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# At-Home Testing for Infectious Diseases: The Laboratory Where You Live

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Interest in at-home testing for infectious diseases is growing. The need for at-home testing, specifically for coronavirus disease 2019 (COVID-19), has been hotly debated in the media, but this is not the first time nor the first infectious indication for which at-home testing has been advocated. At-home testing for infectious diseases such as HIV and other sexually transmitted infections is available and has been vigorously debated. Health equity to marginalized communities and reduction of disease transmission are among purported benefits of widespread availability of at-home testing. A number of questions remain regarding at-home test accuracy and the ability to impact patient outcomes and public health while protecting patient privacy. Here, expert clinical microbiologists, physicians, and public health officials weigh in on these outstanding questions with specific emphasis on newly approved at-home tests for COVID-19 during the global pandemic.

***What at-home COVID-19 testing is currently available, both in the United States and globally?***

**Susan Butler-Wu:** When it comes to at-home COVID-19 testing in the United States, the majority of Emergency Use Authorizations (EUAs) issued by the Food and Drug Administration (FDA) to date involve at-home collection. By definition, at-home collection involves self-collection of a specimen outside of a healthcare setting and then either shipping it to or dropping it off at a designated location, such that it is tested in a CLIA-certified high-complexity laboratory. Some at-home collection tests only have authorization for use by prescription, whereas others have authorization for direct-to-consumer testing, and a prescription is not required. More than 50 authorizations for at-home collection have been issued by the FDA since the beginning of the pandemic, and all involve nucleic-acid amplification tests (NAATs), such as RT-PCR.

The number of tests with EUA for at-home COVID-19 testing is far more limited by comparison. Unlike at-home collection, EUAs for at-home testing have been issued for both NAAT and antigen tests. There are currently 2 NAAT-based assays with EUA for at-home testing (at the time of writing), and both use reverse transcription followed by isothermal amplification. Both require the use of manufacturer-provided instrumentation and have EUA for over-the-counter (OTC) testing of symptomatic and asymptomatic individuals.

There are currently 3 manufacturers with EUA for at-home antigen testing in the United States: Ellume Limited, Abbott Diagnostics, and the Quidel Corporation. The Ellume COVID-19 Home Test is unique among currently authorized at-home antigen tests in that it includes a Bluetooth connected analyzer that requires use of a smartphone app for test interpretation. In contrast, results of the BinaxNow COVID-19 (Abbott) and QuickVue (Quidel) tests rely on visual inspection for test interpretation. The Ellume test has authorization for OTC testing, while the BinaxNow and QuickVue assays have both OTC and prescription-based offerings. Although all 3 manufacturers' tests are authorized for symptomatic testing, only the Ellume test is authorized for single testing for asymptomatic screening. In contrast, the EUAs granted for Abbott and

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Quidel for OTC use specify that serial testing should be performed 1 to 3 days apart for asymptomatic screening, depending on the test.

**Kimberle Chapin:** There has been a rapid evolution for tests to detect severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Initially, all COVID-19 testing involved provider-collected specimens, and all testing was performed in CLIA-certified laboratories. As the pandemic progressed, public health was compromised when the demand for testing was not aligned with the supply. As the unprecedented demand for COVID-19 testing continued, approvals of traditional testing and capacity building, along with the inability to access and be seen by providers coupled with long test report times, created the perfect storm for many suppliers to not only commercialize COVID-19 tests but also develop new ways for patients to access tests and services. Today, several self-collection and home testing options for COVID-19 exist in the United States (as described in the FDA In Vitro Diagnostics EUAs—Molecular Diagnostic Tests for SARS-CoV-2 document). The number of tests and collection options with EUA exploded rapidly and changed in 2 important ways. First was in-home collection (with laboratory-based testing) and next, capitalizing on lack of provider access, was in-home testing. The first testing kits for home were offered by multiple commercial laboratories and were self-collected specimens that were sent to a centralized laboratory; these tests required a prescription and were reimbursable. Now, direct-to-consumer specimen collection kits are available through commercial pharmacies or online vendors (e.g., CVS, Walmart, Amazon). Overall, the home collection laboratory-based tests are amplification-based, provide results in 1 to 2 days and direct reporting to patient and public health, and include customer support, reimbursement guidance, and shipping. Almost all home collections are nasal swab specimens.

