STATEMENT ON THE VALUE OF ACADEMIC LABS AND THEIR SUPPLY CHAIN ISSUES DURING THE 2020 COVID-19 OUTBREAK IN THE UNITED STATES

The goal of this statement is to articulate the unequivocal value that academic labs can have in the nation's recovery from the COVID-19 pandemic, but whose participation in that recovery has been handicapped by the prevalence and persistence of an unstable supply chain for reagents, which is (or was) largely controlled by the Federal Emergency Management Agency (FEMA).

The Tests

1. Since the start of the pandemic, PCR-based tests have been the most accurate and reliable means to diagnose COVID-19.
2. These tests work by identifying the genetic presence of SARS-CoV-2 in samples.
3. Until recently, due to a significant lack of available testing, only symptomatic people or people in likely contact with a confirmed case were tested.
4. Many economic reopening strategies depend on the ability to test large numbers of asymptomatic people.
4. Initially, in January, only the CDC test kit was approved by the FDA for diagnosing COVID-19.
5. Eventually, in March, other laboratory developed tests (LDTs) were authorized by the FDA to diagnose COVID-19. Many of these were authorized to be performed by academic labs.
6. Many PCR-based tests are performed on high-throughput platforms that, among other supplies, require materials called reagents.
7. Most reagents are manufactured for the specific platforms on which they operate. Some are integrated into cartridges designed to run on specific platforms.

The Supplies

1. Most reagents (and cartridges, where applicable) are produced by commercial equipment manufacturers and, unlike viral transport media and swabs, cannot be independently purchased or manufactured by labs or alternative entities.
2. Starting in February, the distribution of commercially manufactured reagents was directed by FEMA under the command of Rear Admiral Brett Giroir, who stepped down in early June.
3. A common refrain among manufacturers, who were and are delaying or cancelling shipments to academic labs, was/is that their top-level leadership takes direction from FEMA on how to allocate available reagents, thereby causing the delays and cancellations in academic labs' orders.
4. Numerous attempts by the Association of Pathology Chairs and the Association of American Medical Colleges to understand how FEMA prioritizes the allocation of reagents have been unsuccessful.
5. There is no transparency in the prioritization process and manufacturers seem to be compelled to cooperate with FEMA directives under the presidential authority invoked by the Defense Production Act.
6. All evidence suggests that FEMA's highest priority goes to commercial labs for reagent allocations.

The Labs

1. In-house academic labs provide direct support to frontline clinicians in academic health systems. Academic labs are community-based, not remote, which enables them to serve their patient communities more directly and quickly.
2. Academic lab turnaround times on PCR-based diagnostic tests (LDTs) are typically 12 to 24 hours, with the ability for faster turnaround times in some laboratories for special circumstances.

