

# At-Home Diagnostic Testing for Infectious Diseases: A Tool for Accelerating COVID-19 Diagnosis and Building Pandemic Preparedness for the Future

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# Executive Summary

## Background and Purpose of Report

Before an infectious disease outbreak of any size can be addressed and before illness can be treated, the disease itself must first be identified through diagnosis. Accordingly, diagnostic testing is a crucial step for both clinical medicine and epidemiologic investigation. Concerns about limited access to diagnostic testing have dominated much of the current response to coronavirus disease 2019 (COVID-19) and highlight the need for more rapid, convenient, and equitable access to testing. With the increasing diffusion of health technology to consumers and patients, it is becoming more feasible for diagnostic testing to be placed in the hands of the patient. Such tests, when used to diagnose infectious disease and coupled with information technology, could have a transformative benefit for future pandemic response.

The Johns Hopkins Center for Health Security conducted this study to develop an expert assessment of the promise and challenges posed by at-home infectious diagnostic technologies. A major aim of this study is to inform pandemic preparedness activities that rely on diagnostic technologies and determine how at-home approaches can integrate with and augment existing diagnostic protocols.

## Findings

*Self-testing for HIV is a successful precedent for at-home infectious disease diagnostic testing.*

The development of new at-home diagnostics tests will be greatly simplified by the fact that a successful at-home HIV diagnostic test has been on the market for several years. It is the only US Food and Drug Administration (FDA)-approved at-home diagnostic test for an infectious disease. Although there are important distinctions between HIV, pandemic influenza, or other infectious disease threats, companies developing tests to diagnose new infectious diseases will be able to study, gain knowledge from, and build on learnings from HIV self-testing to bring new at-home diagnostic products to market.

*At-home influenza testing is now being pursued, largely to improve antiviral prescribing and infection control.*

Currently, no at-home diagnostic tests are available for seasonal influenza, but companies and healthcare stakeholders are keen to develop them. The current drive for at-home influenza diagnostic testing is to improve both infection control and antiviral prescribing—2 important aspects of seasonal influenza response that merit improvement. Antiviral prescribing is inconsistent, not always evidence-based, and often excludes the people who would benefit from antivirals. Infection control in outpatient settings is often inadequate and provides ample opportunity for influenza transmission. By testing at home, potential patients may be able to reduce their risk of

becoming infected or infecting others in an outpatient setting, thereby decreasing the force of spread of influenza at the population level.

*At-home influenza testing could be harnessed to improve pandemic preparedness for COVID-19, influenza, and beyond.*

As at-home influenza diagnostic testing becomes available and improves seasonal influenza response, it will have direct positive impacts on pandemic influenza response. Such tests will have the capacity to identify novel influenza A strains, some of which may have pandemic potential or regional importance and others that will be novel to humans. By employing home influenza tests, the healthcare community will improve antiviral prescribing, infection control guidance, and diagnostic capacity, all of which can be harnessed to improve pandemic response. Additionally, such technologies may have the potential to be relatively easily expanded to target other respiratory viruses with pandemic potential. This could be accomplished through the use of platform diagnostic devices or the development of standalone diagnostic testing for new targets.

The novel coronavirus pandemic provides us with an opportunity to harness this technology in real time. This can be accomplished by accelerating development and adapting at-home diagnostic technology to the novel coronavirus. At-home testing would augment diagnostic capacity and increase crucial situational awareness about the spread of the virus. Already, saliva-based testing methods and at-home unsupervised nasal swab collection devices have been approved for use. There has been strong interest in self-testing during this pandemic, which could be channeled to develop self-testing capacity by increasing funding for developing or adapting this technology and supporting pilot projects, with the end goal of having a system in place for further waves of this virus and future threats.

*At-home diagnostic testing will face challenges regarding linkage to public health, cost, and uptake.*

The greatest challenges to the success of at-home diagnostics may be the cost and the willingness of the public to use them. It will be important for developers to keep costs in mind and consider avenues for third-party payers to cover some or all of the costs. If costs are not prohibitive, public acceptance and use will likely occur, especially when access to clinical testing is limited, as it was in the first wave of the COVID-19 pandemic.

## **Recommendations to Realize the Full Potential of At-Home Infectious Disease Diagnostics**

- Strong coupling of at-home diagnostic test results with public health authority surveillance activities is critical to their success in improving public health preparedness. Results should not only inform clinical care, but also be shared with relevant public health agencies in order to inform and shape response.

