How Can Workplaces Offer COVID-19 Testing?

PRESCOUTER

June 4th, 2020

For most companies, setting up in-house testing that is similar to COVID-19 testing at pharmacies is the best option for regular, preventative testing.

While we explore a wide range of options in this report, from *At-Home Kits* to setting up your own complex lab, given that the pandemic won't be ending soon, most companies will want to optimize for the most cost-effective, long-term solution that provides test results quickly, before a viral outbreak spreads at a work site. We think this is simple, in-house pharmacy-style testing.

While preventative workplace testing can prevent site closures and the resulting financial and reputational damage, there is currently a shortage of supplies for every aspect of COVID-19 testing. Nevertheless, the entire supply chain is working hard to expand capacity over the next few months.

In the meanwhile, workplaces can start the process for obtaining necessary local licenses and establishing testing protocols, so they can begin workplace testing as and when it becomes necessary. Infection rates within the community that a workplace resides in may be a good indicator for when, and the extent to which, workplace testing is regularly conducted.

Employees with COVID-19 symptoms should not enter the worksite. They can get tested through the healthcare system or through an At-Home Kit, paid for by the employer if necessary.

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

Important Disclaimer: The information provided in this briefing report is based on advice from public health authorities, other regulatory agencies and vendors, as well as news reports and scientific publications. This information has been analyzed, reviewed, and summarized by PreScouter. It is not a substitute for medical or legal advice about your employees, workplace, or obligations.

The Pandemic Won't Be Ending Soon

"I would say in a four to five-year timeframe, we could be looking at controlling this."

- Dr. Soumya Swaminathan,
Chief Scientist at the World Health Organization
(Source: CNBC).

Analysis by PreScouter's own experts suggests that measures to control the pandemic will not be lifted before 2022.

Learn more in our report, *When Will The COVID-19 Pandemic End?*

Workplace testing can prevent work sites from becoming the next hotspot, preventing financial and brand damage.

Many workplaces are conducting daily wellness checks, such as temperature reads and questionnaires asking employees about COVID-19 symptoms, before entering a site is permitted. While these, and other safety measures, reduce the risk of viral spread, many carriers of SARS-CoV-2 (the COVID-19 virus) are asymptomatic. This means the virus may be continuing to spread, but at a slower rate, because of the safety practises in place.

Even work sites with the most stringent safety practises may be “ticking time-bombs” that result in media headlines and shut-downs of business-critical facilities.

Preventative, regular testing of workers can catch asymptomatic carriers of the virus and further prevent a viral outbreak at company facilities. The EEOC, which regulates anti-discrimination laws, has provided guidance permitting such tests.

How Viral Spread Directly Shuts Down The Work Sites Where The Spread Started

Virus spreads at worksite due to asymptomatic employees not caught by wellness checks

Local healthcare system overwhelmed with COVID-19 cases

Increased fatalities from COVID-19 patients and patients of other conditions not having access to hospital beds

To reduce infection rates, authorities shut down areas where virus is prevalent, including work sites.

Case Example:

Tyson’s Pasco Plant Shut Down

Even with rotating shifts and other safety practises, 19% of the 1,482 workers at Tyson’s Pasco, Washington, plant tested positive for COVID-19. Half of the workers who tested positive were asymptomatic. The plant was closed for about 12 days, in order to test all workers and conduct deep cleaning. Only enough workers were able to return to work to operate the plant at at little over half of normal production.

Image: Tyson workers passing through infrared temperature scanners. (Source: tri-cityherald.com)

Testing capacity - *having sufficient resources to conduct testing* - is currently limited.

At the current testing rate, it would take 24 months to test everyone in the US once.

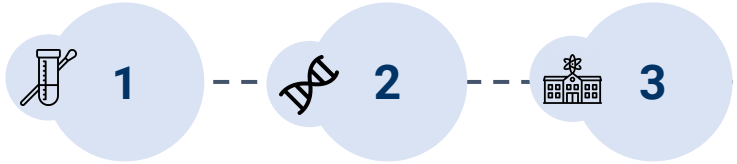
There are severe shortages across all aspects of testing:

- Manufacturers of swabs and other testing kit components are reporting a shortage in the materials they need to produce these items. Because these are low margin products, obtaining investments to scale up production has been difficult for them.
- Testing labs are reporting trouble obtaining diagnostic machines to run tests which would allow them to increase capacity. Machine manufacturers, Roche and Abbott, have confirmed that demand is outstripping supply.

