



RICK SNYDER
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF COMMUNITY AND HEALTH SYSTEMS

MIKE ZIMMER
DIRECTOR

September 3, 2015

Immucor GTI Diagnostics, Inc
dba Immucor DX
301 Michigan Street NE Suite 580
Grand Rapids, MI 49503-3314

Dear Director:

RE: CLIA #23D1054909

On August 27, 2015, we received a CMS 116 CLIA Application from you requesting the changes listed below. These changes were entered into the CMS database on September 3, 2015.

Previous Data

Facility Name: Sequenom Center for Molecular
Medicine LLC dba Dequenom Laboratories

Federal tax i.d.#: 26-3863718

Laboratory Director: Daniel H. Farkas, PhD

Corporate Address:

Current Data

Immucor GTI Diagnostics, Inc
dba Immucor DX

39-1430953

Tiffany K. Roberts, PhD

20925 Crossroads Circle
Waukesha, WI 53186

Your current CLIA Certificate of Accreditation is valid through December 27, 2015.

YOU WILL NOT BE ISSUED A NEW CLIA CERTIFICATE FOR THIS CHANGE. PLEASE RETAIN THIS LETTER TO BE USED IN PLACE OF YOUR CLIA CERTIFICATE. Please contact this office at (517) 241-2648 should you have further questions. For additional information about CLIA topics, please go to: <http://www.cms.hhs.gov/clia>.

Sincerely,

Michelle Roepke, BS, MT(ASCP)
Manager - Laboratory Improvement Section
Division of Licensing and Certification
LARA Bureau of Community and Health Systems



RICK SNYDER
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF HEALTH CARE SERVICES

MIKE ZIMMER
DIRECTOR

January 16, 2015

Sequenom Center for Molecular Medicine LLC
dba Sequenom Laboratories
301 Michigan Street Ne Suite 580
Grand Rapids, MI 49503-3314

Dear Director:

RE: CLIA #23D1054909

On January 7, 2015, we received a CMS 116 CLIA Application from you requesting the changes listed below. These changes were entered into the CMS database on January 16, 2015.

Previous Data

Facility Name: Sequenom Center for Molecular
Medicine LLC

Add Specialty/Subspecialty Tests:

Current Data

Sequenom Center for Molecular
Medicine LLC, dba Sequenom Laboratories

Chemistry: Routine-310
Immunohematology: ABO Group & Rh Group-510
Pathology: Histopathology-610
Clinical Cytogenetics: Clinical Cytogenetics-900

Your current CLIA Certificate of Accreditation is valid through December 27, 2015.

YOU WILL NOT BE ISSUED A NEW CLIA CERTIFICATE FOR THIS CHANGE. PLEASE RETAIN THIS LETTER TO BE USED IN PLACE OF YOUR CLIA CERTIFICATE. Please contact this office at (517) 241-2648 should you have further questions. For additional information about CLIA topics, please go to: <http://www.cms.hhs.gov/clia>.

Sincerely,

Michelle Roepke

Michelle Roepke, BS, MT(ASCP)
Manager - Laboratory Improvement Section
Division of Licensing and Certification
LARA Bureau of Health Care Services

CENTERS FOR MEDICARE & MEDICAID SERVICES
CLINICAL LABORATORY IMPROVEMENT AMENDMENTS

CERTIFICATE OF ACCREDITATION

LABORATORY NAME AND ADDRESS

SEQUENOM CENTER FOR MOLECULAR MEDICINE
301 MICHIGAN STREET NE SUITE 580
GRAND RAPIDS, MI 49503-3314

CLIA ID NUMBER

23D1054909

EFFECTIVE DATE

12/28/2013

LABORATORY DIRECTOR

DANIEL H FARKAS Ph.D.

EXPIRATION DATE

12/27/2015

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.



Judith A. Yost

Judith A. Yost, Director
Division of Laboratory Services
Survey and Certification Group
Center for Medicaid and State Operations

132 Certs2_120313

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>	<u>LAB CERTIFICATION (CODE)</u>	<u>EFFECTIVE DATE</u>
ROUTINE CHEMISTRY (310)	10/20/2009		



FOR MORE INFORMATION ABOUT CLIA, VISIT OUR WEBSITE AT WWW.CMS.HHS.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.