What Options Do Companies Have For Implementing COVID-19 Testing?

PRESCOUTER

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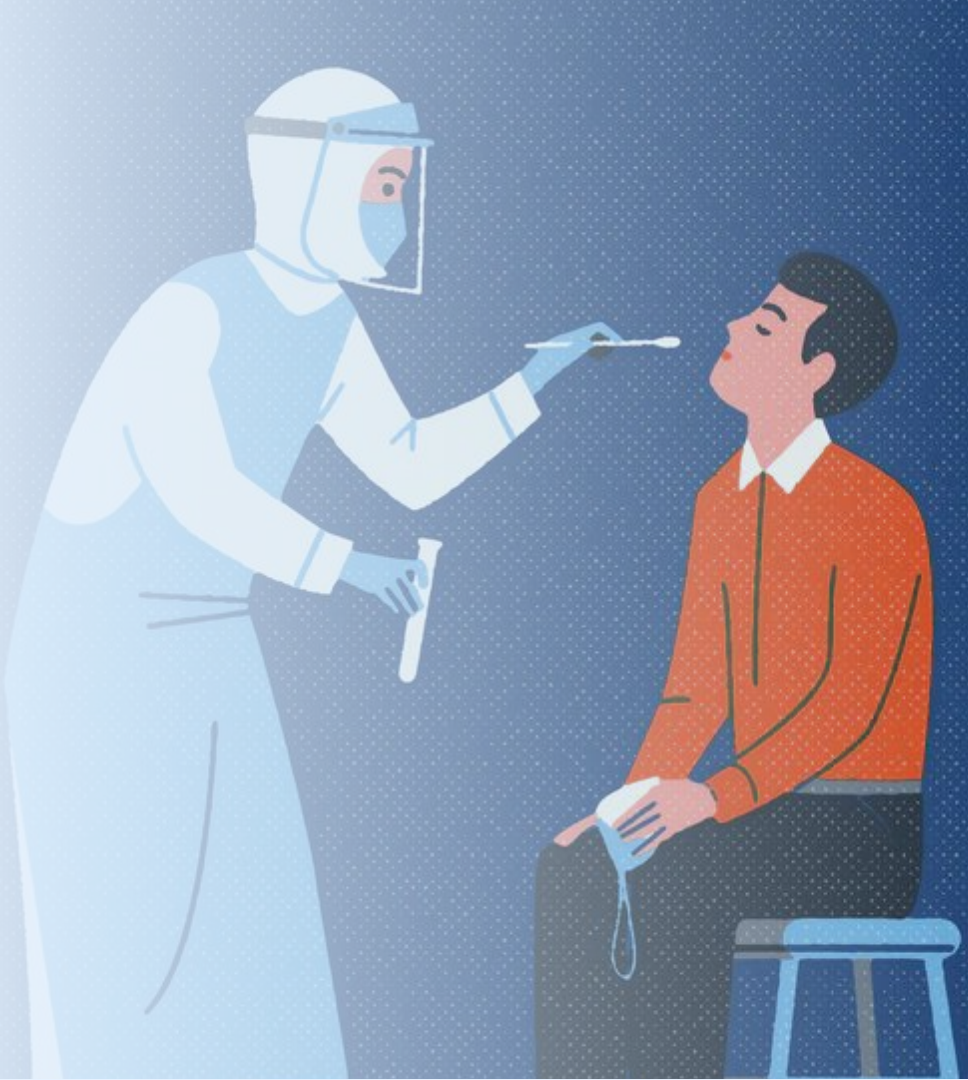


Companies Have Six Option For Implementing RT-PCR Testing

Companies will need to focus on RT- PCR tests, which identify current, active infections. These tests are processed using test kits or through clinicals labs. All six of the current available approaches to testing use one of these methods to process the results.

Unsupervised Testing

#1: **Walk-in / Drive-through testing** by appointment at pharmacies.

#2: **At-Home Kits** provided by several start-up companies.

Working With External Diagnostic Labs

#3: **Commercial Labs**.

#4: **Academic Labs**.

In-House Testing

#5: **Simple**.

#6: **Complex**.

The information provided is US centric; please contact PreScouter for advice on other regions.

During this pandemic, PreScouter is leveraging its network of 4000+ experts, lab partners and prototyping firms to provide clients with the testing expertise and resources they need to safeguard their workplaces. While this report provides general recommendations, we welcome inquiries to help determine what may be best for your specific situation.