However, both manufacturers and labs expect the availability of items across the supply chain to improve in the coming months.

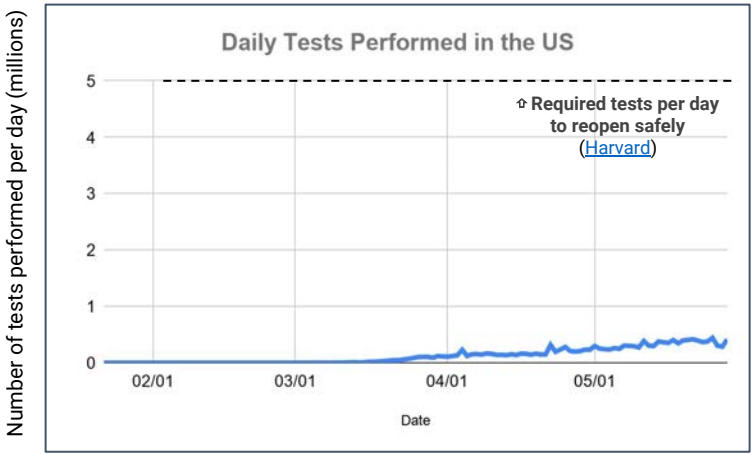
As availability of supplies improve, companies will be able to start workplace testing. This in turn will help the US to achieve the testing levels that are needed to prevent regional lockdowns.

There are shortages at each step of the COVID-19 diagnostic testing chain



Stage: *Example items that are in shortage:*	**Sample Collection** Swabs; Transport media; Collection tubes	**Testing Kits** RNA isolation; Diagnostic kits	**Labs** Testing devices; Diagnostic lab space

Current testing levels are well below the need for testing

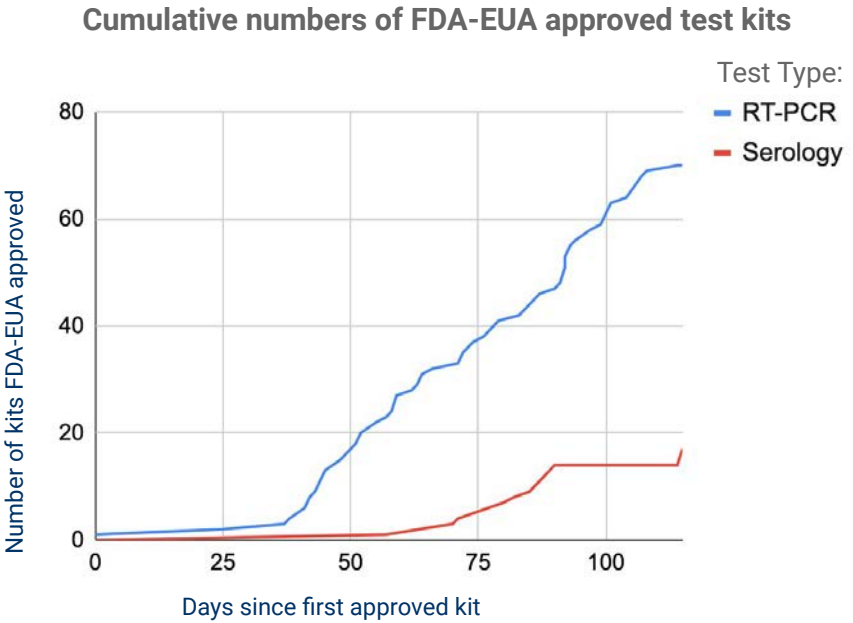


Nevertheless, testing capacity is rapidly expanding.

The Department of Health and Human Services (HHS) announced on May 18, 2020, that it is delivering $11 billion in new funding to support testing for COVID-19. In the meanwhile, the US Food & Drug Administration (FDA) has used its Emergency Use Authorization (EUA) authority to allow new test kits to be introduced and marketed without the usual the approval and licensing provisions.