In-home testing, or OTC testing, is also available, and the kits include all supplies to run the test (e.g., swab, test device, instructions). Collection and testing are authorized for symptomatic and asymptomatic people $\geq$2 years old, and results are available in 15 to 30 min. Currently, there are 3 antigen tests for at-home use; all detect nucleocapsid protein antigen and are lateral flow assays. Two are visually interpreted, and one uses fluorescent technology that requires a smartphone app for interpretation and result transmission to public health. Importantly, negative predictive value compared to high-complexity RT-PCR has a wide range depending on patient population, clinical presentation, and prevalence of disease. Thus, serial antigen testing every 3 days, or twice per week, is recommended to identify infection in early stages. Specificity is reported to be high. Two loop-mediated isothermal amplification tests are authorized by FDA for OTC use; both target the nucleocapsid region of the viral genome and take less than 1 h to provide results.

**Nitika Pant Pai:** Home COVID-19 tests can be conducted by any intended user (anyone with health literacy) in the comfort of their private space (home or workspace). Home-based COVID-19 test kits may also be self-sample collection tests. For example, the Binax Now Home Test (antigen) in the United States can be performed in self-collected swab specimen in those who meet COVID-19 clinical criteria and/or epidemiological criteria. In the United Kingdom and Germany, rapid antigen home tests have also gathered momentum. Users are encouraged to test themselves and their family members frequently.

***What role can at-home COVID-19 testing play in the pandemic response?***

**George Turabelidze:** Expanding testing with at-home tests enhances pandemic response at the individual (prompt diagnosis improves person's disease management and protects close contacts) and the community level (improves disease prevalence estimates, timing of prevention measures, lessens healthcare burden). The key question is whether at-home tests are accurate enough to accomplish those goals. However, even if inferior to conventional tests, the epidemiological concept of at-home testing represents a paradigm shift in disease surveillance from seeking to accurately diagnose a single individual at any given time to a testing regimen that emphasizes capture of infected persons

while those persons are most infectious. Future real-world data generated from at-home testing experience will be crucial in confirming validity of this concept. Greater convenience of at-home testing may also help communities with limited access to healthcare, as well as promote testing among people who otherwise might not go to a public testing site. The home testing approach works best when it is done in a serial fashion rather than as a 1-time test. The concern with this is that populations impacted the most by COVID-19 could be unable to afford frequent and serial at-home testing. Reducing the cost while maintaining quality of the product is very important going forward.

**Nitika Pant Pai:** If we examine the health system issues faced in controlling the pandemic response in New York and currently in Delhi and many cities in India, the turnaround time to results with an RT-PCR test is a huge bottleneck. It varies between 1 and 5 days, which is not an effective turnaround time in the setting of acute COVID-19 infection; long turnaround time impedes a rapid initiation of treatment and can lead to a rapid deterioration in the clinical condition of some patients.

In the mitigation phase of a pandemic, home tests can play a huge role in self-staging COVID-19 in populations with a certain level of health literacy. These tests can help provide a test result in both the asymptomatic and symptomatic phases of the infection. They can reduce long lines at a facility and anxious delays associated with waiting for a test result. They can help individuals self-triage, stage their COVID-19 infection, and manage their infection at home by monitoring their oxygen saturation levels with a pulse oximeter until they get to the point where they need hospitalization.

In India, people are not interested in showing up at free testing centers, for fear of contracting the virus at these super spreader centers. Self-tests help allay fear, minimize the possibility of contracting SARS-CoV-2, and triage moderate/severe COVID-19 cases requiring hospitalization from milder cases that can managed at home. With that, they may ease the burden on many overstretched healthcare systems. This is a welcome relief in a pandemic setting. However, regulatory systems must be ready to approve them with an EUA or honor the EUA from other credible agencies and provide the option to individuals to use them fast enough.

In areas where access to healthcare is a concern (such as the mountains of Nepal or rural areas of India), rapid antigen tests have already shown a promising uptake. In such settings, quality-assured self-tests can empower communities to stage their infection in the comfort of their own home. However, self-testers should be assisted by a telemedicine line or remotely supervised by doctors. If perchance their COVID-19 condition deteriorates and they require transportation to a hospital, the system should be ready to accommodate them. Self-tests are useless if they do not inform the next step in care (i.e., linkages to treatment and triage).

***What preanalytical or sample collection factors need to be considered with at-home tests for COVID-19? Please consider sample type (i.e., nasopharyngeal vs nasal swab, evidence of adequate sample collection by nonhealthcare workers).***

**Omai B. Garner:** Appropriate sample collection is critical for accurate test results. Home sample collection needs to be as easy as possible. Because of this, only saliva or anterior nares collection is feasible. Instructions for collection must be clear and easy to follow. Evidence for adequate sample collection within the test kit would be a significant improvement over most OTC tests.

