

## UC Systemwide Testing and Tracing Task Force Recommendations to the President and Chancellors

*This is a working document. It is anticipated to evolve in response to new information as it emerges and the dynamic nature of the pandemic. These recommendations are based on what is currently known about SARS-CoV-2 and COVID-19.*

### **Retirement effective April 1, 2021**

- As of April 1, 2021, **this document is retired**. While the fundamental concepts identified in this document remain applicable, a separate targeted document has been developed to specifically support UC locations in **Fall 2021** planning efforts.
- The Fall Planning 2021 recommendations include updated guidance related to SARS-CoV-2 vaccination, student testing and surveillance, asymptomatic screening, and campus density planning scenarios.
- UC Health Coordinating Committee recommendations, including the Fall 2021 guidance, can be found [here](#).

### **Summary of Revisions**

*(Revisions effective as of September 1, 2020)*

#### **I. Modeling Strategies**

- Aligned recommendation regarding campus housing occupancy with [State of California COVID-19 Guidance Institutions for Higher Education](#) and/or locally issued guidance (p. 5).
- Removed “Symptomatic Testing Only” as a strategy for reducing early seeding of outbreaks as students arrive to campus and revised task force recommendation to support testing of all students at entry as described in the asymptomatic testing strategy for returning students (p. 6).
- Revised to include task force recommendation for **required** periodic asymptomatic community-based screening for faculty, staff, and students at a frequency aligned with local conditions and the recommended screening strategies described in Appendix B (p. 8).
- Updated testing guidance for employees returning to work (p.9).
- Added antigen testing to the list of additional testing strategies to consider (p. 9).
- Aligned testing guidance with updated CDPH COVID-19 testing priorities (all sections).
- Added an additional asymptomatic community-based screening strategy to Appendix B (p. 18).
- Updated legal guidance for non-CLIA laboratories in Appendix C (p. 22)

*(Revisions effective as of July 9, 2020)*

#### **I. Modeling Strategies**

- Revised section to align with the [CDC’s Interim Considerations for Institutions of Higher Education Administrators for SARS-CoV-2 Testing](#). Specifically, recommendations related to the diagnostic testing of asymptomatic individuals with recent known or suspected exposure to SARS-CoV-2 (entire section).
- Clarified the context in which symptom screening would be required for campus community members (entire section).

- Revised to emphasize the importance of lowering campus density and to include a recommendation on limiting on-campus congregate housing to one person or family unit per room.
- Added reference to specific county criteria that should be monitored via local public health to help make informed decisions based on local conditions.
- Revised to include new data related to the symptomatic only testing strategy.
- Modified *Table A: Strategies for Students Arriving to Campus* to clarify the required sequestration period timeframe for both testing strategies and to include updated close contact testing requirements from the CDC.

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- Removed reference to the prevalence of SAR-CoV-2 estimated to be low in the State of California. Updated to include reference to June surge of COVID-19 cases in California due to the relaxation of stay-at-home orders across the state.
- II. Diagnostic Testing**
- Revised to align with CDC guidance regarding recommended diagnostic testing of asymptomatic individuals with recent known or suspected exposure to SARS-CoV-2.
  - Revised to include UC testing capacity inventory.
  - Updated the options for future testing modalities based on current research.
- III. Case Investigation and Contact Tracing**
- Revised to include information on the status of campuses seeking delegated authority from local public health authorities for contact tracing responsibilities.
  - Revised to include a recommended timeframe for contact tracing and case investigation workforce capacity implementation and language related to compliance, participation and enforcement.
  - Modified to include recommendation on a systemwide digital contact tracing solution.

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**Introduction**

In early 2020, the novel coronavirus, SARS-CoV-2 pandemic quickly swept the globe and significantly impacted all UC locations. In March 2020, the University moved quickly to modify operations in order to mitigate the spread of COVID-19. Campuses transitioned to remote instruction, curtailed non-essential research, and implemented telework for many administrative services and functions. As the pandemic is expected to continue through at least 2021, additional action is needed to continue to protect the UC community as locations ramp up onsite operations.

The novel coronavirus challenges normal operations in a number of ways and an increase in onsite operations is not without risk of morbidity and mortality for the students, faculty and staff living, learning, and working on our campuses. The dynamics of the SARS-CoV-2 pandemic continue to evolve, and it is reasonable to expect ongoing transmission and outbreaks in US communities until herd immunity is achieved or an effective vaccine is available.

To decrease opportunities for viral transmission on UC campuses, significant mitigation measures will be required. The cornerstone of mitigation will be decreasing normal campus population density, in order to decrease interactions that may result in person-to-person transmission of the virus. Non-pharmaceutical interventions (NPI), including performing frequent hand hygiene, practicing physical distancing, and wearing facial coverings while in public, should be required to reduce opportunities for viral spread. Other measures, including influenza vaccination and education for all individuals who enter UC locations will be critical to the University's ability to increase onsite activities.

Diagnostic testing, case investigation, and contact tracing are also strategies for mitigating risk, and can inform how best to deploy resources – such as isolation, quarantine, and other support activities – to facilitate containment. The extent to which UC locations are able to implement these strategies will be vital to determining their capacity for onsite activities. However, even these strategies, will not completely eliminate risk or prevent disease transmission and should not be seen as a guarantee of safety. They can also create a false impression of safety, and unintentionally signal to many who test negative that it is acceptable to relax social distancing practices. Given the scale of the UC System and community prevalence of the virus, illness and even death from COVID-19 may occur among members of the UC community following a ramp up of onsite operations.

***To inform campus decision-making, a systemwide Testing and Tracing Task Force was convened to make recommendations for UC locations, with the exception of the academic health systems, which are already following previously-developed, specific infection prevention guidance for the health care setting. The charge of the Task Force was not to determine whether, when, or to what extent campuses should return to normal onsite operations.***

The task force focused on issues related to 1) modeling for diagnostic testing and viral transmission dynamics, 2) conducting diagnostic testing, and 3) contact tracing. The task force, chaired by Carrie L. Byington, MD, EVP of UC Health, Theresa Maldonado, PhD, VP of the Office of Research and Innovation, and Larry Anstine, CEO emeritus, UC Irvine Health, included subject matter experts, administrators, faculty (including Academic Senate representation), and staff from across the UC System (click [here](#) for full roster).