Contact us at covid19@prescouter.com or (708) 613-7132

Test type matters. Workplaces should be using RT- PCR tests.

There are two main types of tests: a diagnostic RT-PCR test and a retrospective serological test.

RT-PCR tests indicate a current infection. Diagnostic RT-PCR tests detect viral RNA from patient sputum, saliva or nasal swabs.

Serology tests detect a past infection. Serology tests detect antibodies that have been made in response to infection. Serology tests use patient blood or blood plasma. Serology tests are variably reliable and are used to detect late-stage or past infections.

For preventative testing, workplaces should be using RT-PCR:

- RT-PCR tests have a high sensitivity and high specificity. This means they can reliably and reproducibly detect infections.
- RT-PCRs can detect infections early on and are informative of a current infection.
- RT-PCRs are offered in a traditional format as well as so-called “rapid tests”.

Comparison of Diagnostic Test Kit Types

	Traditional RT-PCR	Rapid RT-PCR	Serology
Time to result	2-6 hours	0.5-2 hours	0.2-2 hours
Sensitivity / Specificity	High	High	Highly variable
Cost per test	$5 - $25	$40 - $135	$15 - $50
Diagnostic value	Current infection	Current infection	Past infection or near end of current infection

RT-PCR tests are quick, highly sensitive and specific. There are two subtypes of RT-PCR tests: traditional and rapid tests. Traditional RT-PCRs are slightly cheaper and allow for processing more tests at the same time. However, they take longer to run and are generally more complex. Rapid tests are quick, easy to use and can be used in point-of-care settings. Compared to traditional RT-PCR tests, rapid tests are more expensive and fewer of the tests can be processed at the same time.

Samples from RT- PCR tests are processed using test kits or through clinical labs' own diagnostic methods.

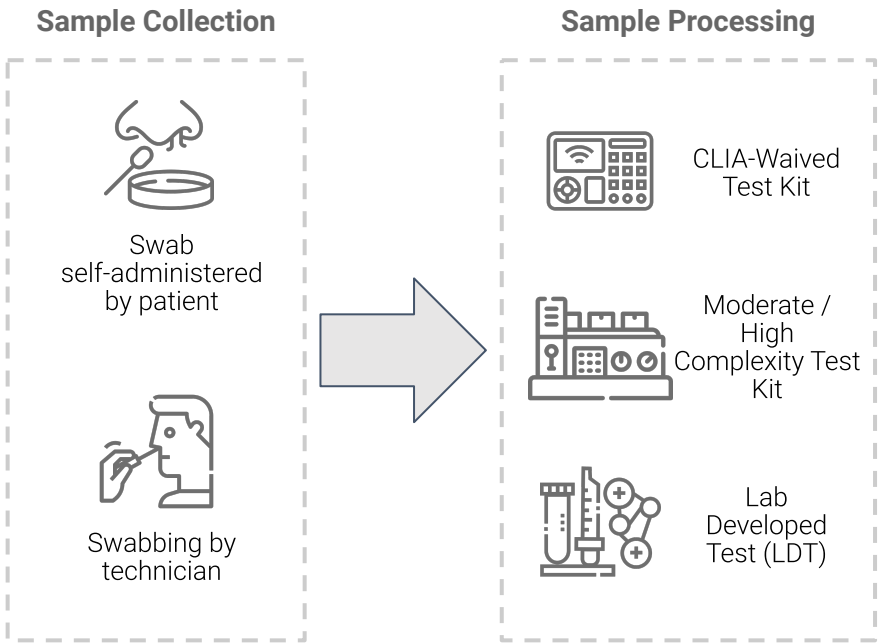
Nasal swabs are typically used for collecting samples, but saliva can also be used. While some of the available test options have patients self-administer nasal swabs for sample collection, the sampling and results will be more accurate when done by a trained technician.

Traditionally, academic or commercial laboratories with a CLIA* certification would use one of the **76 test kits approved for moderate and/or high complexity settings** to process test samples. These tests kits require a high level of expertise to administer.

However, there are now **4 test kits that are CLIA-waived**, meaning they can process test samples in patient care settings, outside of traditional labs.

Some labs - particularly academic labs - have in-house expertise in setting up their own COVID-19 diagnostic methods and processing tests samples for these at large scale. There are **33 such *Lab Developed Tests* (LDTs)**.