Unprecedented government actions, such as these, to drive increases in testing has meant that:

- New test kits are being introduced to the market at a rapid rate. (*See chart on the right*).
- Commercial laboratories are continuing to expand capacity, primarily to support the testing demands of the healthcare system. Quest Diagnostics and LabCorp are expecting to increase their testing capacity in the coming months.
- Suppliers of reagents and other testing materials, such as Meridian Bioscience, have expanded production to support tens of millions of COVID-19 tests per month.
- New, innovative testing approaches, including those based on Next-Generation Sequencing (NGS) and CRISPR, are being developed.



Plotted are the numbers of RT-PCR and serology test kits approved starting from the 4th of February, 2020, when the first RT-PCR kit was approved. There is a steep increase in the number of PCR kits available. The amount of new approved serology kits seems to have stagnated. (Based on data presented by the FDA).

Workplaces can start making preparations for testing as resources become available.

Beyond placing orders for equipment and waiting for them to become available, companies will need to consider how they will conduct testing.

Some considerations, when determining the amount and extent of workplace testing needed, are the following:

- How frequently should testing be conducted?
- What are all the costs associated with setting up an environment suitable for testing?
- Are there some job categories or groups of employees who are more critical for the functioning of the business?
- What is the exposure of employees to hotspots and communities where infection rates are high? How are these trending?
- What percentage of the workforce can be in isolation before it impacts the business?
- What percentage of employees showing a positive result would trigger more drastic actions? What are those actions?
- What is the best testing strategy that balances corporate risk with cost?

PRESCOUTER EXPERT NOTE:

"While daily workplace testing is both cost-prohibitive and logistically difficult, testing every week or two weeks can be a valuable preventative measure -- particularly for catching asymptomatic or presymptomatic cases.

Workplace testing and contact tracing can help identify cases of SARS-CoV-2, the virus that causes COVID-19, while rotating shifts and other distancing strategies can help minimize its spread.

The feasibility of regular workplace testing depends on both company resources and the capacity of the facility processing the samples.

Workplace testing is an additional measure to the daily wellness checks we hope companies conduct for everyone who enters a work site. Employees with COVID-19 symptoms should not come to work to get tested. They should instead contact their healthcare provider.

Diagnostic tests can only identify positive cases. A negative result must not be used to clear employees of social distancing measures."

- Jessie Abbate, PhD
Infectious Disease Expert | French National Institute for Development

PreScouter's experts can help clients work the through their plans for workplace testing, weighing the different considerations.

What Options Do Companies Have For Implementing COVID-19 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**.

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.

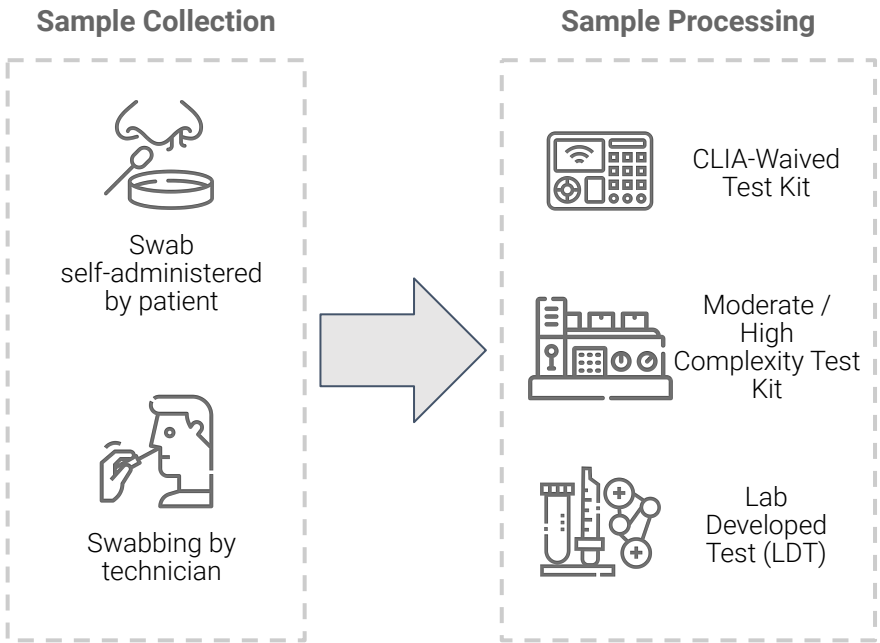
Nasal swabs are typically used for collecting samples, but saliva can also be used. While some of the available test options have patients self-administer nasal swabs for sample collection, the sampling and results will be more accurate when done by a trained technician.