The task force reviewed data and materials from public health authorities, published and preprint literature, recommendations from other industries, and data emerging from campus pilot studies. Members also consulted with experts outside the UC System and grounded their recommendations in the following guidance:

- Campus planning to increase onsite operations will be driven by the [six principles](#) adopted by the Board of Regents on May 20, 2020 and a set of [consensus standards](#) adopted by the President and Chancellors. Task force recommendations are directly related to and support the implementation of Principle 2<sup>1</sup> and Consensus Standard 4.<sup>2</sup>
- Federal, state, and local public health guidelines, including [guidance](#) issued by the State of California to reduce risk as different sectors ramp up operations consistent with the Governor's [Blueprint for a Safer Economy](#) (released August 31, 2020).

Task force deliberations were informed by coronavirus guidance issued by the [US Centers for Disease Control and Prevention \(CDC\)](#), as of July 6, 2020:

- Approximately 35% of individuals infected with SARS-CoV2 may remain asymptomatic.
- COVID-19 disease can range from mild to life-threatening. Several risk factors for severe COVID-19 disease have been identified including underlying medical conditions and age > 65 years. Many UC community members may have these risk factors.
- Early data suggest that person-to-person transmission occurs easily, with each infected person (whether symptomatic or not) likely to infect 2.5 more people.
- Individuals may transmit virus for a number of days before symptom onset; a significant proportion of viral transmission (approximately 40%) occurs prior to symptom onset.
- [Super-spreading events](#) have occurred in multiple countries including the US and have led to large outbreaks.

The University cannot eliminate the risk of COVID-19 transmission, but can aim to achieve an effective reproductive value ( $R_t$ ) < 1.0, meaning that fewer than one new infection on average from an infectious person, **OR** consistent with that in the surrounding communities. Given the dynamic nature of the outbreak and the emergence of new scientific insights, these recommendations likely will need to be updated over time.

Although Fall 2020 density will be decreased across all campuses, it is recommended that each location continue to prepare for the full return of in-person operations by further developing and testing a campus plan that meets the expectations of the UC systemwide Consensus Standards as well as state and local guidance.

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<sup>1</sup> "While the elimination of risk is not possible, the University will implement scientifically appropriate COVID-19 practices including, to the extent appropriate, screening, testing, contact tracing and utilize other public health data to inform decisions and mitigate the spread of COVID-19."

<sup>2</sup> "Plans will include provisions for screening individuals entering University-owned or operated facilities, arranging for clinical tests of any students, faculty, or staff who exhibit symptoms consistent with COVID-19, and investigating any COVID-19 illness to determine if conditions should be altered to further mitigate risks, and identify other University-affiliated people who may have been in close contact. Testing and contact tracing may be performed by the campus, a sister campus, local health officials, or other community resources."



## I. Modeling Strategies

A number of models were reviewed to inform diagnostic testing strategies. However, no model identified with confidence a testing strategy that can detect all new infections, whether symptomatic or not, before transmission occurs. Models can help to inform mitigation measures by estimating (i) the number of infections that occur on campus before a cluster is detected, (ii) the probability and size of a location-specific outbreak within three months following the return to campus, or (iii) the campuses' effective reproduction values. Taken together, these metrics suggest testing frequency schedules for all campus members that range from once per month, to once per week, to once every 2-3 days.

The task force recommends that each UC location work with its local public health authorities to understand the transmission dynamics in the communities surrounding that location in order to understand the overall risk for transmission, and to inform and ultimately determine testing method, frequency, and priority. [California Department of Public Health \(CDPH\) criteria for elevated disease transmission](#), including the local rate of new cases and test positivity, should be carefully monitored and considered as UC locations develop plans to resume onsite activities. Targeted testing of groups that are at increased risk for severe illness, including all symptomatic individuals, is strongly recommended and is consistent with both [CDC](#) and CDPH guidelines.

### Modeling Strategies for Students Arriving to Campus

The resumption of in-person educational activities on campuses, with thousands of students traveling to campuses from multiple countries and US communities, will inevitably result in viral “seeding” events. The task force recognizes this as a unique risk factor for campuses. To mitigate this risk and that of future outbreaks, campuses should limit onsite activities and housing to the lowest densities possible. The task force recommends campuses prioritize single room occupancy wherever possible (except for family housing) and follow any additional state and/or local guidance on housing and room occupancy. Testing asymptomatic individuals has been recognized as an important strategy for determining risks in congregate settings (see Infectious Diseases Society of America [guidelines](#)). Sequestering students (i.e., minimizing in-person interactions) for a period of time before engaging in campus activities could also reduce the risk of seeding events<sup>3</sup>.

Multiple testing strategies were evaluated by the task force. The task force previously recommended asymptomatic and symptomatic testing strategies as potential strategies with equipoise as related to reducing the early seeding of outbreaks as students arrive to campus (see Appendix D for details on prior testing recommendations). As of September 1, 2020, the preponderance of data supports asymptomatic transmission as a significant mechanism in the spread of SARS-CoV-2. Further, the pandemic has accelerated across the US and in California, with cases in younger people (20-30 years) driving transmission. Finally, numerous outbreaks have been reported on college campuses, associated with summer sessions, return

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<sup>3</sup> See Stephen A. Lauer *et al.*, *The Incubation Period of Coronavirus Disease 2019 (COVID-19) From Publicly Reported Confirmed Cases: Estimation and Application* ([AIM May 5, 2020](#)).

of sports teams, Greek life, and other campus activities. These outbreaks have demonstrated the failure of sequester or of a single, pre-entry test alone. The task force recognizes the importance of combining multiple non-pharmaceutical interventions with a strong testing plan that includes testing all individuals twice upon re-entry to be followed by periodic testing of asymptomatic individuals. In summary, the task force has determined that the preponderance of evidence supports broad asymptomatic testing and that there is no longer equipoise between the two strategies originally proposed. The task force therefore recommends each campus adopt the asymptomatic testing strategy for returning students as detailed in Table A.

