

# CLEARED4

Safely Reopening Our World<sup>(TM)</sup>

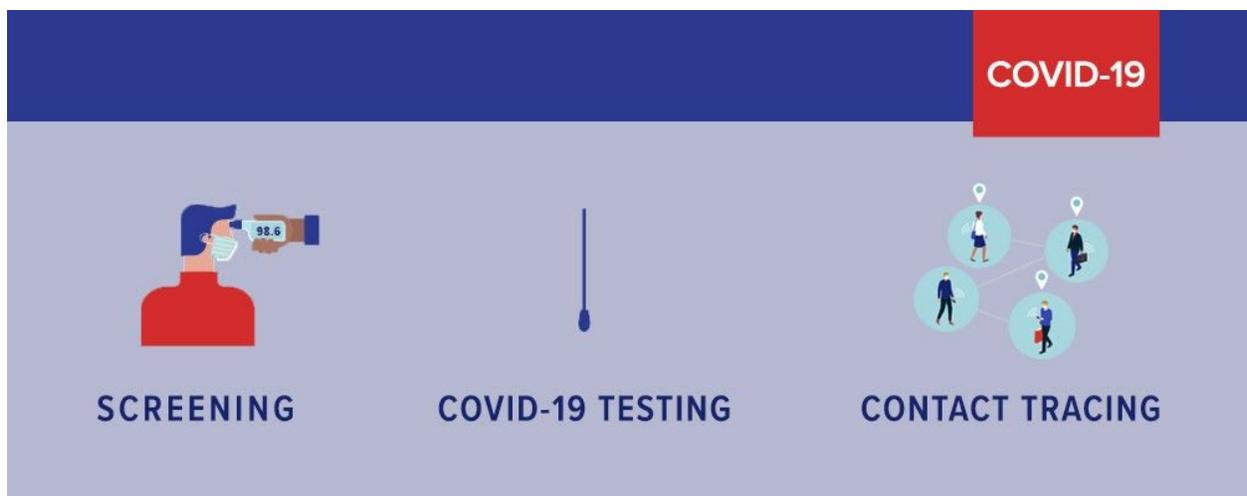
## How To Optimize Covid-19 Testing Within Your Organization

### Background

Covid-19 positivity rates have been consistently going up in the US over the last two months as the rate of new cases per day has reached 200,000 (as of December 5, 2020). These rates are likely to keep increasing through the 2020 holiday season due to increased gatherings, cooler weather, and returning college students. These factors will accelerate the likelihood of more Covid-19 cases in all businesses, schools, and organizations.

### What Should be Done Differently During This Critical Time?

Organizations have three methods to combat this deadly disease: monitoring, testing, and tracing.



All three of these components will be needed to fight Covid-19. As most cases of Covid-19 are transmitted from asymptomatic individuals, the importance of a thorough

symptom monitoring program is mandatory. The most important feature of a strong monitoring plan is that it has universal adoption by all constituents.

A tracing program will alert those individuals that they may be infected or exposed to Covid-19 and allow them sufficient time for evaluation, testing, and treatment.

**However, testing asymptomatic individuals and subsequently identifying those who are infected with Covid-19 could prevent the most damage to organizations as these individuals could be blindly spreading the disease to others.**

Until vaccination becomes widespread, testing asymptomatic individuals for Covid-19 could become the most important vehicle to decrease the spread of the pandemic. Groups can choose from several different testing strategies depending on the risk of Covid-19 in their community and their budgets. They can choose to test only symptomatic individuals or random asymptomatic individuals or do some combination. Since testing for symptomatic individuals in many communities is performed through local physicians and facilities, businesses and schools may only need to support a testing program for asymptomatic individuals.

There are many potential advantages that a strong asymptomatic screening program could provide for an organization. Certainly a carefully constructed program could definitively prevent major outbreaks from occurring in a workforce. Such a program could also alert the organization that Covid-19 is present and the entity could actively take measures to preclude a potentially damaging increase in cases. Additionally, the detection of Covid-19 in certain divisions could allow proactive reallocation of resources and responsibilities so that productivity would not be compromised.

