Maintaining Laboratory Services in a Rural Academic Medical Center During the Severe Acute Respiratory Syndrome Coronavirus 2 Pandemic

What Worked and What Did Not (February 29–May 1, 2020)

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In this crisis, leaders are not made, they are revealed
—EDWARD J. MERRENS, MD, CHIEF CLINICAL OFFICER, DARTMOUTH-HITCHCOCK HEALTH, NH

INTRODUCTION
Rural health care systems have their own set of challenges. As the only academic medical center in the state of New Hampshire, the recent severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic heightened those challenges, especially given our close proximity to so many hot-spot states (Massachusetts, New York, Connecticut) where the prevalence and death rates of SARS-CoV-2 have been very high. Accurate, timely, and clinically relevant statewide testing took center stage early on in this pandemic. It dictated how patients should be triaged to dedicated treatment areas of the hospital and how health care workers, first responders, employees, and vulnerable members of society should be protected from unnecessary exposures. A critical part of our early statewide response to this crisis was the coordinated decision making of laboratory medicine, infectious disease, and epidemiology

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- Laboratory services
- Rural
- Academic medical center
- SARS-CoV-2
PREPARATIONS AND TIMELINES FOR THE DARTMOUTH-HITCHCOCK RESPONSE TO THE SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2 PANDEMIC

Dartmouth-Hitchcock Health (DHH), a nonprofit academic health system, provides primary as well as tertiary and quaternary health care to a rural population base of 1.5 million individuals coming from a wide geographic area in New Hampshire and eastern Vermont. Affiliated with Dartmouth College’s Geisel School of Medicine and the National Cancer Institute–designated Norris Cotton Comprehensive Cancer Center, DHH employs more than 1500 primary care doctors and specialists and 500 advanced practitioners in almost every area of medicine throughout the health system, with major community practice locations throughout New Hampshire. DHH is the largest employer in New Hampshire aside from the state itself.

In the last decade, the United States has responded to the threats of the H1N1 influenza A pandemic (2009), Middle East respiratory syndrome (2012), H7N9 avian influenza (2013), Ebola virus disease (EVD) in West Africa (2014) and the Democratic Republic of Congo (2018), and Zika virus (2015). DHMC’s Readiness and Response to Epidemic Infectious Disease Threats (RARE) subcommittee has monitored each of these emerging infections. We have had an epidemic response plan in place since 2003. A high-threat infection (HTI) team evolved out of Dartmouth-Hitchcock’s (DH) response to EVD in 2014. Regularly participating in drills and competency assessments to test DHMC’s readiness, the HTI team of doctors, nurses, laboratory technicians, patient-decontamination technicians, and respiratory therapists have all volunteered to be first responders if a patient suspected of having an HTI arrives at DHMC.

The Laboratory for Clinical Genomics and Advanced Technology (CGAT), within the Department of Pathology and Laboratory Medicine at DHMC, is supported by a director, physician-level and doctoral-level assistant directors, and highly trained technologists. CGAT offers a diverse spectrum of high-complexity DNA testing for genetic diseases, infectious diseases, hematologic diseases, oncology, and pharmacogenomics. As a Clinical Laboratory Improvement Amendments (CLIA)–certified, College of American Pathologists (CAP)–accredited clinical laboratory, CGAT maintains a high level of quality assurance through technical, administrative, and structural mechanisms. Institutional investment in this infrastructure over the last 10 years ensured a readiness that was crucial to our rapid response in this pandemic crisis. With this investment and expertise, 5 new diagnostic SARS-CoV-2 molecular assays were developed and validated in-house to meet the needs of high-throughput testing (symptomatic outpatients) and lower-volume rapid testing (symptomatic inpatients and triaging from the emergency department). Choosing the right test, evaluating the best instrument on which to run it, and predicting the availability of reagents and other supplies were all keys to allowing the institution to remain immune to manufacturer and federal promises that could not match demand as the pandemic spread. An appreciation of the technical time and effort needed to offer SARS-CoV-2 testing throughout the state, stretching from covering 1 shift to 3, resulted in a better understanding by many providers of the complexity of the testing.