**Table A: Asymptomatic Strategy for Students Arriving to Campus\***

<b>Requirement</b>	<b>Guidance</b>
Daily self-performed symptom monitoring	Required beginning 10 days prior to arrival and every day thereafter
Test prior to arrival on campus	All students required to show proof of a negative FDA EUA authorized SARS-CoV-2 clinical test within 7 days prior to arrival
Test again after arrival on campus	All students who reside in on-campus housing will be retested by PCR or other validated testing platform between 7-14 days after arrival on campus.
Sequester with minimal social interactions (essential activities only)	7 days for all students upon arrival or until the second negative PCR test or other validated testing platform is completed
Refer symptomatic students for medical evaluation	Evaluate and provide care as determined by medical professional
Test symptomatic students and return results in $\leq 24$ hours	Required if recommended per symptom screening algorithm and/or evaluation by medical professional
Isolate symptomatic students pending results	Required
Refer students who test positive for case investigation and contact tracing	Required
Test AND quarantine for 10 days close student contacts of students who test positive	Required
Face coverings worn in public at all times	Required
Other NPI and adherence to all required public health measures	Required

\* As a general matter, graduate and health professions students should be treated the same way as undergraduates on campus. Different strategies may be employed for different campus segments, however, if a decision is made locally that such an approach is warranted. For example, medical residents and fellows may have different obligations and these, in turn, may limit sequester options.

Symptom screening is required for all students beginning 10 days prior to arrival on campus and every day thereafter. Following arrival, anyone planning to enter any campus facilities must be screened each day they plan to be onsite thereafter. Symptom screening, using an app or web-based platform,<sup>4</sup> has been useful in health care settings to identify individuals with

<sup>4</sup> This approach requires, of course, that all students have access to such tools. In developing its local plans, a campus should assure that students have reliable daily access to an appropriate device and to internet access and, V3.0

symptoms of COVID-19 and may identify a group of individuals for priority diagnostic testing. Students with positive symptoms should not travel to campus until they have received a medical evaluation, if indicated, and care, and are symptom-free for 72 hours.

The task force recommends referring to [CDC guidance](#) for the definition and identification of COVID-19 symptoms, and the UC Health Coordinating Committee for COVID-19 has organized a systemwide task force to share knowledge and best practices related to app or web-based symptom screening. Harmonization of systems used for symptom screening, prioritization of diagnostic testing, and creation of platforms that allow data acquisition, aggregation, and visualization for the purpose of informing System operations and public health efforts should be the priority. Data on symptom screening and diagnostic testing should be captured in a secure manner with appropriate controls to maintain individual privacy while assisting campus leaders and health experts in identifying and responding to potential outbreaks and coordinating reporting to public health authorities. See [Appendix A](#) for recommendations on privacy practices. Diagnostic test results must be reported to CDPH consistent with applicable law.

The asymptomatic testing strategy requires testing for all students within 7 days prior to arrival on campus. If testing is not available in the student's home community, testing must be available and performed on campus arrival. A second test is required within 7-14 days of arriving on campus (or more frequently consistent with the location's asymptomatic testing strategy) for all those students residing on campus.

Staggering student return to campuses could facilitate implementation and limit campus density. No student who is symptomatic should travel to campus until they are symptom-free for 72 hours. Any student who develops symptoms *en route* to campus, or at any time after arriving on campus, should be referred for medical evaluation and care. Testing results should be available within 24 hours. See Section II for additional information about testing and Section III for information about how to proceed if a test result is positive.

All students enrolled and arriving to campus for the fall term should be required to sequester for seven days. Sequestering means minimizing in-person interactions among students, faculty and staff, whether in the dorms, dining facilities, classrooms, or other campus locations where students congregate, or off campus for those students who live at home or in off-campus housing. Students should leave their on- or off-campus residences only to participate in [essential activities](#) (e.g., to purchase food, participate in low-risk outdoor recreational activities, or obtain health care services).<sup>5</sup> Each location will need to identify strategies that minimize in-person interactions on campus during this period and educate students as to the requirements.

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if not, make alternative accommodations in order to avoid exacerbating inequities already faced by underserved populations.

<sup>5</sup> Students enrolled in the health professions schools may also participate in clinical activities consistent with state and local public health guidelines and school and training site policies.

No strategy is sufficient without added [non-pharmaceutical interventions \(NPI\)](#). On June 18, 2020, for example, the CDPH issued [updated guidance](#) requiring the use of face coverings in most settings.

### **Employee Return to Work Testing Strategies**

The task force recommends a testing strategy for all employees (faculty and staff) returning to onsite work. The relaxation of California's statewide stay-at-home order, starting in late May/early June, has led to an increase in the prevalence of SARS-CoV-2 in nearly all California counties. Some higher-risk situations may require **diagnostic clinical testing** from a CLIA certified laboratory prior to workplace entry, for example an employee who is a known close contact of a confirmed case or has a recent history of travel to areas with high transmission levels. In addition, some campuses are considering or already have adopted diagnostic testing of all new hires.

All symptomatic employees should be referred for evaluation and diagnostic clinical testing (PCR or other validated testing platform), as indicated. Employees may receive testing onsite if available in the work place or be referred to their medical provider. Symptomatic employees should not return to work until they have been tested for SARS-CoV-2 and if negative are symptom-free. Employees found to be SARS-CoV-2 positive on testing should follow CDC, state and local guidance for return to work.

Faculty and staff must also be included in a location's ongoing asymptomatic community-based screening program, which should include testing criteria for employees prior to returning to onsite work. All employees should follow recommendations regarding use of NPIs to reduce viral transmission and should be required to screen for symptoms at least each day they are scheduled to work or learn onsite and prior to admission to any campus building.

### **Periodic Asymptomatic Community-Based Screening<sup>6</sup>**

Campus locations must adopt, in addition to symptomatic testing for all employees and students, a community-based screening program for periodic testing of asymptomatic individuals for SARS-CoV-2. Asymptomatic testing should be made available to all onsite students, faculty, and staff using tests authorized for use with asymptomatic populations. Campuses must include a plan for testing off-campus students in any asymptomatic community-based screening program as high density off-campus housing presents additional challenges to SARS-CoV-2 transmission containment.

