



State of New Jersey
DEPARTMENT OF HEALTH

DIVISION OF PUBLIC HEALTH AND
ENVIRONMENTAL LABORATORIES

PO BOX 361

TRENTON, N.J. 08625-0361

www.nj.gov/health

August 11, 2025

PHILIP D. MURPHY
Governor

TAHESHA L. WAY
Lt. Governor

JEFFREY A. BROWN
Acting Commissioner

VIA ELECTRONIC, FEDEX NEXT DAY DELIVERY, and REGULAR MAIL

Ayad Mudarris, PhD
Laboratory Director
Dae Chul Choi, Laboratory Owner
Advanced Comprehensive Laboratory-
DBA Top Lab
67-71 East Willow Street, Suite 2
Millburn, New Jersey 07041

**Re: Notice of Penalty Assessment
Control No. 2025-CLIS 43637ACL-02**

Dear Sirs:

The New Jersey Department of Health (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. (Act), which was enacted in part to ensure that clinical laboratories in New Jersey are of highest quality. To this end, the Act grants the Commissioner of Health the power to license clinical laboratories in this State and to prescribe standards for the operation of these laboratories. As such, in furtherance of each of the aforementioned statutory objectives, the Department adopted rules that govern the licensure and inspection of clinical laboratories. Those rules are set forth in their entirety at N.J.A.C. 8:44 and 8:45.

The Department is issuing this Notice of Penalty Assessment pursuant to N.J.S.A. 45:9-42.43, after determining that Advanced Comprehensive Laboratory – DBA Top Lab (Laboratory), is in violation of both N.J.S.A. 45:9-42.28 for performing unlicensed collections at 24 off-site locations and N.J.S.A. 45:9-42.40c for reporting fictitious results not based on test performance.

On June 24 and 25, 2025 inspectors from the Department's Clinical Laboratory Improvement Services (CLIS) conducted an unannounced onsite complaint investigation of the Laboratory located at 67-71 East Willow Street, Suite 2, Millburn, New Jersey 07041. The investigation revealed that the Laboratory was routinely deploying 18 of its employees to 24 medical facilities across the State where those employees collect and process clinical samples from patients and later transport the samples back to the Laboratory for testing. Records indicate that from February 3 through June 20, 2025, Laboratory employees collected a total of 10,132

patient blood, urine, oral fluid, and respiratory swabs from those medical facilities that were not licensed as clinical laboratories.

The Department notified the Laboratory by letter dated July 18, 2025, that it must cease and desist collecting clinical samples for testing from all of the 24 off-site facilities because those off site- facilities are not licensed by the Department for clinical laboratory collections. The names and addresses of those facilities are listed in the State deficiency report.

The inspection also revealed that the Laboratory reported fictitious results not based on test performance, in violation of N.J.S.A. 45:9-42.40c. A review of Laboratory records and Respiratory Pathogen Panel (RPP) patient tests performed in the period from March through May 2025, indicated that the Laboratory failed to provide RPP patient reports substantiated by actual true raw instrument data, specifically 58 invalid Luminex Results were released as negative on the final patient reports. Further, eight Rhinovirus/Enterovirus Positive Luminex Results for testing during the same period were altered and released as negative on the final patient reports. When questioned by CLIS inspectors, the Laboratory director was unable to explain why technologists altered instrument data and released fictitious results.

Also by letter dated July 18, 2025, the Department notified the Laboratory that its license to perform bacteriology, chemistry, diagnostic immunology, endocrinology, hematology, toxicology/ TDM, and virology testing was summarily suspended based on the serious nature of the numerous deficiencies found, including, but not limited to, the reporting of fictitious results, which pose a serious threat to public health and safety, and thus, the Laboratory must immediately cease all clinical testing on patient samples.

Pursuant to N.J.S.A. 45:9-42.43, the Commissioner of Health may assess a monetary penalty for violating any provision of the Act or of any rule adopted thereunder shall be subject to a penalty of not less than \$100.00 nor more than \$1,000.00 for each violation. The penalty shall be collected and enforced in summary proceedings under the penalty enforcement law (N.J.S.A. 2A:58-1 et seq.). The cited violations demonstrate a serious disregard for and failure to comply with the Act and the Department's rules. Indeed, the Act and the rules are in place to ensure that clinical laboratories operate in a safe, efficient, and clinically sound manner so that patients receive accurate and reliable test results.

Based upon the foregoing, CLIS has determined that Top Lab is in violation of N.J.S.A. 45:9-42.28 for performing unlicensed clinical laboratory collections at 24 off-site locations from February through June 2025, and as a result, Top Lab is hereby assessed a monetary penalty of \$5,000 (5 months of unlicensed collections x \$1,000). CLIS has also determined that Top Lab is in violation of N.J.S.A. 45:9-42.40c for altering instrument test result data and reporting fictitious results not based on test performance for certain tests collected, performed, and reported during the period from March through May, 2025, and as a result, Top Lab is hereby assessed a monetary penalty of \$6,600 (66 instances of fictitious result reporting x \$100), **for a total monetary penalty of \$11,600.**

Payment of \$11,600.00 must be 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 2025-CLIS 43637ACL-02.**

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 2025-CLIS 43637ACL-02** 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:58-1 et seq.

If you have any questions concerning this matter, please contact Joan Mikita at (609) 718-8081.

Sincerely,



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

c: Thomas Kirn, Medical Director
Rosalind Finney, Assistant Commissioner
Joan Mikita, CLIS CLL Manager