- Symptom as well as exposure and travel history are important pieces of information that should be collected in tandem with testing. Collecting data regarding symptoms will help gauge severity of the disease and guide treatment decisions. Exposure and travel history will help identify the presence of potential novel strains.
- As influenza at-home testing is pursued, other respiratory viral targets should also be explored. As we have seen with COVID-19, many respiratory viruses other than influenza pose pandemic risks. At-home testing, especially if leveraged on diagnostic platform devices, would enhance surveillance for these viruses, most of which are often not formally tracked.
- During the ongoing COVID-19 pandemic it is essential that the Biomedical Advance Research and Development Authority, FDA, and Congress prioritize the funding, development, and review of at-home COVID-19 diagnostics.

## Introduction

Before an infectious disease outbreak of any size can be identified, it must be first be detected. Initially, clinical symptoms might serve to delineate who may be infected and who is free of clinical infection. However, relying exclusively on clinical criteria may result in inexact diagnoses, fail to capture asymptomatic or minimally symptomatic cases, and severely limit the practitioner’s ability to learn anything about the etiologic agent (including its identity). To this end, diagnostic testing is a mainstay of not only clinical medicine but also epidemiologic investigation. Diagnostic tests are an essential component of biosecurity, health security, and pandemic preparedness. Indeed, improving diagnostic testing will have direct impacts on how quickly and strongly response activities—which will determine the size and scope of an outbreak, epidemic, or pandemic—are pursued.

Diagnostic tests are traditionally performed by trained healthcare workers either in lab settings or at the point of care. However, with the increasing diffusion of health technology to consumers and patients, it has become feasible for diagnostic testing to be placed in the hands of patients. A new generation of at-home tests involve more than simple sample collection, they also provide the user with a direct result. This trend has been largely driven by convenience and rapidity access to results as well as for linkage to a prescribed medication such as insulin. However, such tests, when used to diagnose infectious disease and coupled to information technology, have an added potential benefit of increasing our ability to identify potential epidemics and pandemics sooner in order to improve pandemic preparedness and response.

Although at-home influenza tests are not yet available to the public, they are in active development, and the Biomedical Advanced Research and Development Authority (BARDA) within the Department of Health and Human Services has awarded contracts to at least 2 diagnostic companies for these technologies.<sup>1</sup> Funding from BARDA has supported the development of at-home influenza tests, which will likely become available in the United States in the next few years. The diagnostic testing shortfalls that were so prominent early in the coronavirus disease 2019 (COVID-19) pandemic may also serve to drive increased demand and interest in at-home influenza testing.

An at-home influenza diagnostic test would likely take 1 of 2 forms. One might be a standalone diagnostic kit, similar in many ways to at-home HIV tests and home pregnancy tests. The other might be a device that employs cartridges for different target organisms that could be changed periodically. This last form would be more advanced and likely require greater regulatory scrutiny. Both would likely be paired to companion technology that would provide information about the test and diagnosis, collect symptoms, and offer a conduit to a healthcare provider and public health agency.

Based on our analysis, we make the case in this report for pursuing at-home, over-the-counter diagnostic tests for infectious diseases as a supplemental and worthwhile component of epidemic intelligence and pandemic preparedness as well as a tool to optimize clinical management.

# Purpose, Methods, and Analysis

## Purpose

The Johns Hopkins Center for Health Security conducted this study to develop an expert assessment of the promise of and challenges posed by at-home infectious diagnostic technologies. A major aim of this study is to inform pandemic preparedness activities that rely on diagnostic technologies and determine how at-home approaches can integrate with and augment existing diagnostic protocols.

## Methods and Analysis

### *Review of Published Literature and Previous Reports*

The Center project team surveyed current biomedical literature on the topic of at-home infectious disease diagnostic technologies. The literature review was accomplished with extensive PubMed searches on these subjects. Relevant US government policy and strategy documents were also reviewed.

### *Informational Interviews*

The Center project team conducted 7 informational interviews of experts from biotechnology companies, government agencies, and industry consultants to inform and refine the scope of the project and preliminary assessments made by the project team.

### *Report*

This final report presents the Center's assessment of the promise and challenges of at-home infectious disease diagnostic technologies, informed by our literature review, discussions with various subject matter experts, and our analysis. The findings and recommendations in this report are those of the Center and do not necessarily reflect the views of those who were interviewed.

## Findings

### **Finding 1: Self testing for HIV is an important precedent for at-home infectious disease diagnostic testing.**

In the United States, only 1 Food and Drug Administration (FDA) at-home infectious disease diagnostic test has been licensed and it is for HIV.<sup>2</sup> This at-home serology test, which tests for antibodies to HIV-1 and HIV-2, can be performed using saliva or fingerstick blood and its results return rapidly. This test, which diagnoses a high-consequence infectious disease with major public health and epidemiologic import, serves as an important example for other tests that target disparate pathogens using varied technology.