Asymptomatic community-based screening is critical in early identification and containment of clusters and outbreaks. The frequency of asymptomatic testing required should be based on

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<sup>6</sup> **Periodic asymptomatic community-based screening** is also referred to as **SARS-CoV-2 surveillance testing** and can be performed in a facility that is not CLIA certified, and may use a test or technique NOT authorized by the FDA, provided that patient-specific results are not reported. As of 8/31/20, the Centers for Medicare and Medicaid (CMS) has [temporarily implemented enforcement discretion within certain defined parameters](#). For locations to utilize a non-CLIA certified laboratory that refers presumptive positives to a CLIA certified laboratory, CDPH will need to implement similar enforcement flexibility.

local conditions, campus density, and align with one of the testing strategies described in Appendix B. All models require intensive testing and none eliminates the possibility of an outbreak.

Asymptomatic community-based screening must not interfere with or replace the testing of symptomatic individuals and their close contacts or other public health measures described in this document.

### **Additional Strategies to Consider**

- 1) **Testing of sewage for SARS-CoV-2 RNA:** According to one [study](#), can predict, one week in advance, COVID-19 cases requiring hospitalization. Testing by PCR of sewage sludge and waste water can be done in basic science laboratories. All UC facilities are encouraged to work with facilities and maintenance departments to evaluate campus buildings and determine if acquisition of samples is possible. If sludge is available, this type of screening should be considered on a regular basis (e.g., daily or weekly) in higher-risk settings, such as residential living facilities. Positive test results would prompt targeted diagnostic testing, case investigation and contact tracing.
  
- 2) **Antibody testing:** SARS-CoV-2 antibody testing has been developed and validated commercial assays are available at all UC Health clinical laboratories. Antibodies detected in the blood of people show an immune response to infection. Antibody tests can detect previous infections with SARS-CoV-2, including in people who had few or no symptoms. We do not yet know if the antibodies that result from SARS-CoV-2 infection will provide an individual with protection (immunity) from getting infected again. It is not known yet if people with antibodies can carry SARS-CoV-2 or transmit the virus to others. If antibodies do provide immunity, we do not yet know how much antibody is protective or how long the protection might last. Additionally, at this time, because of the low prevalence of SARS-CoV-2 in US communities, according to the [CDC](#), positive antibody test results may represent false positives in up to 50% of cases. The CDC guidance states, “serologic test results should not be used to make decisions about grouping persons residing in or being admitted to congregate settings, such as schools, dormitories, or correctional facilities,” and “should not be used to make decisions about returning persons to the workplace.” Antibody screening of large populations including students and employees may play a role in the future in our efforts to mitigate viral transmission in our learning environments and workplaces but are not recommended for operational, as opposed to research, purposes until additional data are available. For these reasons, antibody testing should not be mandatory for any group.
  
- 3) **Antigen testing:** Currently, two rapid antigen tests have received FDA emergency use authorization. These tests are approved for testing of individuals within 5 days of symptom onset. Negative antigen results in symptomatic individuals may warrant confirmation by PCR. Antigen testing technology continues to evolve with some showing clinical sensitivity of 96%. Campuses should weigh the cost-benefit of antigen testing to supplement higher sensitivity molecular-based methods.

## II. Diagnostic Testing

Diagnostic testing using appropriately validated assays in a CLIA certified laboratory with 24-hour turn-around time for results should be available at all UC locations (on campus, through sister campuses, or through community labs) for all symptomatic individuals identified through symptom screening or other means. Students, faculty, or staff (including any families living on campus) who are close contacts of confirmed cases should also be tested<sup>7</sup>. All sites should consider offering validated, onsite diagnostic testing to ensure rapid turn-around of results to inform isolation, quarantine, case investigation and other contact tracing efforts.

The capacity to do testing will depend on the model chosen by the location, weighing test performance, specimen type, and feasibility. *Testing of asymptomatic individuals who are not close contacts must not compromise a location's ability to test all symptomatic individuals and their close contacts, or impede the ability of the academic health centers, student health centers, and occupational health clinics to test patients.* The process of testing is not solely a matter of conducting the test in a lab but also includes all activities associated with acquiring the test specimen, getting the test to the lab, and managing the results after. The cost of conducting testing and the funding required to support it are also factors to be considered, as well as the potential for other future testing modalities that might become available.

Campuses have been working on establishing and increasing testing capacity and capabilities in partnership with CLIA-certified clinical laboratories. Campuses without a medical center affiliation have experienced more challenges as they try to develop high-quality, fully certified testing laboratories and return results within a 24-hour period. Therefore, strengthening new and existing formal partnerships across the system offers an important strategy for sharing best practices on testing, contact tracing, isolation/quarantine, and other epidemic control measures. Campuses can benefit from any excess capacity at UC Health testing sites and conversely, capacity in campus-based research laboratories may be used to support UC Health locations during times of surge or interruptions in supply chain.

The task force has developed an inventory of the current diagnostic testing capacity for each UC campus, the three affiliated national laboratories, and Agriculture and Natural Resources (ANR). It may serve as a tool to identify current gaps in testing and facilitate regional partnerships.

### **Pre-testing Processes**

Pre-testing begins with identifying the locations where testing will be available and taking the necessary actions to have appropriate staff and sufficient supplies available at those locations. For example, the student health center is an appropriate location to test students. Faculty and staff should be referred to their healthcare provider for evaluation and testing. If feasible, locations may choose to offer onsite testing to faculty and staff. Convenient, alternative locations should be identified for each campus.

Self-collection of specimens is preferred for large-scale testing and is ideally conducted under the supervision of experienced staff to minimize false negative results due to inadequate

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<sup>7</sup> [CDPH COVID-19 Testing Guidance \(August 3, 2020\)](#): Close contacts of confirmed cases are a Tier Two testing priority.

sampling. Supervised self-collection of samples minimizes re-sampling and re-testing, and preserves resources, including PPE, collection devices, transport media, test reagents, and human resources.

Processes to minimize pre-analytic error need to be developed and implemented, including procedures to ensure correct specimen labelling with the required individual identifiers and accessioning into a laboratory information system for billing and reporting. Specimen identification methods could include the use of a phone app and bar codes. Logistics to ensure timely transportation of the specimen to the laboratory under appropriate environmental conditions must be in place. Additionally, proper sample identification must be in compliance with established State and Federal regulations. Diagnostic test results must be captured electronically to meet reporting requirements to local public health agencies, for contact tracing or epidemiological case investigation, and to ensure situational awareness of campus outbreaks.

