

# HOME-BASED TESTING FOR COVID-19

Updated on December 2, 2021

## BACKGROUND

In the United States, testing throughout the COVID-19 pandemic has been characterized by rapid developments and frustrating delays, and by cycles of scarcity and surplus. Scientists scrambled in early 2020 to develop and then manufacture highly sensitive tests in the necessary volume; laboratories around the country were backlogged for days – often long enough to make test results useless for protecting others when they were finally returned. Public health departments rapidly stood up mass testing sites and mobile units, but despite these efforts, testing remained inequitable and out of reach for many. [According to the Surgo Foundation](#), in January 2021 “7.5 million people live in counties with no test sites, and over 15 million people have to travel 10 or more miles to reach their nearest site. ... Indigenous Americans... are nearly twice as likely to live in a county with no reported test sites.” While [disparities in accessing COVID-19 testing sites](#) improved over the course of the pandemic, we have much more progress to make, and in many areas, have gone backwards in terms of access [amidst supply chain issues and recent scale downs of testing programs](#).

Increased availability of home-based testing—particularly tests that support rapid return of results—presents an important opportunity to decentralize testing and to help address persistent gaps in access and improve the overall testing landscape. Furthermore, home-based tests can support the general population to make informed decisions about their movement and social behavior within the community. Recognizing the promise and the profound shortage, federal investments (billions of dollars by the [Biden Administration](#) and the [US Department of Defense](#)) were recently announced to scale up availability of rapid tests around the country and to offer tests at low to no cost to consumers. However, to fully realize the benefits of this investment, tests must be offered in a way that promotes equitable access.

This document reviews the two major approaches considered “home-based testing” (See Box 1) and walks through key operational considerations for public and community health practitioners looking to incorporate such methods into their COVID-19 response plans, and most importantly, to do so in a way that does not deepen disparities in access to COVID-19 testing, treatment, and prevention.

### BOX 1: TYPES OF HOME-BASED TESTING



#### Self-collection

Sample collection (nasal swab or saliva) is performed at home, often under remote supervision. Sample processing occurs outside of the home, and a third-party provider delivers results (“swab and send” model). Most often molecular tests (appropriate for diagnosis in a clinical setting, detecting individuals at the post-infectious stage).



#### Self-testing

Sample collection (nasal swab or saliva) AND sample processing are performed in the home. Results are delivered within 15-30 minutes within the home setting, with the user interpreting based on instructions. Self-tests are also referred to as “home tests” or “at-home tests”. Mostly rapid antigen tests, and one molecular test (Lucira), can be completed entirely at home.

## EQUITABLE IMPLEMENTATION CONSIDERATIONS

Home-based testing can make access to testing significantly more equitable, addressing privacy and logistical concerns, which are of particular importance for communities who face major barriers in the traditional testing landscape, including insurance status, immigration status, transient living situations, language barriers, and fear of lost work or income. When on-site testing capacity is limited, more testing conducted at home stands to lower the burden on community testing sites, expanding capacity and reducing exposure and infection risk to testing site staff.

However, home-based testing presents challenges along with opportunities; among them are user error, reliance on behavioral adherence to guidelines in accordance with tests results, and incomplete reporting of results into state public health reporting systems. Without reporting to public health authorities, neither contact tracing nor subsequent linkage to [Care Resource Coordination](#) services for quarantine can occur. For these reasons and more, despite its potential in terms of equitable access, home-based testing has potential to increase disparities if cost and usability are not considered. Key considerations for home-based testing are detailed below, along with specific considerations for self-collection and self-testing (Box 2A/B).

### Overarching Implementation Considerations for Home-based Testing (Self-collection & Self-testing)

**Prevent User Error:** Tests must be performed exactly as instructed for results to be correct. For both self-collection and self-testing, testing kits should have clear instructions in multiple languages, guidance on how to proceed after obtaining results and how to access social supports. Kits should also include informational materials on COVID-19 transmission, prevention (including isolation when positive), and vaccination.

**Mitigate Barriers:** Programs must be explicitly designed to mitigate barriers faced in traditional testing as follows:

- Home-based testing should be accessible to communities – ideally, delivered to homes, free of charge.
- All testing materials and instructions should be provided in multiple languages, tailored to local needs.
- When possible, prioritize tests with home-collection methods that do not require a telehealth consult or supervision from a provider to eliminate the need for an internet connection or smartphone/computer.
- Home-based testing programs should partner with care resource coordination programs that arrange wraparound social supports for those who need assistance to safely isolate or quarantine.

**Establish Clear Guidance & Protocols:** Jurisdictions have struggled to navigate reporting of false positives and protocols for confirmatory testing. [Establish guidelines](#) and ensure that stakeholders are aware of them. For example, when should I test after possible or confirmed exposure? What should I do if an antigen test is positive, but a confirmatory test is negative? What should I do if a test is negative but probability of infection is high?

