Overview of Tests for COVID-19

There are three main testing methods for COVID-19:

1. **RNA test**: A test for the virus that causes COVID-19 respiratory illness. (Figure 1)

   The test is conducted usually from a swab of the deep nasal cavity, although saliva has been explored as alternative sample. The RNA test’s maximum usefulness extends from a period of about a week before symptoms occur to about 20 days following symptom onset. During this entire period the infected person is considered able to spread the virus. This test is typically used to diagnose symptomatic individuals but has also been useful to identify asymptomatic carriers of the virus who do not get sick but do spread the virus, and mildly symptomatic individuals who require minimal medical intervention but can also spread.

   This virus RNA test has been used effectively in South Korea to control COVID-19 pandemic spread by testing anyone who would volunteer and all who showed some clinical symptoms.
of a respiratory disease. But due to severe test shortage in the U.S., the policy so far has been to restrict RNA testing only to symptomatic individuals, to healthcare providers who were demonstrably exposed to a virus-infected individual, to people with underlying medical vulnerabilities who had a high chance of being exposed to the virus, and, to a rarer extent, to people who were identified as having come in contact with an infected individual.

In the future, the testing capacity in the U.S. might increase, at which time regular surveillance of new infection might become a reality.

RNA testing for coronavirus is typically performed in central laboratories such as LabCorp or Quest on large instruments that can test hundreds to thousands of samples in a day (Figure 2a).

Central lab testing of The Claremont Colleges (TCC) students, faculty, and staff can be facilitated by setting up on-campus sample collection and shipment sites in collaboration with a central laboratory such as Quest or LabCorp. At this time, testing priority needs to be on individuals who are at least mildly symptomatic.

One important limitation is that central laboratory testing typically provides results in 3 to 5 days, which hampers the ability to rapidly respond with contact tracing and other measures to contain and control the virus. There are, however, faster alternatives. Of the coronavirus RNA tests currently authorized by the FDA, three can be used in healthcare clinics that are officially registered with CMS.
through a CLIA certificate of waiver and therefore authorized to
perform simple diagnostic tests. One example of such a CLIA
waived test is shown in Figure 2b. This system can provide a test
result in 5-13 minutes, but can only run one sample at a time, or ~5
samples per hour, therefore will not facilitate high volume testing.

It is in principle possible to arrange for testing at a professional
healthcare site on the TCC campus that holds a CLIA certificate of
waiver and is suitably staffed. Such a test will be useful to rapidly
test individuals who are mildly or obviously symptomatic, and
should therefore be of high priority for testing in TCC campus.

2. Serological tests detect antibodies against the virus
in the blood sample of a person. (Figure 3)

It takes some time for the body to produce antibodies against the
virus. Serological tests are therefore mainly used to identify
individuals with a prior infection. However, a positive serological test
does not guarantee that a person cannot get re-infected. Some of
these tests are simple, but as of now they cannot be used on campus
in facilities with a CLIA certificate of waiver. Tests of this category are
currently also not very accurate: approximately 1 among 100
uninfected persons may falsely give a positive test; 1-12 persons out
of 100 people previously infected by the virus may fail to give a
positive test. Although in the near future this test may become more
accurate, at this time, we do NOT recommend for serological tests to
drive policy at TCC.
3. **Body temperature measurement:**

Another method that may lower COVID-19 transmission is to identify and triage individuals with fever on campus by installing thermographic imaging cameras (Figure 4). These may be complemented by manual IR thermometer readings in locations where automated imaging is not possible. Individuals so identified to have an elevated temperature may be approached and advised to quarantine themselves and be tested on a voluntary basis. Artificial Intelligence (AI)-enabled networked thermal imaging has been used widely in China by the government and by Amazon in Spain to monitor and locate high-risk individuals.

![Figure 4. Thermographic Body Temperature Measurement Camera (feverdetecting.com).](feverdetecting.com)
Executive Overview

Acting upon a request from the Council of Presidents, a faculty advisory group from Keck Graduate Institute (KGI) was formed to consider various strategies and alternatives that might be pursued to best protect The Claremont Colleges (TCC) students, faculty, and staff from COVID-19 during the resumption of campus and residential operations at The Claremont Colleges. To date, this group has met several times to brainstorm and gather information for this initial report. The report makes a set of broad recommendations, and initiates a framework for improving the existing guidelines as the local COVID-19 pandemic evolves. Further input from other TCC faculty members, as well as external vendors, health-related service providers, and health experts will be necessary, and these will together contribute to a SWOT analysis to be completed by June 15.