In mid-February, 2020, as the coronavirus outbreak in Wuhan, Hubei Province, China worsened, laboratory directors in the CGAT laboratory at DHMC started to consider molecular SARS-CoV-2 assay options in terms of the test type, instrument, likely availability of reagents and other supplies, and laboratory workflow [1]. On February 26, 2020, the New Hampshire Department of Health and Human Services (DHHS) released an updated health alert discussing 3 levels of travel advisories, in response to reports that SARS-CoV-2 had spread to 47 other countries, with more than 82,000 cases reported worldwide (95%–96% in mainland China). Even though there were no confirmed SARS-CoV-2 cases in New Hampshire or Vermont at this time, DHMC had begun planning and anticipating potential needs. Supplies were inventoried, including all personal protective equipment (PPE) that health care workers would need to wear while caring for infected patients. Over the next 6 weeks, 3500 employees were trained in all forms of PPE. We started to coordinate a response with our regional system members, as well as with the states of New Hampshire and Vermont. On February 29, 2020, health officials in Washington State confirmed the first US death from SARS-CoV-2, a state that would become an epicenter for the disease early on. The same day, DHMC stood up incident command (DH-IC), which included physician experts in Infectious disease and public health, a planning chief, safety chiefs, operations chiefs, the Chief Medical Officer, the Chief Clinical Officer, an emergency management team, coordinators for ambulatory and inpatient areas as well as the community group practices, a logistics chief, and a public information officer. The timeline of our response from February 29 to May 1 is summarized in Fig. 1.
By March 2, 2020, there were about 105 SARS-CoV-2–positive cases in 13 states and the first positive case in New Hampshire was reported. On March 11, 2020 the World Health Organization (WHO) declared SARS-CoV-2 a pandemic. Travel bans from Europe (initially excluding the United Kingdom and Ireland), went into effect on March 13, the same day that President Donald J. Trump proclaimed that the SARS-CoV-2 outbreak in the United States constituted a national emergency. Shortly after, DH made the decision to halt all elective procedures in order to preserve PPE and inpatient capacity. Starting on March 19, DH-IC revealed the implementation of its “surge plan” readiness procedures. Daily communications to leadership included a DH-IC scorecard detailing numbers of tested and confirmed positive patients with SARS-CoV-2 in New Hampshire and Vermont; numbers of beds and ventilators in use and available statewide; staffing levels; and availability of supplies, PPE, critical medications, and blood products. A dedicated SARS-CoV-2 unit, capable of critical care delivery, was created and the holding capacity of the emergency department (ED) was expanded. Incoming patients and employees were screened at all medical center entrances for coronavirus disease 19 (COVID-19) symptoms and any out-of-state travel. Self-quarantine requirements were instituted for staff with high-risk exposures, requiring coordination with occupational medicine. Staff and faculty reassignment surveys were completed. The emergency management plan was coordinated with other hospitals in both New Hampshire and Vermont, including multistate triage and transfer plan. Preparations were made to augment the number of inpatient beds, including an increase in critical care bed capacity by 250% as well as a morgue expansion.

CGAT went live with the US Centers for Disease Control and Prevention (CDC) assay (2 runs per day, results 12–24 hours after specimen receipt in laboratory) on March 17 and the Abbott m2000 assay (4 runs per day, results in 12–24 hours) on March 24 [1]. In the state of Vermont, a stay-home-stay-safe requirement went into effect on March 25 followed, the next day, by Vermont school closures for the rest of the academic year. On March 27, a New Hampshire stay-at-home requirement and closure of schools went into effect. By March 28, confirmed US deaths from coronavirus doubled from 1000 to 2000 in 2 days, with more than 55,000 confirmed cases in New York, 4257 confirmed cases in Massachusetts, and 1524 in Connecticut. By March 30, 27 states had stay-at-home orders.

As of April 29, 2020, the number of active cases in the United States had risen to 1,012,583 with 58,355
deaths (Table 1). The deaths from SARS-CoV-2 in New Hampshire on that date (n = 60) represented 3% of the total diagnosed cases (n = 2010). Positive cases by county within the state showed many more cases in more densely populated counties of Rockingham, Hillsborough, Strafford, and Merrimack in the south-east of the state bordering with Massachusetts (Fig. 2). Across the 26 hospital sites from which we received specimens for SARS-CoV-2 testing (some from across the Vermont border), the positivity rate increased from 3.37% (the week of 3/17/20–3/23/20) to 6.45% (the week of 4/28/20–5/4/20). On May 1, CGAT went live with a newly validated and readily available rapid Atila isothermal assay (results in 3–4 hours). Limited reagents also became available for the Diasorin Focus assay (results in 3–4 hours).

WHAT WORKED
Clinical laboratories are held accountable by numerous national and federal accrediting bodies (College of American Pathologists [CAP], US Food and Drug Administration, American Association of Blood Banks [AABB], Foundation for the Accreditation of Cellular Therapy [FACT], Centers for Medicare & Medicaid Services [CMS]). They provide millions of quality test results and interpretations to diagnose, treat, and monitor human disease in a highly efficient environment. They serve the needs of every department by competently operationalizing complex workflows to get specimens delivered to the laboratory for testing. However, they often remain the silent partner. The public (even those in the medical field) do not know what clinical laboratories are and the role they now play in medicine. This pandemic crisis changed that, shining a bright light of public attention and putting testing at the forefront of the national response. The efforts to provide the testing needed to identify, isolate, and treat SARS-CoV-2–positive patients were both facilitated and challenged. The following worked well:

