State of New Jersey
DEPARTMENT OF HEALTH
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Commissioner

April 26, 2022

VIA ELECTRONIC, UPS NEXT DAY, CERTIFIED and REGULAR MAIL
Zhonghua Li, MD, PhD, Laboratory Director
Alexandr Zaitsev, MD, Laboratory Owner
Ridgewood Diagnostic Laboratory, LLC
126 State Street, 2nd Floor
Hackensack, New Jersey 07601

CLIS # 0010888

Re: Notice of Proposed Revocation

Dear Drs. Li and Zaitsev:

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 the highest quality. To this end, the Act grants the Department 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. 8:44-2.1 et seq.

On December 28, 2021, the Department's Public Health and Environmental Laboratories' Clinical Laboratory Improvement Services (CLIS) conducted an unannounced routine inspection of Ridgewood's clinical laboratory testing, excluding its molecular SARS-CoV-2 testing. Prior to this inspection, CLIS confirmed that Ridgewood was licensed for the following specialties and tests: Bacteriology: Antibiotic Sensitivities and Urine Culture; Diagnostic Immunology: SARS-CoV-2 IgG and Total Antibody Testing, Allergen specific IgE and Total IgE; and Toxicology: Confirmatory and screening drug testing. The inspection found serious deficiencies with Ridgewood's quality systems for these tests, namely, quality control, quality assurance, documented annual review of written procedures, and personnel, which are necessary to ensure accuracy in and reliability of patient testing and result reporting. The violations found during the inspection were described in detail in a routine inspection report that was provided to Ridgewood on January 3, 2022. A summary of the violations is outlined below:

1. The technical supervisor's refusal to provide documentation to confirm the laboratory had not performed Allergen, Urine Culture, Antibiotic Sensitivities and Antibody patient testing for several tests over an extended period of time, as required by N.J.S.A. 45:9-42.38;

2. Failure to provide complete employee records and documentation of competency as required N.J.A.C. 8:44-2.6(g)(1);
3. Failure to provide documentation of annual review of several written procedures as required by N.J.A.C. 8:44-2.7(c) and N.J.A.C. 8:44-2.8(a)(4); and
4. Failure to ensure quality controls are followed to prevent potentially erroneous patient results as required by N.J.A.C. 8:44-2.8(b)(1).

CLIS required Ridgewood to submit an acceptable plan of correction with acceptable evidence of correction that addresses the deficiencies within 10 days of receipt of the survey report. As explained to Ridgewood, an acceptable evidence of correction needed to include:

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

A plan of correction was received by the Department on January 31, 2022, but it was deemed unacceptable on February 3, 2022. It was unacceptable because Ridgewood failed to provide complete testing personnel records for all personnel in violation of N.J.A.C. 8:44-2.6 (g)1; failed to provide complete total IgE control records; failed to provide documented corrective action for the total IgE quality control failures and failed to provide documented corrective action for the numerous toxicology quality control results that were out of range in violation of N.J.A.C. 8:44-2.8(b). Additionally, the plan of correction stated that Ridgewood would no longer perform SARS-CoV-2 antibody testing, Antibiotic Sensitivities and Urine Culture testing. Accordingly, CLIS removed these tests from Ridgewood's clinical laboratory license.

No additional plan of correction was received as of February 23, 2022. As a result, on February 23, 2022, CLIS performed a follow-up inspection of Ridgewood Diagnostic Laboratory and issued a deficiency report dated March 1, 2022, which cited the laboratory for failing to follow occupational safety and health laws. Specifically, the laboratory failed, as required by N.J.A.C. 8:44-2.7(d)(7), to properly secure a nitrogen gas cylinder and failed to properly store various chemicals in the ancillary toxicology room.

On March 11, 2022, Ridgewood submitted a second plan of correction, which incorporated planned corrections for the occupational safety violations found by CLIS on February 23, 2022. However, this plan of correction was also deemed unacceptable by CLIS as it failed to adequately address the violations. Accordingly, on March 16, 2022, Ridgewood was advised that CLIS rejected its second plan of correction.

After receiving notice that the second plan of correction was rejected, Ridgewood requested a conference call with CLIS. On March 23, 2022, CLIS staff held a conference call with Ridgewood. During the call, CLIS staff explained that some of the documentation submitted by Ridgewood was confusing and not clear as to how the documents addressed the corresponding deficiency.

Regarding the quality control deficiencies, CLIS staff emphasized that the Levey Jennings' quality control charts submitted in the plan of correction for 62 toxicology analytes from May 2021 through November 2021 showed controls that were out of acceptable limits that required corrective action. In addition, the Levey Jennings' charts showed shifts and trends that also needed to be addressed. These were major issues of concern for CLIS because if controls generate a positive or negative shift or trend, the patient specimens tested during this time period may also be affected by the out of control or uncontrolled runs. False positive or false negative results due to the out of control runs provide inaccurate results to the patient's physician who may use these results in assessing the patient's diagnosis and treatment.

On March 24, 2022, Ridgewood submitted a third plan of correction. Despite receiving additional guidance from CLIS during the March 23, 2022 conference call, CLIS found the third plan of correction to be unacceptable in that it again failed to ensure quality controls were followed to prevent potentially erroneous patient results, as required by N.J.A.C. 8:44-2.8(b)(1), specifically for the Diagnostic Immunology IgE allergy testing and Toxicology screening and confirmatory drug testing. Thus, on April 26, 2022, CLIS issued a notice advising that the third plan of correction was unacceptable.

Based upon Ridgewood's failure to correct the serious deficiencies listed above, CLIS has determined that Ridgewood's Allergen specific IgE and Total IgE and Toxicology Confirmatory and screening drug testing should be revoked. Pursuant to N.J.S.A. 45:9-42.40, the Department may revoke a clinical laboratory license for good cause, including but not limited to:

> b. A reasonable finding by the department that the quality of performance of clinical laboratory tests is below those set by the department and that remedial measures such as consultation and training are not accepted or do not result in improvement to a level of proficiency acceptable to the department.

CLIS finds that Ridgewood's quality of performance of the IgE allergy and Toxicology testing are unacceptable, and that Ridgewood has been unable to remediate the violations to the level necessary to demonstrate proficiency. The statutory and regulatory requirements for the operations of a clinical laboratory 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 requirements unquestionably poses a threat to patients. Although Ridgewood was afforded multiple opportunities to correct the deficiencies cited by CLIS, Ridgewood has demonstrated an inability to comply with CLIS's rules and failed to show that it can operate in a clinically sound manner. Because Ridgewood's poor laboratory practices and inability to comply with the statutory and regulatory requirements for clinical laboratory operations negatively impacts the patients who rely on Ridgewood to perform accurate and reliable clinical laboratory testing services, CLIS finds that Ridgewood's clinical laboratory license must be revoked.

Pursuant to N.J.S.A. 45:9-42.41, you may request a hearing before the Office of Administrative Law to contest the Department's decision to revoke your Allergen specific IgE and Total IgE and Toxicology Confirmatory and screening drug testing licenses. 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 revocation 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 forward your request to:

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

Failure to submit a written request for a hearing within thirty (30) days from the date of this notice shall be interpreted as an acceptance of the Department's decision to revoke your Allergen specific IgE and Total IgE and Toxicology Confirmatory and screening drug testing licenses, thereby negating any further appeal rights and converting this action into a final agency decision.

If you have any questions concerning this matter, please contact Joan Mikita, at (609) 406-6830.

Sincerely,

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

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

SENT VIA UPS
RETURN RECEIPT REQUESTED