

COVID-19 Rapid Response Impact Initiative | White Paper 9

# The Mechanics of the COVID-19 Testing Supply Chain

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We need to deliver 5 million tests per day, with results returned in 12-24 hours, to deliver a safe social opening. This number will need to increase over time to 20 million a day to fully re-mobilize the economy. We acknowledge that even this number may not be high enough. In the considerably less likely eventuality that 20 million tests a day do not suffice to contain the disease, we will need to scale testing up much further. If we need to do that, we would by then be in a better position to know how to do it. By identifying individuals before they have had much opportunity to transmit the virus to others, massive testing will dramatically decrease new cases and progressively drive down the infection rate to low levels. We believe the first is do-able by the end of June, and the second by the end of July.

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# 01 Elements of the Plan

Massive-scale testing would involve rapid development of:

- Streamlined sample collection — for example, involving simple saliva samples (“spit kits”), rather than deep nasal swabs that have to be taken by healthcare workers (an innovation that should soon be available);
- Transportation logistics systems able to rapidly collect and distribute samples for testing;
- Mega-testing labs, each able to perform in the range of 1 million tests per day, with automation, streamlined methods, and tightly managed supply chains; and
- Information systems to rapidly transmit test results;
- Technology necessary to certifying testing status.

A testing system big enough to restore trust and get the economy moving again would mean testing tens of millions of Americans a day — enabling those who test negative to go to work, while at the same time isolating and supporting those who test positive and tracing their contacts to choke off transmission. With such a system, the number of new cases will drop dramatically.

The cost for large-scale testing is projected to be roughly \$15b per month (over the next year or more until reliable treatments and vaccines are available), and would likely fall over time as technology progressed — compared to an estimated cost of \$350b for every month of continued collective quarantine. A ramp up to 5m tests per day and deployment of required information systems should be possible by late June.

## Elements of the Plan

### ***Mechanics of Massively Scaling Up Testing***

Massively scaling up testing will require (1) coordinating the ramp up of existing capacity; (2) integrating the ramp up of innovation-based capacity; and (3) building the supporting infrastructure.

There are two possible forward pathways to increase numbers of tests and speed of analysis. We can seek to **scale up existing** test production, distribution, sample collection, and analysis methods, or we can simplify the methodologies through innovation and **build even greater scale through process simplification**. Probably we need both. We need to maximize what we can already do, while innovating to do much more. A Pandemic Testing Board should consider all options for scaling before deciding precisely how to combine these two pathways.

### ***Scaling Existing Test Capacity (achieving the first 2 million):***

In aggregate, **the country's existing virus testing capacity** (using PCR) is probably sufficient to handle an order of magnitude more testing above current test levels if it was better organized and coordinated with demand. From channel checks with major commercial labs (beyond LabCorp, Quest, BioReference, etc), it is clear that latent capacity is present as long as there is a sufficient demand signal to expand, a better means to coordinate with the demand, and where the economics are rational for these players to make fixed cost investments.

This requires overcoming some CDC regulations, accelerating the production of the materials for test kits, and building mega-labs with higher throughput. The current limiting factors include the volume of swab production and PPE production, as well as lab throughput. Both swab and PPE production could be addressed by repurposing idle plant capacity, in the textile industry in the first instance and in

## Elements of the Plan

### ***Scaling Existing Test Capacity (achieving the first 2 million):***

plants in Puerto Rico in the second instance. A broader survey of available capacity should be done. Higher rates of lab throughput could be achieved by building mega-labs.

A core of mega-labs around the country should be the rallying point for creating new capacity; a single mega lab should be capable of handling >100,000 PCR tests/day. These mega-labs can be either existing labs with the footprint to grow or greenfield labs that are set up near population centers. Creating these labs should be done in consultation with key equipment and reagent suppliers (e.g., Roche, Thermo Fisher, Beckman Coulter, and Abbott), who can supply their newest machines and dedicate increasing reagent supply. Other key elements that would need to be part of an industrial ramp-up include: collection kits, test tubes, transport media, barcoding systems, pipette tips, chemical reagents, etc. For manufacturing of general purpose biomedical supplies, excess capacity in plants across the country and in Puerto Rico can meet this need.

Samples must be collected somewhere by someone. Three options are point-of-care testing (doctor's offices, urgent care facilities), newly established testing sites (e.g. drive-thru sites), and do-at-home test kits. The first two would require setting up separate spaces for infection control as well as PPE. The third has the lowest demand on personnel and infrastructure and should be a high priority for the FDA. Mayors and county health officials are already engaged in the question of how they could support ramp-up of testing locations. A key component for ramp-up would be a Health Reserves Corp, working alongside the national guard, that could re-employ the unemployed in this industry.

### ***Innovating for Scale: achieving a more efficient 2 million & reaching 100 million***

A potentially more powerful approach may be to develop simpler protocols. We are seeing rapid innovation to accomplish this — for example, replacing nasal swabs with spit kits. Rapid innovation

<https://ethics.harvard.edu/covid-supply-chain>

## Elements of the Plan

### *Innovating for Scale (achieving a more efficient 2 million and getting to 100 million):*

would favor lab structures with generic robots and plates that can be easily adapted. Innovative lab designs can then be cloned and replicated.