The HIV test, unlike many of the current generation of at-home tests for other conditions, was not initially an at-home consumer test nor was it developed with that target in mind. Rather, it was first approved to be used in laboratories on blood; however, through a decade-long process punctuated by intermediate steps (using saliva rather than blood and requiring a Clinical Laboratories Improvement Amendment waiver), it eventually gained licensure to be used at home. Important challenges to its development included developing sufficient sensitivity of the assay and then ensuring the label and instructions could be easily understood by the general public.

That this type of testing was developed in an era just before the ubiquity of smart phones, Bluetooth technology, Clinical Laboratories Improvement Amendment-waived molecular diagnostics, at-home genetic testing, and the connectivity of the “internet of things” may speak to the relative ease that regulators and others may view future technologies in the at-home testing space.

The convenience of at-home HIV testing has been important for public health outreach and testing in nontraditional venues and for removing many barriers to testing. HIV testing can now be done at home, at pop-up testing sites at special events such as concerts, and even in nightclubs. Additionally, when patients are provided with at-home HIV tests, they have been shown to use them more frequently.<sup>3</sup> Similarly, a study conducted in China in 2018 using a home syphilis test demonstrated that the people who used the tests were more likely to report it being their first syphilis test and to never have been tested for syphilis in a hospital setting.<sup>4</sup>

There are, however, a few important points worth noting. Home HIV diagnostic testing was developed in large part to address stigma and provide anonymity for those desiring to be tested. As such, no public health or epidemiologic linkage with test results was sought. The test was intended to be an initial screening step, to be followed by confirmation by an ELISA test in a clinical setting. Quick, private access to results means that people can change their behavior and seek confirmation and care based on the result they received. Ideally, though, at-home tests, including those for influenza and other respiratory pathogens, would be most beneficial with epidemiological linkage, healthcare provider notification, and public health notification.

## **Finding 2: At-home influenza testing is largely being pursued to improve antiviral prescribing and infection control.**

In the current seasonal influenza environment, the rate of antiviral prescribing is suboptimal and has led to cascading effects that have had negative impacts on the burden of seasonal influenza—and by extrapolation, on pandemic influenza preparedness.

It has been well established that influenza antivirals reduce the duration of symptoms in ordinary cases of influenza and can be lifesaving in severe cases of influenza or in the treatment of cases that occur in high-risk patient populations, such as pregnant women. However, many patients with influenza are not prescribed antivirals due to the lack of a specific diagnosis, a diagnosis thought to be made too late for maximal antiviral benefit, the use of poorly sensitive influenza diagnostic tests, or lack of awareness.<sup>5</sup> Those with influenza not treated with antivirals are more likely to suffer severe consequences of influenza such as pneumonia, respiratory failure, and death. They are also more contagious to others and, therefore, add to the spread of the virus in the community.<sup>5</sup>

Also, antivirals—like all classes of antimicrobials—are important medical countermeasures for infectious disease emergencies, and a steady pipeline and supply are important national security concerns. However, the lack of robust market demand means that pharmaceutical companies often choose other, more lucrative commercial products to develop because of their greater potential return on investment. Strong market demand for influenza antivirals during influenza season can convince manufacturers to stay in this space, maintain production capacity, and develop new influenza antivirals for the future.

At-home influenza tests, which are currently planned to be linked through smartphone technology to telemedicine providers or the patient’s own primary care providers, have the potential to increase the rate of antiviral prescribing. Influenza tests have also been shown to improve antibiotic stewardship—a positive influenza diagnosis reduces the likelihood of incorrect antibacterial prescribing and use. This may improve even more as plans to make influenza antivirals prescription free and available over-the-counter progress and a positive self-test result would prompt patients to seek antiviral therapy.

In addition to its impact on antiviral prescribing, at-home influenza diagnostic testing may divert individuals with flu-like symptoms from doctors’ offices, urgent care centers, and emergency departments. Not only will this ease patient surge, which is common during influenza season, but it could also reduce the risk of influenza transmission in waiting rooms and patient care areas. In addition, those who know they have influenza are less likely to have close contact with others in their household, workplace, and other settings, thereby reducing exposing others to the virus.

### **Finding 3: At-home influenza testing could be harnessed to improve pandemic preparedness for COVID-19, influenza, and beyond.**

The response to seasonal influenza can be viewed as an annual stress test for pandemic influenza response. Vaccine development, vaccine distribution, disease diagnosis, antiviral prescribing, hospital operations, and myriad other activities occur each influenza season. Improving each of these components has a direct connection to improving pandemic capacities more broadly, as the steps are virtually identical—with the stakes raised much higher during a pandemic.

