



State of New Jersey
DEPARTMENT OF HEALTH

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www.nj.gov/health

PHILIP D. MURPHY
Governor

SHEILA Y. OLIVER
Lt. Governor

JUDITH M. PERSICILLI, RN, BSN, MA
Commissioner

March 18, 2022

VIA ELECTRONIC, UPS NEXT DAY, CERTIFIED and REGULAR MAIL

Muhammad Usman, aka Usman Ghumman, Owner
Best Care Diagnostics Services, LLC
301 Carnegie Center Drive, Suite 100
Princeton, New Jersey 08540

VIA HAND DELIVERY

Muhammad Usman, aka Usman Ghumman
[REDACTED]

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

Dear Mr. Usman:

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.

Investigators from the Department's Public Health and Environmental Laboratories (PHEL), Clinical Laboratory Improvement Services (CLIS) conducted a complaint investigation of Best Care Diagnostics Services, LLC (Best Care Diagnostics) on March 15, 2022, at its principal location, 301 Carnegie Center Drive in Princeton. CLIS also conducted an investigation at three SARS-CoV-2 testing collections sites located at 7 Van Dyke Avenue in New Brunswick; 237 North Harrison Street in Princeton; and 3000 NJ-27 in Kendall Park. Relevant here, the investigator was told by the collection/testing employees at these three sites that they work for Best Care Diagnostics, that the SARS-CoV-2 PCR specimens they collect go to Best Care Diagnostics, and that Best Care Diagnostics was previously called Ridgewood Laboratory, in Hackensack, New Jersey.

Additionally, an employee from Best Care's principal location emailed the investigator a written agreement, dated December 17, 2021, between Best Care Diagnostics and Agile Urgent Care, which is located at 20 Meadowlands Parkway in Secaucus. In this agreement, Best Care Diagnostics agrees to provide Agile Urgent Care with specimen collection services for SARS-CoV-2 testing. Specifically, the agreement provides that Best Care Diagnostics will provide Agile Urgent Care with "specimen collection for testing COVID-19 and other viral respiratory infections," "temporary storage of specimen[s]," and "transportation of specimen[s] to a lab . . . for processing." Of note, the agreement also provides that Best Care Diagnostics will provide Agile Urgent Care with "assistance in maintaining compliance of test collection locations under State or local health department guidelines." However, Best Care Diagnostics did not obtain prior written approval or licensure from the Department for SARS-CoV-2 specimen collection or testing. Additionally, Agile Urgent Care is not licensed or authorized to provide SARS-CoV-2 specimen collection services anywhere in the State.

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.

Best Care Diagnostics falls squarely within the statutory definition of a clinical laboratory as it is collecting, processing and transmitting specimens to another facility for the performance of SARS-CoV-2 PCR testing. Accordingly, Best Care Diagnostics must be licensed by CLIS to conduct this collection. However, Best Care Diagnostics is not a CLIS licensed clinical laboratory collection facility. To the extent that Best Care Diagnostics claims that it is operating under the auspices of Agile Urgent Care, Agile Urgent Care is also not licensed by CLIS to conduct laboratory specimen collections in this State.

Based on the above, Best Care Diagnostics is in violation of the Act as it is collecting swabs for SARS-CoV-2 testing without a CLIS clinical laboratory license. As such, Best Care Diagnostics must immediately **CEASE AND DESIST** performing the collection of patient samples in New Jersey. 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,

A handwritten signature in black ink, appearing to read "Alan Rimmer", with a long horizontal flourish extending to the right.

Alan Rimmer, MD
Executive Director
Clinical Laboratory Improvement Services
Public Health & Environmental Laboratories
NJ Department of Health

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

SENT VIA UPS
RETURN RECEIPT REQUESTED