#### Box 2A. Key considerations for self-collection



- **Intended Use:** Recall that these are molecular tests appropriate for diagnosis. Due to higher TAT (see below), they are not as appropriate as screening tests.
- **Sample processing:** Sample collection kits should include pre-paid shipping labels and sample drop-off points should be conveniently located.
- **Turnaround Time (TAT):** Labs must guarantee processing capacity for every at-home collection kit to ensure that individuals utilizing them can obtain timely results (<24 hours from receipt at lab).
- **Reporting:** Labs and local health departments are required to report testing data to state epidemiology systems to enable case investigation, contact tracing, and linkage to wraparound social services (care resource coordination) for positive results.

#### Box 2B. Key considerations for self-testing



- **Intended Use:** These tests answer the question: “am I infectious now?”. As such, they are most appropriately performed frequently as a screening test, or just before attending an event or gathering, rather than 3 days in advance as is commonly advised.
- **Reporting:** Self-testing poses a [unique challenge to state health departments seeking to understand where outbreaks occur](#). While [some self-test kits deliver results through an app](#) that will automatically report results to the public health department, others do not – and reporting depends on a user knowing they should report and taking initiative to do so. Kits also request that people report positive test results only – [in the UK, people are expected to report the result of a rapid test every time they do it – positive, negative, or void](#).
- **Cost:** Self-test kits have been expensive, ranging in cost from \$24 to > \$100, prohibitively expensive for many. Recent federal investments in tests to be sold at-cost may mitigate this challenge – along with the supply shortage that has been contributing to high costs.

## AVAILABILITY OF HOME-BASED TESTING

The FDA has granted Emergency Use Authorization (EUA) to an increasing number of sample collection devices. As of December 2, 2021, EUA had been granted to:

- 89 molecular tests (4 with self-testing capabilities – 1 prescription and 3 OTC)
- 14 antigen tests (all with self-testing capabilities; 3 prescription and 11 OTC)

For real-time information on FDA EUA for home-based testing, visit the FDA's [website](#) and search for “home” in both the antigen and the molecular test databases.

### BOX 3: CURRENT USE OF HOME-BASED TESTING

#### Test-to-Stay (TTS) Models in K-12 Schools

A potential application of frequent rapid antigen testing is Test-to-Stay (TTS), also referred to as [close contact testing](#). This is a [modified quarantine strategy](#) that aims to allow students to remain in school despite exposure to COVID-19. TTS requires that students who have been exposed to COVID-19 undergo school-located testing for at least five days, provided that they are not experiencing COVID-19 symptoms and are following other mitigation methods, such as mask wearing. While protocols vary and some schools use saliva-based PCR testing conducted on site, others use rapid antigen tests for their immediate return of results. Note that the CDC does not currently endorse this but is actively evaluating schools around the country who are employing the approach.

#### Say Yes! COVID Test (SYCT)

The CDC is partnering with select state and local health departments to evaluate community-wide self-testing as a way to limit transmission. Community members receive free test kits that they are to administer three times per week for a month. [Evaluation is ongoing](#).

#### Self-collection Programs around the Country

Jurisdictions are making sample collection kits available to their residents. Several states, including [Wyoming](#), [Minnesota](#), [Wisconsin](#), [New Mexico](#), [South Dakota](#), and [Delaware](#), have partnered with Vault Health for their home-based testing programs. [Vault Health](#) uses two FDA EUA authorized saliva-based COVID-19 tests, Infinity BiologiX and Spectrum Solutions. These programs are **self-collection** models, and generally require the following of clients:

- An internet connection and smart-phone or computer access for a remotely supervised saliva collection
- Email address (to receive results)
- Photo ID
- Ability for client to transport collection kit to UPS for shipping

These requirements can act as barriers to individuals looking to access home-based testing who do not have a stable internet connection, for example. Most of these statewide programs are available at no cost to their residents, and do not require health insurance. Specimens collected at home are sent to a lab with prepaid, expedited shipping. Results are communicated by email to clients within 24-72 hours after arrival at the lab.

#### Home-based testing for identified contacts of COVID-19 confirmed cases

New York City's Test & Trace Corps program, run by NYC Health + Hospitals, [offers free, opt-in home-based testing](#) to all contacts of confirmed COVID-19 cases in NYC. The program uses Fulgent Genetic's at-home test, now included as part of Test & Trace Corps "[Take Care Package](#)," which also contains PPE, cleaning supplies, and monitoring equipment like a thermometer. The "Take Care Package" is one piece of Test & Trace Corps efforts to support cases and contacts to safely isolate and quarantine at home. The test is also an at-home collection model, although it does not require remote supervision of specimen collection, which is a nasal swab. Once clients collect their sample, they drop it off through FedEx or can contact Test & Trace Corps to collect the sample from their home directly. Test kits are processed Monday—Thursday and turnaround time is expected to be 24-48 hours. Individuals are notified of their results through their Picture Genetics portal account.

*The ideas presented in this document reflect the latest public health thinking and scientific evidence as of December 2021. You are advised that the COVID-19 vaccine landscape remains highly fluid, and it is your responsibility to ensure that decisions are made based on the most up-to-date information available. Partners In Health does not provide medical advice, diagnosis or treatment in the United States. Always seek the advice of a physician or other qualified health care provider with any questions regarding a medical condition. The information, including but not limited to, text, graphics, images and other material contained in this document, are intended for informational purposes only.*