**Benefits of a strong testing program:**

- Could potentially save the life of a vulnerable member of an organization by early detection of disease
- Detect asymptomatic cases
- Facilitates contact tracing
- Can help avoid a potential superspreader situation which could close a school or business and create disastrous negative publicity
- Increase productivity within a workforce because employees feel safer
- Evoke more employee trust in management and help employee retention.



## Considerations For Starting A Testing Program

When an organization starts a new Covid-19 testing program, it needs to decide which of its members it will test and how frequently. The organization also needs to consider under what conditions it would conduct additional testing based on the results of the screening tests. A circumstance that could necessitate increased testing might include detection of a cluster of positive cases or a change in the local community status of Covid-19. The organization also must decide where it wants to screen the individuals, either onsite or at another location such as the individual's home. For asymptomatic individuals who continue to attend a central location, an onsite testing program there might be the most practical choice.

### Summary of checklist for starting a new testing program:

- Determine testing budget
- Decide if the program will cover asymptomatic individuals, symptomatic individuals or both
- Decide how frequently each individual will be tested
- Establish what proportion of the population will be tested each time
- Find a method for storing the testing information that is retrievable
- Make a game plan for what actions to take when a test is positive
- Have a contact tracing strategy

If the organization also wants to test for symptomatic individuals, it should decide whether it will test them at the institutional locale or their home. Often, the organization will just allow symptomatic individuals to be tested at the locale chosen by the individual's personal doctor or local emergency room as the symptomatic person is likely going there anyway. Since the CDC has created [this guidance](#) for symptomatic individuals, the majority of this discussion is focused on how to fashion a testing program for asymptomatic individuals.

## Four Key Factors For A Covid-19 Screening Program

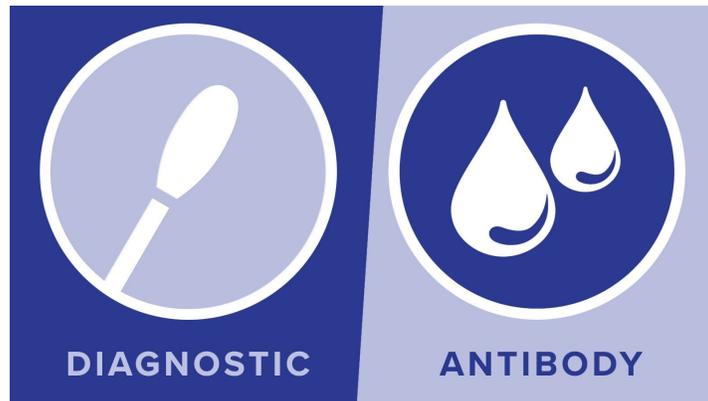
There are four key factors that need to be considered for any asymptomatic screening program:

- 1. The type of Covid-19 test used and the methodology used for testing**
- 2. The frequency of the testing**
- 3. The proportion of individuals tested at each frequency**
- 4. The storage and use of the testing data within the organization**

The combination of these four factors will determine the success of any program for Covid-19 screening. Generally, the most accurate test given the most frequently to the most people will capture the most Covid-19 cases within the organization. However, budgets and logistics often play a role in the number of tests that can be performed. Consequently, a prioritization matrix should be developed.

### 1. Covid-19 Test Types

Different types of tests are available for Covid-19 including laboratory-based PCR tests, point-of-care based antigen, LAMP tests (the “rapid” bedside tests) or serology tests (the “antibody”) tests. The PCR, antigen, and LAMP tests detect the possible presence of current Covid-19 infection through a nasal swab or saliva. Someone who tests positive for these tests could be contagious for Covid-19 and could potentially infect others. Serology tests are drawn from the blood and indicate whether someone has had a Covid-19 infection in the past. Serology tests carry minimal or no current clinical value as the active infection is likely to have subsided by the time of this test. Organizations should understand that [antigen tests](#) are notably inferior to PCR-based tests in their specificity and sensitivity, causing a “miss” of detection in early stages of infections.



