Empowering academic labs and scientists to test for COVID-19

James Jordan Steel1, John C Sitko1, Matthew G Adkins1, Steven CM Hasstedt1, Joseph W Rohrer1,2 & Erin A Almand1
1Department of Biology, USAir Force Academy, Colorado Springs, CO 80840, USA; 210th Medical Group, USAir Force Academy, Colorado Springs, CO 80840, USA; *Author for correspondence: james.steel@usafa.edu

BioTechniques 69: 00–00 (October 2020) 10.2144/btn-2020-0079
First draft submitted: 3 June 2020; Accepted for publication: 4 June 2020; Published online: 25 June 2020

KEYWORDS:
asymptomatic ● COVID-19 ● higher education ● RTPCR ● SARS-CoV-2 ● testing

The lack of widespread COVID-19 testing and the prevalence of asymptomatic infections have been major factors in the current pandemic. Despite the improvements in clinical testing, as we move toward reopening USA, widespread surveillance testing becomes critical. Academic (nonmedical) labs can help provide such testing; the CDC-approved guidelines for COVID-19 testing require routine equipment and protocols that are commonly used in academic research labs around the country. Faculty at the authors’ institution were successfully able to test asymptomatic students for COVID-19. By empowering nonmedical academic scientists with preexisting knowledge, expertise with the protocols, and access to the instruments, an additional 1.2–3.5 million COVID-19 tests could be processed each day at local universities and academic labs.

SARS-CoV-2, the causative agent for COVID-19 continues to decimate high-risk populations, cripple economies and stress an overtaxed medical system. On the front lines, medical personnel plead for increased personal protective equipment, more test kits and faster turnaround times. With this highly communicable virus, rapid testing is essential to identifying and isolating infected individuals, slowing the spread and containing the disease. Some countries, such as South Korea and Iceland, implemented widespread testing of their populations, resulting in less cases, fewer fatalities and an intact economy [1]. This inverse relationship, whereby increased COVID-19 testing leads to decreased impacts on society, means businesses and schools can reopen safely and the public health concerns remain low because the presumptive infection status of each individual is known, regardless of disease severity. Recent studies of complete populations on cruise ships and isolated aircraft carriers have shown that up to 50% of cases are asymptomatic [2–4]. These individuals do not have symptoms and therefore may not be isolating, further spreading the virus to individuals who may not be so fortunate. Despite this important, poorly understood population of asymptomatic individuals, the scarcity of reagents and the testing backlog in overworked diagnostic labs currently limits testing to symptomatic individuals. According to CDC guidelines, only hospitalized patients (Priority 1) and healthcare workers (Priority 3) are tested if asymptomatic [5]. With calls for the economy to reopen, implementation of robust testing could reduce the potential risk for a resurgent outbreak [6]. Large-scale testing programs can be (and have been) instrumental in identifying asymptomatic and presymptomatic carriers, yet this approach comes down to capacity: who will perform these tests and how will they do it? In a time of social media, crowdsourcing, citizen scientists and resource pooling, one invaluable group remarkably remains overlooked: the nonmedical academic scientist.

Early in the pandemic, efforts at universities in California [7] and Washington [8] proved the utility of research labs performing large, wide-scale testing in their communities. Academic labs have the expertise and capabilities to test for COVID-19; however, this vast resource remains untapped and left out of most public health conversations. Nonmedical academic scientists provide the scientific knowledge that allows companies to develop diagnostic kits, vaccines and therapeutics, yet a majority of them are not involved in COVID-19 testing. A recent survey of NIH-funded labs showed that nearly 40% have the capability for COVID-19 testing, but only 3% are actually involved in current testing [9]. The technique most commonly used to detect current infection is already routinely utilized across the country in labs of all sizes, and even taught to undergraduate students: quantitative reverse transcription PCR (qRT-PCR).

