State of New Jersey
DEPARTMENT OF HEALTH
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March 25, 2022

VIA ELECTRONIC, UPS NEXT DAY, CERTIFIED and REGULAR MAIL
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 Proposed Revocation

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 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.

The Department's Public Health and Environmental Laboratories' Clinical Laboratory Improvement Services (CLIS) received a complaint regarding improper and inadequate SARS-CoV-2 specimen collection and testing conducted by Ridgewood Diagnostic Laboratory (Ridgewood). As a result, CLIS opened an investigation into the complaint. Upon opening the investigation, CLIS investigators confirmed that Ridgewood was licensed by CLIS to provide SARS-CoV-2 molecular testing and was also licensed, through a waiver issued by the Department in response to the COVID-19 pandemic, to operate sixty (60) SARS-CoV-2 specimen collection sites in New Jersey.

After confirming licensure of the laboratory, CLIS investigators conducted an unannounced inspection of one of Ridgewood's collection sites, Indian Chief Tavern, located in Medford, New Jersey, and found multiple deficiencies related to SARS-CoV-2 specimen collection, processing and transmission to the main Ridgewood laboratory for testing. Based on the multiple deficiencies identified during collection site inspection, CLIS investigators immediately conducted an unannounced inspection of the main Ridgewood molecular SARS-CoV-2 testing laboratory on December 17, 2021. The inspection revealed egregious 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 were described in detail in a complaint investigation report that was previously provided to Ridgewood. A summary of the violations is outlined below:

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; and
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 even though Ridgewood was previously cited for similar quality systems deficiencies during a CLIS complaint inspection of its 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.

Due to the serious and egregious rule violations, the Department determined that Ridgewood's continued operation as a SARS-CoV-2 testing and collection laboratory posed an imminent threat to public health, safety and welfare. As such, the Department summarily suspended Ridgewood's SARS-CoV-2 laboratory license on December 21, 2021 for all SARS-CoV-2 testing and patient sample collections, processing and transmission, pursuant to N.J.S.A 45:9-42.41.

To have the summary suspension lifted, CLIS required Ridgewood to: 1) submit an acceptable plan of correction with acceptable evidence of correction that addresses the deficiencies; 2) take corrective action for patients tested for SARS-CoV-2 within the past 3 months of the date of the summary suspension, including submitting an excel file to CLIS with all patient names, patient addresses, dates of birth, telephone numbers, Ridgewood collection site locations, specimen collection dates, final results, and results reported to the Department's Communicable Disease Services; 3) notify all patients tested within 3 months prior to the summary suspension that anyone currently experiencing COVID-19 symptoms or who are concerned about their COVID-19 status should get re-tested immediately and provide CLIS with documentation that the patient notifications were completed; and 4) 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 investigation. To date, Ridgewood has not fully complied with these requirements. While Ridgewood submitted three plans of correction, none of them were acceptable to CLIS. Additionally, Ridgewood submitted incomplete patient information to CLIS and failed to issue evidence of all patient notifications.

Furthermore, Ridgewood continued to test, collect, process and transmit SARS-CoV-2 specimen samples after CLIS summarily suspended its license. Specifically, on December 28, 2021, CLIS conducted an unannounced inspection of Ridgewood's laboratory and discovered that it was still

collecting and testing SARS-CoV-2 samples. As a result, CLIS issued Ridgewood a notice of violation of the summary suspension on December 30, 2021, again advising Ridgewood that it was prohibited from conducting SARS-CoV-2 testing and collection activities. Ridgewood ignored CLIS's violation notice and continued to receive, process and transmit SARS-CoV-2 samples, which was revealed during another follow up unannounced CLIS inspection conducted on February 23, 2022. Ridgewood's refusal to comply with the summary suspension necessitated CLIS to move in Superior Court to enforce the summary suspension, which resulted in a Court Order entered against Ridgewood on March 16, 2022.

Based upon Ridgewood's actions, CLIS has determined that Ridgewood's SARS-CoV-2 testing and collection license 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:

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> 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.
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> . . .
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> g. Violating or aiding and abetting in the violation of any provision of this act or the provisions of the State Sanitary Code.
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> . . .
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> i. Representing that the laboratory is entitled to perform any laboratory procedure or category of procedures not authorized in its license.

CLIS finds that Ridgewood's quality of performance of SARS-CoV-2 testing and specimen collections are unacceptable and that Ridgewood has been unable to remediate the violations to the level necessary to demonstrate proficiency. Even more, Ridgewood blatantly ignored the summary suspension of its license and continued to act as a clinical laboratory for SARS-CoV-2 testing and specimen collections, thereby placing the public's health at risk. Indeed, the above actions demonstrate Ridgewood's serious disregard for and a consistent failure to comply with the Department's rules. 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. Ridgewood's actions evidence that it cannot be trusted to perform appropriate and sound SARS-CoV-2 testing or sample collections. Given the grave consequences that could result from Ridgewood's poor laboratory practices and inability to comply with the statutory and regulatory requirements for clinical laboratory operations, including the potential spread of COVID-19 by individuals who were wrongly given negative test results by Ridgewood, CLIS finds that Ridgewood's SARS-CoV-2 testing and collection 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 SARS-CoV-2 testing and collection license. 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. **You are also reminded that your**

SARS-CoV-2 testing and collection license remains under a summary suspension and, as a result, you are PROHIBITED from operating 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. If you wish to request a hearing, 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

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 SARS-CoV-2 testing and specimen collection license, 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