Summary of Covid-19 tests:

- PCR (gold standard for Covid-19 testing)
- Antigen (rapid, point-of-care tests but less accurate than PCR tests)
- LAMP tests (rapid but much less proven to be accurate than PCR tests)
- Serology (test for past infection of Covid-19 only)

Screening tests for Covid-19 are performed in asymptomatic individuals. Diagnostic testing is performed in those with symptoms of Covid-19. Since screening asymptomatic individuals is less likely to give a positive result than diagnostic testing, many institutions testing large numbers of individuals such as the major sports leagues choose to use “pooled testing.” Here, multiple individuals (usually around 5) give separate samples that are pooled together for evaluation by the laboratory to be tested. If the test is negative, then all the individuals in the pool are presumed to be negative for Covid-19. If the pooled sample is positive, then the laboratory will have to test each individual or sample again separately from the pool to determine which individual has tested positively for Covid-19. Some laboratories do not require a new sample to do the second test while others may require another sample.

## **2. Test Frequency**

Different Covid-19 screening programs test at different time intervals and can be perhaps daily, twice a week, weekly, biweekly, or monthly. Testing each individual only once a month will yield more missed cases than if each member is tested more frequently. Missing a positive case with a longer interval for the next screening could create a higher likelihood of a potential outbreak of Covid-19. The risk of missed Covid-19 cases will be

lower with any strategy if there is a low Covid-19 rate in the community and will be higher for the group if the community Covid-19 rate is higher.

The most important considerations for determining the frequency of screening individuals within each particular organization should focus on the potential risk incurred by a missed positive case or the likelihood of having multiple positive cases. Here are some common reasons why there could be a high likelihood of Covid-19 cases within an organization or why a certain case of Covid-19 case could be especially damaging:

- **Community Prevalence** (How high is the Covid-19 prevalence rate in the area that is being considered? A higher rate could mean that the organization is having multiple positive cases that are missed.)
- **High Value Individuals Or Contacts** (Does the individual have particularly important skills to the organization or the community that are difficult to replace? An example here would be the CEO of a company, someone who is the only doctor in a rural area, or an IT specialist within an organization. Another case would be someone who interacts frequently with a particular high-client value)
- **Travel** (Did any work or personal travel occur for the individual or their contacts and if so, did they go to an area with a higher rate of Covid-19?)
- **Health Of Individuals Or Their Contacts** (Are there vulnerable individuals who might fare worse with a case of Covid-19 in the population to be tested?)
- **Longevity** (Does this person bring potential new exposures to the community or obtain a new job in a new location?)
- **Hygiene** (Does the person's occupation allow the individual to be able to comply with standard Covid-19 hygiene protocols such as mask wearing, distancing, and frequent hand-washing? Is the individual likely to have any breaches in these safety measures due to their occupation? Examples here would include crowded or hot manufacturing areas where individuals may not always be able to distance or wear masks adequately)

- **Number Of Likely Contacts** (Does the individual interact with a disproportionate number of other individuals? An example of this person would be a receptionist, a food server or someone at a checkout counter at a retail store.)

The logistics of testing frequency can be managed by partnering with a testing company or organization that specializes in Covid-19 testing. These groups can arrange testing schedules at different locales and arrange for the actual tests. They can also create a prioritization scale to evaluate the most important testing parameters.

A common strategy for an organization is to test their employees weekly on the same day of the week. Another strategy entitled “ Rotational testing” could also be incorporated where different individuals are tested each time testing is performed. In this way over a given time period, such as a month, everyone has been tested once. The actual frequency of the tests could be determined by the risk factors, the level of concern by the stakeholders, and the budget allocated for testing. Other more complex strategies have also been described using mathematical algorithms that ensure the greatest yield of information with the fewest tests. These methods could also give the most insight into whether clustered outbreaks are occurring without every single individual being tested every day.