1. DH-IC shaped our laboratory response to the pandemic by recognizing very early on the importance of understanding and leveraging the testing capabilities at DH. The synergistic relationship between experts in infectious disease, epidemiology, and laboratory medicine to facilitate new assay validation and develop evidence-based testing algorithms, ordering menus, and reporting templates was critical in helping the rural health system avoid being overwhelmed. This crucial support to the clinical laboratories was enabled by the following:

- The appointment of the DH Administrative Director of the Clinical Laboratories as the DH-IC Planning Chief: In this position, this individual’s exceptional operational skills and expert advice about all testing ensured optimized laboratory communications with members of the DH-IC, and new and detailed insight by DH-IC into the challenges of selecting, developing, and validating new clinical diagnostic molecular assays.

- Communication coordination: DH-IC helped to provide regular and consistent decisions regarding testing updates, with evidence-based information, timelines, specific clinical indications, and standardized ordering triages (aligned with state recommendations).

- New Hampshire state laboratory coordination: DH-IC epidemiologists and laboratorians coordinated policy and procedure updates with colleagues at the state laboratory. This coordination enabled test backlogs throughout the state to be cleared by DHMC to maintain result turnaround times.

- SARS-CoV-2 test ordering control: early on during the surge planning, DH-IC decided to limit

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<tr>
<th>TABLE 1</th>
<th>Severe acute respiratory syndrome coronavirus 2 cases in New Hampshire and nationally, April 29, 2020</th>
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<tbody>
<tr>
<td>United States active cases</td>
<td>1,012,583</td>
</tr>
<tr>
<td>New Hampshire active cases</td>
<td>2010</td>
</tr>
<tr>
<td>Vermont active cases</td>
<td>862</td>
</tr>
<tr>
<td>United States deaths</td>
<td>58,355</td>
</tr>
<tr>
<td>New Hampshire deaths</td>
<td>60</td>
</tr>
<tr>
<td>Vermont deaths</td>
<td>47</td>
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</tbody>
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In New Hampshire (DHHS data)
- Persons, in total, diagnosed with SARS-CoV-2 | 2010 |
- Recovered | 936 (47%) |
- Deaths attributed to SARS-CoV-2 | 60 (3%) |
- Current cases | 1014 |
- Persons, in total, hospitalized for SARS-CoV-2 | 249 (12%) |
- Current hospitalizations for SARS-CoV-2 | 106 |

Data from NH Division of Public Health Services.
the providers who were allowed to order a SARS-CoV-2 test. This decision standardized the test requests and provided clean, clinically relevant data. It also helped the institution better understand the need for test assays with shorter and shorter result turnaround time to enable patient triaging from the ED.

- Emergency capital requests: DH-IC immediately approved any capital, test reagents, and supplies purchases to bring up SARS-CoV-2 molecular testing capabilities, serology testing, and convalescent plasma treatment through our departmental Apheresis/Blood Donor Program. By May 1, the products received and invoiced totaled $1,343,275, with additional purchase orders issued for $3,683,849 to sustainably meet the increased need for polymerase chain reaction (PCR)-based and antibody-based SARS-CoV-2 testing (Table 2).

- Supply chain: DH-IC assigned the clinical laboratories a dedicated supply chain representative to facilitate, wherever possible, the rapid acquisition of contracts, capital, reagents, and PPE.

- Access to state relief funds for testing capital and supplies: DH-IC ensured that the clinical laboratories had immediate access to letters of need from our Chief Legal Officer & General Counsel for State to justify state relief funds.

2. A laboratory COVID task force comprising DHH laboratory managers, section supervisors, a quality manager, the client response team, phlebotomy, and the laboratory specimen receiving staff from every hospital laboratory in the health system helped identify and coordinate responses to staffing shortages, risk assessments, test run times, couriers, and critical supplies such as swabs, universal transport medium, and PPE. Initially meeting by WebEx at the same time daily (March 16–20), the meetings were spread out to 3 times a week, starting March 23. The cooperation between the regional health system laboratories was swift and comprehensive.

3. Research opportunities: research opportunities to collect patient specimens for new assay development and validation, and many epidemiologic studies, highlighted the importance of storing high-quality biospecimens in a CLIA-approved environment to swiftly translate research initiatives into clinical reality. These specimens, collected from consented patients recovering from SARS-CoV-2
throughout the state, were used in the development and validation of clinical serology assays as well as evaluating the use of antibody-rich plasma as a COVID-19 treatment. Supported by federal government agencies, including the FDA and the Biomedical Advanced Research and Development Authority, and with the Mayo Clinic serving as the institutional review board, the blood donor program at DHMC collected and processed COVID-19 convalescent plasma to treat patients throughout the state of New Hampshire. The established DHH institutional biorepository, housed in the Department of Pathology and Laboratory Medicine, was capable of accommodating new initiatives such as these.

