS (320)	10/11/1995
ENDOCRINOLOGY (330)	10/20/1999
TOXICOLOGY (340)	02/27/1998
HEMATOLOGY (400)	10/11/1995
ABO & RH GROUP (510)	10/11/1995
ANTIBODY TRANSFUSION (520)	10/11/1995
ANTIBODY NON-TRANSFUSION (530)	10/11/1995
ANTIBODY IDENTIFICATION (540)	10/11/1995
COMPATIBILITY TESTING (550)	10/11/1995

<u>LAB CERTIFICATION (CODE)</u>	<u>EFFECTIVE DATE</u>
HISTOPATHOLOGY (610)	10/11/1995
CYTOLOGY (630)	06/13/2003



FOR MORE INFORMATION ABOUT CLIA, VISIT OUR WEBSITE AT [WWW.CMS.GOV/CLIA](http://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.







# OHIO DEPARTMENT OF HEALTH

246 North High Street  
Columbus, Ohio 43215

614/466-3543  
[www.odh.ohio.gov](http://www.odh.ohio.gov)

John R. Kasich/Governor

Richard Hodges/Director of Health

CLIA #36D0336529

January 27, 2015

Lutheran Hospital Laboratory  
Attn: Dr. Sarah M Share, M.D., Laboratory Director  
1730 West 25th Street  
Cleveland, OH 44113

Dear Dr. Share:

**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:

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

You will not receive a new CLIA certificate. 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](http://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

Failure to provide this documentation within the required time frame puts your laboratory in non-compliance with CLIA regulations 42 CFR, Part 493: Notification Requirements. If further assistance is needed, please contact us at [CLIA@odh.ohio.gov](mailto:CLIA@odh.ohio.gov), call (614)644-1845 or fax (614)564-2478.

Sincerely,

Shannon Richey, RN  
Assistant Bureau Chief, CLIA Laboratory Program Supervisor  
Bureau of Community Health Care  
SR/mdd