



State of New Jersey
DEPARTMENT OF HEALTH

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www.nj.gov/health

PHILIP D. MURPHY
Governor

TAHESHA L. WAY
Lt. Governor

KAITLAN BASTON, MD, MSc, DFASAM
Commissioner

July 12, 2024

VIA ELECTRONIC, UPS NEXT DAY DELIVERY

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

Re: Notice of Penalty Assessment

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. The rules are set forth in their entirety at N.J.A.C. 8:44-2.1 through 8:45-2.1.

The Department is issuing this Notice of Penalty Assessment, pursuant to N.J.S.A. 45:9-42.43 after determining that Princeton Women's Services (PWS) located at 1345 Kuser Road, Suite 1, Hamilton, New Jersey is in violation of N.J.S.A. 45:9-42.28 for operating as a clinical laboratory without the requisite license from January 1, 2024 through June 2024, as described in further detail below.

On May 9, 2024, inspectors from the Department's Clinical Laboratory Improvement Services (CLIS) conducted an unannounced inspection of PWS. The inspectors observed that the laboratory was performing Rh(D) testing on patient samples without a current clinical laboratory license. The inspection also revealed serious deficiencies in proficiency testing, failure of the laboratory director to appropriately supervise procedures and ensure quality control, failure to maintain complete and accurate records, and other deficiencies that must be addressed, and were described in the survey report that was sent to PWS by CLIS.

During the inspection, the inspectors informed testing staff of PWS of the need to submit an application to renew the clinical laboratory license along with the requisite fee, and subsequently provided instructions via email on how to create an account in order to submit an application to renew.

On July 11, 2024, CLIS conducted a follow-up inspection of PWS during which CLIS inspectors observed evidence that PWS had performed Rh(D) testing on patient samples in June 2024. By letter dated June 17, 2024, the Department informed PWS that it must cease and desist from performing unlicensed laboratory testing. As of July 12, 2024, the Department has not received an application for renewal of licensure from PWS.

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.

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. Yet PWS has been performing the Rh(D) testing without a license since January 1, 2024 and has failed to submit an application for renewal of its license and the requisite fee.

Pursuant to N.J.S.A. 45:9-42.43, the Department may assess a monetary penalty against a clinical laboratory for violating any provision of the Act or any rule promulgated thereunder in an amount not less than \$100.00 nor more than \$1,000.00 for each violation. Based upon the foregoing, CLIS has determined that PWS is in violation of N.J.S.A. 45:9-42.28 for operating as a clinical laboratory without the requisite licensure from January 1, 2024 through June 2024. **As a result, you are hereby assessed a total monetary penalty of \$6,000 (\$1,000 per month in which unlicensed clinical laboratory testing was performed) pursuant to N.J.S.A. 45:9-42.43.**

Payment of \$6,000.00 must be electronically submitted within 30 days from the date of this notice through the e-payment link on the CLIS website located at <https://www.nj.gov/health/phel/epayments.shtml>. Please select License – Clinical Laboratory/Collection Station following Assessment of Penalty link. Please include **Control Number 2024-CLIS33PWS-01**.

Pursuant to N.J.S.A. 52:14B-1 et seq., you may request a hearing before the Office of Administrative Law to contest this monetary penalty. Your request for a hearing on this matter must be submitted in writing and must be accompanied by a response to the charges contained herein. In the event that you request a hearing, the penalty shall be held in abeyance until such time as the hearing has been concluded and a final decision rendered. If you wish to request a hearing, please include the **Control Number 2024-CLIS33PWS-01** on your correspondence, and forward your request to:

New Jersey Department of Health
Office of Legal & Regulatory Compliance
P.O. Box 360
Trenton, NJ 08625-0360

Email: olrc@doh.nj.gov

Finally, please note that failure to submit a request for a hearing within 30 days from the date of this Notice shall be interpreted as an acceptance of the Department's penalty, thereby negating any further appeal rights and converting the penalty as final and immediately due. In accordance with N.J.S.A. 45:9-42.43, failure to pay this penalty may result in the delinquent account being referred for collection, pursuant to N.J.S.A. 2A:58-10. If you have any questions concerning this matter, please contact Department of Health's Clinical Laboratory Improvement Services at (609) 718-8081.

Sincerely,

A handwritten signature in black ink, appearing to read "Alan Rimmer", with a long horizontal line extending to the right.

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

c: Thomas Kirn, Medical Director
Rosalind Finney, Division Director
Joan Mikita, CLIS Manager

SENT VIA UPS – RETURN RECEIPT REQUESTED