### **Testing Processes**

Testing for the purpose of surveillance, diagnosis and clinical management of COVID-19 is available in CLIA certified laboratories at the five UC medical centers and at “popup labs”<sup>8</sup> at some health and non-health campuses. Current testing capacity at each UC Health clinical laboratory ranges from 1,000 to over 2,000 tests per day (and growing), depending on the institution, with turnaround times of <24 hours (from time of sample receipt in the laboratory) for patients.

Turn-around time of <24 hours should be expected for testing of symptomatic individuals as described in **Section I**. All sites should work to develop processes and procedures for implementation prior to start of the fall term.

The potential to augment the clinical testing capacity of the CLIA-certified clinical laboratories through extension of an existing CLIA facility has been employed for research laboratories at several campuses across the UC System. The coordination of these activities is vital and the dedication of basic science resources for COVID-19 testing comes at a significant cost of equipment, personnel, reagents and supplies. There are also compliance requirements under Federal and State regulations and national accreditation standards that address the acquisition, processing, running, and reporting of specimen results in any case where a laboratory intends to return individual results. In late August, CMS [temporarily implemented enforcement discretion](#) for non-CLIA certified university labs conducting SARS-CoV-2 surveillance testing under certain defined parameters. For campus locations to utilize this approach, CDPH would need to implement similar enforcement discretion for non-CLIA certified laboratories under the parameters identified in the CMS guidance.

The infrastructure for compliance and oversight must be in place before laboratory testing can begin. This includes having appropriate personnel to serve as the laboratory director, testing and quality assurance staff, standard operating procedures, validation plans, laboratory information systems, and more. The UC System has a responsibility to ensure that its

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<sup>8</sup> See, e.g., Doudna JA, [Blueprint for a Pop-Up SARS-CoV-2 Testing Lab](#).  
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laboratory facilities are used in a manner that optimizes the stewardship of limited resources. The task force recommends coordinating research laboratory testing with the UC Health Laboratory Working Group to ensure compliance with all CLIA regulatory requirements, as applicable.

To address the requirement that a campus be able to test or refer for testing any symptomatic student, faculty, or staff member within 24 hours, any campus that does not operate a CLIA-certified and compliant laboratory must have access to a CLIA-certified and compliant laboratory that can turn around results within 24 hours of testing at a sister campus or medical center or in the community. Likewise, if a campus intends to offer diagnostic testing through Student Health Services it must ensure it has sufficient capacity to meet the 24-hour turnaround requirement.

### **Potential for Future Testing Modalities**

Campuses with CLIA-certified labs are equipped to do standard testing and may have means to deploy alternative methods including laboratory developed tests (LDTs). The task force received reports from a number of research laboratories across the system that identified cutting-edge research techniques that may mature over the course of the next several months. As a research intensive institution, the UC System should encourage and invest in the development of these techniques. Emergency use authorizations (EUAs) are recommended for these tests, even in those cases where not required, to protect the campuses from legal exposure.

### **Post-testing Processes**

The technology required to collect and tie a sample to an individual at the time of collection must be in place to report the result back to that individual through a qualified health care provider or public health authority. Methods to quickly communicate actionable results (*i.e.*, positive PCR result) must be established. Speed to communicate positive results facilitates rapid epidemiological case investigation and/or contact tracing and isolation to limit further transmission of disease, as described in **Section III** below.

CDPH [has observed in published guidance](#) that “all testing should be accompanied by a seamless plan for follow-up of disclosure of test results and linkage to care.” Any campus testing plan should address the steps that will be taken by a campus in the event a student or employee tests positive, including isolation, quarantine of close contacts, referrals for care and connection to other services.

### **Testing Costs and Funding**

The task force is not aware of a common UC standard for calculating the cost of a test. The total cost goes beyond the materials themselves and includes, at a minimum, the following elements:

- Supplies required for sample collection, including individual collection materials and also racks or other storage supplies
- Transportation to and from collection sites

- Staffing and other variable costs required for collection, testing, reporting, and quality management and oversight
- Fixed costs required to support the testing labs
- Technology costs required to support all testing phases; integrations with other systems if needed for reporting or other purposes
- Startup costs for any “popup” labs

Further defining and modeling common standards for calculating the cost of testing would be helpful. The level of funding and source of funds required to implement testing strategies does not appear to have been fully resolved at most campuses but is especially critical given the level of asymptomatic testing needed to support a return to onsite operations.

### III. Case Investigation and Contact Tracing

[Contact tracing](#) is a term of art that refers to a disease control measure employed *by public health authorities* to prevent the spread of communicable diseases. Normally the responsibility of local public health departments, universities may perform these functions under contract with those agencies. It is rare for universities to take on this responsibility. However, universities responding to communicable disease on campus *do* play a role in diagnosis, reporting, and treatment. Working closely with and under the direction of their respective health departments, they also facilitate case investigation and other related activities.

In the context of the SARS-CoV-2 pandemic, the CDC [recommends](#) that institutions of higher education identify and notify close contacts of students, faculty or staff who have been diagnosed with COVID-19 and advise them to self-quarantine and monitor for symptoms. The CDPH has [suggested](#) that *all* industry sectors “investigate any COVID-19 illness and determine if any work-related factors could have contributed to risk of infection [and update] plan[s] as needed to prevent further cases.” In the case of higher education, we read “work-related” to include “school-related” or “instruction-related”. Cal/OSHA [requires](#) that when an employee is confirmed to have COVID-19, the employer must inform others of their possible exposure in the workplace, temporarily close the general area where the infected employee worked until cleaning is completed, and conduct disinfection of that area and related common areas, restrooms and travel areas. Collectively, these recommended activities will be referred to below as “epidemiological case investigation.”

Epidemiological case investigation is not the same as contact tracing. To the extent campuses wish to assume the responsibility of a local public health authority for contact tracing, this must be done under a formal contract and delegation, in which case the activity will be governed by the contract as well as state laws and regulations governing local public health authorities in performing this work. If not, a mechanism for contacting and working with local public health departments must be developed. As of July 2020, UC Irvine and UC Merced are in the process of pursuing formal delegated authority from local public health authorities to conduct formal contact tracing at their respective campus locations. These locations may serve as a resource for other UC campuses interested in pursuing a similar course of action.