Key Recommendations:

• **Build Capacity**: Allocate adequate staffing and resources to TCC Student Health Services to coordinate all efforts related to COVID-19 student health, and in parallel, establish processes for monitoring infections among faculty and staff. Enhance protection to the TCC community, for example, by providing masks and enforcing distancing policies under local guidelines with compassion.

• **Surveil**: Implement a multipronged surveillance system to detect, as early as practically feasible, an emerging contagion in the TCC community through symptom identification, on-campus sample collection, off-campus clinical laboratory testing, adoption of rapid on-site testing, and contact tracing.

• **Engage**: Create a campus-wide environment of active participation, including in research, to allow informed decision making using reliable and innovative approaches.
Faculty Advisory Group Members

Barbara Fortini, PhD, MSGDA Program Director

Barbara Fortini joined KGI in July 2017 to lead the Master of Science in Human Genetics and Genomic Data Analytics (MSGDA) program. The first cohort of MSGDA students enrolled in August 2018. Within the KGI curriculum, Fortini teaches four courses: Human Molecular Genetics, Human Genomics, Human Genomics NGS Lab, and Functional Genomics. Fortini’s research is focused on how non-coding genomic variation affects colorectal cancer risk.

Prior to joining KGI, Fortini served as a visiting assistant professor of biology at the W.M. Keck Science Department of the Claremont McKenna, Pitzer, and Scripps Colleges. Fortini completed her postdoctoral training at the Keck School of Medicine of USC in the Department of Preventive Medicine at the USC Norris Comprehensive Cancer Center. She received her BS in 2002 and her PhD in 2011 at the California Institute of Technology.

Alexander Zambon, PhD, Associate Professor of Biopharmaceutical Sciences

Alexander Zambon's research interests involve understanding how cell signaling pathways and transcriptional circuits drive cell fate decisions and pathological tissue remodeling. His PhD training at the University of California, San Diego was in the area of molecular pharmacology and G-protein coupled receptor signaling, one of largest classes of therapeutic drug targets.

Zambon's postdoctoral training at the Gladstone Institute of Cardiovascular Disease/UCSF was in genomics and systems biology, where he developed bioinformatics approaches to identify transcription networks and pathways that control cardiac myocyte cell division during development and remodeling. Zambon joined KGI in July 2014.

Quintin Broussard, PharmD, BCPS, BCCCP, BCNSP, Assistant Professor of Clinical Sciences

Quintin Broussard completed a Bachelor of Science in Chemistry and a minor in Mathematics from McNeese State University in Lake Charles, LA. He received his Doctor of Pharmacy degree from the University of Houston College of Pharmacy. After graduating from the University of Houston, Broussard completed a PGY1 Pharmacy Practice Residency and a PGY2 Critical Care Pharmacy Residency at Baylor St. Luke’s Medical Center in Houston, TX, within the Texas Medical Center. He is board certified by the Board of Pharmacy Specialties in Pharmacotherapy, Critical Care, and Nutrition Support.

Prior to joining KGI, Dr. Broussard was an Assistant Professor of Clinical Sciences at California Health Sciences University (CHSU), practicing in medical/surgical intensive care and nutrition support. During his two years at CHSU, he was honored as the Clinical Faculty Preceptor of the Year for IPPE 3, P3 Teacher of the Year, and as the Course Director for the P3 Course of the Year (PHR 746: Patient Care III). Broussard joined KGI in August 2018.
Robert Stein, PharmD, JD, Professor of Practice for Pharmacy Law and Ethics and Healthcare Information Technology

Robert L. Stein received his PharmD from the University of Southern California School of Pharmacy, and his JD from Western State University College of Law. Previously, he practiced in a variety of clinical, management, and consulting roles, most recently in clinical Informatics and Information Technology as applied to healthcare. His professional interests focus on developments at the intersections of pharmacy law, ethics, healthcare technology and analytics, and e-discovery of health records. Stein is actively involved in the national dialog (both clinical and legal) over the role of pharmacists in recommending and monitoring use of medical cannabis.

Stein is an active member of American Society of Health System Pharmacists (ASHP), California Society of Health System Pharmacists, American Society for Pharmacy Law (ASPL), and the Orange County Bar Association. He was a panelist in Western State University College of Law’s symposium on medical marijuana, presenting a health care professional’s view. He has participated on numerous committees for ASHP and is a past member of the Health Information Management Systems Society’s national Public Policy Committee. Stein joined KGI in July 2014.