**CLIA (Standards and Certification: Laboratory Requirements) is a US regulatory standard for laboratory testing performed on specimens from humans. Certification against this standard is provided by the Centers for Medicare & Medicaid Services (CMS).*



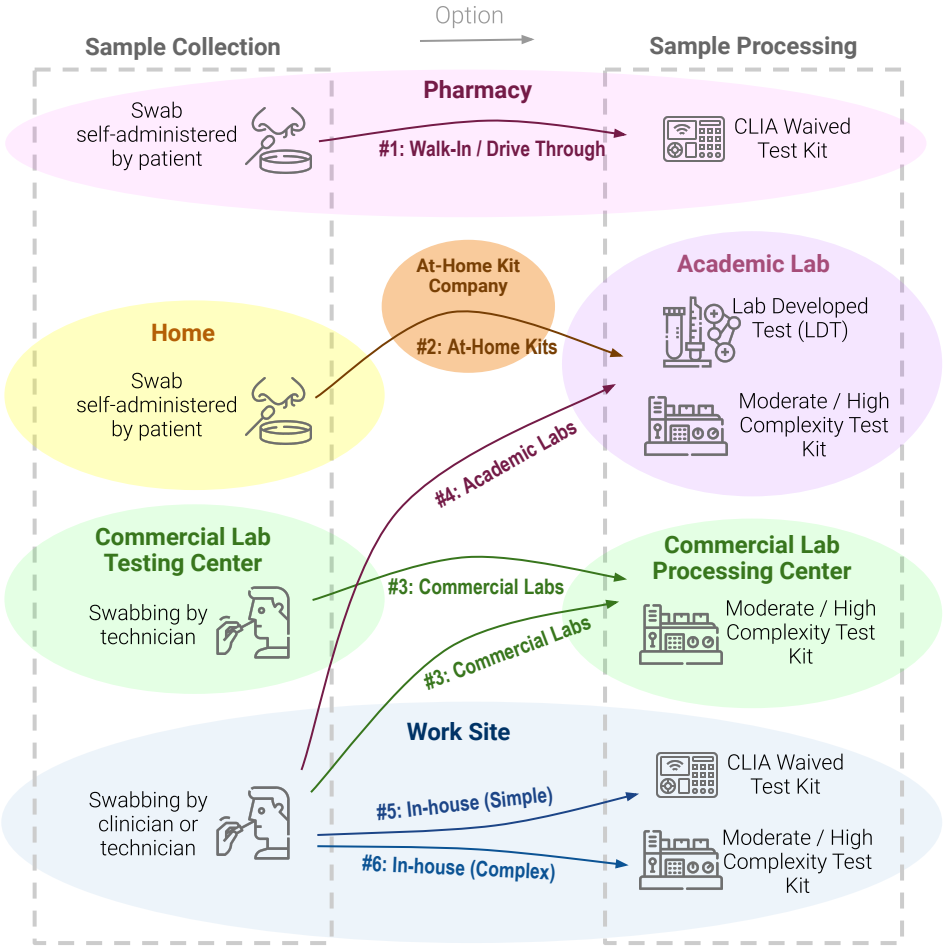
The available testing options deploy sample collection and sample processing in differing settings.

Pharmacies are having patients self-administer, providing a sample, before processing the swab within the pharmacy using a CLIA-waived kit.

A number of startups have been commercializing test processing through LDTs by providing *At-Home Kits*, which are sampling kits patients use to mail in their samples to the LDT labs.

For workplace testing, some companies may seek to take advantage of the existing moderate / high complexity test kits and LDT capabilities at academic and commercial labs. Samples collected on-site could be sent to these labs for processing. However, the turnaround time may be as much as 3 or 4 days. The resources at these labs are also in high demand from public testing efforts and *At-Home Kits*.

Alternatively, workplaces may consider using the CLIA-waived test kits used in pharmacy settings to process the samples on-site. More ambitious companies may also purchase moderate / high complexity test kits and build their own lab.



Option #1: Walk-in / Drive-through Testing By Appointment

This option is not suitable for regular, preventative testing. It is only presented to show the range of available options. While there is a shortage of capacity, testing at pharmacies is a public good, prioritized for testing sick patients.

How It Works:

CVS and Walgreens offer eligible patients testing appointments, either as walk-ins or drive-through. Patients self-administer a nasal swab. The nasal swab sample is analyzed by a pharmacy technician using the Abbott ID Now device, a CLIA-waived test kit.

The Abbott ID Now Device

Advantages:

- The employer does not need to setup testing themselves.