New capacity of this type is already coming online. A good example of the elements and pace for establishing a new high throughput lab can be found in this account of the Broad's rapid transformation: <https://news.harvard.edu/gazette/story/2020/03/broad-institute-races-to-enable-coronavirus-testing/>.

With prior experience analyzing 250,000 samples a day for the Human Genome Project, the Broad Institute is a good example of the kind of lab that might be stood up to achieve a capacity of 1 million tests per day. South Korea also leveraged automation. Standing up approximately 30 mega-labs across the country to do high throughput processing (1-3 million a day) with 12-24 hour turnaround would achieve the necessary maximum scale. Entities like the Los Alamos National Laboratories could also play a valuable role in the mix.

The best way to redesign and maximize the efficiency of testing is to focus on removing choke points and scaling up through simplification and reliance on generic solutions. To pursue this innovation pathway, you would want to set up and coordinate multiple work streams focused on eliminating all these choke points.

Chokepoints	Solutions
<b>The need for PPE to collect the samples;</b>	<ul style="list-style-type: none"> <li>Taking saliva samples—FDA granted EUA for the first saliva kit this week (an application from Rutgers, with more expected); many companies (such as 23&amp;Me) routinely collect samples with spit kits, which can be obtained from generic suppliers; also necessary would be a validated at-home sample collection protocol using lower nasal and/or throat swabs that can be transported at ambient temperature to a central lab facility. For the last, the FDA must work with academic labs and entities like the Gates Foundation to validate an at-home sample collection protocol.</li> </ul>
<b>The need to transport the samples as biohazardous waste;</b>	<ul style="list-style-type: none"> <li>Use a viral inactivation buffer in the test tube collecting the saliva sample; then the material is no longer a biohazard for transport; and you can use an easy infrastructure of drop off facilities or boxes;</li> </ul>
<b>The need for reagents to purify RNA.</b>	<ul style="list-style-type: none"> <li>Eliminate the need for RNA purification; Various labs (e.g., Color Genomics in California) are working on this; right now, the demand signal is not significant enough for them to invest in this but if it were, they could accomplish this quickly.</li> </ul>

# 02 Further Detail

## *Existing Firms and Products*

This website has a list of all tests available – however, most manufactures haven't given detailed commentary. Many of the commercial players would probably comment on earnings. For example Quest said they can do 45k/day now. [https://www.finddx.org/covid-19/pipeline/?section=molecular-assays#diag\\_tab](https://www.finddx.org/covid-19/pipeline/?section=molecular-assays#diag_tab)

## *Current State of Supplies*

*Swabs & PPE:* Sample collection has been a choke point for increasing testing throughput in the United States, in part due to a shortage of swabs from the two manufacturers (Copan, Puritan). There are only ~6M/week nasal swabs being made now (1M from Puritan and 5M from Copan) and that needs to increase significantly to meet any goals. The FDA has a list of alternatives due to shortages, but we don't know much about their supply:

### **Nasopharyngeal:**

- Puritan: 25-3316-H, 25-3316-U, 25-3317-H, 25-3317-U, 25-3318-H, 25-3318-U, 25-3319-H, 25-3319-U, 25-3320-H, 25-3320-U, 25-3320-H EMB 80, 25-3320-U EMB 80, 25-3320-H EMB 100, 25-3320-U EMB 100, 25-1406 1PF 50ff, 25-800 1PD 50\*\*, and 25-800 1PD ALUM 50\*\*
- Copan: 503CS01, 518CS01, 501CS01, and 502CS01
- BD: 220252 and 220251
- DHI/Quidel: 503CS01.DHI
- Fisher Healthcare : 23600952, 23600956 and 23600950



## Further Detail

### *Current State of Supplies*

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#### **Oropharyngeal:**

- Puritan: 25-1506 1PF SOLIDf, 25-1506 1PF 100f, 25-3206-H, 25-3206-U, 25-3706-H, 25-806 1PD\*\* and 25-806 1PD BT\*\*
- Copan: 502CS01, 519CS01, 164KS01\*\* and 175KS01\*\*
- BD: 220250
- Fisher Healthcare: 23600950, 23600957 and 1490650\*\*

#### **Mid-Turbinate:**

- Copan: 56380CS01, 56750CS01, 56780CS01

#### **Anterior Nares:**

- Puritan: 25-3206-H, 25-3206-U, 25-3706-H, 25-1506 1PF 100f , 25-1506 1PF solid f, 25-1506 1PF BTf, 25-1506 1PF TT MCf, 25-1506 2PF BT f, 25-1406 1PF BT\*\*\*f
- Copan: 502CS01, 519CS01
- BD: 220144f, 220145 f, 220250
- DHI/Quidel: 20103f
- Fisher Healthcare: 23600950, 23600957

f Foam swab

\*\* Polyester swab

Additionally, swabs may be provided with transport media as identified below.