**Susan Butler-Wu:** It is important to note that not all specimen types have equivalent sensitivity for SARS-CoV-2 detection. Nasopharyngeal (NP) specimens are widely considered as the gold standard to which all other specimen types are compared but can only be collected by trained healthcare workers wearing specific personal protective equipment and are relatively uncomfortable for the patient. Home collection can involve a variety of specimen types, depending on what has validated for use with the test system. In some cases this is saliva, while for others it includes midturbinate (also known as deep nasal specimens) or anterior nares swabs.

Compared with NP swabs, saliva obtained after coughing, midturbinate swabs, and combined anterior nares and oropharyngeal swabs produce the best results, with several studies showing the latter specimen to have similar sensitivity to NP swabs for laboratory-based NAAT testing. Anterior nares are somewhat less sensitive than these specimen types. The reliability of saliva for SARS-CoV-2 detection can be compromised if collection instructions are not carefully followed. It should also be noted that "saliva" is not a single sample matrix; differences in performance have been described between saliva specimens collected with prior coughing, by drooling, or by actively spitting into the specimen collection device.

***How does the performance of at-home COVID-19 tests compare to tests performed in a CLIA-certified laboratory? What strategies should be in place to optimize performance of at-home-tests?***

**Susan Butler-Wu:** There is a relative paucity of data directly comparing the performance of at-home unsupervised specimen collection and/or testing compared to testing performed in a traditional CLIA-certified laboratory environment. In 1 study, unsupervised at-home collection of midturbinate nasal swabs for RT-PCR was only 80% sensitive compared to clinician-collected NP swabs for symptomatic patients. This was lower than the difference reasonably expected based on swab types alone. In contrast, the Ellume Health EUA study found that unsupervised self-sampling and self-testing performed in a simulated home setting had high rates of agreement for both symptomatic and asymptomatic patients compared to healthcare worker–collected specimens tested by RT-PCR. To date, the only published study describing the performance characteristics of the Cue Health assay test showed high (>90%) concordance with laboratory-based NAAT performed with NP swabs. However, all specimens were collected by healthcare workers, and all testing was performed by laboratory professionals. Finally, although antigen testing is often discussed by the popular press as if it was 1 test, it is important to note that a spectrum of performance can be observed between assays. When evaluating the performance of at-home tests and particularly for antigen testing, it is important to differentiate between symptomatic testing and asymptomatic screening. This fundamentally comes down to RT-PCR being inherently more sensitive for the detection of SARS-CoV-2 than isothermal amplification and antigen-based methods. For symptomatic patients, viral loads are highest within the first week of symptom onset, and antigen positivity generally decreases as viral load decreases. For symptomatic patients, specimens are more likely to be positive if collected and tested beyond the first week of symptoms.

The subject of at-home testing among asymptomatic individuals has been one that has garnered much attention in the popular press and the scientific community alike. Interest in asymptomatic testing stems from the fact that asymptomatic and/or presymptomatic transmission is believed to account for a sizeable fraction of COVID-19 cases (estimates range between 12.6% and 65%). There has been much discussion regarding the concept that at-home antigen testing could potentially represent a "contagiousness" or "infectiousness" test. This idea stems from the observation that antigen positivity generally correlates with viral load and that high viral load predicts positive viral culture. However, it should be noted that the infectious dose of SARS-CoV-2 remains unknown and that viral culture practices vary widely between laboratories. Critically, a secondary infection attack rate of 12% was observed when index cases had viral loads below what would reasonably be expected to be detected by antigen tests compared with 24% when index cases had high viral loads ($1 \times 10^{10}$ copies/mL or higher). Finally, evidence of viral replication (subgenomic RNA) was present in over half of false-negative antigen tests in 1 study, even though only 12% of these specimens were viral culture positive.

There is, to put it frankly, currently no such thing as an infectiousness test for COVID-19. Thus, the ability to evaluate the performance of at-home antigen testing for this purpose is challenging. Unfortunately, studies using asymptomatic antigen testing as the sole public health intervention are lacking. However, there are now several reported examples of outbreaks connected to false-negative antigen test results in both the scientific literature (college football) and popular press (White House outbreak of 2020). The at-home component of testing introduces further complexity because there are no assurances that users will properly follow instructions for use or take appropriate measures based on the test results they obtain.