Angelika Niemz, PhD, Arnold and Mabel Beckman Professor

Angelika Niemz, a native of Germany, received her undergraduate degree in chemistry in 1992 at the University of Konstanz in Germany and her PhD in chemistry in 1999 at the University of Massachusetts Amherst. After working as a postdoctoral fellow in chemical engineering at the California Institute of Technology, she joined KGI in February 2002 as an Assistant Professor. In 2008 she became an Associate Professor and in 2009, after a six-month sabbatical where she worked for Roche Molecular Diagnostics in Switzerland, she began serving as Director of Research at KGI and was named the Arnold and Mabel Beckman Professor.

Niemz teaches courses on medical diagnostics, high throughput technologies, and instrumentation development at KGI. Additionally, she has taught short courses on IVD automation and nanobiotechnology at the annual conference of the Association for Laboratory Automation for seven years. She has obtained independent research funding from the National Science Foundation, the National Institutes of Health, and the Department of Defense, and has frequently served on grant review panels.
James D. Sterling, PhD, Professor

James Sterling received his bachelor’s degree in mechanical engineering from Texas A&M University and MS and PhD degrees in mechanical engineering from the California Institute of Technology. His scientific interests have focused on fluid mechanics, chemically-reacting fluid flows, heat transfer, dynamical systems and Lattice Boltzmann numerical methods. He worked at Los Alamos National Laboratory, TRW and Advanced Projects Research, Inc. as a systems engineer and project manager, developing a keen interest in new product development and entrepreneurship.

As a founding faculty member at KGI since 2000, Dr. Sterling helped develop curriculum that prepares students of the applied life sciences to work in the development of laboratory research tools, laboratory automation, and micro-bioanalytical methods. Sterling led the development of the Marsh A. Cooper Bioengineering Laboratory at KGI and directed the Team Master’s Projects (TMP) program, KGI’s industry-sponsored capstone project program for professional masters degree students, from 2004-2010. Sterling served as Vice President for Academic Affairs and Dean of Faculty at KGI from 2009-2014 and has led the establishment of the Professional Science Master’s (PSM) National Office at KGI. From 2013-2015, Sterling joined the Minerva Schools at KGI and served as the founding Interim Dean of the College of Natural Sciences and the Director of Minerva Labs.

Animesh Ray, PhD, Professor

Animesh Ray earned his PhD in microbial genetics from Monash University in Melbourne, Australia. His PhD research led to the identification of a gene for efficient plasmid maintenance in Escherichia coli and a method for generating a multi-copy infectious plasmid that is packageable inside a virus coat—an early example of synthetic biology. He subsequently conducted research at the Institute of Molecular Biology, University of Oregon, and the Department of Biology, Massachusetts Institute of Technology, during which periods he developed methods for precise in vivo chromosome engineering in yeast and in an experimental plant. He was an Assistant Professor from 1991 to 1995 and Associate Professor from 1996 to 2001 at the University of Rochester, New York, and an adjunct associate professor at the University of California, San Diego from 2001 to 2004.

Ray was a visiting professor at the University of Rochester from 2001 to 2004, at Institute for Systems Biology in Seattle in 2009, University of Hyderabad in 2009, and is currently a visiting faculty in California Institute of Technology, Pasadena. Research in his laboratory led to the discovery of the first known maternal effect embryo pattern formation gene in plants. His student, Teresa Golden, cloned a plant gene (DCL1) that later became known as the first member of the Dicer group of genes required for microRNA biogenesis. His PhD student Stephen Schauer identified the remaining known plant Dicer genes (DCL2-4). From 1999 to 2001, while on extended leave of absence from the University of Rochester, Dr. Ray directed research programs on regulation of gene expression and gene targeting at a plant biotechnology start-up company in San Diego. Ray joined KGI in July 2001.
Detailed Recommendations

1. Capacity Building

The local pandemic situation, government guidelines, testing technology and capacity, and medical/scientific knowledge on COVID-19 are rapidly evolving. In this context, the primary recommendation is to build capacity at TCC based on existing guidelines, available resources, and expert knowledge.

