State of New Jersey
DEPARTMENT OF HEALTH
PO BOX 361
TRENTON, N.J. 08625-0361
www.nj.gov/health

PHILIP D. MURPHY
Governor

TAHESHA L. WAY
Lt. Governor

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: Notice of Summary Suspension of License

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. To this end, the Act grants the Commissioner of Health the power to license clinical laboratories in the State and to prescribe standards for the operation of these laboratories. As such, in furtherance of the aforementioned statutory objectives, the Department adopted rules that govern the licensure and minimum standards of clinical laboratories. Those rules are set forth in their entirety at 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. While the Laboratory has been licensed by the Department to conduct Vitamin C testing, the inspection revealed that the Laboratory is performing additional chemistry and toxicology testing for which it is not licensed, an issue that the Department is addressing under separate cover.

The inspection also revealed serious deficiencies with the Laboratory's quality systems, 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 on the attached survey report. The most serious violations found during the investigation are listed below, and those and others are described in detail in the attached report:

1. The laboratory failed to provide documentation of annual competency assessments for the general supervisor and technical supervisor, which are employee records required to be maintained by N.J.A.C. 8:44-2.6(g)1.

2. The laboratory failed to provide complete written procedures as required by N.J.S.A. 45:9-42.34, N.J.A.C. 8:44-2.7(a), N.J.A.C. 8:44-2.7(c) & N.J.A.C. 8:44-2.8(a)4.i.-iv.

3. The laboratory failed to maintain work records of quantitative tests as required by N.J.A.C. 8:44-2.7(b), and final patient reports as required by N.J.A.C. 8:44-2.7(i) 1.

4. The laboratory failed to control all patient testing and the laboratory failed to provide documentation of the establishment of quality controls for all patient testing as required by N.J.A.C. 8:44-2.8(a)1.

Based upon the foregoing, the Department has determined that the Laboratory's license to perform Vitamin C testing must be summarily suspended.

Pursuant to N.J.S.A. 45:9-42.41, the Commissioner of Health may summarily suspend a clinical laboratory's license when the continued operation poses an imminent threat to public health, safety or welfare. In the present matter, the failure to maintain adequate records to allow the Department to assess the safety and efficacy of laboratory procedures, the failure to institute quality controls for patient testing and the large number of violations of Department regulations discovered by CLIS inspectors demonstrate a serious disregard for and a consistent failure to comply with the Department's regulations. Indeed, the regulations 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 rules unquestionably poses an imminent threat to patients. **Therefore, Health Diagnostics and Research Institute, Inc. must cease Vitamin C testing on patient samples.** Health Diagnostics and Research Institute, Inc.'s license to perform Vitamin C testing shall remain suspended until such time that it provides CLIS with an acceptable plan of correction with acceptable evidence of correction that addresses the deficiencies in the attached report. For your information, acceptable evidence of correction must include:

1. **How the deficient practice will be corrected or how it was corrected;**
2. **Documentation showing what corrective action has been taken for patients found to have been affected by the deficient practice;**
3. **How the laboratory has identified other patients that could be affected by the same deficient practice and what corrective action has been taken;**

4. **What measure has been put into place or what systemic changes have you made to ensure that the deficient practice does not recur, and**
5. **How the corrective action(s) is being monitored to ensure that the deficient practices do not recur.**

The Laboratory must implement the acceptable plan of correction so that all deficiencies are corrected to the satisfaction of CLIS before CLIS will consider lifting the summary suspension and permit Health Diagnostics and Research Institute, Inc. to resume Vitamin C testing.

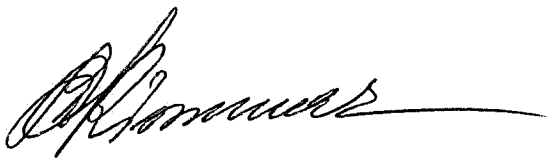
Please be advised that you may not, under any circumstances, operate as a clinical laboratory anywhere within the State of New Jersey for the purposes of performing Vitamin C testing during this period of suspension. You have the right to apply to the Commissioner of the Department of Health for emergency relief to contest this summary suspension. A request for emergency relief shall be submitted in writing and shall be accompanied by a response to the charges contained in this notice. Please include the control number **2025-CLIS1513HDRI-01** 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

Email: olrc@doh.nj.gov

Finally, please note that failure to submit a request for a hearing within 30 days from the date of this Notice shall result in the continued summary suspension of your clinical laboratory license for Vitamin C testing, therefore forfeiting all rights to emergency relief. If you have any questions concerning this matter, please contact Alan Rimmer, MD at Alan.Rimmer@doh.nj.gov

Sincerely,



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