**Kimberle Chapin:** Right now, extensive comparative data between various molecular methods are not available. Variables that may alter the predictive value of the test include the stage of disease, the prevalence in the community, and whether the test is being used for screening or diagnosis. Big picture, a RT-PCR test for COVID-19 with an NP swab has performed best in most studies for people who were in all phases of COVID-19, especially early in exposure.

For home testing, a clear understanding by the consumer of how the test is being used (screening vs diagnosis), result interpretation, and subsequent next steps are critical for optimal performance. For example, in a person with symptoms consistent with COVID-19, a negative home test should prompt a confirmatory molecular test at a CLIA-certified laboratory while a positive home test should spur a call to their provider, self-quarantine, and provider reporting to public health.

***What diagnostic tests for infectious diseases are cleared for at-home use in the United States? How do they compare to current at-home testing options for COVID-19? Are there lessons from other infectious disease tests that can be applied to COVID-19 home testing?***

**Kimberle Chapin:** The only at-home, self-collected infectious disease test that is FDA-cleared in the United States is the Oraquick HIV test for HIV-1 and HIV-2 antibodies (OraSure Technologies, Inc.). The test is a

lateral flow assay that uses a self-collected oral swab that is attached to the cartridge reader. The test requires visual interpretation of control and test lines and takes about 20 min to perform. The OTC test was available in 2012, and the path to clearance as an OTC test was scientifically rigorous. To ensure optimal support to consumers, OraSure not only provides live support 24/7 for testing but also referrals for follow-up and care for clients with positive results. The website is extremely user friendly, including clear instructions about next steps, (e.g., that a positive test must be confirmed). The current COVID-19 tests certainly did not undergo the scientific performance rigor that Oraquick underwent, obviously because of public health needs created by the pandemic and an overall assessment of risks to consumers by the FDA. However, many of the attributes we desire for point-of-care testing (e.g., near patient care and convenience; simple to perform; clinically actionable results in minutes; potential for reduced overall costs, especially if performed at home where a sick person may not have to come into a healthcare setting exposing others) are clear benefits. What's currently missing, in part, from current COVID-19 test systems is the total package of quality parameters expected for patient testing, including not only assurance about test performance by the consumer but also about performance for the analyte over time, controls, reporting requirements, quality of results in specific settings, and follow-up for the patient.

**Nitika Pant Pai:** The HIV self-testing narrative gathered massive momentum with the FDA approval of the OraQuick home test for HIV in 2012. Since then, about a dozen self-tests are either approved 'Conformité européenne' (French for 'European conformity') (CE) mark, FDA, World Health Organization Prequalification (WHO PQ) or on the market globally. These include both blood-based self-tests and saliva (oral fluid)-based self-tests. In parallel, inspired by HIV self-tests, sexually transmitted infection self-sample collection kits are also gaining in popularity. Although self-tests are not available for any other sexually transmitted infection besides HIV, self-collection of samples (blood samples, urine samples, dried blood spot) has generated credible data. Self-testing for hepatitis C is in the works, while self-sampling for chlamydia, gonorrhea, and human papillomavirus will pave the way for innovative ways to control these infections in communities.

***How might results from at-home infectious diseases tests change patient behavior?***

**Omai B. Garner:** Patient behavior in relation to at-home test results is a very difficult variable to control. Will positive patients believe the results and quarantine or see a healthcare professional? Will negative results drive patients to ignore public health recommendations on masking and social distancing? It's hard to know unless at-home testing is rolled out on a massive scale.

**George Turabelidze:** The behavior for many people will likely change in a desirable way, but we may see some undesirable changes as well. As eloquently stated in recent publication, positive at-home test should be a "red light" prompting the person to immediately self-isolate. Conversely, a negative test result should not be interpreted as a "green light" to disregard prevention measures because one feels "free of infection." The home test could have been falsely negative, and a negative test today does not mean an individual cannot be positive tomorrow. So, desirable public behavior would be that at-home testing by itself is not a substitute for personal responsibility in following public health recommendations. Would the public get frustrated and distrustful of home testing when sometimes there will be no simple answers? Meaningful interpretation of any test requires knowledge of its sensitivity, specificity, pretest probability, and the person's specific circumstances. Therefore, at-home testing may not always result in a simple yes-or-no answer; rather, the answer could be "it depends." Posttesting communication with a healthcare provider and/or public health authorities will need to occur to guide this person on further steps regardless of the positive or negative result. For example, symptomatic people exposed to COVID-19 who have a negative home antigen test may need a confirmatory PCR test. Positive results in asymptomatic individuals are less accurate and will need confirmation by more accurate test or repeat testing. Will people faithfully test themselves? After all, physicians know that some patients do not take medication as prescribed. Strict adherence to manufacture instructions for home testing is also necessary behavior for successful home testing.

