



State of New Jersey
DEPARTMENT OF HEALTH
PO BOX 361
TRENTON, N.J. 08625-0361

PHILIP D. MURPHY
Governor

SHEILA Y. OLIVER
Lt. Governor

www.nj.gov/health

JUDITH M. PERSICILLI, RN, BSN, MA
Commissioner

December 22, 2022

VIA ELECTRONIC, UPS NEXT DAY, CERTIFIED and REGULAR MAIL

Nateasha Robinson-Burns, Owner
Gentle Hands Mobile Phlebotomy Service
1999 Morris Avenue, Suite 1
Union, New Jersey 07083

VIA HAND DELIVERY

Nateasha Robinson-Burns, Owner
Gentle Hands Mobile Phlebotomy Service
1999 Morris Avenue, Suite 1
Union, New Jersey 07083

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

Dear Ms. Robinson-Burns:

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 an unannounced complaint investigation of Gentle Hands Mobile Phlebotomy (Gentle Hands) on November 3, 2022, at its principal location, 1999 Morris Avenue, Suite 1, Union, NJ 07083. The investigation revealed serious deficiencies with Gentle Hands' compliance with, most notably, clinical laboratory licensure requirements, in addition to deficiencies with employee recordkeeping, occupational safety and health, and quality control requirements. Relevant here, the investigation revealed that Gentle Hands' is collecting patient specimens and sending the specimens to clinical laboratories for testing, even though Gentle Hands does not have a CLIS collection station license authorizing it to collect, process and transmit specimens for clinical testing.

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.

Gentle Hands falls squarely within the statutory definition of a clinical laboratory as it is collecting, processing and transmitting samples to another facility for the performance of laboratory testing. Accordingly, Gentle Hands must be licensed by CLIS to conduct this collection. However, Gentle Hands is not a CLIS-licensed clinical laboratory collection facility. In fact, CLIS advised Gentle Hands March 2017 that it required a clinical laboratory collection station license to operate, yet it continued to operate without a license in violation of the Act.

While on December 15, 2022, Gentle Hands submitted a licensure application to CLIS as well as a plan of correction for the serious statutory and rule violations CLIS inspectors found at Gentle Hands during its inspection, Gentle Hands cannot operate until the deficiencies are corrected to the satisfaction of CLIS and a collection station license is issued to it.

Based on the above, Gentle Hands must immediately **CEASE AND DESIST** performing the collection of patient samples in New Jersey until it is properly licensed by CLIS. 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.

Be advised your failure to cease and desist from collecting samples for 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