Disadvantages:

- Prioritized for high risk individuals (e.g. those of 65+ of age, with underlying health conditions or who are healthcare workers).
- Difficult to obtain appointments.
- Abbott's ID NOW shown to miss at least a third of the samples detected positive by Cepheid's Xpert Xpress.

Case Example: Walgreens

The Walgreens in Pleasant Grove, Dallas, Texas, started providing drive-through testing by appointment from April 24th, 2020. The location has a capacity of up to 160 tests/day.

Source and Image: FoxNews4.com

Example pricing for 100 tests/week:	Free. Under recent legislation, testing is paid for through the individual's health insurance or government plans (e.g. Medicaid). Some plans may have eligibility requirements, e.g. that it is medically necessary to be tested or that the patient is referred by a licensed healthcare provider.

Option #2: At-Home Kits

How It Works:

While a number of At-Home Kits have emerged, most are not taking orders. Patients are mailed a kit to self-administer a saliva or nasal sample. The patient mails the kit back to recieve their result within 2-3 days.
At-Home Kits, used to collect specimen, are distinct from test kits, which are used to process specimen.

Spectrum Solutions' At-Home Kit, which is also the basis of the Vault At-Home Kit.

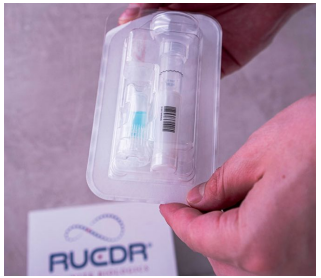
Advantages:

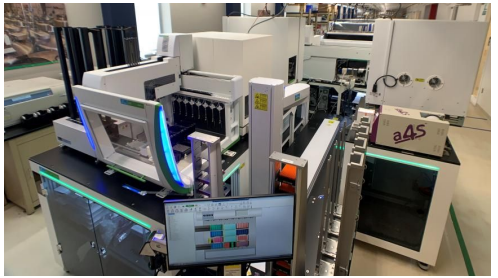
- Available nationwide; ease of rolling out tests.
- No concerns related to employee privacy.

Disadvantages:

- Kits are in high demand. Most suppliers are currently not taking new orders.
- Depending on testing schedule, can be very expensive.

Case Example: Vault





Vault Health is one of the few At-Home Kit providers we found to currently have capacity. Vault plans to scale up to a capacity of 50,000 tests per day by the end of June. Vault manages all state reporting requirements. Rutgers University processes all of Vault's tests, as well as those of other At-Home Kits, which may create competition for lab capacity.

Images: The Vault Kit and Rutgers' RUCDR Infinite Biologics system that processes the saliva samples. (Source: vaulthealth.com; rutgers.edu).

Example pricing for 100 tests/week:	$0 Setup Costs	$195,000 For 3 Months	$780,000 For 1 Year

Pricing scales linearly at $150/test

Option #3: External Lab Services - Commercial

How It Works:

Commercial labs, such as Quest Diagnostics and LabCorp, perform about 85% of COVID-19 tests performed in the US. Some commercial labs are starting to offer employee-employer testing services. These can take the form of on-site testing or testing at one of the labs' network of testing centers.

LabCorp can perform about 80,000 diagnostic tests per day.

Advantages:

- Once at capacity, these labs can run far more tests than public health labs.

Disadvantages:

- Time to results is roughly 2 to 4 days.
- Depending on testing schedule, can be very expensive.
- Where employees are tested at external testing centers, they could become exposed to the virus.

Case Example: Aegis Sciences

Aegis Sciences offers workplace RT-PCR testing. Their approach is to send a clinician to the work site. The clinician collects samples, which are sent to one of Aegis' central laboratories for processing. Aegis' capacity is 14,000 tests per day with a turn-around time of 2-3 days, from swabbing to when results are available. Aegis currently operates in 48 states.

Images: Sample collection and shipping to Aegis is done by a third party; the Aegis lab in Nashville. (Source: aegislabs.com; NEJM).

Example pricing for 100 tests/week:	Variable Setup Costs	$304,000 For 3 Months	$1,006,000 For 1 Year

Since commercial lab services are only starting to offer on-site employee testing, pricing is approximate and may fluctuate.

Option #4: External Lab Services - Academic

How It Works:

Samples can be obtained in-house and then sent to a centralized external testing lab to process the result. This is likely to be a university lab that has developed its own EUA authorized tests or which is using moderate / high complexity test kits.

