



Montville Township Health Department
195 Changebridge Road, Montville, NJ 07045
(973)331-3316 phone (973) 331-9287 fax
health@montvillenj.org



Public Health
Prevent. Promote. Protect.

NOTICE OF VIOLATION

March 16, 2021

P4 Clinical
Attention: Dr. Chiraag Patel, Laboratory Director
25 Riverside Drive, Unit 6
Pine Brook, NJ 07058

Re: Compliance Failure

Sent via regular mail and Certified Mail 7015 1520 0000 0482 0250

Dear Dr. Patel,

Since the beginning of the COVID-19 pandemic, our office has received numerous reports of positive COVID-19 results in the Communicable Disease Reporting and Surveillance System (CDRSS) that list your laboratory's address at 25 Riverside Drive in Pine Brook, instead of the address of the patient, and often these reports either include no phone number for the patient, or include the laboratory phone number instead of the patient's. Our office has made numerous previous attempts to have this issue resolved, including several phone calls and emails to your facility. However, this compliance failure continues to occur frequently.

Most recently, on Friday, March 12, 2021, our office was notified of over 300 reports of positive COVID-19 results, and on Monday, March 15, 2021 approximately an additional 30 reports, all listing 25 Riverside Drive as the residential address of the patient, and your facility as the laboratory that processed the samples and entered the report. You and I have communicated several times via email this week in regards to this issue. Per your request, I provided to you via email a CDRSS report with information on each case so that your office could identify and attempt to correct these reports. In an email to me dated March 15, 2021, you indicated that this most recent compliance failure appears to be due to an issue related to software/interfaces. In response, your IT Director, Abhishek Kumar, emailed that she would have the issue reviewed and would respond.

These continued compliance failures are concerning for multiple reasons.

First, it artificially inflates the number of cases for each municipality that Morris County reports each day, which is an inaccurate representation to the public. The Montville Township Health Department also reports our municipality's daily case count to the public, however, we only report those cases that our contact tracers have verified are Montville Township residents. Our department, and our members of the public, are rightly concerned about the number of cases in our municipality, and in accuracy in

reporting. A sudden surge of over 300 cases in 24 hours in our municipality could have caused unnecessary panic among our residents. Thankfully, the county noticed this anomaly, and after contacting our office, noted on their daily report that the current case number for Montville Township is inaccurate due to laboratory error. However, until these reports are corrected, they will still erroneously appear in the case count for our municipality that is reported to the public each day.

Second, it creates a significant amount of additional work for our department at a time during which we are already operating under an unprecedented and challenging workload. Each report of a positive result necessitates a timely response by the local health department which has jurisdiction over the municipality where the patient resides. By inputting 25 Riverside Drive as the patient address, our department is charged with the initial response to reports that do not belong to our jurisdiction, and should be responded to by other departments.

For each report with this inaccurate address, our department does everything that we can to ensure that contact tracing and communicable disease investigation can be conducted by the appropriate health department within the required time frame (first contact attempt within 24 hours of receiving the report). Our contact tracers access the report and then attempt to reach the patient to obtain the correct residential address. If there is an accurate patient phone number, and we are able to reach the patient, we have frequently been told with these reports that 25 Riverside Drive is their work address, and they refuse to provide us with their correct residential address. Other times, there is no phone number, the laboratory phone number, or the phone number is not accurate.

We have in the past also contacted your laboratory by phone and by email to have these reports corrected by your facility, with varying degrees of success.

If our office is unable to obtain the correct residential address from the person tested, and your laboratory refuses or is unable to correct the address in the report, our department has no choice at that point but to revise the residential address to "unknown", add a comment with details explaining the revised address, and note it for our files.

Third, and even more concerning, is that these persons who have tested positive for COVID-19, some of whom have stated that they are your employees, are either refusing contact tracing, or can't be contacted at all. Contact tracing and communicable disease investigation, conducted by local health departments throughout the state, are crucial actions that stop the spread of COVID-19 in our communities and keep the public safe and healthy. During this process, patients are notified of their test results, they are given accurate and timely information on self-isolation, close contacts are identified and given accurate and timely information on self-quarantine, patients and close contacts are provided with answers to any questions that they may have, are linked with additional resources that they may require, and are monitored throughout their isolation and quarantine periods.