Epidemiological case investigation is regularly performed by the campuses for communicable diseases other than COVID-19, typically by Student Health Services (SHS) for student cases and by Risk Management, Environmental Health & Safety (EH&S), or Occupational Health offices for faculty and staff cases, both in close consultation with local public health departments.

Neither contact tracing nor epidemiological case investigation is an end in and of itself. Rather, they are tools used to help identify interventions like quarantine and isolation that may be needed to avoid further outbreak; offer testing and, as necessary, treatment to other individuals who have been exposed; and provide information necessary to update or expand on risk assessments and mitigation or containment plans. Implementation of contact tracing or epidemiological case investigation plans requires substantial professional support.

### **Workforce Requirements**

In California, counties pursuing variances to the state's stay-at-home orders are certifying that they can allocate 15 trained contact tracers per 100,000 residents. Statewide, the plan is to train 20,000 contact tracers, or as many as 50 per 100,000 residents. To provide sufficient resources to perform epidemiological case investigation on campus, including in response to an outbreak, the task force recommends that campuses have available or train at least 15 professional staff per 100,000 students, faculty and staff expected to train, live or work on campus in the fall. Greater numbers may be required for campuses performing the full range of contact tracing activities under contract with their respective local public health departments. The task force recommends against over-reliance on existing SHS, Risk Management, EH&S, or Occupational Health resources for this task, as this may risk compromised performance or non-performance of other critical school and workplace health and safety activities.

The workforce necessary for epidemiological case investigation and contact tracing should be identified, hired, and fully trained by at least four weeks before the start of the fall term. The ability to launch campus-based case investigation and/or contact tracing immediately upon student arrival will be a critical factor in attempting to contain any initial "seeding" clusters or outbreaks.

Campuses must be able and ready to act on the information they receive through any testing, epidemiological case investigation or contact tracing effort. This may include, for students, setting aside facilities for those in residential housing that may be necessary to support quarantine and isolation; identifying resources for case management and treatment; and developing protocols for notification of close contacts as necessary to comply with public health and workplace safety recommendations and mandates.

The task force observed that compliance with campus-based epidemiological case investigation and contact tracing efforts may present challenges, especially among certain campus populations. The task force recommends locations focus on creating a culture of participation that rewards positive behavior and fosters community-based responsibility to the safety of others. Additionally, locations should explore viable options for enforcement especially in higher-risk settings and for individuals who are consistently non-compliant.

## **Digital Proximity and Exposure Management Mobile Application**

The task force also recommends that campus plans for epidemiological case investigation or contact tracing squarely address related privacy and information security concerns. The task force considered the adoption of a systemwide digital contact tracing mobile application. However, due to several concerns, including the development time required and the significant privacy, operational and sociological challenges, the task force is not recommending adoption of a systemwide exposure management mobile application at this time. This type of application should be developed and deployed at the state level. The task force encourages UCOP to continue collaborating with the state on any statewide adoption of this type of application.

### **Appendix A: Privacy Recommendations**

*The systemwide Chief Privacy Officers are in the process of developing recommendations on privacy principles in support of COVID-19 mitigation and control efforts. Following is their current set of recommendations. Campuses are encouraged to consult with their local privacy officers when developing their local plans.*

#### **Individuals**

- Should be informed about each program and about the data handling practices of each component
- May be required to give explicit consent for some program elements (e.g., secondary use of data obtained from mandatory screening or testing programs for research purposes)
- Should be giving a single point of contact for questions and concerns

#### **Programs**

- Should be limited to concrete public health activities
- Should have a written protocol developed describing practices and procedures
- Should have a communications plan developed for rollout
- Should be reviewed each time a location moves between stages along the resilience roadmap, and adjusted to fit the circumstances
- Should be sunsetted when no longer needed
- Require oversight, to include ethical and human rights aspects, for accountability and to ascertain that measures are necessary and proportionate to their impact and effectiveness, and that use of personal data are firewalled from other functions

#### **Data**

- Should be collected only if necessary and relevant for the stated purpose(s) and for the relevant population (e.g., teleworking employees generally would not need testing); and should distinguish between collection by a healthcare provider and a location
- Use should be for a specified purpose that is communicated to individuals
- Should be properly secured from unauthorized use or disclosure (including applications that collect data)
- Should be wrapped with written procedures to ensure data subject access rights (e.g., by students, represented staff, and the community)

- Access should be limited to those with a need to know, and should distinguish between medical professionals providing healthcare and administrators protecting public health and facilitating University operations
- Should be retained no longer than necessary, and maximally for the duration of a program; if kept beyond a program's sunset, it should be considered a new program
- Practices should be informed by input from the campus privacy officer for alignment with existing campus practices

## Appendix B: Summary of Asymptomatic Community-Based Screening Strategies

Please also refer to [Appendix C](#) for a discussion of legal considerations for any strategy that contemplates return of results or that mandates testing of individuals as a condition of living, learning, or working on campus.

- I. **UCSF Employee Testing Strategy (this strategy is only applicable to UCSF due to its unique distinction of being a graduate level campus only)**: The goal of the UCSF strategy is to inform mitigation strategies and ensure safe work environments by detecting Covid-19 monthly incidence levels if they exceed 1% across campus and clinical work environments.
    - A. The UCSF Testing Strategy conducts Covid-19 RT-PCR testing of the following:
      1. All current employees and students entering a UCSF facility with any symptoms of Covid-19.
      2. Appropriate individuals identified through contact tracing investigations.
      3. Planned: All new employees, faculty, trainees and students before starting on-site work or training.
      4. Proposed: Asymptomatic individuals working in UCSF clinical, administrative and research buildings based on a stratified random sampling strategy to achieve total monthly testing of 15% of our population (approx. 1700 tests per month) when combined with symptom-based testing.
      5. Under Development: Campus student housing and child care facilities.
    - B. Sampling Areas (n=9): is comprised of multiple clinical units or floors.
      1. Parnassus Heights Campus: (1) Hospital; (2) Ambulatory Care Center + LPPI; (3) School of Dentistry; (4) Medical Sciences/HSW/HSE/SON/Millberry Union
      2. Mission Bay Campus: (5) Childrens/Adult Hospital; (6) Gateway/Precision Medicine (Cancer Center); (7) Orthopedic Institute; (8) Mission Hall/Genentech/Byers/Sandler Neurosciences
      3. Mt Zion Campus: (9) All sites
1. Intensive contact tracing of all positive cases
  2. When 3 or more cases are identified in the same Sampling Area in a 30day period, implement additional mitigation procedures as appropriate for all employees and students on the relevant unit(s)/floor(s): asymptomatic testing, quarantine, unit closure