4. Nimble and responsive laboratory testing and validation: when faced with shortages of swabs, our laboratory worked to validate other potential swabs. With a national shortage of viral transport media, our laboratory developed our own media. In ongoing reductive work, the laboratory developed mechanisms and validations on dry swabs that did not require transport media.

WHAT DID NOT WORK
1. Conflicting recommendations and erroneous information: efforts to combat the SARS-CoV-2 pandemic were hindered by erroneous and conflicting national information as to the availability and validity of the coronavirus diagnostic test. This confused and misled not only our patients but our staff and many providers. Areas of particular confusion included:

- Recognizing the difference between a diagnostic test on symptomatic patients (for which our assays were validated) versus a screening test in an asymptomatic population.
- Trying to explain the nuances of what a robust new assay validation entails so that better comparisons and contrasts can be made with the Emergency Use Authorization products that have flooded the market since March 2020.
- Distinguishing between specimen sampling and testing: specimen sampling took place at sites throughout the state but testing for DH patients was only performed at DHMC.
- Understanding that accurate test results depend on appropriate and competent sampling, and that the result turnaround time depends on the transport time to the laboratory where testing will occur, receipt and preparation of that specimen, the assay and instrumentation used, the technical expertise required to perform these highly complex molecular tests across multiple shifts, and appropriate resulting into the patient’s electronic medical record (or other methods of submitting results back to providers if the specimens have come from nonaffiliated collection centers).

2. New Hampshire state politics: while we continued to work collegially and professionally with our New Hampshire state laboratory to clear state-testing backlogs and share reagents and supplies, political decisions about testing sometimes over-ruled sound, evidence-based science. State health alerts and advisories from adjacent New Hampshire and Vermont were often uncoordinated, which resulted in

<table>
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<th>TABLE 2</th>
<th>Emergency capital requests for testing capabilities approved by Dartmouth-Hitchcock Health, as of May 1, 2020</th>
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<tbody>
<tr>
<td>Category</td>
<td>Purchase Orders Issued ($)</td>
</tr>
<tr>
<td>SARS-CoV-2 PCR testing supplies</td>
<td>4,093,050</td>
</tr>
<tr>
<td>Capital</td>
<td>138,728</td>
</tr>
<tr>
<td>Serology testing: clinical chemistry</td>
<td>130,798</td>
</tr>
<tr>
<td>Convalescent plasma: apheresis/blood donor program</td>
<td>26,951</td>
</tr>
<tr>
<td>Swabs/transport media</td>
<td>637,602</td>
</tr>
<tr>
<td>Total</td>
<td>5,027,124</td>
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different testing strategies for hospitals situated on the state borders. Although physically being treated at our institutions in New Hampshire, we were required to abide by the testing requirements of the state of Vermont for residents in that state.

3. Elective surgery planning: carefully considered, evidence-based test triaging by DH-IC, based on CDC published guidelines, was misinterpreted by providers in the name of published statements by their professional associations (American College of Obstetricians and Gynecologists, American College of Surgeons, American Society of Anesthesiologists, Association of Perioperative Registered Nurses, American Heart Association) [2,3]. It took the influence of DH-IC to raise awareness that appropriate PPE was always made available to our providers and that a test performed on an asymptomatic patient coming in for elective surgery was not what the SARS-CoV-2 molecular test was validated for.

4. School and daycare closures: when local school and daycare centers closed, the impact on the ability of both staff and faculty to continue to provide patient services was profound. When elective surgeries were suspended, the reduction in specimen volumes allowed flexibility in coverage in the clinical laboratories. With the return to elective surgeries, and a ramp up in ambulatory testing while schools and daycare centers remained closed, staffing the coverage of key services remained a challenge. Efforts by the College of American Pathologists to get CMS approval for surgical pathologists to sign out patient slides from an office at home, as well as render primary diagnoses from digital images [4], enabled more flexibility for faculty to get back to work.

**SUMMARY**

Through the early establishment of a DH-IC, planning for a surge in SARS-CoV-2 cases in New Hampshire was highly efficient, building on prior institutional preparations for the monitoring of new, emerging infections. The proactive and visionary work of molecular diagnostic teams in the DH clinical laboratories resulted in us being able to validate an array of new diagnostic test platforms for SARS-CoV-2, to meet the turnaround time and sensitivity needs of the regional population that we serve. We used our existing regional laboratory infrastructure to coordinate testing strategies, reagents, and supplies. A respectful and supportive relationship with the New Hampshire state laboratory maintained a consistently fast SARS-CoV-2 test result turnaround time, statewide. We met the challenges head-on and were not overwhelmed.

**DISCLOSURE**

The authors have nothing to disclose.

**REFERENCES**