TCC should continue working with current LA County and Pomona Valley public health and governmental partners. We recommend establishing additional partnerships with commercial clinical laboratories. Importantly, we recommend building supplementary capacity on-campus to facilitate testing of students, faculty, and staff as further described below. TCC Student Health Services (SHS), which is uniquely positioned to coordinate testing of students, needs adequate staffing, funding, and infrastructure to handle the anticipated increase in workload and ensure safe working conditions. Meanwhile, TCC needs to establish processes and infrastructure to facilitate testing of faculty and staff, who do not qualify for access to SHS. Finally, Information Technology (IT) departments of the colleges will need to be involved in implementing the infrastructure needed for screening efforts to identify potentially symptomatic individuals, who should then be referred for testing. A role for the campus security department, with adequate personnel training in safety and sensitivity, may become necessary for monitoring activities.

Phased resumption of campus activities must be undertaken gradually. Staff attendance on campus should be based on informed consent and voluntary, and should be managed by Human Resources (who also should be trained for the particular of risks and mitigation).

Prevention is even more important than mitigation: in this sense, social distancing guidelines must be informed by physical dimensions of building and infrastructure, as well as the density of people who are expected in these locations. The principle should be to minimize personnel density in maximum capacity areas, constrained by building designs. TCC should seriously consider making available adequate quantities of masks to the campus communities. Each TCC facilities department should use dimensional measures to formulate a plan to distribute people (students, faculty, and staff) across buildings, classrooms, and offices over different intervals of time. Of particular concern are the laboratories; a proposal for safe laboratory teaching is provided in Appendix I.
2. Implement a Multi-Pronged Surveillance System

In a rapidly evolving pandemic environment, it will be important to constantly update the current best practice information, not only from the local area, but also from other educational campuses in the U.S. and in other countries. At this time, three factors are considered the most important—testing for the virus, protective equipment use (masks) and social distancing, and regular temperature recording of the community members. Below we summarize our recommendations on the development of a campus-wide surveillance system.

A. Implement a decision process for prioritizing who should be tested. The goal of surveillance is to identify infected individuals who may transmit the novel coronavirus (SARS-CoV-2). Confirming such cases requires molecular diagnostic testing for CoV-2 viral RNA, as opposed to serological tests that detect the antibody response to prior infection.\(^1\) Molecular diagnostic tests require a nasopharyngeal swab sample; therefore, sample collection involves a painful, and somewhat invasive, procedure. Furthermore, RNA testing may provide false negative results early on in the incubation period; therefore, it is only recommended once symptoms have manifested, or for contact tracing in some high-risk cases with known exposure. As a result, broad testing of asymptomatic individuals is not currently recommended. Testing is recommended for individuals with self-reported symptoms, for individuals identified through contact tracing to be at high-risk, and for febrile individuals who are unaware, and therefore may not self-report, but who might be identifiable as described below.

B. Identify febrile individuals on campus through installation of thermal imaging cameras (see Appendix II), as well as manual IR thermometer readings in locations where automated imaging is not possible, such as in high-traffic locations. These individuals may be approached and advised to be tested on a voluntary basis; such individuals would then be added to the list of those approved for testing through existing symptom-based approval processes. A triage decision tree needs to be established for guidance on the priority for testing, in case there is an overwhelming number of such cases relative to the available number of tests.

C. Establish several on-campus locations for sample collection for testing. To provide easy access to and promote compliance with testing, we further recommend that TCC sets up several collection sites for swab samples for COVID-19 tests, which are then either

\(^1\) We do not recommend using the current commercially available serological tests that detect host antibodies. See next section (i).
shipped to a central laboratory for testing or potentially tested on-site if and when such a capacity is attained. Sample collection from potentially-infected individuals can be performed by SHS employees and/or suitably trained and authorized KGI Doctor of Pharmacy students (see Appendix III for legal implications). Sufficient PPE will be required by all staff and students who directly interact with suspected COVID-19 positive individuals.

D. It is imperative that there is a **system in place to provide sample collection and testing for faculty and staff**, which may require sample collection sites in addition to those operated by SHS.

E. **Enable high volume off-site COVID-19 testing**. The number of individuals that will be referred for testing per day, based on the above-mentioned decision tree, is difficult to estimate. To err on the side of caution, this number may be substantial. Therefore, we recommend that TCC establishes a partnership with a large central laboratory, such as LabCorp or Quest, to identify acute symptomatic cases and prevent transmission. On-campus sample collection and sample shipment should be set up in collaboration with such a laboratory. One limitation is that current central laboratory testing may provide testing results in 3-to-5 days, which hampers the ability to rapidly respond with contact tracing and other measures of infection containment and control.