- II. UC San Diego Testing Strategy: We assess what testing frequency is required to detect an outbreak with >90% probability before there are 10 detectable infections. A dynamic compartmental transmission model of SARS-Cov-2 was developed among a university community. After introducing a single infection, we calculate the probability of detecting at least one case on each succeeding day with various NAT testing frequencies (daily testing achieving 25%, 50%, 75%, and 100% of the population tested per month) assuming an 85% test sensitivity. Widespread testing of 100% of the campus population every month is required to detect an outbreak with 90% probability when there are 10 detectable infections, assuming an 85% test sensitivity. Early detection is necessary, but not sufficient, to curtail disease outbreaks; the proposed testing rates would need to be accompanied by case isolation, contact tracing, quarantine, and other risk mitigation and social distancing interventions.
- III. UC Berkeley Model: A simple Berkeley model (Joe Lewnard) suggests that if the underlying reproductive number  $R_0$  is 2, then a testing protocol would have to test everyone every 1.7-2.3 days to reduce  $R_0$  to 1 (and stop exponential growth). Note that this is a different metric than the UCSD model (Natasha Martin) which is less strict since it does not limit the risk of outbreaks, only that they be detected (with probability at least 0.9), with sufficient testing, before the total number of infections exceeds 10. However, this means there are likely an additional 9 infected individuals who must be identified, and this is dependent on very effective contact tracing. The UCSD model also does not allow for continuous importation of infections from the outside community. The Berkeley model also does not account for effective contact tracing that will reduce the  $R_0$ ; but even with an  $R_0$  of 1.25, the testing strategy to reduce  $R_0$  to 1 is testing everyone every 2.8-3.7 days. Thus, effective contact tracing in and of itself does not significantly impact the required testing frequency. The Berkeley calculations align closely with the [preprint from the Basu lab](#) that suggests a testing frequency of at least twice a week to prevent workplace outbreaks (again assuming no contact tracing).
- IV. Yale Model: The Yale approach uses the metric of total number of infections in a campus setting from September 1 until Thanksgiving. The calculations assume that the campus starts with 3 undetected infections on September 1 (amongst a 10,000 campus population) and various imported case frequencies (ranging from 0 to 1/week to 5/day) and a test sensitivity of 70% (reflecting a failure to detect in some cases early on in an asymptomatic infectious period). In summary, the authors find that weekly testing for all is necessary to limit cumulative infections to no more than 5% of the student population.
- V. ["Frequency of routine testing for SARS-CoV-2 to reduce transmission among workers"](#)  
Abstract: Shelter-in-place policies have been considered effective in mitigating SARSCoV-2 transmission. To end such policies, routine testing and self-quarantine of those testing positive for active infection have been proposed, yet it is unclear how often routine testing would need to be performed among workers returning to workplaces, and how effective this strategy would be to meaningfully prevent continued transmission of the virus. We simulated SARS-CoV-2 polymerase chain reaction testing to estimate the frequency of testing needed to avert continued epidemic

propagation as shelter-inplace orders are relaxed. We find that testing strategies less frequent than twice weekly (e.g. weekly testing or testing once prior to returning to work) are unlikely to prevent workforce outbreaks. Even given unlimited testing capacity, the impact of frequent testing may not be sufficient to reliably relax shelter-in-place policies without risking continued epidemic propagation, unless other measures are instituted to complement testing and self-isolation.

- VI. [Harvard/Yale Model](#): This analytic modeling study of a hypothetical cohort of 4990 college-age students without SARS-CoV-2 infection and 10 students with undetected asymptomatic cases of SARS-CoV-2 infection suggested that frequent screening (every 2 days) of all students with low-sensitivity, high specificity test might be required to control outbreaks with manageable isolation dormitory utilization at a justifiable cost. This modeling study concludes that screening every 2 days using a rapid, inexpensive and even poorly sensitive (>70%) test, coupled with strict behavioral interventions to keep  $R_t$  less than 2.5, is estimated to maintain a controllable number of COVID-19 infections and permit the safe return of students to campus.

## Appendix C: Legal Considerations

Laws, regulations, and industry guidance concerning screening and testing have been fluid and are expected to continue evolving.

Before implementing a screening or testing program, a campus should: (i) define the type of screening and testing that will be used, referencing the above recommendations or other scientific support; (ii) the purpose or rationale of the screening or testing program (e.g., prevention of outbreaks, early containment, or mitigation); (iii) who will be screened or tested; (iv) who will conduct the screening or testing and how; (v) the frequency of screening or testing; (vi) the purpose of the screening or testing; and (vii) whether the screening or testing will be voluntary or used as a condition of continued enrollment, employment, or entry to the campus. All of this should be documented in a clear, written, and broadly disseminated protocol that explains to all affected individuals the procedure for screening and testing, how the information collected will be used, stored, and externally reported, and what an individual's rights are related to screening and testing.

Any screening or testing plan must be administered uniformly (to avoid discrimination claims) and provide clear guidelines for responding to students, employees, visitors, or others who refuse to submit to screens or tests. It must also address what steps the campus will take (e.g., making mandatory reports to local public health officials, isolation of the test subject, epidemiological case investigation, quarantine of close contacts, care and other supportive services) in the event a student or employee tests positive or the campus learns of a positive result from a test administered externally. Student health, occupational health, and infection prevention teams should consult with coordinators charged with managing the interactive process to advise on reasonable accommodations in response to employee, student, or visitor requests. Consultation with local campus privacy and security officials in the course of developing any screening or testing program is also highly recommended.

### 1. Mandated Screening

Various [federal](#) and state agencies have recommended or mandated screening procedures as a mechanism to mitigate the risks of known workplace hazards. For example, the [State of California mandates](#) implementation of individual screenings to promote workplace and customer safety. The University likewise may mandate (in fact, has little choice but to mandate) screening for symptoms and recent positive test results as a condition of access to University facilities (symptom screening may include temperature checks, but the efficacy of such checks is disputed). If the University collects individually identifiable responses, this information must be treated as confidential student or employee health information, segregated from other records, and maintained in a secure fashion. Some screening applications do *not* collect such data but instead merely issue a token confirming the individual is eligible for entry to University facilities on a given day.

