HARVARD GLOBAL HEALTH INSTITUTE

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The Path to Zero: Utilizing Interstate Compacts to Unleash Testing Capacity

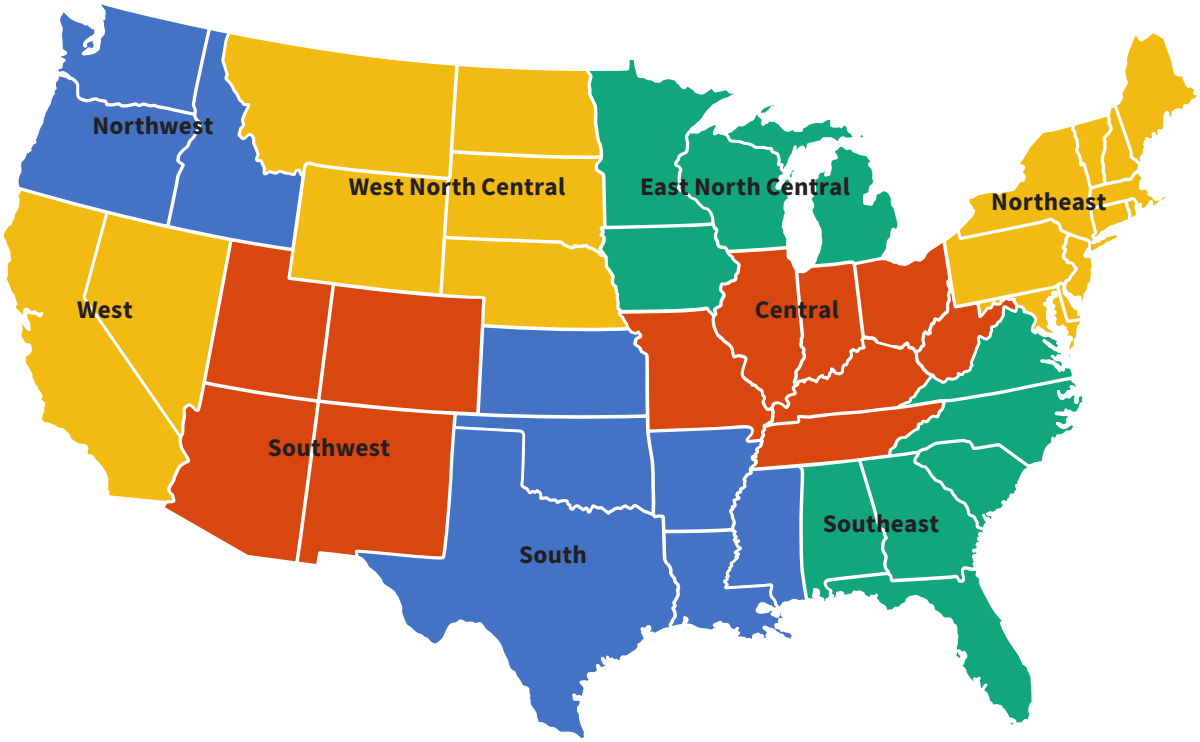
Severe testing shortages and processing delays are hampering the COVID-19 response. Here is how to rapidly build the arsenal of timely tests we need to suppress and defeat the coronavirus

As coronavirus cases soar across the United States, viral testing has become a bottleneck. People are standing in line for hours in some hotspot states to get tested, and many wait over a week or longer for their results. Containment of the virus is impossible in such conditions – we cannot break the chain of transmission if the virus outpaces us at every step.

This is the second time the nation faces severe testing shortages as case counts rise. Yet this time, innovators and labs are ready to unleash millions more tests. What these entrepreneurs and state leaders need is a framework to do so at scale. In this briefing, we explain how interstate compacts can unleash the much needed yet un-activated testing capacity in this country.

WHAT IS AN INTERSTATE COMPACT?