**Nitika Pant Pai:** In the context of HIV, the frequency of self-testing and use of preexposure prophylaxis in tandem is being explored in clinical trials. Some implementation programs benignly adopt it. By frequently self-testing and using preexposure prophylaxis judiciously, one can manage one's risk of HIV acquisition.

In the context of COVID-19, provision of home tests may make people take a positive test status seriously. It might lead to responsible behaviors, in terms of protection, masking, and minimizing risk of transmission to others. Isolation and quarantine could follow naturally. The onus will be on the people to control and regulate their exposure to SARS-CoV-2. Provision of self-tests will be a step up from preaching masks and social distancing and getting vaccinated.

With vaccine rollout reaching high levels in high-income countries, we anticipate isolated outbreaks of SARS-CoV-2 in the workplace, newly opened entertainment areas, or possible travel-related exposures (visiting a red country). In such instances, home-based tests will come in handy when a person is coming down with a flu-like illness, and RT-PCRs are not readily available (without an appointment) in the infectious period (the first week of illness). It just simplifies the process of knowing, and from then on, informed action follows (that's the assumption, in this case).

***COVID-19 testing data, like all other health data are protected by HIPAA in the United States. How does this impact COVID-19 at-home testing? What data security measures need to be in place for more widespread at-home testing?***

**Omai B. Garner:** At-home testing is performed by the patient, but if the results of the at-home test are automatically transmitted to a healthcare professional, security measures would have to be in place to make sure that the results are only transmitted to healthcare professionals directly involved in the patient's care. It would be important to protect the information transfer from hackers.

**George Turabelidze:** There are multiple ways of conducting and reporting at-home tests. Work on personal data security issues is ongoing, and I do not think we have security issues worked out for every possible scenario right now. In general, those manufacturers who electronically communicate with consumers as part of the testing procedure are required to have HIPAA-compliant applications for the personal data collection and reporting. If a person's test result is reported by the healthcare provider or reported by persons themselves directly to the public health agency, already-established process that complies with HIPAA requirements will be followed.

***Many infectious diseases are nationally reportable. CLIA-certified laboratories performing COVID-19 testing are required to report all test results to public health authorities. How do at-home COVID-19 tests meet this mandate? Please consider with whom the responsibility for public health reporting lies.***

**Kimberle Chapin:** All tests with reportable results to public health, both positive and negative, performed in CLIA laboratories are the responsibility of the institution where the tests are performed. This applies to all laboratories (e.g., hospital or reference laboratories) and reporting requirements include, for example, COVID-19, sexually transmitted infections, and highly resistant bacterial infections. For all at-home collection kits where the specimen is sent to a laboratory for testing, the CLIA laboratory is responsible for this reporting, and it is stated on their websites that positive results will be reported. However, this reporting piece varies for the at-home test kits available to the consumer. Should this requirement fall on the consumer or the test manufacturer? The manufacturer could be made responsible to have a mechanism for meeting this requirement as part of the path to FDA clearance and/or use a provider mechanism (e.g., telehealth) for being the responsible reporting entity as well as address any follow-up issues related to the testing and interpretation. It should be known to the consumer that diseases with significant public health consequences, such as COVID-19, will be reported.

**George Turabelidze:** There is an important distinction between the 2 main types of at-home tests. In 1 type of at-home test, the person self-swabs and sends the sample to a laboratory the same day. The test manufacturer communicates test results back to the person, as well as notifies public health authorities as required by the FDA authorization of that test. With another type of at-home test, testing kits enable results at home but requires a smartphone or computer to report findings. Thus, responsibility primarily lies with the consumer. If a person communicates results to the healthcare provider, then that provider will be required to make a public health notification. Persons can also report test results directly to the local public health agency. Some degree of undercounting of COVID-19 cases detected by at-home testing is very possible because not everyone has access to a smartphone or digital device or because a person may simply choose not to report test result.

