State of New Jersey
DEPARTMENT OF HEALTH
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Commissioner

December 21, 2021

Rakesh Abbi, MD, 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 Summary Suspension of License

Dear Drs. Abbi 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 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. 8:44-2.1 et seq.

On December 17, 2021, surveyors from the Department's Public Health and Environmental Laboratories' Clinical Laboratory Improvement Services (CLIS) conducted an unannounced complaint investigation of the molecular SARS-CoV-2 testing at Ridgewood Diagnostic Laboratory, LLC (Ridgewood) at 126 State Street, 2nd Floor, Hackensack, New Jersey. The investigation revealed serious deficiencies with Ridgewood's quality systems for its SARS-CoV-2 testing, namely, sample collection, quality control, quality assurance, complete written policies and procedures, and personnel, which are necessary to ensure accuracy in and reliability of patient testing and result reporting. The violations found during the investigation are listed below and also described in detail in the attached complaint investigation report:

1. Laboratory Director's failure to adequately monitor the operation of the laboratory and establish and implement the policies and procedures to support good laboratory practice as required by N.J.A.C 8:44-2.3(b)3;
2. Failure to ensure that SARS-CoV-2 patient samples were properly collected and tested as required by N.J.S.A. 45:9-42.34, N.J.A.C. 8:44-2.7(a) and N.J.A.C. 8:44-2.8(a)7.;
3. Failure to provide complete employee records and documentation of training and competency as required by N.J.A.C. 8:44-2.6(e)1., N.J.A.C. 8:44-2.6(e)2., N.J.A.C. 8:44-2.6(e)3., and N.J.A.C. 8:44-2.6(g)1;
4. Failure to provide complete 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);
5. 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.;

6. Failure to ensure the health and safety of SARS-CoV-2 testing employees by implementing physical and procedural work site controls as required by N.J.A.C. 8:44-2.7(d)7;
7. Failure to ensure the laboratory promptly reported all SARS-CoV-2 patient results to the New Jersey Communicable Disease Service as required by N.J.A.C. 8:44-2.11.

The above deficiencies were found despite the fact that Ridgewood was cited for similar quality systems deficiencies during a CLIS complaint inspection of the SARS-CoV-2 testing and collection practices on April 26, 2021, and thereafter submitted an acceptable plan of correction for the deficiencies to CLIS as a condition for receipt for its clinical laboratory license.

Based upon the foregoing, the Department has determined that Ridgewood Diagnostic Laboratory, LLC's SARS-CoV-2 testing license 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 unquestionable poses an imminent threat to patients. **Therefore, Ridgewood Diagnostic Laboratory, LLC is immediately suspended for all patient SARS-CoV-2 testing and SARS-CoV-2 patient sample collection.** Ridgewood Diagnostic Laboratory, LLC'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.**

Ridgewood Diagnostic Laboratory, LLC 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 Ridgewood to resume SARS-CoV-2 testing and patient sample collection. Corrective action for patients tested for SARS-CoV-2 within the past 3 months should be performed as they may have been affected by the deficient practice. Specifically, Ridgewood 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, Ridgewood collection site location, specimen collection date, final result, and results reported to NJDOH CDS from those collection sites. Additionally, the laboratory should notify all patients tested within that timeframe and advise that anyone currently experiencing COVID-19 symptoms or who are concerned about their COVID-19 status get re-tested immediately. Documentation of this patient notification must be provided to the Department.

Ridgewood must also provide Disclosure of Ownership and Control Interest (CL-9) forms for all current owners of the laboratory, as a discrepancy regarding multiple owners was discovered during the survey.

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 SARS-CoV-2 testing or SARS-CoV-2 patient sample collection 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 **C28-21** 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 SARS-CoV-2 testing and SARS-CoV-2 patient sample collection, therefore forfeiting all rights to emergency relief. If you have any questions concerning this matter, please contact Mary Marks, at (609) 406-6830.

Sincerely,

Alan Rimmer, MD
Executive Director
Clinical Laboratory Improvement Services

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

SENT VIA UPS
RETURN RECEIPT REQUESTED