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

PHILIP D. MURPHY
Governor

TAHESHA L. WAY
Lt. Governor

JEFFREY A. BROWN
Acting Commissioner

July 18, 2025

VIA ELECTRONIC, FEDEX NEXT DAY, 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 Summary Suspension of Clinical Laboratory License

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 (Act), N.J.S.A. 45:9-42.26 et seq. 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 regulations that govern the licensure and inspection of clinical laboratories. Those regulations are set forth in their entirety at N.J.A.C. 8:44 and 8:45.

On June 24 and 25, 2025, inspectors from the Department's Clinical Laboratory Improvement Services (CLIS), Clinical Laboratory Licensing Program conducted an unannounced onsite complaint investigation of Advanced Comprehensive Laboratory - DBA Top Lab, ("Top Lab") at 67-71 East Willow Street, Suite 2, Millburn, New Jersey. The investigation revealed multiple serious deficiencies, including Top Lab's reporting of fictitious results not based on test performance, lack of adequate direction and supervision of clinical testing, failure to maintain documentation evidencing employee training and competency to perform toxicology and virology (respiratory panel) testing, failure to perform and document proficiency testing, and use of expired reagents for toxicology testing, among other issues. In addition, and as addressed under separate cover, Top Lab staff are collecting specimens at numerous offsite medical facilities without having the requisite training and without those facilities being licensed as clinical laboratories as required by N.J.S.A. 45:9-42.28. The most serious violations found during the complaint investigation are listed below and those and others are described in detail in the attached survey/deficiency report:

1. Reporting of fictitious results not based on test performance, which is grounds for

suspension of licensure pursuant to N.J.S.A. 45:9-42.40c;
2. Failure of laboratory director and owner to provide adequate direction and supervision of clinical testing, as required by N.J.A.C. 8:44-2.4 (a) and (b);
3. Failure to provide documentation of employee training and annual competency assessments for all testing personnel, as required by N.J.A.C. 8:44-2.6 (e)1-3, and 2.6(g)1;
4. Failure to properly perform and document proficiency testing as required by N.J.A.C. 8:44-2.5(b)2 – 3; and
5. Failure to properly discard expired items as required by N.J.A.C. 8:44-2.8(a)3.

While onsite at the laboratory on June 25, 2025, CLIS inspectors recommended that Top Lab immediately cease all clinical testing based on the serious nature of the deficiencies found.

Based upon the foregoing, the Department has determined that Top Lab's license to perform bacteriology, chemistry, diagnostic immunology, endocrinology, hematology, toxicology/ TDM, and virology testing must be summarily suspended. Pursuant to N.J.S.A. 45:9-42.41, the Commissioner of Health may summarily suspend a clinical laboratory's license when the continued operation poses an imminent threat to public health, safety or welfare. In the present matter, the cited deficiencies demonstrate a serious disregard for and a consistent failure to comply with the Department's regulations. Indeed, the regulations 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; a laboratory's inability to comply with these necessary rules unquestionably poses an imminent threat to patients. In addition, Top Lab's reporting of fictitious test results that were not based on test performance constitutes grounds for suspension of its clinical laboratory license pursuant to N.J.S.A. 45:9-42.40. **Therefore, Top Lab must immediately cease all clinical testing of patient samples.**

Top Lab's license shall remain suspended until such time that it provides CLIS with an acceptable plan of correction with acceptable evidence of correction that addresses the deficiencies in the attached report. For your information, acceptable evidence of correction must include:

1. **How the deficient practice will be corrected or how it was corrected;**
2. **Documentation showing what corrective action has been taken for patients found to have been affected by the deficient practice;**
3. **How the laboratory has identified other patients having the potential to be affected by the same deficient practice and what corrective action has been taken;**
4. **What measure has been put into place or what systemic changes you have made to ensure that the deficient practice does not recur, and**
5. **How the corrective action(s) is being monitored to ensure the deficient practices do not recur.**

Top Lab must implement the acceptable plan of correction so that all deficiencies are corrected to the satisfaction of CLIS before CLIS will consider lifting the summary suspension and permit Top Lab to resume testing. **Additionally, Top Lab must notify all patients who received results for Respiratory Pathogen Panel (RPP) testing during the period from April 1 through June 30, 2025 and recommend that these patients be immediately retested at a different licensed clinical laboratory concerning their RPP status. Documentation of this patient notification must be provided to the Department.**

Please be advised that you may not, under any circumstances, operate as a clinical

laboratory anywhere within the State of New Jersey for the purposes of performing any clinical testing during this period of suspension. You have the right to apply to the Commissioner of the Department of Health for emergency relief to contest this summary suspension. A request for emergency relief shall be submitted in writing and shall be accompanied by a response to the charges contained in this notice. Please include the control number **2025-CLIS 43637ACL-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 result in the continued summary suspension of your clinical laboratory license for all clinical testing, therefore forfeiting all rights to emergency relief. 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

c: Thomas Kirn, Medical Director, PHEL, NJDOH
Rosalind Finney, Asst. Commissioner, PHEL, NJDOH
Joan Mikita, CLIS, PHEL, NJDOH