Interstate compacts are legally binding agreements between states, territories, and/or tribal nations that allow them to take collective action to solve shared problems or enact a common agenda. The Compacts Clause of the U.S. Constitution grants states the right to create interstate compacts for their common benefit. The text of the Compacts Clause requires congressional consent to these agreements. Compacts that receive congressional approval have the force of federal law and therefore supersede state laws.



WHAT COMPACTS EXIST TODAY?

Today, over two hundred interstate compacts are in operation. Many compacts are regional, and roughly two dozen are national. The average state is a party to twenty-five of these interstate agreements. Up until the 1922 creation of the Port Authority of New York and New Jersey—one of the most famous examples of interstate compacts—states mostly used compacts to address boundary issues rather than complex interstate challenges. But since the 1970s, the majority of compacts have emerged to serve regulatory purposes, including creating regulatory agencies to manage complex interstate problems. All fifty state and federal territories have entered into the congressionally approved Emergency Management Assistance Compact (EMAC). EMAC enables states (usually through the state equivalents of FEMA) to deploy personnel to assist in times of crisis, such as wildfires or hurricanes.

Interstate compacts simultaneously activate the flexibility of federalism by supporting state-led policy development and implementation while also empowering states with the tools they need to address complex problems, where the solutions depend on scale.

WHY WOULD A STATE WANT TO JOIN A COMPACT TO BUY TESTS?

States are still facing a massive **scarcity in tests**, with **5+ day turn-around times**. This is worse for smaller or rural states, like Alaska, that have to compete with more population dense states for tests. Moreover, despite the demand for test, the **price of a test** is not going down, but is still on average $100.

Yet, there remains **un-activated latent capacity**, such as hospital labs, commercial non-clinical labs, academic labs, and veterinary labs. And there's also **innovation capacity** that could be a game-changer for a state's pandemic response. For example, one next generation sequencing (NGS) lab could turn 1,000,000 tests for $25 per test. However, no state individually has enough demand for 1 million tests, nor sufficient funds to enable such diversification in testing.

INDICATOR	GOAL	CURRENT
Volume	3.5 – 5 million daily tests	500,000-800,000
Price	$25 or lower per test	$100+ per tests
Speed	24- hour turn around	5+ days
Lab Activation & Diversification	**state public health labs, commercial clinical labs, hospital labs, commercial non-clinical labs, academic labs, and veterinary labs**	**state public health labs, commercial clinical labs, & partial activation of hospital labs**
Access	Abundant access across all states	Big states win, small and rural states lose
Innovation	NGS & CRISPR rapid results	Limited progress beyond PCR

Interstate compacts have the necessary scale to solve such coordination problems and rapidly improve speed, volume, pricing and diversification in testing. By pooling funds allocated for testing from participating states, compacts will have more funding than any individual state to make diversified investments in novel technologies like NGS labs that service an entire region, as well as have a birds-eye view to activate latent capacity across a region and build capacity where they are gaps.

For example, low-population density areas will require more point-of-care testing such as Abbott machines, whereas high population density areas require more centralized labs. Compacts will be able to diversify capacity appropriately and to load-balance tests across its region to ensure its smaller, rural member states have sufficient access to tests for suppression.

Moreover, compacts can make unprecedented bulk orders on a scale test suppliers have yet to see, transforming test suppliers from **price-makers to price-takers**. High volume bulk-orders would give compacts significant bargaining power to negotiate **lower cost and faster tests** with existing test suppliers, who currently enjoy unfettered demand and monopoly-like powers. Test suppliers will be accountable and responsive to compacts which supply them business, rather than cherry-picking or prioritizing state relationships based on contract sizes.

Compacts will also have the **market power to give firms a market incentive to accelerate ramping up testing capacity**. In particular, because compacts can load-balance excess tests across states as the virus moves and spikes, compacts will be in a unique position to make massive guaranteed off-take contracts which guarantees future purchases of 1M+ tests from suppliers. These offtake contracts would serve an important **market-making function**. They would **eliminate uncertainty** for current firms who hesitate to build capacity out of fear of market volatility, and the worst-case scenario of showing up to market without sufficient buyers. Guaranteed bulk orders (even at a lower price point) would give firms the certainty to enter the marketplace and **compete on price**.

