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

LABORATORY DIRECTOR

SHALINI MOHINDRA M.D.

CLIA ID NUMBER

36D0336529

EFFECTIVE DATE

02/09/2015 EXPIRATION DATE

02/08/2017

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, 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:

LAB CERTIFICATION (CODE)	EFFECTIVE DATE
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

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

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.

CLIVICAL LABORATORY IMPROVEMENT AND ADMINISTRA

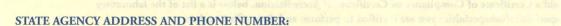
SOUNDS CHAID

STACE OF THE CONTROL OF THE CONTROL

+ 05-80/50 Тма иот ганажт - 60/80/50

anomics of the common of the c

CLIA ID Number: 36D0336529 LUTHERAN HOSPITAL LABORATORY LUTHERAN HOSPITAL LAB, ATTN DR MOHINDRA 1730 W 25TH STREET



CLEVELAND, OH 44113

OHIO DEPARTMENT OF HEALTH
CLIA LABORATORY PROGRAM
246 NORTH HIGH STREET, SECOND FLOOR
COLUMBUS, OH 43215
(614)644-1845

LABORATORY MAILING ADDRESS:

OHIO DEPARTMENT OF HEALTH



246 North High Street Columbus, Ohio 43215 614/466-3543 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.

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, 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