

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

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KAITLAN BASTON, MD, MSC, DFASAM Acting Commissioner

October 23, 2023

VIA ELECTRONIC, UPS NEXT DAY. Ms. Janice Picking Laboratory Owner Janice Picking's Nutrition & Functional Medicine Center 646 W. Ocean Heights Avenue, Suite 101 Linwood, New Jersey 08221

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

Dear Ms. Picking:

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, <u>N.J.S.A.</u> 45:9-42.26 <u>et seq</u>. (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. <u>See</u> N.J.A.C. 8:44-2.1 <u>et seq</u>.

The Department's Public Health and Environmental Laboratories, Clinical Laboratory Improvement Services (CLIS) became aware, after receiving a complaint, that Janice Picking's Nutrition & Functional Medicine Center (JPN&FMC) located at 646 West Ocean Heights Avenue, Suite 101, Linwood, New Jersey, may have been performing clinical laboratory specimen testing without a clinical laboratory license issued by CLIS. As such, on September 19, 2023, CLIS inspectors conducted an unannounced survey of JPN&FMC. The surveyors discovered that live blood cell analysis and Vitamin C and Nitric Oxide strip testing of patient samples was being performed at JPN&FMC without the required license. When interviewed by the surveyors during this inspection, you stated that you have been performing live blood analysis at JPN&FMC since 1998. Further, you stated that between 1998 and the onset of the COVID pandemic, you

PHILIP D. MURPHY Governor

TAHESHA L. WAY Lt. Governor typically performed live blood analysis testing on six patients each week at JPN&FMC. You estimate that you have performed live blood analysis testing on 10 patients in 2023. The survey also revealed serious deficiencies with the laboratory's quality systems, failure to use sterile technique when collecting blood samples by finger prick, use of expired test strips, and numerous other issues about which you were notified by letter dated October 5, 2023.

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." <u>N.J.S.A.</u> 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 of Health. <u>N.J.S.A.</u> 45:9-42.28.

Based on the statutes outlined above, JPN&FMC falls squarely within the statutory definition of a clinical laboratory because testing of patient blood, urine, and saliva samples to determine whether the patient has been infected with pathogens or suffers from a nutritional deficiency is being conducted at that location. These tests are considered high complexity tests and require extensive validations as lab developed tests. Accordingly, JPN&FMC must be licensed by CLIS as a clinical laboratory to conduct these clinical laboratory tests. However, JPN&FMC is not a CLIS-licensed clinical laboratory.

Based upon the foregoing, JPN&FMC is in violation of the Act because it has been conducting the live blood cell analysis and Vitamin C and Nitric Oxide strip testing, which includes chemical, bacteriologic, virologic, parasitologic, and hematologic testing, without the requisite CLIS clinical laboratory license. As such, JPN&FMC must immediately **CEASE AND DESIST** performing all live blood cell analysis and Vitamin C and Nitric Oxide strip testing on patient samples.

Please provide the Department with written confirmation, within five (5) days of the date of this letter, that these practices have ceased. This written confirmation should be sent to Joan Mikita, Manager of the Clinical Laboratory Improvement Services State Licensure/PT Review Program, New Jersey Department of Health, P.O. Box 361, Trenton, New Jersey 08625.

If you wish to obtain a CLIS license in order to perform live blood cell analysis and Vitamin C and Nitric Oxide strip testing, then you must submit an application for clinical laboratory licensure. The required forms can be found on the CLIS website at http://www.nj.gov/health/phel/clinical-lab-imp-services/. A license must be issued by CLIS before any testing of patient samples can be performed.

Be advised that 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 Joan Mikita at (609) 718-8012 or (609) 718-8083.

Sincerely,

Alan Rimmer, MD **Executive Director** Clinical Laboratory Improvement Services New Jersey Department of Health