The technique of qRT-PCR is simple, effective and in widespread use. It is the starting point for most viral clinical diagnostics and was the first screening technique developed for SARS-CoV-2, using a nasal swab sample to screen for viral RNA from the virus. Specific primers and probes complementarily bind to the viral genome and allow highly specific identification of SARS-CoV-2 RNA, indicating the presence of the virus in the infected sample. In addition to the CDC-approved qRT-PCR protocol for detecting SARS-CoV-2 in nasal swabs, there are over 60 other USFDA Emergency Use Authorized kits. For these kits, the primers, probes and reagents are publicly available for purchase, while the diversity of manufacturers ensures there is a protocol for most labs’ current setups, meaning that no additional instrumentation is required. The ease of these techniques and their widespread use in collegiate teaching and research labs means the capabilities to perform these tests exist in most college and university biology laboratories. Could this untapped capacity...
make a meaningful difference to the testing gap? Our research team explored the feasibility of using the expertise of PhD and MS level faculty to run the qRT-PCR CDC protocol with the currently existing infrastructure at our university.

Our team used the CDC-recommended protocol and reagents to develop a robust sampling plan for students at our university. Including the initial swabbing, the RNA extraction, qRT-PCR setup and the 75-min qRT-PCR cycling parameters, the entire protocol took under 4 h. Our sampling and protocol process had the capacity to run up to 22 samples every 90 min, the rate-limiting step being that our lab is equipped with only a single qRT-PCR thermocycler.

Due to processing restrictions based on the availability of the thermocycler, we sought to determine how common these instruments are and whether there are enough to provide a valuable resource in testing efficiency. To determine abundance of these machines, the test team used market research and conservative estimates (Table 1). The data showed a growing demand among research institutions for qRT-PCR. Market estimates show that between 9975 and 23,460 qRT-PCR or digital thermocyclers are present in research facilities and whether there are enough to provide a valuable resource in testing efficiency. To determine abundance of these machines, the test team used market research and conservative estimates (Table 1). The data showed a growing demand among research institutions for qRT-PCR. Market estimates show that between 9975 and 23,460 qRT-PCR or digital thermocyclers are present in research facilities.

| Description                                      | Low estimate | High estimate |
|--------------------------------------------------|--------------|---------------|
| Estimates of the US qRT-PCR market size          | $1.5 billion‡ | $1.8 billion¶ |
| Research share of qRT-PCR market                 | 38%†         | 38%†          |
| Research market for qRT-PCR in USA               | $570 million | $670 million  |
| Market share that is equipment purchases         | 35%‡         | 35%‡          |
| Value of qRT-PCR equipment purchased each year for research in USA | $200 million | $234 million  |
| Price of qRT-PCR thermocycler                    | /$100,000§   | /$50,000§     |
| Number of qRT-PCR thermocyclers purchased in US research last year | 1995         | 4681          |
| Number of qRT-PCR thermocyclers purchased in last 5 years | 9975         | 23,406        |
| Hours available to run each day                  | 8            | 10            |
| Hours to run a 96-well plate                     | 1.5          | 1.5           |
| Patients per 96-well plate                       | 22           | 22            |
| Number of individuals that US research institutions could test daily | 1,170,400    | 3,432,330     |

US research institutions could test between 1.2 and 3.4 million samples for SARS-CoV-2 each day if their RT-qPCR thermocyclers were fully utilized. All monetary amounts are in US dollars.

1 https://www.grandviewresearch.com/industry-analysis/real-time-pcr-qpcr-digital-pcr-dpcr-market
2 https://www.verifiedmarketresearch.com/product/global-real-time-pcr-and-digital-pcr-market-size-and-forecast-to-2025/
3 https://www.marketsandmarkets.com/Market-Reports/genomics-market-613.html
4 https://www.alliedmarketresearch.com/polymerase-chain-reaction-technologies-market
5 Based on prices listed by ThermoFisher and Bio-Rad.

Table 1. Estimates of the number of individuals that could be tested for SARS-CoV-2 in research institutions.
figures, the lab must be CLIA certified. This process requires extensive paperwork, record keeping, training logs and certified equipment; however, it is feasible, especially if seeking CLIA certification as an extension of an existing CLIA-certified lab.

Another potential barrier for COVID-19 testing in an academic setting is the availability of appropriate personnel to run the tests. Despite qRT-PCR’s relatively easy experimental setup, it does require trained and qualified personnel to run the assays, which would pull these scientific experts away from other productive projects. At the authors’ institution, a rotation has been developed in order to help provide routine COVID-19 testing for students and staff while having minimal impact on other teaching and research requirements.