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).*



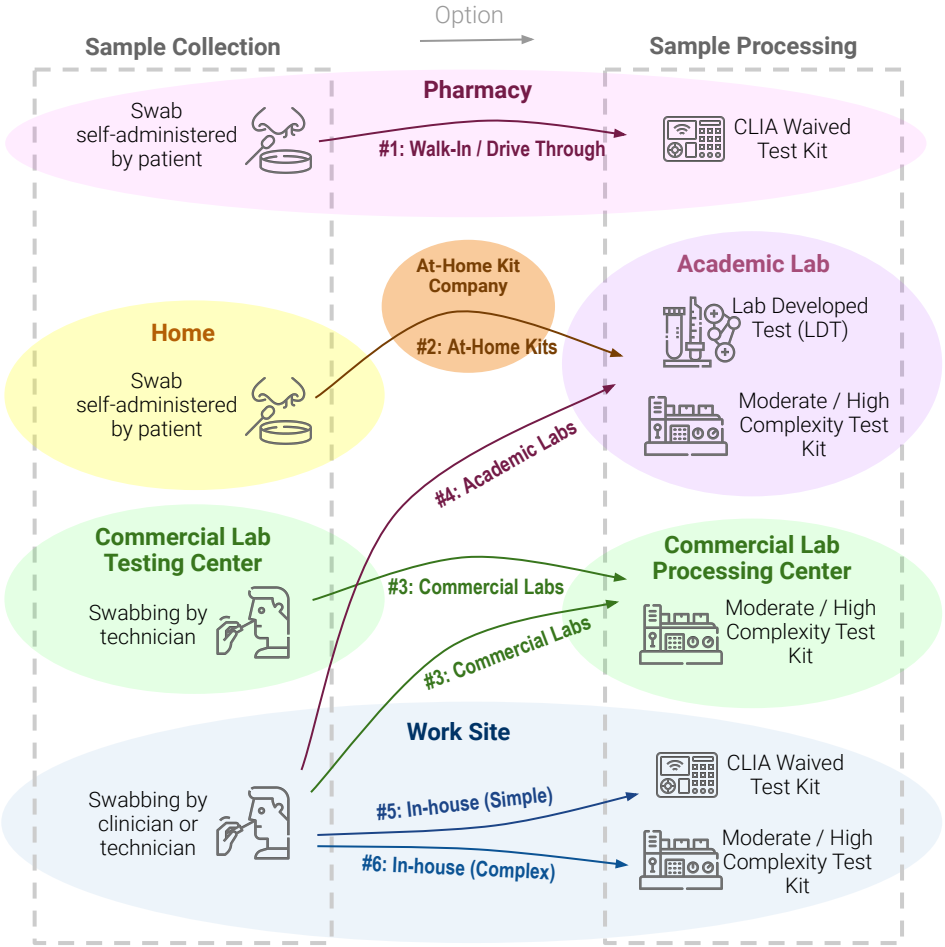
The available testing options deploy sample collection and sample processing in differing settings.

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

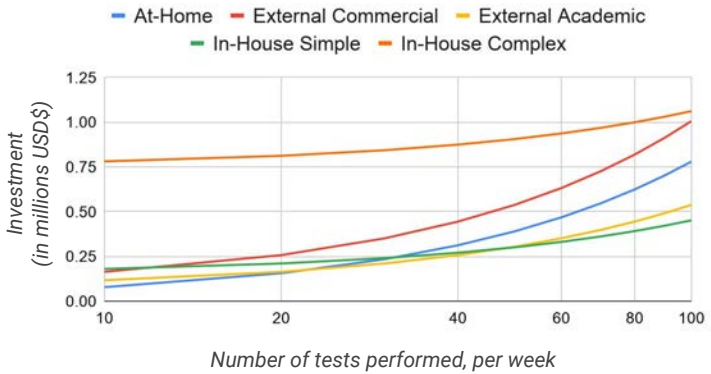
The best option for most companies is in-house testing (simple), while using *At-Home Kits* as a backup.