F. **Enable low volume rapid on-site testing**. To circumvent the above barrier for nimble decision-making, we suggest that TCC considers implementing molecular diagnostic testing for COVID-19 at SHS. There is a need to establish specific guidelines for the optimal combination of on- and off-site diagnostic testing. For example, on-site testing, followed by contact tracing, may rapidly identify an “index case” who may have exposed a substantial number of other individuals. Upon proper training of clinic personnel, TCC SHS can, in principle, perform emergency use authorized (EUA) molecular diagnostic tests that are Clinical Laboratory Improvement Amendment (CLIA)-waived. Since there is a high demand for these test instrumentation platforms, it is recommended that the TCC begins the process of acquisition of a representative platform technology as soon as possible. CLIA-waived molecular diagnostic tests\(^2\) for COVID-19 can be administered in a professional point of care setting registered with the Center for Medicare and Medicaid Services (CMS) through a CLIA Certificate of Waiver. For a list of CLIA-waived molecular diagnostic tests see Appendix IV.

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\(^2\) In the U.S., under the Clinical Laboratory Improvement Amendments (42 CFR 493), diagnostic tests are categorized into high complexity, moderate complexity, or waived tests, based on difficulty of test execution. High and moderate complexity tests have to be run in a CLIA certified or accredited central laboratory.
G. Hire qualified contact tracing professionals to work with SARS-CoV-2 positive students, staff, or faculty to identify potentially exposed individuals using the tried and true manual collection methods. The contact tracing personnel will require sufficient support and training to understand the structure of TCC’s campuses and community patterns in order to complete these tracings effectively. Access to card swipe data and other location and personal movement information currently collected will be required, and an algorithm for streamlined communication and management of information transfer should be developed. IT and Security Departments may play important roles in this process.

H. Implement technology-driven contact tracing solutions to augment the efforts of the contact tracing team. These efforts may be a blend of data mining of existing network connectivity data or opt-in adoption of tracking apps or wearables. The options for these solutions may use AI to process data in the form of cellphone, WiFi, or Bluetooth connectivity, RFID sensors, or cameras with facial recognition. Privacy concerns will need to be carefully weighed against risk, safety, and utility for contact tracing. Software firms are beginning to tackle these challenges, and an early partnership with a software-driven contact tracing technology company may be important (see Appendix V).

I. We do not recommend using the current commercially available serological tests that detect host antibodies. Serology tests determine prior infections, and could in principle be used to assess the level of herd immunity. However, a positive serological response may not indicate protective immunity. Reinfection of a seropositive individual may occur, which limits the utility of serological assays. Furthermore, there are concerns regarding low specificity and/or sensitivity of the currently authorized serological tests Okba et al., Emerg Infect Dis. (2020). (doi.org/10.3201/eid2607.200841). See Appendix IV.

3. Create a campus-wide environment of awareness and participation

A. Refine the decision tree for campus-wide risk mitigation through a validated statistical model. It is important to develop a framework for a decision tree based on numerical risk assessments conducted on testing data, clinical community risk data, and local/state data. We suggest a statistical model be framed and be validated, with participation from the Claremont Graduate University School of Community and Global Health and the Institute of Mathematical Sciences, using a range of simulated data. Such a model should form the basis of a decision tree to inform campus operations. It should be noted that such an endeavor may require IRB approval.
While we do not recommend using a serological test at this time, higher fidelity serological tests are likely to arise with time. A decision-process on when to adopt widespread serological testing should be established for how and when an approved method/technology might be adopted for clinical use. Newer approved method/technology will be considered to either replace the current method or to be performed in parallel for continued evaluations and/or increased throughput (see Appendix IV on the status of existing tests/instruments and emerging/proposed systems). There could be a role for some IRB-approved studies in assessing the potentials of some of these emerging technologies.

B. **Foster a culture of knowledge-driven participation in TCC.** A culture of knowledge-driven participation is of paramount importance in a heterogeneous campus for maximizing buy-in, therefore, compliance to preventive measures. Moreover, in a knowledge-rich institution such as TCC, ideas are important and ground up initiatives are desirable. We recommend that TCC strategizes the best ways to utilize these resources. We suggest a few ways to augment initiatives in this direction.

