



State of New Jersey
DEPARTMENT OF HEALTH

PHILIP D. MURPHY
Governor

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Lt. Governor

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KAITLAN BASTON, MD, MSc, DFASAM
Commissioner

February 10, 2025

VIA ELECTRONIC and FEDEX NEXT DAY

Misja Vogelaar, Laboratory Owner
Natasja Vogelaar, Laboratory Owner
Christine Vogelaar-Pabbruwe, Laboratory Owner
Amjad Aziz, DVM, Laboratory Director
Andy L. Ngo, MD, Laboratory Director
Health Diagnostics and Research Institute, Inc.
540 Bordentown Avenue, Suite 2300
South Amboy, New Jersey 08879

**Re: CEASE AND DESIST NOTIFICATION FOR PERFORMANCE OF
UNLICENSED CHEMISTRY AND TOXICOLOGY LABORATORY TESTING**

Dear Laboratory Owners and Directors:

The New Jersey Department of Health (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. (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 and 8:45.

On September 24, September 25 and September 27, 2024, inspectors from the Department's Public Health and Environmental Laboratories, Clinical Laboratory Improvement Services (CLIS) conducted an unannounced routine inspection of Health Diagnostics and Research Institute, Inc. (Laboratory) located at 540 Bordentown Avenue, Suite 2300 in South Amboy, New Jersey 08879. The inspection revealed serious deficiencies with the Laboratory's quality systems. In addition, the inspectors learned that the Laboratory was performing 19 laboratory tests in chemistry and toxicology. The Department confirmed, following a review of records and interviews with Laboratory staff, that of these 19 tests, the Laboratory is only licensed by CLIS for one test; the Laboratory has been performing the remaining 18 tests in chemistry and toxicology, without first obtaining a license to perform those tests from the Department. Specifically, the

Laboratory was licensed only to perform Vitamin C testing in 2024. Yet, the Laboratory had been performing the following tests without having first obtained the requisite licensure: Asymmetric Dimethylarginine (ADMA), Homocysteine, Kryptopyrrole, Nagalase, Sulphur Amino Acids, Vitamin B1, Vitamin B2, Vitamin B3, Vitamin B5, Vitamin B6, Vitamin A, Vitamin D, Vitamin E, Vitamin K1/K2, Carnitine, Carotenoid, and CoQ10, all of which are chemistry tests, and Histamine, a toxicology test.

During the inspection, the CLIS inspectors identified other serious deficiencies, including failure to perform the required validation of performance specifications before testing and reporting patient test results, failure to control all testing, and failure to maintain complete and accurate records, as further described in the attached survey report.

As defined by the Act, a clinical laboratory is “any facility used for the performance of chemical, bacteriologic, virologic, parasitologic, serologic, hematologic, immunohematologic, biophysical, cytologic or other examinations of materials derived from the human body for the purpose of yielding information for the diagnosis, prevention or treatment of disease or the assessment of medical condition.” N.J.S.A. 45:9-42.27 (emphasis added). 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. N.J.S.A. 45:9-42.28.

Based on the statutes outlined above, the Laboratory falls squarely within the statutory definition of a clinical laboratory because it is performing a variety of clinical testing, including ADMA, Histamine, Homocysteine, Kryptopyrrole, Nagalase, Sulphur Amino Acids, Vitamin B1, Vitamin B2, Vitamin B3, Vitamin B5, Vitamin B6, Vitamin C, Vitamin A, Vitamin D, Vitamin E, Vitamin K1/K2, Carnitine, Carotenoid, and CoQ10 testing.

Although Health Diagnostics and Research Institute, Inc. is currently licensed by CLIS to perform Vitamin C clinical testing, the Laboratory failed to seek approval from CLIS prior to commencing testing for the above-listed 18 clinical tests and is therefore conducting unlicensed testing. As such, the Laboratory must immediately **CEASE AND DESIST** performing ADMA, Histamine, Homocysteine, Kryptopyrrole, Nagalase, Sulphur Amino Acids, Vitamin B1, Vitamin B2, Vitamin B3, Vitamin B5, Vitamin B6, Vitamin A, Vitamin D, Vitamin E, Vitamin K1/K2, Carnitine, Carotenoid, and CoQ10 testing on patient specimens.

Please provide the Department with written confirmation, within five (5) days of the date of this letter, that the Laboratory has ceased performing the above testing. This written confirmation should be sent to Alan Rimmer, MD, Executive Director of the Clinical Laboratory Improvement Services at P.O. Box 361, Trenton, New Jersey 08625 or by email to CLIS@doh.nj.gov, with a copy to Alan.Rimmer@doh.nj.gov.

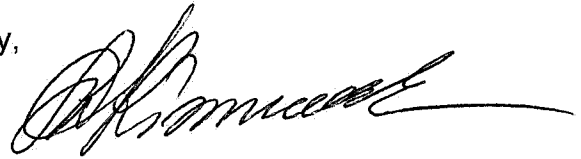
If you wish to obtain licenses to perform any or all of the 18 tests listed above, then you must first submit a written request with supporting documentation to the Department

for same and receive the Department's approval before performing such testing.

Be advised that your failure to cease and desist from conducting unlicensed 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 Alan Rimmer, MD at Alan.Rimmer@doh.nj.gov

Sincerely,

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

Alan Rimmer, MD
Executive Director
Clinical Laboratory Improvement Services
NJ Department of Health

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