### 3. Organizational Testing Coverage

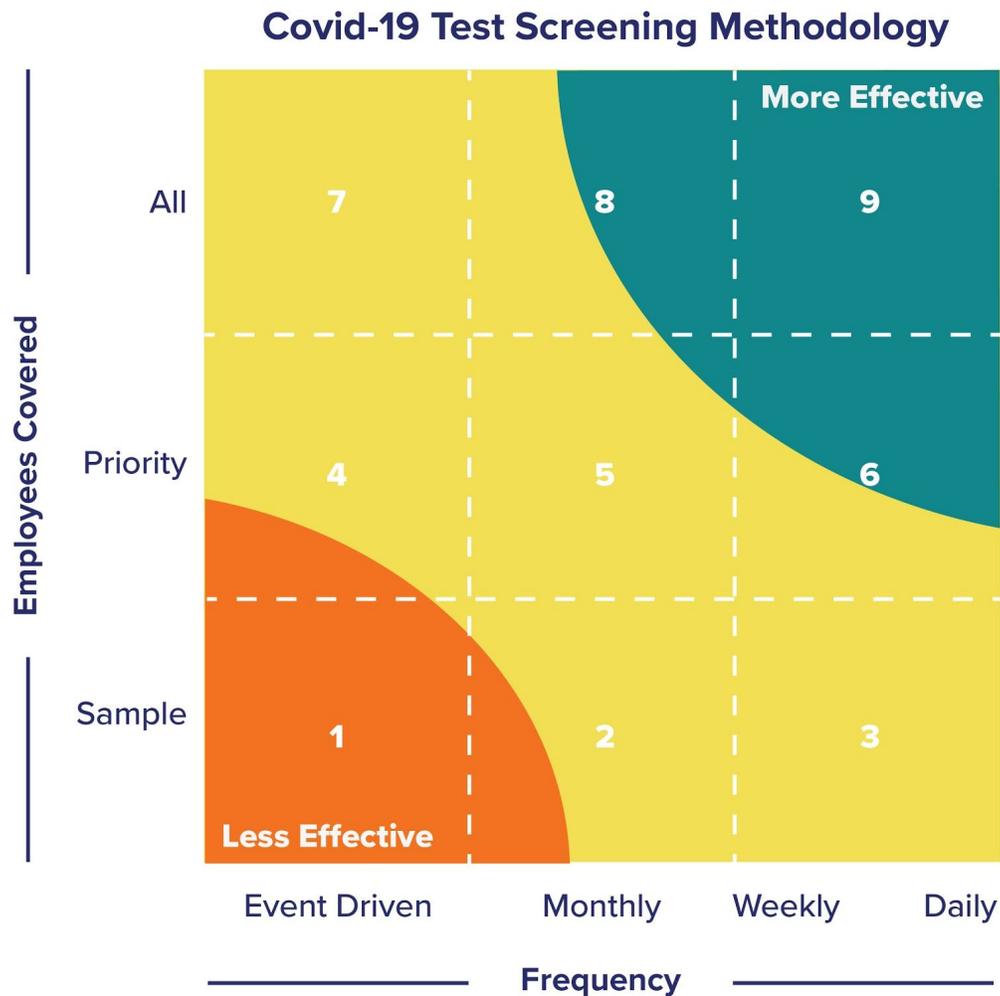
Ideally, organizations would be able to test as many individuals as possible on a regular basis. However, due to cost and logistical concerns, this approach might not be practical. Consequently, each organization should create a schedule based on some prioritization of who should be tested and how frequently.

An organization could choose to test a sample of individuals, possibly 10% of the total employees at a given time. However, a positive test within different employees might lead to different organizational consequences. The following are examples of groups who could potentially be treated with a different priority for initial testing given their role in an organization.