It will be important to engage staff, students, and faculty at all levels of decision making, such that the campus-wide policies, which often will be intrusive and restrictive relative to normal times, do not appear to be ‘top-down’. One approach is to conduct regular interviews/sample surveys of all TCC members to estimate the mood of the campus and to simultaneously assess the values of the measures being taken, with the possibility of recruiting volunteer members on campus-wide groups who will help readjust policies and mitigate shortcomings.

Community engagement through the conveying of information on the latest research into the biology, pathology, and treatment of COVID-19 in an accessible format should be encouraged. Several on-going and future research programs led by the faculty may benefit the community through knowledge dissemination and in turn benefit from college-wide coordinated participation with input from all stakeholders. These topics include epidemiology, vaccine development, antiviral drug discovery and development, genetic predisposition, biomedical devices for health worker protection and pulmonary health, sample collection/preparation technology, bioinformatics/phylogenetics of coronaviruses, and bio-surveillance with aerosol physics and biosensors, among other relevant topics.
About Keck Graduate Institute (KGI)

In 1997, Founding President Henry E. Riggs conceived the idea of KGI, and through a $50 million grant from the W.M. Keck Foundation, KGI was born as a member of The Claremont Colleges. Since 2003, under the leadership of President Sheldon Schuster, KGI continues to grow both in terms of its number of enrolled students and in its reputation for excellence.

KGI offers innovative postgraduate degrees and certificates that integrate life and health sciences, business, engineering, pharmacy, and genetics. With a focus on team projects and hands-on industry experiences, KGI provides pathways for students to become leaders within healthcare and the applied life sciences.

KGI consists of four schools: Henry E. Riggs School of Applied Life Sciences, School of Medicine, School of Pharmacy and Health Sciences, and the Minerva Schools at KGI. More information about KGI can be found at kgi.edu.

About The Claremont Colleges

The Claremont Colleges is a consortium of five undergraduate liberal arts colleges and two graduate institutions reminiscent of the Oxford-Cambridge model. The undergraduate colleges include: Pomona College, Scripps College, Claremont McKenna College, Harvey Mudd College, and Pitzer College. The two graduate institutions include Claremont Graduate University and KGI.

Each has its own campus, its own students and faculty, and its own distinctive mission. The seven independent institutions, located on more than 560 acres of land, offer rigorous curricula, small classes, distinguished professors, and personalized instruction in a vibrant residential college community that provides intensive interaction between students and faculty.
Appendices

Appendix I: Safety in Lab Classes
Provided by Dr. Ilya Tolstorukov, KGI Research Professor

- Limit the number of students in lab classes so as to reduce density.
- Use single-use coats or autoclave coats every day.
- Provide personal googles for each student (do not allow to exchange googles between students).
- Supply all staff and students with masks (one mask per every 2 hours presence in campus).
- Supply all staff and students with gloves (at least 4 pairs per day).
- Masks and gloves must be changed every two hours.
- Put as many as needed stations with masks, gloves, and hands-free biohazard containers for collecting the used PPE in each building.
- The biohazard bags from the containers must be collected every day and autoclaved before disposal by authorized staff.
- Provide sanitation wipes to the labs and classes (they must be used along with 70% ethanol for cleaning surfaces, parts of the would-be-touched equipment before and after use).
- If possible, limit the use of common equipment and computers.
- If possible, setup voice control in commonly used equipment, like copy/printer machines
- Wipe all handles as often as possible.
- If possible, install the foot opening devices in doors used by many people and keep all doors unlocked during the day.
- Install sanitizing dispensers near all common rooms and toilets.
- Do not allow to work in groups, do not communicate without appropriate distancing or exchange materials.
Appendix II: Networked Tele-thermographic Sensors for IR imaging for COVID-19 Control

Artificial Intelligence (AI)-enabled networked thermal imaging has been used widely in China by the government and by Amazon in Spain to monitor and locate high-risk individuals.

The U.S Food and Drug Administration (FDA) has released a detailed enforcement policy for networked and remotely controlled infrared sensors for monitoring individuals’ temperature in workplaces: fda.gov/media/137079/download

Importantly, “To help ensure the availability of products that might offer benefit to healthcare providers and the general public during the public health emergency, the FDA does not intend to object to the distribution and use of telethermographic systems intended for initial body temperature assessment for triage use as described in the Scope (Section III) without compliance with the following regulatory requirements where such devices do not create an undue risk in light of the public health emergency: submission of a premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and 21 CFR 807.81, Reports of Corrections and Removals requirements in 21 CFR Part 806, Registration and Listing requirements in 21 CFR Part 807, the Quality System Regulation in 21 CFR Part 820, and Unique Device Identification (UDI) requirements in 21 CFR Part 830 and 21 CFR 801.20.” (p. 4 in the above referenced FDA policy document).