	#1: Walk-in / Drive-thru Testing	#2: At-Home Kits	#3: External Labs Commercial	#4: External Labs Academic	#5: In-House Testing (Simple)	#6: In-House Testing (Complex)
Speed (in days)	1-2 days	3-5 days	2-3 days	1-3 days	< 1 hour	1 - 3 hours
Ease for employee	Low	High	Low	High	High	High
Burden on existing labs	Yes	Yes	Yes	Yes	No	No
Required expertise	None	None	None	Low	Low	High
One-time setup costs	Free*	$0	Variable	Variable	$50,000	$500,000
3 month cost for 100 tests/week	Free*	$195,000	$234,000	$187,000	$150,000	$640,000
Annual cost for 100 tests/week	Free*	$780,000	$1,006,000	$538,000	$451,000	$1,062,000
Verdict	✗ Prioritized for sick patients	! Scales well; poor speed of results	✗ Expensive, slow	✗ Very limited availability	✓ Best for most	✗ High capacity; expensive

** Eligibility and availability is based on insurance plans, CDC patients prioritization and other factors.*

These are general recommendations. Estimated costs are inclusive of equipment, personnel and other expenses. Costs will vary by organization based on existing internal capabilities. PreScouter has experts on hand who are able to asses, set up and manage the right testing solution for each client's unique workplace testing needs.

Companies can make a small "setup" investment in workplace testing to have the option of performing tests as it becomes necessary.



If more than 42 tests/week need to be performed, in-house (CLIA-waived) testing makes sense as a long-term solution, with At-Home Kits providing immediate short-term testing capacity, should local infection rates suggest testing is necessary.

Local regulatory approval for CLIA-waived tests can take 4 to 12 weeks, as can the wait time for procuring the test kit. Companies can make the investment to set up workplace testing capability without committing to conducting workplace testing until it is necessary.

EXAMPLE, SIMPLE WORKPLACE TESTING PLAN

1. Conduct daily wellness checks. Isolate and externally test:
   - (i) individuals with COVID-19 symptoms
   - (ii) individuals who have come into contact with anyone who has tested positive

   External testing is performed at local healthcare system (where there is capacity), via At-Home Kits that have already been procured.

2. Build onsite testing capacity for manufacturing plants critical to business continuity.

3. Start twice monthly workplace testing for critical facilities when community infection rates reach *x%**.

   Start weekly workplace testing for critical plants when community infection rates reach *y%**.

   Immediately isolate individuals testing positive from workplace testing and have them consult their healthcare provider.

4. Wind down work workplace testing to just daily wellness checks when community infections are below *z%**.

* *x%, y% and z% - calculated based on several factors; PreScouter experts can advise on this.*

PreScouter's experts can help clients develop workplace testing plans for different levels of coverage against infection risk for differing levels of investment in workplace testing.

The Testing Landscape Is Evolving

The gap in where the US needs to be for testing comparative to current testing levels is leading to continued, rapid innovation to overcome the bottlenecks that prevent wider testing. From simplifying how test samples are collected to processing large numbers of samples at the same time, a wide range of innovations are expected to emerge in the near future.