- Business decision-makers and leaders whose absence might cause a negative business impact
- Individuals who interact with many others during their work day (within 6 feet) and could potentially become superspreaders
- Individuals who might be in closer contact with higher-risk populations such as hospital workers or EMT workers
- Certain individuals who interact with clients and would have a higher business impact if they transmitted the disease to other individuals and were unable to fulfil their duties
- Frequent travelers who are exposed to other individuals outside the workplace.

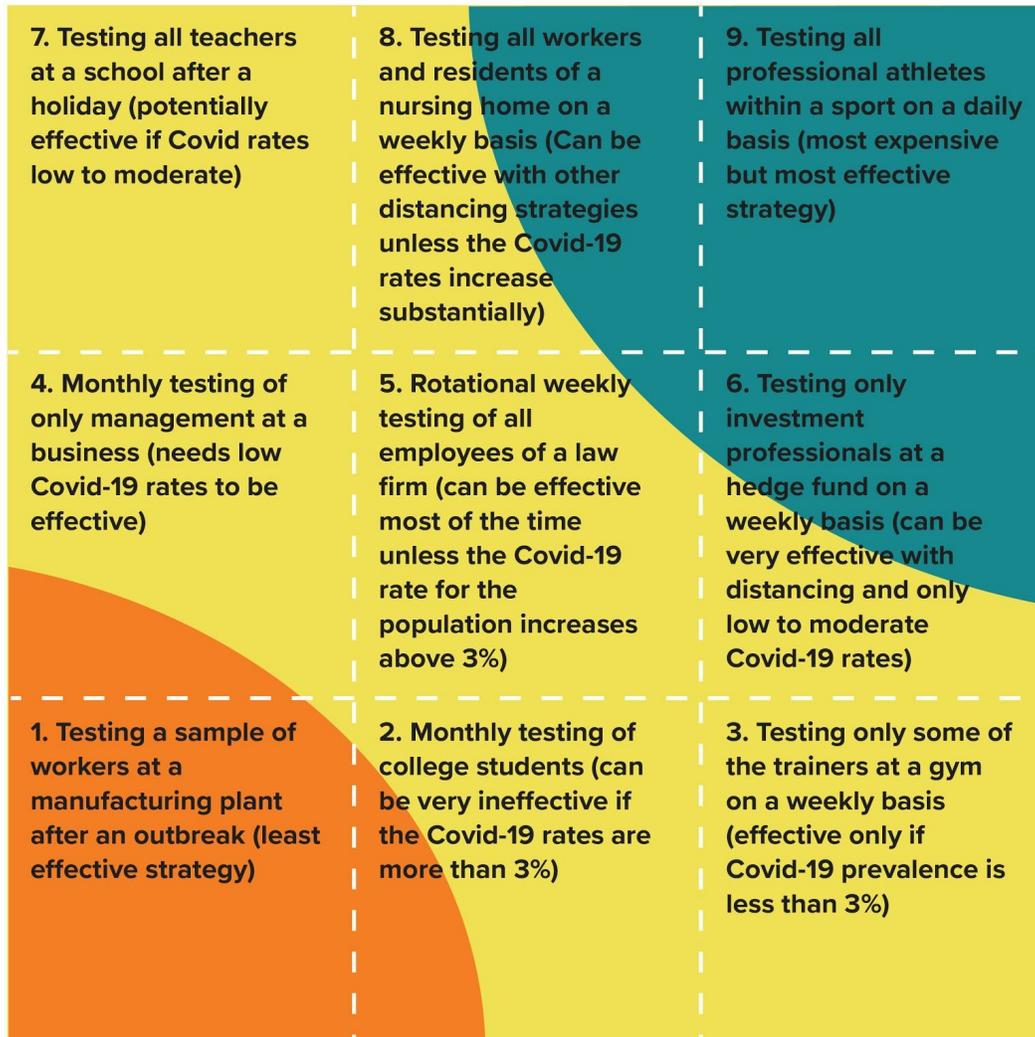
Based on the approach above, some individuals or groups undergo more frequent testing than others. This prioritization will create a testing matrix like the example shown below. In the chart, testing strategies with “High Effectiveness” (those on the upper right portion of the graph) are those where a high proportion of true positives with Covid-19 in the organization are captured and minimal additional risk or damage to the entity may be created by Covid-19. “Low Effectiveness” strategies on the left lower portion of the chart indicates that a low proportion of true Covid-19 cases are captured and the organization could incur severe risk or damage from Covid-19.