Companies that have fabricated and/or sell IR imaging products for COVID-19 screening include:

• IPVM, a reviewer of video surveillance and security technologies [https://ipvm.com/reports/iec-fever, which tested three standard system parts (available for about $550):

  iso.org/standard/69346.html
  iso.org/standard/67348.html
  iso.org/standard/69347.html

  (and found these to be sufficiently reliable)

• Athena Security

  athena-security.com/coronavirus-detection.

Commercially available systems include, but are not limited to:

• MoviTHERM FLIR A320 Tempscree

  movitherm.com/?s=fever
Appendix III: Legal/Regulatory considerations in Monitoring/Testing

Logistical/regulatory considerations for collection of laboratory specimens

California law permits any person collecting specimens at a remote collection site (such as on TCC campuses), for processing by a clinical laboratory, to be “authorized” by the medical director of the laboratory.

As of May 12, 2020, the State of California through an executive order has allowed licensed pharmacists with appropriate training to collect COVID-19 samples and participate under appropriate guidance in laboratory testing of these samples. As a consequence of this rule, it is possible that Doctor of Pharmacy (PharmD) students at KGI may be trained to assist in nasopharyngeal swab collection under this rubric if the director of the processing clinical laboratory authorizes PharmD students to collect specimens.

Non-invasive methods for screening of students

Passive methods of screening (infrared detection) are preferable to active methods of screening that require individual scans of students entering a building.

There are commercially available infrared cameras that detect febrile persons by color coding and computer algorithms. Such devices are deployed in airports and other high-risk areas to screen large numbers of persons in real-time.

Deploying passive infrared camera temperature screening at building entrances is not desirable because there is no reliable automated method of identifying the individual after they pass through the monitored area. Such a system would require a person to monitor for persons with elevated body temperature passing the detector.

Therefore, the optimal locations of such cameras are in classrooms, where students remain in one spot for sufficient time for real-time follow-up of students showing elevated temperature.
Appendix IV: Current Testing Technologies

COVID-19 diagnostic tests with emergency use authorization are listed on the following website:

fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations

Molecular Diagnostic Testing for CoV-2 RNA

Most of the currently EUA approved molecular diagnostic tests are authorized for use in CLIA certified laboratories that perform high and moderate complexity testing. Quest and LabCorp have developed their own EUA approved tests, and can also use commercially available tests manufactured by large IVD companies such as Roche or Hologic, which are run on high throughput systems.

TCC SHS, which is a professional heathcare setting that holds a CLIA certificate of waiver, can however use CLIA waived CoV-2 molecular diagnostic platforms, of which three are currently approved through an EUA. These systems are easy to use, provide rapid results, and consist of a compact instrument and single use disposable test cartridges.

1. Cepheid Xpert Xpress SARS-CoV-2 test
   cepheid.com/coronavirus

2. Abbott Diagnostics ID NOW COVID-19 test

3. Mesa Biotech Inc. Accula SARS-Cov-2 Test
   mesabiotech.com/coronavirus
To add value, these systems need to provide accurate results. Clinical evaluation studies under EUA are limited to running a small number of contrived positive and negative samples. Based on these EUA requirements, each system claims a clinical sensitivity of 100% (20/20, 95% confidence interval: 83.9% - 100%), and specificity of 100% (30/30, 95% confidence interval: 88.7-100%). Larger independent evaluation studies with actual clinical samples are required to assess the true clinical accuracy. In one study that is not yet peer reviewed and published, the clinical sensitivity of the Abbott ID NOW test has been found to be ~85%, which would lead to 15% false negative results. However, for this study samples were shipped to a central laboratory for testing with the ID NOW rather than testing at the point of care, which could have resulted in low sensitivity.

A brief comparison of other key metrics for these systems is given in the table below.