When local health departments do not receive reports from laboratories in a timely manner, or at all, then critical information is withheld that they need about cases in their jurisdiction, and they are unable to perform contact tracing and communicable disease investigation. These two tasks, so vital to reducing the spread of this disease, are time-sensitive, and must be accomplished swiftly by local health departments in order to effectively halt the spread of COVID-19 and protect their communities.

Fourth, and perhaps most serious, is that according to the CDRSS report that I provided to you, some of the over 300 reports in this most recent incident date back to as early as August of last year. This delay in reporting renders moot any contact tracing and communicable disease investigation efforts for these cases, and constitutes a serious threat to the public health of each and every community that the persons tested actually do reside in.

Due to the serious nature of these concerns, and the continued failure of your laboratory to comply with communicable disease reporting requirements, our department is issuing this Notice of Violation to your laboratory.

Furthermore, please be advised that:

- As per N.J.A.C. 8:57-1.7(c), a communicable disease report shall contain the home address and telephone of the person tested.
- As per N.J.A.C. 8:57-1.15(c): "A clinical laboratory director who fails to report pursuant to the requirements of this subchapter shall be subject to a fine as set forth at 26:4-129 and 130, or 26:1A-10.
- As per N.J.A.C. 8:57-1.15(c)1, the Department may issue a written notification of this failure and a warning to comply prior to initiating any other enforcement action.
- As per N.J.A.C. 8:57-1.15(c)2: "The Department may also report the clinical laboratory's failure to comply with the provisions of this subchapter to the New Jersey Department of Health and Senior Services, Clinical Laboratory Improvement Service which may initiate enforcement actions as set forth at 45:9-42.4 O, 42.41, and 42.43."
- As per N.J.S.A. 26:1A-10 Violation of State Code, penalty: "Each violation of any provision of the State Sanitary Code shall constitute a separate offense and shall be punishable by a penalty of not less than \$50 nor more than \$1,000. Each such penalty shall be sued for and recovered in a civil action, in any court of competent jurisdiction, by and in the name of the State Department of Health or by and in the name of the local board of health of the municipality in which the violation occurred."

Please note that each inaccurate and/or delayed communicable disease report constitutes a unique and separate violation of the New Jersey State Sanitary Code. Failure to correct the reports that do not comply with the reporting requirements of N.J.A.C. 8:57-1.7, and/or continued failure to comply with the reporting requirements of N.J.A.C. 8:57-1.7, will result in further legal action from this department. Further legal action may include summons to Municipal Court and the issuance of monetary penalties.

Furthermore, please be advised that our department has reported the clinical laboratory's failure to comply with the provisions of N.J.A.C. 8:57-1 to the New Jersey Department of Health and Senior Services (now New Jersey Department of Health or NJDOH), Clinical Laboratory Improvement Service, and that they may initiate enforcement actions as set forth at 45:9-42.4 O, 42.41, and 42.43.

Finally, please be advised that the Montville Township Board of Health requests that you and/or your legal representative appear at a public hearing that will be held during their next regular meeting scheduled for April 12, 2021 at 7:30pm. All Township open public meetings are at this time being held virtually, and the Board of Health meeting information is available on the Township website at <https://montvillenj.org/347/Board-of-Health>. During this hearing, the Board of Health will seek to determine to their satisfaction the reason for this repetitive compliance failure, the documented actions taken by your laboratory to correct the current compliance failures, and the documented actions taken by your laboratory to prevent the future occurrence of such compliance failures.

Should you have any questions regarding this Notice of Violation, please do not hesitate to contact our office at 973-331-3316. Thank you.

Sincerely,



Aimee Puluso, Health Officer

cc: Montville Township Board of Health
Victor Canning, Montville Township Administrator
June Hercek, Montville Township Assistant Administrator
Frank Cooney, Montville Township Mayor
Mary Martorana, Executive Director, NJDOH Clinical Laboratory Improvement Services
Shereen Semple, Director, NJDOH Office of Local Public Health