Some emerging innovations of note are the following:

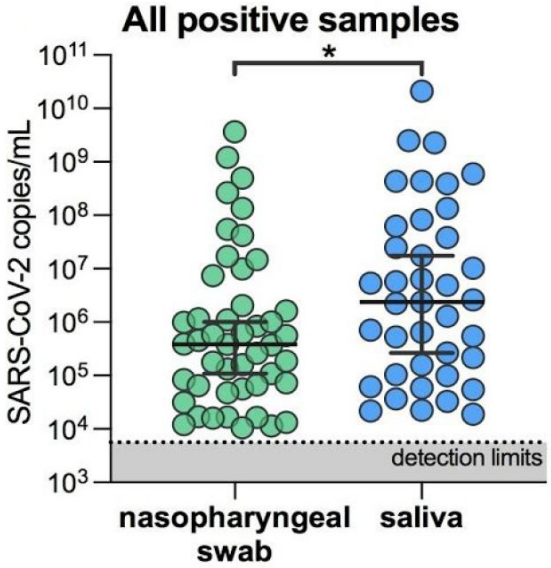
- Using saliva (rather than nasal swabs) to improve ease of self-administration for patients
- Repurposing Next Generation Sequencing machines
- Large scale saliva-based testing
- Expanded availability of At-Home Kits

Reliable, saliva-based PCR testing may be coming soon.

Saliva based PCR testing is generally considered not to have as high a sensitivity as nasopharyngeal swabs. However, it is still used - often in scenarios where patients need to self-administer providing a sample, such as home kits. This is because patients do not push nasopharyngeal swabs high up enough in their nose to obtain a good sample.

However, a group at Yale has developed a saliva PCR testing method that has been shown to have higher sensitivity than traditional nasopharyngeal swabs.

Because collection of saliva is minimally invasive and can be reliably self-administered, this approach can improve accuracy of testing and lead to less false-negative results.



Saliva vs. swab
Compared to nasopharyngeal swabs, saliva samples show a larger average number of SARS-CoV-2 virus detected. This means that the saliva test is more sensitive.

PRESCOUTER EXPERT NOTE:

"Saliva is a viable and more sensitive alternative to nasal swabs and could enable at-home self-administered sample collection for accurate large-scale SARS-CoV-2 testing"

- Anne Wyllie - Associate Research Scientist at Yale University

Repurposing existing NGS machines could make deploying millions of tests a day possible.

Next-Generation Sequencing (NGS) technology was originally designed for sequencing the human genome. However, NGS platforms can be repurposed for diagnostic testing.

The US has 400 NGS machines. Illumina, the Broad Institute, Hudson and others are all developing so-called “multiplexing” tests. Multiplexing - a technique unique to NGS - means a single NGS machine could, hypothetically, test as many as 750,000 individual samples daily.

Since NGS uses different reagents and a different supply chain than existing COVID-19 tests, this approach also effectively creates new testing capacity.

Some limitations of this approach are that it would need to pass EUA approval and need a supporting infrastructure to send samples to the existing 400 NGS machines. The complexity of the technology also means retooling them is not trivial.

NGS compared to the current best approach, RT-PCR

	RT-PCR	NGS
Accuracy	High	High
Ability to scale to US needs	Uncertain	Yes
Tests/day - now	200,000	0
Tests/day - in future	<1 million	Tens of millions
Turn-around time	1-2 days	1-2 days
Sample Type	Nasal swab/ Saliva	Nasal swab/ Saliva
Supply chain risk	Medium	Low

An NGS machine from Illumina. Illumina is developing COVID-19 tests for use on their sequencing platforms. Source: Illumina

Large scale saliva testing could get the US to the levels of testing that are needed.

Regardless of whether the approach used is PCR or NGS, saliva testing eliminates the need for using trained personnel to acquire accurate samples.

What's needed for large-scale saliva testing?

- Multiple, mobile testing locations to collect samples. This includes drive-throughs and walkthroughs.
- Organizing manufacturers to aid in production of clinical swabs, saliva test tubes and kit packaging.
- An infrastructure that allows distribution of kits on a national level.
- Large, high-capacity testing facilities (50,000-100,000 samples/day) that perform high-quality testing.

Challenges in establishing large-scale saliva testing

Step 1.

Increase manufacturing of swabs/kits

Step 2.

Build sample collection points

Step 3.

Design large, high-capacity testing labs

Step 4.

Create an online results platform and integrate with local healthcare

WHAT TO KEEP AN EYE OUT FOR:

CURATIVE KORVA COVID-19 DETECTION

Curative Inc. is a start-up that is working on scaling up saliva testing to nationwide levels. Their aim is to create new supplies of kits and tests without competing for resources with existing testing approaches.

