



State of New Jersey
DEPARTMENT OF HEALTH

PHILIP D. MURPHY
Governor

PO BOX 361
TRENTON, N.J. 08625-0361

TAHESHA L. WAY
Lt. Governor

www.nj.gov/health

KAITLAN BASTON, MD, MSC, DFASAM
Commissioner

June 17, 2024

VIA ELECTRONIC, UPS NEXT DAY and REGULAR MAIL

Richard Blum, MD.
Laboratory Director
Princeton Women's Services
1345 Kuser Road, Suite 1
Hamilton, New Jersey 08619

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

Dear Dr. Blum:

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 (PHEL), Clinical Laboratory Improvement Services (CLIS) was notified that Princeton Women's Services (PWS) located at 1345 Kuser Road, Suite 1, in Hamilton, New Jersey had failed three consecutive proficiency testing events. As such, on May 9, 2024, CLIS inspectors conducted an unannounced inspection of PWS. From the inspection and a review of CLIS records, CLIS inspectors determined that PWS was performing unlicensed Rh(D) testing and that PWS had failed to renew its clinical laboratory license for the 2024 calendar year.

During the inspection, the CLIS inspectors identified other serious deficiencies, including confirmation of PWS's failure to perform the required proficiency testing, failure of the laboratory director to appropriately supervise procedures and ensure quality control and failure to maintain complete and accurate records, as further described in the attached survey report.

As defined by the Act, a clinical laboratory is “any facility used for the performance of chemical, bacteriologic, virologic, parasitologic, serologic, hematologic, **immuno-hematologic**, 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). 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, PWS falls squarely within the statutory definition of a clinical laboratory because it is performing Rh(D) testing, which is an immuno-hematologic test. Accordingly, PWS must be licensed by CLIS as a clinical laboratory to conduct these clinical laboratory tests. However, PWS is not currently licensed to conduct any type of testing as a clinical laboratory. PWS was previously licensed to conduct Rh(D) testing and had been granted multiple extensions of time in order to submit an acceptable plan of correction following its pre-licensure inspection in April 2023. PWS ultimately came into compliance and was licensed as of July 2023. However, to date, PWS has failed to submit to the Department the required application and fee to renew its license for 2024, despite being instructed by inspectors on how to set up an online account to submit an application for licensure renewal.

Based upon the foregoing, PWS is in violation of the Act as it has been conducting Rh(D) testing without the requisite CLIS clinical laboratory license. PWS is similarly precluded from conducting all types of clinical laboratory testing of patient samples since it does not hold any current license to conduct such testing. As such, PWS must immediately **CEASE AND DESIST** performing all testing on patient samples.

PWS is reminded that failure to cease and desist from conducting unlicensed patient sample clinical laboratory 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,

A handwritten signature in black ink, appearing to read 'Alan Rimmer', followed by a horizontal line.

Alan Rimmer, MD
Executive Director
Clinical Laboratory Improvement Services
(PHEL)/ NJ Department of Health