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

October 8, 2024

Ayad Mudarris, MD
Laboratory Director
Oleg Smurygin, Owner
Mark Gladstein, Owner
Victoria Frenkel, Owner
Vadim Dolsky, Owner
Advanced Comprehensive Laboratory-
DBA Top Lab
67-71 East Willow Street, Suite 2
Millburn, New Jersey 07041

Re: Notice of Summary Suspension of License

Dear Sirs and Madam:

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 (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.

As required by the Act, Top Lab notified the Department in the spring of 2024 of a change in the ownership of the laboratory, and submitted a new application for licensure. The Department is currently reviewing that application, and conducted a recent inspection as part of its standard pre-licensure application review process. To date, the Department has not approved the licensure of the laboratory under new ownership.

On September 9, 2024, the Department conducted an inspection of Top Lab's clinical laboratory operations conducted under its current license. Inspectors from the Department's Clinical Laboratory Improvement Services (CLIS), Clinical Laboratory Licensing Program conducted an announced onsite investigation of Advanced Comprehensive Laboratory - DBA Top Lab, ("Top Lab") at 67-71 East Willow Street, Suite 2, Millburn, New Jersey. The investigation revealed, among other issues, serious deficiencies with Top Lab's performance specifications for the Prothrombin Time / International Normalized Ratio (PT/INR) testing, thus, the accuracy and reliability of patient testing and result reporting cannot be assured. The most serious violations

found during the investigation are listed below and those and others are described in detail in the attached survey/deficiency report:

1. Failure of the laboratory to follow written procedures to ensure the documented quality of the accuracy and reliability of its PT/INR testing and reporting, as required by N.J.S.A. 45:9-42.34;
2. Failure of Management of the clinical laboratory to maintain records and facilities, which are adequate and appropriate for the services offered, as required by N.J.A.C. 8:44-2.7(a);
3. Failure of Laboratory Director to administer the technical and scientific operation of the laboratory including the reporting of findings of laboratory tests, as required by N.J.A.C. 8:44-2.3(b)3;
4. Failure of Laboratory Director to ensure that proficiency testing records are complete, as required by N.J.A.C. 8:44-2.5(b)2.
5. Failure of Laboratory Director to provide documentation for proper instrument maintenance and performance verifications as required by N.J.A.C. 8:44-2.7(i)4, N.J.A.C. 8:44-2.7(i)5, and N.J.A.C. 8:44-2.8(a)1.

Based upon the foregoing, the Department has determined that Top Lab's license to perform Prothrombin Time/ International Normalized Ratio (PT/INR) patient 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. **Therefore, Top Lab must cease Prothrombin Time/ International Normalized Ratio (PT/INR) testing on 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 Prothrombin Time/ International Normalized Ratio (PT/ INR) testing. Corrective action for patients tested for Prothrombin Time/ International Normalized Ratio testing within the past 3 months should be performed as they may have been affected by the deficient practice. Specifically, Top Lab is required to submit an excel file with the plan of correction containing the following parameters for all patients tested within the 3 months previous to the date of this notice: patient name, patient address, date of birth, telephone number, specimen collection

date, and final result. Additionally, the laboratory should notify all patients tested within that timeframe and advise that anyone who is concerned about their Prothrombin Time/ International Normalized Ratio status get re-tested immediately at another licensed clinical laboratory. Documentation of this patient notification must be provided to the Department.

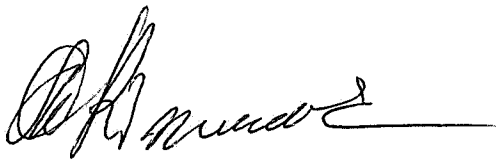
Please be advised that you may not, under any circumstances, operate as a clinical laboratory anywhere within the State of New Jersey for the purposes of performing Prothrombin Time/ International Normalized Ratio (PT/INR) testing during this period of suspension. You have the right to apply to the Commissioner 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 **2024-CLIS43637-ACL-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 Prothrombin time / International Normalized Ratio (PT/INR) 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: Choi Dae-Chul
Thomas Kirn, Medical Director, PHEL, NJDOH
Rosalind Finney, Division Director, PHEL, NJDOH
Joan Mikita, CLIS, PHEL, NJDOH

SENT VIA FEDEX
RETURN RECEIPT REQUESTED