***What do you think the future holds for at-home infectious disease testing, especially for COVID-19?***

**Omai B. Garner:** I'm hopeful that vaccine uptake has a spread wide enough to eliminate the need for at-home testing. If COVID-19 becomes a rare viral respiratory illness, then at-home testing won't be necessary. Until we reach that point, I hope that there are groups that will study the accuracy and impact of large-scale at-home testing for infectious disease so that we can be better prepared for the next respiratory viral pandemic.

**Kimberle Chapin:** Pandora's box is open. The convenience for self-collection and home testing seems a no-brainer, right? For COVID-19, there are 243 molecular assays and 24 antigen assays with EUA designation. There are multiple in-home collection options and several at-home tests. But how many companies will take

the path to FDA clearance and what elements might be required for at-home use? Will analytical performance be satisfactory, especially as COVID-19 genetically drifts in molecular structure, vaccination continues, and the pandemic wanes? The clarity of performance between CLIA laboratory tests and at-home tests may be even more difficult to identify—but even more important to address. What about those who do not have Amazon accounts, local pharmacies, healthcare, live in crowded spaces, and/or are susceptible to unprecedented harm because of race, finances, or job description?

We need to think about the next pandemic. We will need production capabilities and fast, reliable, accurate, and inexpensive test options, paid by insurance or free and readily available to keep up with the public health needs. Working toward this now allows for future viability of success. Use of at-home testing in other high disease state periods (flu season), or high-risk populations (congregate living), would be good test cases. We have not seen the last of home testing, and laboratorians and healthcare providers collaboratively can help guide their optimal design and implementation.

**George Turabelidze:** Current rise in SARS-CoV-2 variant infections leaves open the question of whether at-home tests are capable of detecting such cases. Most antigen tests target nucleocapsid protein. Mutations in the nucelocapsid gene occur less frequently than the spike gene. So, it is likely that antigen test performance will not be affected by variants, at least in the near future. The whole idea of expansion to home testing came up pretty early during the COVID-19 epidemic in the United States because of insufficient testing capacity at that time. As a consequence, we could not gauge more accurately the extent of the pandemic spread in communities across the country: while some places were in the advanced stage of epidemic, others were not even close. More generally speaking about all types of home testing, this option may emerge as a major supplementary testing avenue more consistently. A lot will depend on how successful home testing for COVID-19 will turn out to be. In the future, we will see even more demand for testing capacity and overall laboratory support of epidemiologists responding to public health threats. That's where we need to focus in our overall pandemic preparedness. In the future, when we have individualized, integrated, data-driven healthcare and telemedicine becomes a norm, at-home testing may become indispensable.

**Nitika Pant Pai:** The future is bright for all home-based testing initiatives and digital health initiatives associated with self-testing. Individuals globally have noticed the widespread failure of health systems, alongside massive failures in leadership and governance and delays in informed timely action that have led to uncontrolled pandemics in 4 countries. People felt defeated in the initial surges and still do in parts of the world where the healthcare structures are fragile and failing. The virus has seamlessly invaded and has elegantly exposed the cracks in all healthcare systems that were intelligently hidden from public view.

COVID-19 has disrupted our lives in many aspects. However, it has led to many opportunities to embrace innovative technologies. Home testing is a blessing in disguise, as a consequence of this upheaval! It will still hold promise in the event protection from vaccines wanes over time and then outbreaks occur. In that eventuality, self-tests can come to our rescue to self-stage and check into a hospital facility before it is too late.

**Susan Butler-Wu:** The availability of at-home testing for infectious diseases, and COVID-19 in particular, is no doubt a very exciting development. What remains to be determined, for COVID-19 as well as other potential future home tests for infectious diseases, is how home testing will affect our ability to detect outbreaks and to perform surveillance (e.g., genomic sequencing for variants, antimicrobial resistance detection).

With current pricing, at-home tests for COVID-19 are unfortunately something accessible in the United States only to those with sufficient means to purchase them. This is a luxury that is absent from a large portion of our society. At-home testing is, in many ways, a band-aid that covers the unsightly wound, which was a broken US national response to testing. This response weighed far too heavily on public health and reference laboratory testing in a landscape of siloed and fractured laboratory systems across the country. The inability to provide testing rapidly in all hospital settings came at great cost to healthcare workers and patients alike. We know from experience that testing needs to be close to the patient to have the best clinical outcomes, and it does not get any closer to the patient than in their own home. Nevertheless, the availability of at-home testing does not change a broken system or a broken social safety net. But, hopefully, it does provide a framework for the more rapid deployment of both at-home and laboratory tests when the next pandemic comes along.

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