<table>
<thead>
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<th></th>
<th>Cepheid Xpert Xpress</th>
<th>Abbott ID Now</th>
<th>Mesa Bio Accula</th>
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<td>Estimated Instrument Cost</td>
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<td>~$9,500</td>
<td>$144</td>
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<td>Instrument Size</td>
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<td>Medium</td>
<td>Small</td>
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<tr>
<td>Time to result</td>
<td>30 min</td>
<td>5-15 min</td>
<td>30 min</td>
</tr>
<tr>
<td># of samples that can be run in parallel</td>
<td>1 per module, 4 for a 4-module instrument</td>
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</table>

Instrument costs are rough estimates. The cost per test for comparable assays is ~ $30, but test costs are volume dependent. It is recommended that TCC contact the vendors to explore the cost and availability of instruments and test cartridges, since these systems may be back-ordered.

3 npr.org/sections/health-shots/2020/04/21/838794281/study-raises-questions-about-false-negatives-from-quick-covid-19-test
Serological testing (we do not recommend implementing these at TCC at this time)

COVID-19 serological tests with emergency use authorization are listed in the table below and their further details can be accessed from centerforhealthsecurity.org/resources/COVID-19/serology/Serology-based-tests-for-COVID-19.html.

<table>
<thead>
<tr>
<th>Type of serological test</th>
<th>Company (Country)</th>
<th>Reported sensitivity</th>
<th>Reported specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>RDT</td>
<td>Cellex (US/China)</td>
<td>93.8%</td>
<td>95.6%</td>
</tr>
<tr>
<td>ELISA</td>
<td>Orthoclinical diagnostics (US)</td>
<td>87.5%</td>
<td>~100%</td>
</tr>
<tr>
<td>RDT</td>
<td>Autobio diag. (US)</td>
<td>95.7-99%</td>
<td>99%</td>
</tr>
<tr>
<td>ELISA</td>
<td>Diasorin, Inc. (US)</td>
<td>90-97%</td>
<td>98%</td>
</tr>
<tr>
<td>RDT</td>
<td>ChemBio (USA)</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>ELISA</td>
<td>Mt. Sinai Lab (USA)</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Modified ELISA</td>
<td>BioRad (USA)</td>
<td>98%</td>
<td>99%</td>
</tr>
<tr>
<td>ECLIA</td>
<td>Roche (US/Switzerland)</td>
<td>88.1-100%</td>
<td>99.8%</td>
</tr>
<tr>
<td>ELISA</td>
<td>Eurommune AG (Germany)</td>
<td>90%</td>
<td>100%</td>
</tr>
<tr>
<td>Microsphere immunoassay</td>
<td>Wadsworth (US, NYSDH)</td>
<td>NA</td>
<td>93-100%</td>
</tr>
</tbody>
</table>
Appendix V: Technological Augmentation to Contact Tracing Procedures

The gold standard for contact tracing during infectious disease spread is to utilize trained personnel to conduct interviews of positive patient cases to identify those requiring quarantine or additional testing/monitoring. In addition to such people, there are technological aids that can assist this process. The use of such methods should be weighed against privacy concerns, and steps should be taken to protect identifiable location information. These options include:

- Tracking cell phone locations via GPS
- Tracking cell phone locations via Bluetooth
- Tracking cell phone and laptop locations with WiFi
- Dedicated contact tracing apps on cell phones—these may record location data passively, or require active “check ins”

An obvious weak point in any data collection scheme is that students, staff, and faculty may not carry their phones with them at all times, phones may lose power, or phones may not have a strong connection to establish their own location via GPS, Bluetooth, or WiFi connections.
inside buildings or in areas with poor signal. Additional methods to track the location of community members that do not require cell phones are:

- Recording door access via card swipe
- RFID sensors passively collecting proximity information
- Dedicated wearable devices
- Cameras with facial recognition software
- AI prediction-based models using campus maps, course registration info, dorm assignments, etc.

These five options do not require access to cell phone data, but the top three still require community members to carry a trackable item, such as their ID card or a wearable location device. Door swipes are useful pieces of information, but obviously not everyone passing through a door will need to swipe to open it. RFID locators may be able to be imbedded in ID cards and tracked passing through constriction points, such as cafeteria doors or key hallways where large groups may move together. Dedicated wearables are also available but may be in very high demand shortly as more large businesses re-open.

All TCC campuses have existing security cameras for safety. Adding a software solution with facial recognition to identify contact may be possible, although upgraded camera equipment and monitoring may be required. This solution would work well integrated with IR temperature monitoring.

Lastly, some AI algorithms may be developed to integrate campus information such as campus layout, dorm assignments, course schedules and locations, card swipe data, and more to predict probable contacts that may be missed by other measures. The availability of such a solution is unknown at this time, but could be developed by commercial sources in response to these needs.
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