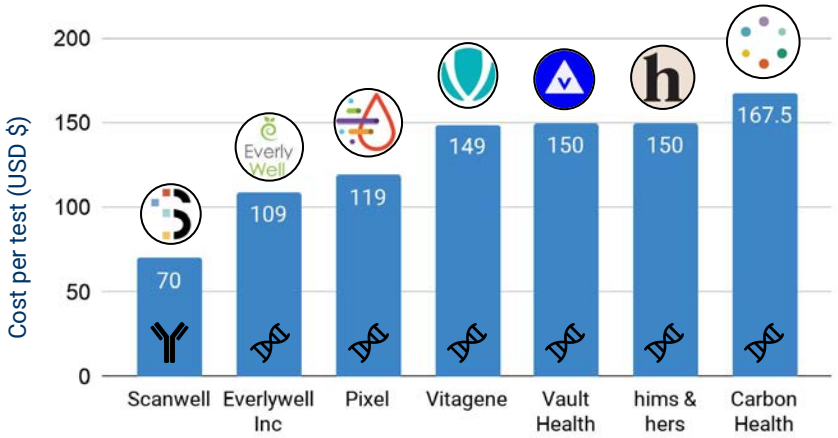
At-Home Kits are expected to expand in availability.

Vault is the only At-Home Kit provider that is currently taking bulk orders. However, as capacity expands, others vendors are expected to start taking orders again. There are also a plethora of new vendors emerging.

At-Home Kits have gained popularity as a convenient way to conduct tests. There are currently 7 At-Home Kits (6 RT-PCR, 1 serology) that use FDA-EUA approved diagnostics for processing samples.

- Kit prices range from $70 - $181/kit.
- Tests results for RT-PCR based kits are generally available within 1-3 days after samples are shipped back to the test provider.
- 4 of 7 of the approved kits use saliva as the sampling method for RT-PCR testing. Patients are more likely to provide an accurate sample with this approach, compared to a nasal swab.

Total Cost Per At-Home Kit



Listed are the total prices, including lab diagnostic testing per service. Icons indicate the type of diagnostic test performed (Serology, followed by the 6 RT-PCR).

Time-To-Result For Each At-Home Kit

These are the estimated times to result after samples have been received by the lab. Scanwell's antibody test does not require shipping and is almost immediately available.

Companies can start the process of implementing workplace testing.

Companies as diverse as Smithfields and Ford closed plants due to COVID-19 outbreaks. Beyond existing safety practises, workplace testing can provide additional *peace of mind* for companies and workforces by preventing asymptomatic carriers from spreading the virus at work sites.

Companies don't need to spend the $1Bn Amazon is spending to establish workplace testing. Companies can make a small "setup" investment in workplace testing to have the option of performing calculated numbers and frequencies of tests conducted, as it becomes necessary, to mitigate high-risk scenarios.

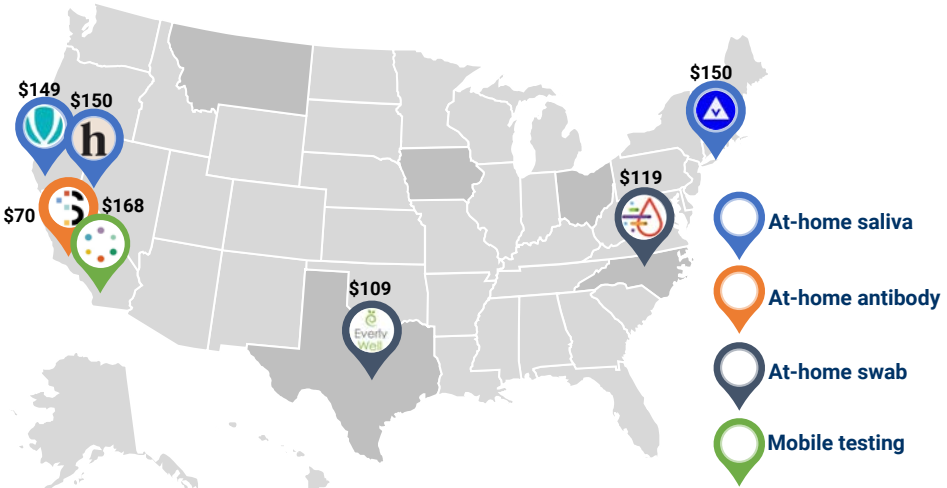
Because of the long lead time to obtaining local licenses, as well as to obtaining the necessary equipment, companies that are considering implementing workplace testing would be well advised to start down this path sooner rather than later.

