



State of New Jersey
DEPARTMENT OF HEALTH

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KAITLAN BASTON, MD, MSc, DFASAM
Acting Commissioner

August 10, 2023

VIA ELECTRONIC, UPS NEXT DAY

Tingliang Shen, MD
Laboratory Director
University Urology Associates of New Jersey Lab
490 Highway 530
Manchester Township
Whiting, New Jersey 08733

**Re: CEASE AND DESIST NOTIFICATION FOR PERFORMANCE OF
UNLICENSED LABORATORY TESTING AND COLLECTION STATION
SERVICES**

Dear Dr. Shen:

The New Jersey Department of Health (the Department) is vested with the responsibility of carrying out the provisions of the New Jersey Clinical Laboratory Improvement Act, N.J.S.A. 45:9-42.26 et seq. (the Act), which was enacted in part to ensure that clinical laboratories in New Jersey are of the highest quality. The Act further grants the Commissioner of Health the power to license clinical laboratories in the State and to prescribe standards for the operation of these laboratories. In furtherance of the aforementioned statutory objectives, the Department adopted regulations that govern the licensure and minimum standards of clinical laboratories. See N.J.A.C. 8:44-2.1 et seq.

The Department's Public Health and Environmental Laboratories, Clinical Laboratory Improvement Services (CLIS) became aware the University Urology Associates of New Jersey (University Urology) located at 490 Highway 530, Manchester Township in Whiting, New Jersey may have been performing clinical laboratory specimen testing without a clinical laboratory license issued by CLIS. As such, on July 20, 2023, CLIS inspectors conducted an unannounced inspection of University Urology. From the inspection, the CLIS inspectors confirmed that University Urology was conducting molecular urinary tract infection (UTI) and antibiotic resistance (ABR) marker panel testing on patient samples without a clinical laboratory license. During the inspection, the inspectors reviewed University Urology's records on site and confirmed that it began molecular UTI and ABR marker panel testing in 2019 and continued conducting such testing until the date of the inspection, all without seeking licensure from CLIS.

Specifically, the inspectors determined that University Urology performed 144 molecular UTI test panels on patients in 2019, 2,076 molecular UTI test panels in 2020, 1,868 molecular UTI test panels in 2021, 1,808 molecular UTI test panels in 2022 and 1,260 molecular UTI test panels in 2023. Additionally, the inspectors found that patient urine samples collected at other University Urology Associates of New Jersey locations in Freehold (495 Iron Bridge Road, Suite 3), Hamilton (1374 Whitehorse-Hamilton Square Road, Suite 101), and Howell (2364 U.S. 9) are transported to the Whiting office for UTI/ABR testing. Upon learning this, CLIS reviewed its licensing records, which revealed that none of these offices are licensed by the Department as clinical laboratory collection stations for submission of specimen samples to the Whiting office for laboratory testing.

As defined by the Act, a clinical laboratory is “any facility used for the performance of chemical, bacteriologic, virologic, parasitologic, serologic, hematologic, immunohematologic, biophysical, cytologic or other examinations of materials derived from the human body for the purpose of yielding information for the diagnosis, prevention or treatment of disease or the assessment of medical condition.” N.J.S.A. 45:9-42.27 (emphasis added). Additionally, a clinical laboratory includes “any facility used for the collection, processing and transmission of specimens to another facility for the performance of clinical tests.” N.J.S.A. 45:9-42.27. The Act further provides that “[n]o person shall conduct, maintain, or operate a clinical laboratory or solicit or accept specimens for laboratory examination unless a license therefor has been obtained from” the Department. N.J.S.A. 45:9-42.28

Based on the statutes outlined above, University Urology falls squarely within the statutory definition of a clinical laboratory because it is performing UTI Panel bacteriological testing on patient urine samples to determine whether the patient had been infected with a UTI pathogen as well as antibiotic resistance marker panel testing, which is a bacteriologic test. Accordingly, University Urology must be licensed by CLIS as a clinical laboratory to conduct these clinical laboratory tests. However, University Urology is not licensed as a clinical laboratory.

Likewise, the Freehold, Hamilton, and Howell offices qualify as a clinical laboratory under the Act as they are collecting, processing and transmitting patient specimens to University Urology’s Whiting office for clinical laboratory testing. Accordingly, they must be licensed by CLIS as clinical laboratory collection stations in order to collect, process and transmit specimens to the main University Urology laboratory for testing. But, these locations are not licensed by CLIS.

Even more troubling, a review of CLIS records revealed that in 2020, you were cited by CLIS for performing molecular UTI testing without a clinical laboratory license while you were serving as the clinical laboratory director for the James E. Rotolo, MD laboratory. Thus, you are well aware of the licensure requirements for clinical laboratories generally and for molecular UTI testing specifically.

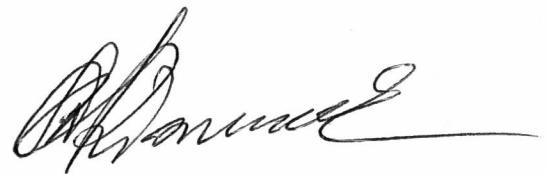
Based upon the foregoing, University Urology is in violation of the Act as it has been conducting UTI/ABR molecular testing without the requisite CLIS clinical laboratory license. As such, University Urology must immediately **CEASE AND DESIST** performing UTI/ABR Panel testing on patient samples. Further, the University Urology Associates of New Jersey locations in Freehold, Hamilton, and Howell that collect patient urine samples that are sent to University Urology for testing must immediately **CEASE AND DESIST** collecting and sending patient urine samples to University Urology.

Additionally, based on the severity of deficiencies found during inspection conducted on July 20, 2023, the Department has a strong concern regarding testing accuracy. Therefore, University Urology must contact all patients who received UTI/ABR panel testing at its Whiting location in the last three (3) months and advise that anyone currently experiencing urinary tract symptoms or concerned about their urinary health status should be re-tested immediately. Documentation of these patient notifications must be provided to the Department within 30 days of the date of this letter. This written confirmation should be sent to Joan Mikita, Manager of the Clinical Laboratory Improvement Services State Licensure/PT Review Program at P.O. Box 361, Trenton, New Jersey 08625.

While University Urology told CLIS on July 24, 2023, that it ceased testing after a CLIS inspector advised University Urology that it was operating without a license in violation of the Act and could face penalties for such actions, University Urology is reminded that failure to cease and desist from conducting unlicensed UTI/ABR panel testing may result in the Department pursuing administrative and civil sanctions against you in accordance with N.J.S.A. 45:9-42.43 and 42.44. This includes but is not limited to monetary fines and/or a court injunction.

If you have any questions concerning this matter, please contact Joan Mikita at (609) 406-6830.

Sincerely,



Alan Rimmer, MD
Executive Director
Clinical Laboratory Improvement Services
NJ Department of Health