### 2. Mandated Testing

The California Department of Public Health [has prioritized COVID-19 testing](#) for asymptomatic residents or employees of congregate living facilities (such as residence halls) prior to admission or readmission and after positive cases have been identified. The U.S. Equal Employment Opportunity Commission [has affirmatively stated](#) that

employers may choose to administer diagnostic COVID-19 tests (but not antibody tests) to employees and take other steps to determine whether employees entering the workplace have COVID-19 because individuals with the virus will pose a direct threat to the health of others. We are not at this time aware of any blanket prohibition on mandatory diagnostic testing, however targeting certain populations for mandatory testing (such as those living in campus-owned housing) may trigger challenges. Please consult with local campus counsel in the development of your testing strategy. As with screening, it is imperative that any individually identifiable information about testing be maintained confidentially in segregated, secure systems.

### 3. Diagnostic Clinical vs. Community-Based Public Health Screening or Research Testing

Under current regulations, **diagnostic** testing must be ordered by a physician or other licensed and authorized practitioner, performed in a CLIA-certified lab, and reported to test subjects through the physician if individual results are to be released at all.

Non-CLIA laboratories may be utilized to perform asymptomatic and other public health surveillance testing, but only if they:

(i) do not return results; (ii) acquire CLIA certification directly or, during the public health emergency, as a satellite site to an existing CLIA lab; or (iii) enter into a formal arrangement with a public health lab. The startup process for a “popup” clinical lab has proved to be expensive and includes costs of retaining appropriately qualified clinical direction, training and retaining personnel, developing policies and protocols, acquiring information systems, performing quality oversight, and obtaining ongoing regulatory support. Accordingly, campuses may prefer to perform asymptomatic surveillance testing in research labs that do not return results, or develop arrangements with public health labs in consultation with counsel. Depending on the nature and circumstances of the testing plan, such activities may or may not qualify as “research” for purposes of regulation under the Common Rule, FDA regulations, and University policies. Consultation with a campus’s Human Research Protections Program is recommended to identify and discuss options and associated compliance responsibilities.

CMS has issued updated guidance for Non-CLIA Laboratories that temporarily provides enforcement discretion. The guidance can be found [here](#). CDPH will need to provide similar flexibility to enable campus locations to utilize the approach summarized in the guidance document.

The updated CMS guidance includes the following:

**With some of the other surveillance platforms that use next-generation sequencing, there is no need for a pooling strategy (the samples are all barcoded) – in that instance, is it acceptable for the university to notify a specific person that he or she should seek testing in a CLIA lab?**

Generally, SARS-CoV-2 surveillance testing can be performed in a facility that is NOT CLIA certified, and may use a test or technique NOT authorized by the FDA, provided that patient-specific results are not reported. If at any time a patient-specific result is reported, the facility is subject to CLIA and required to obtain an appropriate CLIA certificate in accordance with 42 CFR part 493.

However, CMS is temporarily exercising enforcement discretion under CLIA for SARSCoV-2 surveillance testing where patient-specific results are reported (e.g., SARS-CoV2 surveillance testing that does not utilize a pooling strategy). Specifically, neither CMS nor the State survey agencies on its behalf will cite non-CLIA certified facilities, such as university laboratories, that are performing such testing, provided that the facility does not report actual test results, but only refers an individual with a presumptive positive or inconclusive test result to a CLIA-certified laboratory for further testing.

#### 4. Additional Considerations

Screening and testing protocols should be adjusted as necessary to facilitate consistency with developing guidance from federal and state agencies including the Centers for Disease Control & Prevention, the Equal Employment Opportunity Commission, the California Department of Public Health, the Department of Fair Employment & Housing, and Cal/OSHA, as well as local county health department orders and guidance. Mandates that *exceed* federal, state, or local directives or guidelines, or applicable industry standards (which are also in a state of flux) may be challenged legally. The most effective defense will be one that can point to a well-designed program that is scientifically supported, duly adopted, transparently communicated, and consistently administered. Again, any systems used to support information collection or reporting related to the above activities should be designed to address information privacy and security concerns as a priority.

### Appendix D: Testing Strategies for Students Arriving to Campus (ARCHIVE)

As the September 1, 2020 publication of this document, this table is no longer valid. It is included here for reference only. The “*Symptomatic Testing Only*” strategy is no longer recommended by the task force.

**Table A: Strategies for Students Arriving to Campus\***

Requirement	Asymptomatic Testing	Symptomatic Testing Only
Daily self-performed symptom monitoring	Required beginning 14 days prior to arrival and every day thereafter	Required beginning 14 days prior to arrival and every day thereafter
Test prior to arrival on campus	All students required to show proof of a negative FDA EUA-authorized SARS-CoV-2 clinical test (currently PCR) within 7 days prior to arrival	PCR testing required for all symptomatic students prior to arrival on campus
Test again after arrival on campus	All students who reside in on-campus housing will be retested by PCR between 7-14 days after arrival on campus.	Only if a student has developed symptoms <i>en route</i> to campus or reports that they are a close contact of a COVID-19 positive individual
Sequester with minimal social interactions (essential activities only)	7 days for all students upon arrival or until the second negative PCR test is completed	14 days for all students upon arrival
Refer symptomatic students for medical evaluation	Evaluate and provide care as determined by medical professional	Evaluate and provide care as determined by medical professional

Test symptomatic students and return results in $\leq$ 24 hours	Required if recommended per symptom screening algorithm and/or evaluation by medical professional	Required if recommended per symptom screening algorithm and/or evaluation by medical professional
Isolate symptomatic students pending results	Required	Required
Refer students who test positive for case investigation and contact tracing	Required	Required
Test AND quarantine for 14 days close student contacts of students who test positive	Required	Required
Face coverings worn in public at all times	Required	Required
Other NPI and adherence to all required public health measures	Required	Required

\* As a general matter, graduate and health professions students should be treated the same way as undergraduates on campus. Different strategies may be employed for different campus segments, however, if a decision is made locally that such an approach is warranted. For example, medical residents and fellows may have different obligations and these, in turn, may limit sequester options.