During a pandemic of a novel influenza, important questions will require urgent answers. Such questions include: What is the burden of infection? How severe are the cases? What types of strains are we seeing? What is the antiviral resistance profile? The answers to these and related questions will require diagnostic testing. Leveraging the availability of at-home tests and transmitting their results to public health authorities, even in an unidentified form, can help answer epidemiological questions while also providing ready links to antiviral prescribing and minimizing the risk of contagion.

At-home influenza tests, like all influenza tests, will be based on strain identification requirements for tests promoted by the FDA and Centers for Disease Control and Prevention. These tests will detect novel influenza viruses of the A or B subtype, making them useful during the emergence of a novel influenza pandemic as well as for detecting unusual strains of influenza, such as those acquired in agricultural events.

Based on this technology, it is feasible to expand such home tests to identify other microorganisms of public health import. While antivirals may not exist for many of these viruses, many of which have pandemic potential, at-home tests can expand the understanding of their epidemiology, benefit antibiotic stewardship, and help alert the consumer to the need to self-quarantine and diminish contagion. In past outbreaks of emerging infectious diseases, such as Zika, diagnostics tests were almost exclusively available at state health department labs, severely limiting diagnostic testing capacity and creating excessive bureaucratic burdens to ship samples for testing.<sup>6</sup> Had at-home testing been widely available early in the COVID-19 pandemic, it would have allowed people to be tested while maintaining social distancing in the process, thus potentially contributing to reduced spread of the virus.

Some proposed at-home testing devices are designed to be standalone machines in which different assay cartridges can be inserted, making it possible to test for a number of different viruses using the same machine. This flexibility, coupled with the ability to develop supplemental test cartridges or kits for novel pathogens under an FDA emergency use authorization, could facilitate distribution of at-home diagnostics for new threats and substantially change emerging infectious disease outbreak response by increasing diagnostic capacity.

The novel coronavirus pandemic affords us an opportunity to harness this technology in real time. This can be accomplished by accelerating development and adapting at-home diagnostic technology to the novel coronavirus. At-home testing would augment diagnostic capacity and increase crucial situational awareness about the spread of the virus. Already, saliva-based testing methods and at-home unsupervised nasal swab collection devices have been approved for use.<sup>7,8</sup> There has been strong interest in self-testing and self-sample collection during this pandemic,<sup>9</sup> which could be channeled to develop self-testing capacity by increasing funding for developing or adapting this technology and supporting pilot projects, with the end goal of having a system in place for further waves of this virus and future threats.

#### **Finding 4: At-home diagnostic testing will face challenges regarding linkage to public health, cost, and uptake.**

Although at-home diagnostic testing for infectious disease has great potential, important challenges need to be surmounted in order to fully realize the potential of these game-changing technologies.

Linkage of test results not only to prescribers but also to relevant public health authorities is a key challenge. While anonymity and relevant patient privacy concerns were important in HIV self-testing, the use of similar tests for respiratory viruses may face less stigma. As these tests reach commercial markets, developing technological solutions to allow test results to be rapidly transmitted to local health departments, state health departments, or the Centers for Disease Control and Prevention will be crucial. Such data may need to be anonymized to zip code (or partial zip code) level but, even so, that data will still be useful to understand the burden of infection in a given area and detect unusual clusters of positive results that may merit closer inspection.

COVID-19 is a reportable disease, meaning that all positive tests are required to be reported to the health department. Testing for nonepidemic diseases are not required by health departments, so strategies would need to be developed for analyzing and collecting that information in anonymized ways.

The success of these technologies will also rely on the level of public demand and use. The public may not want to incur out-of-pocket costs for a test that, in many cases, will return a negative result and may not directly link them to care and treatment. At the same time, manufacturers will have to determine a price point that will ensure customers will purchase the tests. If insurers and other third-party payers, including the Centers for Medicare and Medicaid, could be persuaded of the benefits of self-testing as a way to control influenza expenses, avoid unnecessary antimicrobial costs, and reduce antibiotic resistance, it may have a substantial impact on uptake.

Lastly, although these tests may be targeted to consumers, they could also be used by providers in office or other traditional settings, positively impacting diagnostic capacities beyond the home and increasing market uptake.

## Recommendations

**Recommendation 1:** COVID-19 or influenza diagnostic tests performed in home settings must have strong linkages to public health authorities.

For COVID-19 testing, reporting to public health authorities would be required and should be automatically built into any system developed in the course of this epidemic.