A Compact's **sole function is to procure tests** for states, so state public health departments can focus on the boots-on-the ground task of testing, tracing and supported isolation. Because compacts will develop a comparative advantage in procuring suppression-volume of tests, they will be able to leverage the benefits of **economies of scale, regional birds-eye view on testing capacity, and lower transaction costs in negotiating contracts**.

The metaphor of real estate is useful. We need a developer not to make contracts for existing housing stock but to develop a new neighborhood. The interstate compacts would be developers of the remaining as of yet un-activated testing capacity in this country. The compacts would have the mandate to contract for *new testing capacity* without disrupting existing contracts. In the long run, this should reduce price, and increase volume and speed.

INDICATOR	COMPACTS	STATES
Volume	Bulk purchasing and guaranteed off-take contracts will give competitor firms the incentive to rapidly expand test production and/or enter the marketplace for guaranteed future purchases.	States lack demand and funds for 1M+ tests bulk off-take contracts that would invite competition into the testing market. Instead, small states fight for priority among existing suppliers.
Price	Competition for bulk contracts, economies for scale, and lower transaction costs would drive down costs to $25 or less. Existing test suppliers would become price takers.	Existing test suppliers are price makers with low-volume contracts from states and little competition.
Speed	Birds-eye view to activate latent testing capacity and build capacity where they are gaps across a compact region; more accountability and responsiveness from test facilities on delays.	Information silos across states on testing capacity and order-placement, contract pile-ups, & less responsiveness for small and rural states.

WHY DO THESE TARGETS FOR TESTING MATTER FOR SUPPRESSION?

To suppress COVID-19 to less than 1 daily new case per 100,000 people (.001% case incidence), we need between 3.5 to 5 million daily viral tests with a 24-hour turnaround time at a less than $25 price point equally accessible to all states, and diversified across a range of technologies and labs.

VOLUME: We need to expand capacity to 3.5 to 5 million daily tests. To root the virus out of circulation, we need to test **symptomatic people and targeted hotspots** as starting points, but then funnel the bulk of testing to contact tracing, where all a positive's contacts are tested down the chain of transmission (on average 12- 25 further tests per covid-positive individual, depending on the degree of social distancing practices in place in the jurisdiction). In addition, we need tests for **routine surveillance testing** in critical contexts, such as health care settings, eldercare facilities, correctional facilities, and other congregate settings ranging from meatpacking plants to colleges and universities, to national security contexts and essential workers in the K-12 context (adult teachers and staff).

PRICE: The current price for a COVID testing is roughly $100 per test. However, this price needs to decline 4X to $25 per test to avoid any further spending bills for testing. While some have thought that a test price point of $100—which is well above actual cost—would incentivize more providers to join the market, the uncertainty in market size and orders has discouraged more firms from entering a market that may be short-lived. High price, low volume orders in an uncertain, fragmented market are a risky gamble for firms. Higher risk carriers a higher cost of capital, likely financed only by venture capital firms, not traditional banks. To reduce risk, more important than a short-lived high price tag is guaranteed volume. Guaranteed bulk orders at a lower price point would give firms the certainty to enter the marketplace and compete on price.

SPEED: We need **viral tests with a 24-hour turnaround time**. Slower than 48 hours makes contact tracing ineffective in breaking the chain of transmission. The current spike of cases has already overloaded the clinical commercial labs. Last week, Quest announced that results take an average of 4 to 6 days whereas in June they were producing results in 2 to 3 days. Although their volume has increased, the slower turnaround makes the volume increases less valuable for disease suppression than the absolute number of tests would suggest. While the nation's current testing **nominal testing rate** is consistently above 500,000 tests a day, and exceeded 800,000 in a single day in early July, **the nation's effective testing rate should be measured via the number of daily tests results returned that have been returned in 48 hours or less**.

ACCESS: States need equal access to the testing market to achieve suppression. However, today smaller, less populous states (e.g. Alaska) are being crowded out of the testing market by larger states with larger purchase orders, resulting in excessively long turnaround times for a state to achieve suppression.