As we move to reopen our economy and brace for the next wave of this pandemic – or perhaps another pandemic altogether – we desperately need to plan for more widespread testing. We need to empower and call upon academic scientists to perform these tests. Academic and research centers have the equipment and expertise to run over 1 million COVID-19 tests per day, and this resource cannot be ignored. Nonmedical laboratories possess the competence and capacity to aid with the massive-scale testing needed to emerge from a COVID-19 lockdown. Instead of underutilizing this resource, we should harness their exceptional knowledge and scientific power to help us overcome this pandemic.

Author contributions
J Steel, J Rohrer and E Almand: conceptualization, methodology, investigation, project administration and writing. J Sitko: data curation, visualization, conceptualization, investigation and methodology. M Adkins: investigation and resources. S Hasstedt: project administration.

Acknowledgments
We would like to thank the USAFA IRB for their expedited review of our project (FAH20200018H). We also appreciate Rushika Perera for providing SARS-CoV-2 RNA for a positive control. We are grateful for USAFA leadership that has supported and encouraged this research study.

Financial & competing interests disclosure
Funding was provided by the Defense Health Agency to the USAFA iGEM team (FA7000-20-2X-9310) and from the United States Air Force Academy, Department of Biology. The authors have no other relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript apart from those disclosed.

No writing assistance was utilized in the production of this manuscript.

Ethical conduct of research
The authors state that they have obtained institutional review board approval from US Air Force Academy for the research described.
Data & materials availability
All data is available in the main text and additional questions/inquiries can be directed to the corresponding author.

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References
Papers of special note have been highlighted as: • of interest
1 Gudbjartsson DF, Helgason A, Jonsson H et al. Spread of SARS-CoV-2 in the Icelandic population. N. Engl. J. Med. NEJMoa2006100 (2020).
   • Highlights the effects of abundant testing and how it lowers the impact on the society and economy.
2 Bai Y, Yao L, Wei T et al. Presumed asymptomatic carrier transmission of COVID-19. J. Am. Med. Assoc. 323(14), 1406–1407 (2020).
   • Discusses abundance of asymptomatic infections which are likely a major contributor to the spread of COVID-19 around the globe.
3 Ali I, Stewart P. USS Theodore Roosevelt: most sailors positive for COVID-19 showed no symptoms of infection. Task and Purpose (2020). https://taskandpurpose.com/news/uss-theodore-roosevelt-sailors-coronavirus-asymptomatic
   • Department of defense-specific example of asymptomatic infections and testing.
4 Abdullah C, Parris J, Lie R, Guzdar A, Tour E. Critical analysis of primary literature in a master’s-level class: effects on self-efficacy and science-process skills. CBE Life Sci. Educ. 14(3), ar34 (2015).
   • Highlights the capabilities of scientists with advanced degrees and their ability to perform the required tests.
5 Interim Guidance: Healthcare Professionals 2019-nCoV | CDC. Centers Dis. Control (2020). http://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-criteria.html
   • CDC guidelines on COVID-19 and asymptomatic infections and proper protocols.
6 Collins K. Coronavirus testing needs to triple before the U.S. can reopen, experts say. New York Times, 17 April 2020. http://www.nytimes.com/interactive/2020/04/17/us/coronavirus-testing-states.html
   • Highlights the need for more testing to stop COVID-19.
7 Conger K. Testing pooled samples for COVID-19 helps Stanford researchers track early viral spread in Bay Area. Stanford Med. (2020). http://med.stanford.edu/news/all-news/2020/04/testing-pooled-samples-to-track-early-spread-of-virus.html
   • Highlights the need for testing to track early spread of virus.
8 Leadership Update from the Seattle Flu Study. Seattle Flu Study (2020). https://seattleflu.org/scan
9 Maxmen A. Untapped potential: more US labs could be providing tests for coronavirus. Nature (2020). https://www.nature.com/articles/d41586-020-01154-6
10 Higher Learning Commission. Determining qualified faculty through HLC’s criteria for accreditation and assumed practices: guidelines for institutions and peer reviewers (2016). https://www.hlcommission.org/Publications/determining-qualified-faculty.html