As the market for at-home diagnostic testing develops for diseases like influenza and other respiratory illnesses, it is essential that those developing these technologies be encouraged to continue to involve public health authorities, of all levels, in their product development process. Understanding the informational needs and technology capacity of public health authorities will ensure that the information collected by these devices will have maximum impact. Reporting mechanisms will need to adhere to patient privacy concerns; these aspects should be addressed from the outset.

Ideally, transmission of a positive result would occur in close-to-real time so that public health authorities could have the best possible situational awareness. In addition to individual test results being reported to public health agencies, geographic clusters of importance should also be reported (eg, from adjacent zip codes) upstream in order to rapidly identify patterns of infection that may indicate an emerging outbreak.

Health authorities could also provide at-home tests to representative or sentinel populations in order to monitor disease activity among these groups. Similar to distributing HIV testing kits to individuals at high risk for HIV, agricultural workers who have high-risk contact with animals, frequent travelers, nursing homes, and other groups could be monitored more closely with at-home tests with close follow up of positive results.

**Recommendation 2:** The collection of symptoms and exposures to gauge severity and determine the need for antiviral or other treatments should be part of any companion technological application.

At this point in the pandemic, no antiviral has been developed for use in COVID-19 outpatients, although it is still possible one could be developed later in this pandemic.

Although a simple positive test result would provide vital information in and of itself, it is more valuable when coupled to patient symptom data. Developers should be encouraged to have the capacity in their companion applications to collect symptom data such as day of onset, presence of fever, past medical history, and other important clinical variables that help gauge severity, provide epidemiological data, and guide antiviral prescribing.

Information regarding exposures to, for example, animals at a county fair, exposure to sick individuals, and travel history should also be incorporated into devices and their applications in order to fully capture relevant clinical and public health data.

**Recommendation 3:** Devices with the ability to test for additional respiratory viruses in the home setting should be pursued as a pandemic preparedness activity and as a countermeasure against COVID-19.

COVID-19 is a considerable threat the country and the world must address. Beyond COVID-19, influenza is arguably the biggest long-term pandemic threat humans face; but other respiratory viruses, including newly emerged coronaviruses, are also potential pandemic threats. Although antivirals—which provide a major incentive for influenza diagnostic testing—have not been developed for most other respiratory viruses, platform diagnostic technologies that can add (or include) other targets may be one way to leverage the economics of influenza to subsidize other viral diagnostics for viruses that have been neglected in formal surveillance activities. Such an approach may also provide a basis for emergency use authorization-driven distribution of diagnostics during an emerging infectious disease outbreak. Even without platform technologies, testing for viruses such as respiratory syncytial virus may have market appeal and have important effects on inappropriate antibiotic prescribing and infection control practices. Encouraging the development of self-testing devices and additional noninfluenza targets should be pursued by those tasked with pandemic preparedness. If this type of technology had been available during the early days of the COVID-19 pandemic, the nation would have greatly enhanced diagnostic capacity to couple to surveillance and containment activities.

**Recommendation 4:** During the COVID-19 pandemic, it is essential that BARDA, the FDA, and Congress prioritize the funding, development, and review of at-home COVID-19 diagnostics.

During the COVID-19 pandemic, individuals and institutions will increasingly seek up-to-date information on the health status of themselves, their employees, their contacts, and others as they undertake various activities. Having at-home rapid diagnostic testing tools available will greatly facilitate the safe conduct of many activities and heighten confidence that life will return to some semblance of normalcy.

To that end, the funding, development, and review of such technologies by BARDA, the FDA, and Congress should be prioritized. At-home diagnostics technologies should be rapidly assessed for adaptability to the novel coronavirus and, once adapted, be prioritized for emergency use authorizations. The most mature existing technologies that exist for home influenza testing should be assayed, and adequately funded, for applicability to the novel coronavirus. This would include also evaluating rapid antigen testing and saliva-based antibody testing for the novel coronavirus for its applicability to home use by nonmedical persons.

## Conclusion

Diagnostic technologies are undergoing rapid advancement in their sensitivity, specificity, rapidity, and simplicity. These trends have ushered in an era of distributed diagnostics and have empowered individual consumers and patients via at-home diagnostics. As these technologies expand to include infectious diseases, it will be important to include their use in pandemic preparedness and emerging infectious disease activities. As diagnostics are crucial to infectious disease response, the availability of at-home infectious disease diagnostics for influenza will be an important opportunity, as it has been with at-home HIV tests, to enhance resilience against influenza and beyond. In the immediate term, at-home diagnostics should be prioritized for COVID-19 as a way of increasing the speed and ease of diagnosis and decreasing the risk of spread involved with in-person testing.

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