PreScouter's experts can make it easy to get workplace testing in place.

HOW PRESCOUTER CAN HELP

- ✔ Advising on the best approach to testing for your company's needs.
- ✔ Analysis of the best available testing options that fit your company's budget.
- ✔ Training employees on the importance of testing for business continuity.
- ✔ Providing a comparative analysis of local or national testing services.

Example Analysis of Available Testing Services Based on Proximity to Work Sites



Workplace Testing Preparation

	Time to result	Capacity	Training Needed
Easy-to-use	 45 minutes	 1 test/run	 Minimal
Complex	 4-5 hours	 96 tests/run	 Extensive

Dependent on the size of your company, expertise of your employees and criticality of each work site, some options may be more feasible and cost effective than others. PreScouter can help you determine and implement the most effective approach for your company's business needs.

- ✔ Procuring best-in-market diagnostic equipment for testing.
- ✔ Picking the most cost-effective assay for the size of your company.
- ✔ Providing necessary licensed personnel for testing.
- ✔ FDA regulatory compliance.
- ✔ Obtaining approval for in-house testing (CLIA).

HOW THIS REPORT WAS PUT TOGETHER

222
Test Kits Identified & Reviewed for Suitability

55
Test Kits Profiled in Detail

15
Vendor & Expert Consultations

20+
Regulatory Documents and Academic Papers Analyzed

200+
Hours of Research & Analysis

AUTHORS

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Infectious Disease Expert

Maikel Boot is a Postdoctoral Fellow in the department of Microbial Pathogenesis at the Yale University School of Medicine. His research focuses on mapping the consequences of bacterial cell-to-cell variation of the causative agent of tuberculosis, *Mycobacterium tuberculosis*, on macrophage infection. Maikel has been a part-time consultant with PreScouter for roughly two years. He is the current Chair of the Yale Postdoctoral Organization, organizing 180+ events per year for 1250 Postdocs at Yale. Maikel is also a team lead on the CORD-19 (COVID-19 literature) database project, spearheaded by Google and Kaggle and is involved as a board member in a COVID-19 public health campaign in Connecticut. In his free time he enjoys listening to music and going to concerts.

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Genevieve Engleman is a PreScouter Research Analyst and has worked on multiple projects spanning across areas such as chronic health disorders, skin health, novel drug developments, companion diagnostics and infectious diseases. She is a state-licensed and registered healthcare provider based in Maryland and her Occupational Therapy specialties include pediatrics and orthopedics. Genevieve comes from a vast background in the healthcare system where she previously served as the Clinical Executive Associate for a large statewide practice. She enjoys attending music festivals with her husband, Thomas, and two boys, Hank & Beau.

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ABOUT PRESCOUTER

PRESCOUTER PROVIDES EXPERTISE ON DEMAND, INCLUDING EPIDEMIOLOGISTS AND OTHER COVID-19 EXPERTS

During COVID-19, PreScouter is leveraging its network of experts to help clients respond to this pandemic appropriately. Our epidemiologists, infectious disease scientists, and biostatisticians combine advanced technical training with years of consulting experience to distill virology into strategies that make sense for a variety of businesses.

EXAMPLE PRESCOUTER PROJECTS:

Managing Viral Outbreak Risks: Experts help clients evaluate and mitigate the risk of infection in their work sites, examples of which include:

- Monitoring of local communities for community spread, hospital capacity and other risk indicators
- Contact tracing training
- Technologies and tactics for reducing disinfection time

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.

500+
CLIENTS WORLDWIDE

4,000+
RESEARCH REPORTS CREATED

150,000+
HOURS OF RESEARCH COMPLETED FOR CLIENTS

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