

State of New Jerzey DEPARTMENT OF HEALTH DIVISION OF PUBLIC HEALTH AND ENVIRONMENTAL LABORATORIES PO BOX 361 TRENTON, N.J. 08625-0361 www.nj.gov/health

JEFFREY A. BROWN Acting Commissioner

Governor

TAHESHA L. WAY Lt. Governor

PHILIP D. MURPHY

July 18, 2025

## VIA ELECTRONIC, FEDEX NEXT DAY, and REGULAR MAIL

Ayad Mudarris, PhD Laboratory Director Dae Chul Choi, Laboratory Owner Advanced Comprehensive Laboratory-DBA Top Lab 67-71 East Willow Street, Suite 2 Millburn, New Jersey 07041

## Re: CEASE AND DESIST NOTICE- PERFORMANCE OF UNLICENSED LABORATORY COLLECTIONS

Dear Sirs:

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 through 8:45.

On June 24 and 25, 2025, inspectors from the Department's Clinical Laboratory Improvement Services (CLIS), Clinical Laboratory Licensing Program conducted an unannounced onsite complaint investigation of Advanced Comprehensive Laboratory - DBA Top Lab, ("Top Lab") at 67-71 East Willow Street, Suite 2, Millburn, New Jersey. The investigation revealed, in addition to serious deficiencies that are addressed under separate cover, that Top Lab failed to obtain licensure for collections at 24 off-site locations where its employees are routinely engaged in the collection and processing of patient samples. Based on inspector review of laboratory records, interviews with the laboratory director and testing personnel, and CLIS records, CLIS determined that approximately 18 Top Lab employees are routinely deployed to 24 medical facilities across the State where those employees collect and process clinical samples from patients, and later transport them back to Top Lab for testing. A review of records shows that from February 3 through June 20, 2025, Top Lab employees collected a total of 10,132 patient blood, urine, oral fluid, and respiratory swabs from those medical facilities. Further, Top Lab failed to provide documentation evidencing the initial training, competencies, or proficiency in proper collection technique, patient safety measures, biohazard disposal, and adherence to laboratory protocols for the 18 employees engaged in collections at those medical facilities.

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.

The Top Lab collection stations listed below fall squarely within the statutory definition of a clinical laboratory as Top Lab staff are collecting and processing specimens at those locations and transmitting those specimens to Top Lab for the performance of laboratory testing. Accordingly, these collection stations must be duly licensed by CLIS. However, none of the Top Lab collection stations listed below are currently licensed by CLIS as a clinical laboratory collection station.

Laboratory Client Code #	Site Name	Site Address
21360	Monica Barrientos, MD	213 60 <sup>th</sup> Street, West New York, NJ 07093
09	New Direction Behavioral	9 Lincoln Park, Newark, NJ 07102
410	Consolidated Healthcare	1000 Broad Street, Bloomfield, NJ 07003
158	Rosa Calderon Service Corporation	15 Broadway, Passaic, NJ 07055
2010	Prime Heart	2010 Springfield Avenue, Maplewood, NJ 07040
901W	Dr. Fiola Sowemimo	901 West Main Street, Freehold, NJ 07728
524	Wilson Antoine, MD	52-4 Underwood Street, 1R, Newark, NJ 07106
1450	Dr. Neelima Vudarla	1450 Parkside Avenue, Trenton, NJ 08638
201C	Dr. Ghassan Chehape	221 Chestnut Street, #201, Roselle, NJ 07203
48P	Rosa Calderon	48 Park Avenue, Paterson, NJ 07501
1551	Sunrise Care	155-157 Mt. Pleasant Avenue, Newark, NJ 07104
55t	Circle of Life Treatment Center	55 Tillinghast Street, Newark, NJ 07108
4771	St. Bridget's Emergency Shelter	47-71 Miller Street, Newark, NJ 07102
131	Community Care	131 Ethel Road, Suite 3A, Piscataway, NJ 08854
43679	Best Care Pediatrics	436 Highway 79, Morganville, NJ 07751

221C	Dr. Ruby Saluja	221 Chestnut Street, #201, Roselle, NJ 07203
2477	Dr. Rizwana Khan	2477 County Road 516, Old Bridge, NJ 08857
605	Irvington Primary	50 Union Avenue, #605, Irvington, NJ 07111
999C	Integrated Wellness	999 Clifton Avenue, Clifton, NJ 07013
1114	Newly Destinied Inc.	1114 Broad Street, Newark, NJ 07114
53g	Apostles' House Grant	24 Grant Street, Newark, NJ 07104
2500	Rothman Institute	2500 English Creek Avenue, #1300, Egg Harbor Township, NJ 08234
404	Jersey State Pain Management	404 32 <sup>nd</sup> Street, Suite 1, Union, NJ 07087
72555	Clinical Neurophysiology & Epilepsy	725 River Road, Suite 55, Edgewater, NJ 07020

Based on the above, Top Lab is in violation of the Act because it is collecting clinical samples for testing from facilities that have not been issued a CLIS clinical laboratory license. As such, Top Lab must immediately **CEASE AND DESIST** performing the collection and processing of patient samples at the above- listed collection stations in New Jersey. **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 at P.O. Box 361, Trenton, New Jersey 08625 or by email to Joan.Mikita@doh.nj.gov.

Be advised that 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) 718-8081.

Sincerely,

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Alan Rimmer, MD Executive Director Clinical Laboratory Improvement Services

c: Thomas Kirn, Medical Director, PHEL, NJDOH Rosalind Finney, Asst. Commissioner, PHEL, NJDOH Joan Mikita, CLIS, PHEL, NJDOH