## Further Detail

### *Transport Media*

VTM/UTM remains the preferred transport media. Examples of universal transport media for viruses and molecular transport media are listed here. All of the products listed below include a nasopharyngeal (NP) flocked swab unless noted otherwise.

- Copan: 305C, 307C, 360C and 519CS01\*
- Puritan: UT-367, UT-317, UT-302\*, UT-366\*\* and UT-300\*\*\*
- Hardy/Healthlink: 330CHL
- BD: 220526, 220527, 220528\*, 220529, 220531
- DHI/Quidel: 330C\*\*\*
- Fisher Healthcare: 23001718, 23600952, 23600956, 23600950 and 23600957\*
- PrimeStore MTM: LH-1-02 and LH-1-03\*\*\*

\* flocked oropharyngeal swab

\*\* Polyester swab

\*\*\* no swab

In the absence of VTM/UTM, alternative transport media can be used to collect and transport patient samples for molecular RT-PCR SARS-CoV-2 assays. These recommendations apply to swab-based specimen collection by healthcare providers (HCP), and to anterior nares (nasal) and mid-turbinate specimen collection onsite by self-collection. The best available evidence indicates that these transport media will stabilize the SARS-CoV-2 RNA without meaningful degradation.

## Further Detail

### *Transport Media*

Labs can create their own viral transport media. Refer to [CDC's SOP#: DSR-052-01: Preparation of Viral Transport Media](#). Specimens can be stored for up to 72 hours at 4°C.

Liquid Amies media may be used for viral transport when universal transport media is not available. Specimens can be stored in liquid Amies media for up to 72 hours at 4°C. All of the products listed below include a nasopharyngeal (NP) flocked swab unless noted otherwise.

- Copan: 481C, 482C 480C\* and 480CFA\*
- Puritan: LA-117, LA-116-H and LA-100\*\*\*
- BD: 220246, 220532 and 220245\*
- ThermoFisher: R723481, R723482 and R723480\*
- Hardy/Healthlink: 481C, 482C 480C\* and 480CFA\*
- VWR: 89136-656, 89136-658, 89136-654\* and 76181-494\*
- Fisher Healthcare: 23600901, 23600902, 23600900\* and 23600905\*

\* flocked oropharyngeal swab

\*\*\* no swab

Other solutions may also be used for viral transport when universal transport media is not available. FDA recommends use of phosphate buffered saline (PBS), including molecular grade PBS when available, and other similar formulations including Delbecco's PBS, to collect and transport samples for molecular RT-PCR SARS-CoV-2 assays. If PBS is not available, normal saline may be used. The FDA believes that a sterile glass or plastic vial containing between 1mL and 3mL of PBS or normal saline is appropriate. Specimens can be stored up to 72 hours at 4°C. All the products listed below are examples of 1-3 mL of normal saline distributed in a vial without a swab.

<https://ethics.harvard.edu/covid-supply-chain>

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### *Transport Media*

- ThermoFisher: R064430, R064432, R064434, R064436 and R064438
- Hardy/Healthlink: D185, K248, R45 and R55
- Edge Biologicals: T-0625 and T-0110f

There is limited data available on test performance with specimens which have been frozen in any transport media; therefore, specimen stability should be investigated if freezing is necessary.

*Inventory Management & IT Support:* The capacity of test sites to deliver tests could also be increased by improvements on the website support for identifying testing locations. A website should allow for individuals to provide information on their symptoms, risks, and exposures with an authorization (i.e., a QR code) that would provide direction on where to get tested along with a fast-pass prioritization for the appropriate testing provider. The highest risk exposures would get prioritized for test supply that is most proximate to the individual (e.g., a drive-through site with a POC system) while lower-risk exposures would get routed to less immediate test channels (e.g., self-administered home test kit). More often than not, the system would direct someone to a testing channel that is not embedded in the health-care system (e.g., ER/hospital, clinic). In addition to specific test recommendations, the system should have visibility into the availability of specific test centers/locations/services along with estimated wait times; every capable COVID testing site or service should be mandated to provide near-real-time data on capacity, utilization, and forward visibility for supply-demand management. This dynamic matching of supply with demand is critical to overcome the supply chain bottlenecks of the current paradigm of lab testing in healthcare, which is not designed for high-frequency routing of tests to a federation of lab vendors. *Some effort at experimentation has already been made in this direction.*

## Further Detail

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### ***Ramp up Production of Abbott Machines:***

These machines are too slow (four samples per hour) to meet the scale needed but can contribute by increasing testing availability in rural areas.

### ***Additional Possibilities for Scale***

*Enhance asymptomatic surveillance capacity with community- or household-based sample pooling.*

To maximize existing testing capacity and throughput for asymptomatic surveillance, each household or community should be offered the option of daily sample pooling to facilitate early detection of the virus. This strategy assumes that the FDA will validate and allow for self-administered nasal or throat swabs without a provider interaction and that an efficient supply chain can be set up between homes through carriers and lab service providers.