Nasal swabs are best administered by a trained healthcare professional.

Advantages:

- Convenient for employees.
- Highly standardized and reliable.

Disadvantages:

- Sample collection and sample processing differs per academic lab and is dependent on the LDT or diagnostic test that is used.
- Severe shortage in available partners. For example, of the labs that have developed their own tests - which are mostly academic institutions - only 32 have EUA Lab Diagnostic Tool (LDT) authorization. Some of these are also processing tests from At-Home Kits.

Case Example: Las Vegas Casinos

Several casinos have partnered with University Medical Center of Southern Nevada to provide employee testing at The Las Vegas Convention Center.

Images: 8newsnow.com culinaryunion226.org

Example pricing for 100 tests/week:	Variable Setup Costs	$187,000 For 3 Months	$538,000 For A Year

Pricing is highly dependent on the contract negotiated with the university/lab partner. Numbers provided are for a university lab we contacted.

Option #5: In-House Testing (Simple)

How It Works:

Companies can essentially set up a testing environment similar to the ones used in pharmacies, but with a higher accuracy than the Abbott ID NOW, which is used in CVS and Walgreens. There are currently 4 CLIA-waived kits that can be considered, but the Cepheid kit is by far the most accurate and reliable.

The Xpert Xpress from Cepheid is highly accurate and the kit we recommend for most companies.

Advantages:

- Convenience for employees. Results within an hour.
- Long-term solution. These kits are platforms that can be adapted for other viruses and future pandemics.
- Testing is independent of external lab capacity.

Disadvantages:

- Current low availability of 'best-in-market' machines.
- Some regulatory approval needed, but comparatively light.

How To Do It

While there are not yet any companies conducting testing using this approach, this approach is the one most likely to emerge as the best fit for most companies.

- Procure a test kit with a high level of sensitivity, as well as sterile saline, a biological waste disposal bin and other equipment.
- Designate a space where the test can be conducted. CMS approval is necessary, which is state-specific.
- Use a trained technician for accurate swabbing. Supervision by a healthcare provider, at least remotely, is necessary.
- Develop a testing plan for who should be tested, at what frequency, and the actions that should be taken based on individual and group test results.

Example pricing for 100 tests/week:	$50,000 Setup Costs	$150,000 For 3 Months	$451,000 For 1 Year

Option #6: In-House Testing (Complex)

How It Works:

Most of the test kits currently available require labs with moderate or high complexity CLIA certification. Given the regulatory and technical hurdles to using these test kits, they are likely best suited for companies in the life sciences who would be able to refit existing labs they have.

The BioFire, for example, is authorized for moderate complexity lab settings.

Advantages:

- Convenience for company and employees.
- Greater testing capacity.
- Able to handle a wider range of testing scenarios.

Disadvantages:

- Greater regulatory hurdles to overcome.
- Greater expertise required to manage tests.

Case Example: Amazon

Amazon plans to spend as much as $1 billion in 2020 to regularly test its workforce, by laying the groundwork to build its own lab near the Cincinnati airport. While little is officially known about the company's efforts, it is widely expected that they will develop their own testing approaches using more complex kits.

Images: blog.aboutamazon.com.

Example pricing for 100 tests/week:	$500,000 Setup Costs	$640,000 For 3 Months	$1,062,000 For 1 Year

ABOUT PRESCOUTER

DURING THIS PANDEMIC, PRESCOUTER IS LEVERAGING ITS NETWORK OF 4000+ EXPERTS, LAB PARTNERS AND PROTOTYPING FIRMS TO PROVIDE CLIENTS WITH THE TESTING EXPERTISE AND RESOURCES THEY NEED.

PreScouter traditionally provides corporate innovation and R&D leaders with expertise on emerging technologies and markets. During this pandemic, PreScouter is vetting, selecting and promoting *best in class* testing solutions from lab partners, to provide clients with the unbiased expertise and the resources they need to deploy testing to safeguard their workplaces.

To learn more, contact us at covid19@prescouter.com or (708) 613-7132.

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Technologies and tactics for reducing disinfection time: What tools can companies use to automate disinfection and other safety practices.

Supply Chain Disruption: When traditional resources or raw materials are not available during a pandemic, PreScouter helps clients find alternative solutions - uncovering connections around the world.

Driving Consumer Confidence: Tactics that give workers and consumers confidence that they are in a safe environment, to ultimately drive their re-engagement in economic activity.

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