LAB ACTIVATION & DIVERSIFICATION: We need to activate capacity that is still latent. The nation has six categories of lab that could be used to fight COVID-19: state public health labs, commercial clinical labs, hospital labs, commercial non-clinical labs, academic labs, and veterinary labs (the last were very important to Germany's response). To date, only the first two categories of lab have been fully activated. While hospital labs have also been activated they are running below capacity. Commercial non-clinical labs, academic labs, and veterinary labs have been activated only sporadically and not systematically. We need to activate all available testing modalities (including pooled testing, where incidence levels are low enough to make it useful).

INNOVATION: There are testing modalities beyond conventional PCR testing that produces rapid results. For example, there is next generation sequencing (NGS) mega-labs that have the potential to process million tests per day. One such facility was recently funded by venture capital, but none other has. In addition, there are CRISPR point-of-use tests that can be administered at home with saliva on paper strips that are also in development and likely to come online in September. These technologies can produce rapid test results for any novel disease. Insufficient public investment has been made in these technologies. While SBIR, BARDA, and NIH are running grant programs, and NIH is investing slightly less than $1billion in grant projects expected to run over a two-year time period, these developmental efforts in themselves won't solve the market structure problems. For instance, NIH's RADX Advanced Technology Platforms is a "two-year effort [that] will award funding by the end of Fall 2020."

This chart reviews categories of testing modality:

SARS-CoV-2 Testing Methods						
Component Detected	**Viral RNA**				**Viral Protein**	
Method	**RT-qPCR**	**iNAAT**	**NGS**	**CRISPR**	**ELISA**	**LFA**
Clinical Accuracy	High	High	High	Medium	Unknown	Medium
Scalable to Meet US Needs?	Maybe	Maybe	Yes	Unknown	Unknown	Yes
CurrentUS Tests/Day	-200,000	-5,000	0	0	0	Thousands
ProjectedAug. 2020Tests/Day	Hundreds of Thousands	Hundreds of Thousands	Millions	Unknown	Unknown	Hundreds of Thousands
Use Case	High-volume Centralized or Point-of-Care	High-volume Centralized or Point-of-Care	High-volume Centralized	Point-of-Use	High-volume Centralized	Point-of-Use
Turnaround Time	24-48 Hrs (Centralized) Minutes (PoC)	24-48 Hrs (Centralized) Minutes (PoC)	24-48 Hours	Minutes	24-48 Hours	Minutes
SampleType	Nasal Swab or Saliva	Nasal Swab	Nasal Swab or Saliva	Nasal Swab	Unknown	Nasal Swab
Quantifies ViralLoad	Yes	No	Yes	No	Yes	No
Key Scale-Up Barrier	Reagent/ Kit Availability	Reagent/ Kit Availability	Logistics	Nosel Technology	Assay Development	Assay Development
Regulatory Status	EUA	EUA	EUA pending	EUA	Unknown	EUA
Supply Chain Risk	Medium	High	Low	Medium	Medium	Low
Representative Companies	• LabCorp • Quest • Roche • ThermoFisher	• Abbott • Hologic • AtilaBio	• BroadInst. • Illumina • HudsonAlpha • Ginkgo	• Mammoth • Sherlock • BroadInst.	• LabCorp • Quest • Abbott • Roche	• Quidel • ChemBio • Cellex • OraSure

Chart sources: Ginkgo Bioworks - https://www.ginkgobioworks.com/2020/05/04/how-to-deploy-millions-of-covid-19-tests-per-day/

See also: https://interventions.centerofci.org/pub/covid-testing-assessment/release/14

This chart explains how those categories should be activated as a testing arsenal:

LOGISTICS: Compacts Expand Arsenal for High-Throughput Testing						
Arsenal	**Testing Modality**	**Companies/Labs**	**Current Daily Capacity**	**Potential Daily Capacity by Oct w/Surge**	**Test Type**	**Accuracy**
Rockets	**Centralized Regional Labs**	High	~400k	10^6	RT-qPCR (swalstsaliva)	High
		High	~143k	10^6	iNAAT (swab)	Medium
Mortars	**Point-of-care**	Roche	~50k-70k	10^5	RT-qPCR (swab'sakva)	High
		Abbott, Atila, Bio	~50k-70k	10^5	iNAAT (swab)	High
		Quidel	10^4	10^5	ELISA (swab)	Medium
Infantry Guns	**Point-of-use**	Mammoth, Sherlock, Broad	0	0	CR ISPR (still in R&D)	Medium
Nuclear	**Cent. Labs**	Illumine, Hudson, Ginkgo	0	10^7	NGS (swaIntsaliva)	High

HOW WOULD A COMPACT BE FORMED?

Congress adopts legislation authorizing the creation of compacts between states with the single mandate to spend $25B in total on procuring tests. The compact takes effect upon three states' passing legislation to join the compact. The compact's authorities should expire on December 31, 2021, unless extended by Congress. Any funding left over on that date would be remitted back to US Treasury.

HOW WOULD TESTS FROM COMPACTS BE REIMBURSED?

The scale of surveillance testing the country now needs is at an unprecedented level. We do not have streamlined funding and payment processes in place to meet this public health need. Insurance companies have streamlined payment processes for viral testing done for therapeutic purposes and with doctor's orders. Most surveillance testing, however, whether from contact tracing or critical context and congregate setting testing, does not enter the pipeline through doctor's orders and payments cannot be processed through existing insurance billing procedures.

Two tools might possibly address this. **Medicare payment processes** might be used to cover surveillance testing or payment processes might be facilitated by the **use of reimbursement vouchers** delivered to individuals for use at point of service. Such vouchers could be delivered both by contact tracing programs and by those managing hot spot, critical context or congregate setting testing programs.

WHO WOULD RUN THE COMPACT?

The compact is run by a board of qualified members who are selected by the majority of governors of the participating states. The governors remove at will (with majority vote) and appoint (with majority vote) in accordance within the membership criteria. This criteria is: 1 current or former head of school public health (phD), 1 virologist (PhD), 1 epidemiologist (PhD), 1 procurement/ contracts lawyer (JD), 1 Medical Doctor with public health background (MD), 1 biotechnology entrepreneur,1 member with medical device manufacturing experience (preferably engineers, MS), 1 member with substantial hospital or health center procurement backgrounds, 1 member with substantial government procurement experience, 1 member with significant biotechnology investment experience, 1 member with lab administration experience. Members select a Compact Chair.

Compacts will have the flexibility to form their own governance structures and rules for test allocations, which participating governors will determine.

The funding to the Compacts for test procurement should be complemented by funding of $50 billion to the states in support of their on the ground implementation of TTSI.

HOW WOULD COMPACTS IMPACT EXISTING STATE CONTRACTS?

Compacts will not supplant existing contracts or obligations. Because they will take time to form and come online, states should not worry about them taking priority to existing orders. By law, it should be stipulated that test suppliers are obligated to fulfill pre-existing states contracts before any new contracts issued by compacts. Suppliers that prioritize compact contracts over prior state contracts will risk losing eligibility for compact contracts.

For future contracts, states will have the incentive to join compacts to enjoy the benefits of lower unit test prices, a diversified testing portfolio, regional load balancing, as well as access to advanced testing technologies that would otherwise be unavailable or difficult to access.

WHO WOULD RUN THE COMPACT?

There are several accountability measures in place. Members of the Compact's Board are required to sell any individual stocks and invest only in total market or broad market index funds. Members are prohibited from purchasing stock in any company doing business with the Compact for an additional year after their time of service. Contracting firms are prohibited from raising CEO pay, offering bonuses to executives, paying out dividends, or buying back stock during the contracting years and for two years thereafter.

In addition, Inspector general would monitor transparency, anti-corruption, and ethics provisions, and conduct oversight of the operations and activities and would refer possible corruption, hoarding, profiteering, fraud, or other unlawful activities to the relevant state attorney(s) general.

WHO

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