



**State of New Jersey**  
**DEPARTMENT OF HEALTH**  
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[www.nj.gov/health](http://www.nj.gov/health)

JUDITH M. PERSICILLI, RN, BSN, MA  
*Commissioner*

February 17, 2022

**VIA ELECTRONIC, UPS NEXT DAY and REGULAR MAIL**

Ramon Rego, MD, Laboratory Director  
Rajesh Shah, Laboratory Director, CEO  
Krunal Shah, COO  
Agile Urgent Care  
20 Meadowlands Parkway  
Secaucus, New Jersey 07094

**Re: CEASE AND DESIST NOTIFICATION FOR PERFORMANCE OF  
UNLICENSED LABORATORY COLLECTIONS**

Dear Dr. Rego, Mr. Shah, and Mr. Shah:

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, N.J.S.A. 45:9-42.26 et seq. (the Act), which was enacted in part to ensure that clinical laboratories in New Jersey are of the highest quality. The Act further grants the Commissioner of Health the power to license clinical laboratories in the State and to prescribe standards for the operation of these laboratories. In furtherance of the aforementioned statutory objectives, the Department adopted regulations that govern the licensure and minimum standards of clinical laboratories. See N.J.A.C. 8:44-2.1 et seq.

A surveyor from the Department's Public Health and Environmental Laboratories, Clinical Laboratory Improvement Services (CLIS) conducted a complaint investigation of Agile Urgent Care on February 9, 2022 and two SARS-CoV-2 collection sites managed by Agile Urgent Care on February 8, 2022. The collection sites were located at 100 College Ave, New Brunswick, New Jersey, and 7 Van Dyke Avenue, New Brunswick, New Jersey. Relevant here, the surveyor discovered that Agile Urgent Care collects swabs for SARS-CoV-2 testing and sends the specimens to Bio-reference Laboratories Inc. and Accurate Diagnostic Labs, Inc. The two collection sites operated under Agile Urgent Care send their specimens to Ridgewood Diagnostic Laboratory, LLC, but the sites are not licensed or approved by the New Jersey Department of Health. It should be further noted that the Department issued Ridgewood Diagnostic Laboratory, LLC a summary suspension of its SARS-CoV-2 testing and collection license and, consequently, Ridgewood is not permitted to conduct SARS-CoV-2 testing or specimen collection. The Act prohibits any person from collecting or receiving specimens for analysis by an unlicensed laboratory. See N.J.S.A. 45:9-42.42(b).

As defined by the Act, a clinical laboratory includes "any facility used for the collection, processing and transmission of specimens to another facility for the performance of clinical tests." N.J.S.A. 45:9-42.27. The Act further provides that "[n]o person shall conduct, maintain, or operate

a clinical laboratory or solicit or accept specimens for laboratory examination unless a license therefor has been obtained from” the Department of Health. N.J.S.A. 45:9-42.28.

Agile Urgent Care’s collection testing sites located at 100 College Avenue in New Brunswick and 7 Van Dyke Avenue in New Brunswick fall squarely within the statutory definition of a clinical laboratory as they are collecting, processing and transmitting specimens to another facility for the performance of SARS-CoV-2 PCR testing. Accordingly, Agile Urgent Care must be licensed by CLIS to operate these collection sites. However, Agile Urgent Care’s collection sites are not CLIS licensed clinical laboratory collection facilities.

Based on the above, Agile Urgent Care is in violation of the Act as it is collecting swabs for SARS-CoV-2 testing at the above sited locations in New Brunswick without a CLIS clinical laboratory license. As such, Agile Urgent Care must immediately **CEASE AND DESIST** performing the collection of patient samples at 100 College Avenue, New Brunswick, New Jersey and 7 Van Dyke Avenue, New Brunswick, New Jersey. In addition, Agile Urgent Care must immediately **Cease and Desist** any sample collection at other collection locations that are operated and managed by Agile Urgent Care without a license. Please provide the Department with written confirmation that these practices have ceased within five (5) days of the date of this letter. This written confirmation should be sent to Joan Mikita, Manager of the Clinical Laboratory Improvement Services State Licensure/PT Review Program at P.O. Box 361, Trenton, New Jersey 08625.

If you wish to obtain a CLIS license to perform collection of swabs for SARS-CoV-2 testing, then you may submit a license application to the Department for same. The proper forms can be found on the CLIS website, located at <http://www.nj.gov/health/phel/clinical-lab-imp-services/>.

Be advised your failure to cease and desist from collecting swabs for SARS-CoV-2 testing may result in the Department pursuing administrative and civil sanctions against you in accordance with N.J.S.A. 45:9-42.43 and -42.44. This includes but is not limited to monetary fines and/or a court injunction. Please guide your conduct accordingly.

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  
Public Health & Environmental Laboratories  
NJ Department of Health