

## The Road to 1 Million COVID-19 Tests at NorDx Labs

By Nick Adler

On January 14<sup>th</sup>, 2022 NorDx performed its one millionth PCR COVID test. What makes this milestone so amazing is how a small regional laboratory, in under two years, was able to process such volume while consistently maintaining turnaround times that are unmatched by fully automated national laboratories. Performing over one million COVID tests represents a true teamwork approach, unconventional outside the box thinking, and remaining agile with the ability to change instantly.



*NorDx Molecular Team Member: Joseph Sandoval*

This journey began in December of 2019 when NorDx President Stan Schofield saw the global pandemic brewing. Based on his experiences 10 years earlier during the SARS-Cov-1 outbreak, Stan made several critical decisions that put NorDx on the path to success. Having experienced previous supply chain issues, the decision was made to purchase testing reagents versus manufactured test kits. This proved to be the right decision as shortly after the start of the pandemic, test kits were in short supply and the federal government began limiting test kit allocations. Concurrently the NorDx molecular department started developing manual assays, which proved to be the second differentiating factor that allowed NorDx to test when many other local and national laboratories did not have the supplies nor capacity as they were dependent on proprietary instruments and reagents.

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When the Federal CDC identified the markers used for COVID-19, the laboratory staff followed these markers to manually develop NorDx assays for PCR testing and began developing Laboratory Developed Tests (LDTs). This is a laborious process since it is the Clinical Laboratory Improvement Amendments (CLIA) process for a laboratory to develop a test for an assay which does not have the manufacturer's direct approval from the FDA. Further complicating this process, every time a reagent was changed, the assay had to be revalidated, which occurred dozens of times over the next two years.

Through focused teamwork, many across NorDx were instrumental in implementing these manual assays which were developed in record times. One noted validation was for that of Roche's Liat analyzer. This analyzer was normally used to test for influenza and through the validation process, NorDx staff was able to operationalize this kit type of assay and began using the Liat for COVID-19 testing. Throughout 2020 and most of 2021 the positivity rate in Maine remained low which allowed the NorDx molecular lab to pool tests. This pooling had to be validated and once complete, allowed the laboratory to test multiple patients together to conserve limited reagent supplies.



*NorDx Molecular Team Member: Jen Gow*

Thinking outside the box, NorDx staff began sourcing supplies from around the world. This allowed NorDx to purchase bulk reagents versus buying test kits. To this day, these supply chain efforts and unconventional thinking have provided NorDx with uninterrupted testing capacity and the ability to remain ahead of demand.

No matter the department, everyone in NorDx contributed to its testing success. Critical to any specimen being processed is the role of the specimen management team. Upon receipt, the team inspects the specimen for proper labeling, stability, and verifies the requested tests. As the pandemic grew, the specimen management team added additional shifts, dedicated specific employees to manage COVID-19 specimens, and had the tedious responsibility of triaging priority specimens. On any normal day, the specimen management team



receives between 5000-7000 non-COVID specimens for testing, but on its highest days with COVID specimens, the team was processing over 8000 specimens a day.

The NorDx HR team was critical in hiring temporary staff to assist in the production of swab test kits. As the number of COVID-19 cases began to rise in 2020, an assembly line was manned 24/7 for an entire year in the Scarborough lab, taking over all the conference rooms and building kits for the testing sites and NorDx clients.

The logistics department worked nonstop ensuring couriers were constantly picking up specimens throughout the day and night across Maine and New Hampshire.

Since COVID testing was a new realm for NorDx, the MaineHealth Information Systems team was continually working to support interfacing diagnostic equipment and the setup and support of clients. In record time, the Information Systems team built algorithms for symptomatic and asymptomatic tests. As new reporting requirements arose from DHHS and the State of New Hampshire, NorDx's compliance team partnered with Information Systems to develop IT processes that had not previously existed.

Phlebotomy staff were instrumental at the 289 U.S. Route 1 test site for community and asymptomatic testing. When NorDx staff were unable to enter long-term care and assisted living facilities to perform phlebotomy services due to local outbreaks, phlebotomy staff and account managers conducted training for facility staff to perform their own collections.

NorDx Client Support continued to operate the phones, providing uninterrupted client support, notification of critical COVID-19 test results, and scheduling of patients for testing.



*NorDx Molecular Team Member: Sophia Leighton*



Early in the pandemic, NorDx only had enough reagents and materials to test 300 patients a day, but within two months had built the capacity to process 1000 tests per day. As its dedicated laboratory, NorDx always placed the highest priority for MaineHealth facilities, staff, and patients for COVID-19 tests throughout the pandemic.

During the summer of 2020, the State of New Hampshire contracted NorDx to support the testing of nursing facilities, driving daily testing to over 3000 specimens per day. In the fall of 2021, NorDx was contracted by Clear Choice MD to support the New Hampshire state initiative of pop-up testing sites. With the volume of Clear Choice MD and the increased number of cases in the region, NorDx found themselves testing over 5000 specimens per day while still maintaining turnaround times faster than most laboratories across the nation.

As long as there is a need to provide COVID-19 diagnostic services, NorDx will continue to adapt and innovate to ensure patients and clinicians have the proper diagnostic information in the least amount of time. Through a synchronized teamwork approach, NorDx is committed to providing timely and superior quality diagnostic services.