Factors other than the absolute number of tests could influence the effectiveness. For example, if there is a very low Covid-19 prevalence rate in the community, many tests may not be needed for the effectiveness to be high.



Each organization needs to decide their own priorities for testing based on their personnel, their likelihood of internal spread, and their own budgets. The table above can help an organization frame some of these needs. To cover the most individuals, the number of required tests needs to increase. To strive for the highest effectiveness, the frequency of testing needs to increase. This strategy will detect the most Covid-19 cases but have the highest cost burden on the organization but may be necessary with a high Covid-19 rate in the community.

Below is an example of different testing strategies, and how they would map to the grid of options from 1 (low effectiveness) to 9 (highest effectiveness).



Importantly, the needs of institutions or a change in the prevalence of a community may warrant changing the recommended frequency of testing. For example, if a school found a large number of positive cases in their area, it might need to expand its testing to more individuals within its community. Also, each group within an organization may represent a different need based on the organizational risk of that group contracting and spreading Covid-19 cases. For example, testing in a nursing home might need to be more frequent and include a higher proportion of the testing population as any missed positive case could be disastrous.

In general, low Covid-19 prevalence rates are less than 3% positivity rates, medium rates are 3 -10% range and high rates are above 10%. There is no one-size-fits-all approach to testing, but the matrix above should provide a methodology to understand the considerations of an appropriate testing plan within each organization. The CLEARED4 team has considerable insight in this area and will be available to help its clients formulate the right testing strategy for their individual needs.

#### **4. Tracking Test Results**

Once a screening program has been created, it is important that all the testing data is being tracked. Safe storage of these data is vital. Importantly, this data can be used to determine who needs to be tested and what is the significance of the results. Evaluation of the data can also ensure that high risk groups or individuals do not miss their testing. In addition, a good data tracking center can alert the organization to those individuals who need quarantine after a positive test. The tracking center can also indicate the need for contacts of positive individuals to be traced. In addition, if some users had symptoms, but were tested negatively, they could potentially shorten their 14 day quarantine period after consultation with their local physician.

#### **CLEARED4 Is Part Of The Solution**

CLEARED4 will help with the economies of testing in multiple ways. CLEARED4 can advise and consult with each organization on where testing resources could be best deployed. CLEARED4 can eliminate the maintenance of sensitive test data in the physical site of an institution by storing the data safely in its HIPAA-compliant cloud. Most importantly, working with CLEARED4 allows access to cost-effective pooled testing through its partners.

**CLEARED4 will show an institution not only how to perform the most efficient testing for its unique characteristics, it will also store the content within its secure platform and provide the most affordable testing strategies to be accessed.**

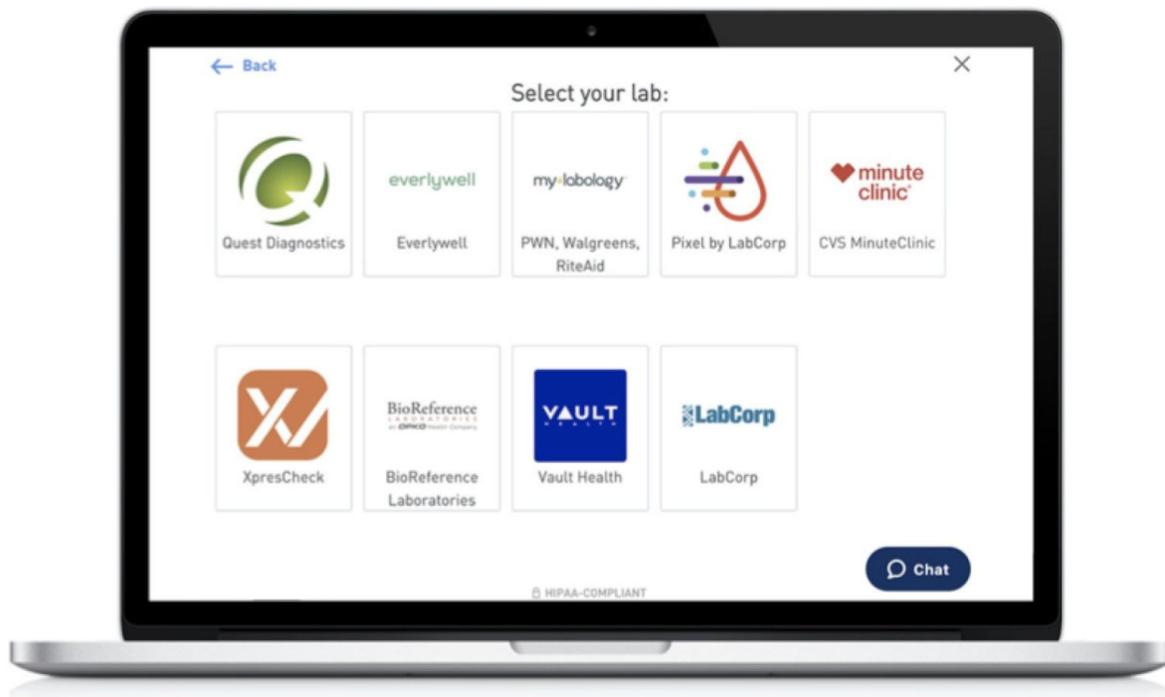
Having a HIPAA-compliant system that helps to manage all the testing activities, results, quarantine states and rules will be an important part of a comprehensive screening testing program. The CLEARED4 platform can complete the tracking steps listed here and is already being used by clients from schools, to sports stadiums, manufacturing sites and corporate offices.

The software of CLEARED4 is designed to keep track of those individuals who have been tested and those who may need later testing.

Medical Tests <span style="float: right;">+ Add</span>					
Name	Covid Result	Tested date	Provider	Status	Action
> Pool test (12345678)	Positive	Nov 20, 2020	ADNAS	Completed	
> COVID-19 RNA (SARS-CoV-2), QL, rRT...	Positive	May 27, 2020	Human API	Completed	
> COVID-19 Routine Screening#Antibo...	Positive	Jul 02, 2020	Human API	Completed	
> COVID-19 RNA (SARS-CoV-2), QL, rRT...	Negative	Jul 02, 2020	Human API	Completed	
> Covid-19 Test	Negative	Nov 10, 2020	N/A	Completed	

*\*Example detail from the CLEARED4 CMS showing an individual's test results:*

Testing data can be added manually with individuals using our mobile application to upload proof of results, or data can be uploaded via our API. The CLEARED4 platform is already integrated with the following Covid-19 test labs and medical sites.



Finally, CLEARED4's partners can test many individuals at the worksite itself in a single day. Alternatively, CLEARED4's partners can send test kits for an individual's test collection to work or home and then mailed back to the laboratory.

## **Summary**

Each organization needs to decide how much testing will benefit their own particular situation. In general, the most important people to test are those the organization needs to fulfil its essential mission or those that would fare most poorly from a medical standpoint if they contracted Covid-19. After that, the amount of testing should be related to multiple factors including community prevalence, risk of contracting Covid-19, and the risk of transmitting Covid-19 to others. The logistics of testing and the management of testing costs can be assisted by smart software like CLEARED4 and the trained medical consultants of CLEARED4 with special expertise in Covid-19.