3. Delays in testing can cause significant patient flow issues for hospitals, drains on resources, and increased lengths of stay.
4. Many in-house academic labs have existing staff expertise and high-throughput equipment to readily develop and perform LDTs quickly, with the capacity to support their local health systems.
5. Some in-house academic labs had the capacity to assume the function of a public health laboratory and support community hospitals, who turned to academic labs for local support when they became overwhelmed by the testing demands for COVID-19.
6. Many academic lab officials acted as local public health testing advisors, consulting with educators, employers, and municipal leaders, helping them to understand the issues and make key decisions.
7. In January, while the FDA effectively blocked academic labs from developing testing, the Federal government apparently reached agreements with Quest and LabCorp to provide these tests, believing that commercial labs were better positioned to provide national testing resources.
8. Quest and LabCorp's turnaround times on testing averaged 7 to 10 days, which was clinically ineffective, particularly when only symptomatic patients or people at risk for COVID were qualified to be tested and they needed more immediate confirmation of their COVID status for appropriate isolation and treatment.
9. On February 29th, the FDA issued an emergency use authorization that enabled in-house academic labs to apply to use LDTs to test for SARS-CoV-2 on high throughput platforms.
10. Academic labs soon found that the availability of reagents and other supplies would be the next limiting factor, with Federal supply prioritization and resulting constraints already in practice.
11. Academic labs quickly made purchasing commitments for multiple high-throughput platforms as a work-around for the unreliable reagent supply chain. In essence, they would revolve platforms in anticipation of which platform would be receiving reagents supplies, in order to maintain some level of consistency in testing capacity for the health system and community they serve.
12. This meant that: 1) academic labs and their health systems made otherwise unplanned major expenses to acquire additional platforms; 2) academic labs had unmet testing capacity due solely to equipment down-time caused by the lack of reagents; and 3) academic labs made significant personnel investments to continuously communicate with manufacturers to ensure orders would not be cancelled or to plan around cancelled orders.
13. In April, when the Federal government shifted testing strategy toward states, they directed governors to use specific commercial labs within their states with "unmet" testing capacity. Those labs also received supply chain priority over academic labs. These commercial labs were, for example, pre-natal genetic disease testing labs, that were not otherwise associated with local health systems.
14. The argument is made that commercial labs use reagents more efficiently per supply, because they fill all test wells with samples per run. However, waiting to fill all runs could render test results clinically irrelevant, if the turnaround times are too long.
15. As academic labs move to support broader community prevalence testing and testing for screening/reopening, they are using reagents more efficiently. They are also developing and validating pooled testing procedures to conserve reagents in appropriate circumstances, under FDA guidance.
16. Commercial labs are inarguably a major part of any viral pandemic recovery effort, but to deny academic labs their priority is to subvert the opportunity to test and treat locally, effectively, in the most clinically actionable manner, which in many cases is life-saving.
17. Academic labs are best positioned to help their health systems and patient communities. Academic hospitals are treating some of the sickest patients and undertaking leading-edge research on disease mechanisms, management, and therapeutics. These labs and health systems need support to serve their communities and the nation. They need to be treated at least as equal to commercial labs.

<u>The Call to Action</u>

1. This is a national patient safety issue that will not be mitigated without action at a level higher than the academic labs and the health systems themselves.
2. The causes of reagent limitations, which have not been made public by manufacturers, should be immediately addressed in order to effectively, equitably and substantially expand and reliably sustain testing capacity in the U.S.

3. The Federal government, with its command over the testing supply chain, should immediately and with urgency use their resources and the Defense Production Act to support reagent manufacturing.
4. To assist states in developing their testing strategies, the Federal government also should provide open public access to all data collected by Federal agencies on rates of testing, positive cases, testing capacity, etc. that would enable states to respond and coordinate more effectively and dynamically to address their public health needs.
5. The Federal government should accept and immediately respond to input from stakeholders on how to optimize their current data collection to maximize public health benefits.
6. In the absence of the Federal improvements recommended above, academic labs should continue working directly with manufacturers to address supply shortages and informally organize to drive strategies within and between states.
7. The National Governors Association should support improved access to PCR-based diagnostic testing with results rendered in clinically optimal turnaround times.
8. The U.S. Chamber of Commerce should represent nationally and locally that a strong, sustained economic reopening depends on the availability of PCR-based testing in communities.
9. Patient advocacy groups should represent the needs of patients, who are dying or risking their health as they await or fail to seek treatment for other illnesses, which hinges on the robust and reliable availability of testing.

Appendix:

Review of common supply constraints as reported by in-house academic labs* as of May 29, 2020:

Supply Issue?	Reagents/ Cartridges	CDC Test Kits	Swabs	Vials	Viral Transport Media
Constant	35%	5%	19%	14%	22%
Intermittent	46%	8%	48%	30%	34%
Not an Issue	14%	14%	30%	45%	30%
N/A	5%	73%	3%	11%	14%

Testing Capacity (tests/day, if fully supplied)	Actual Testing (tests/day, using available supplies)	Unmet Testing Capacity (testing ability not used duet to supply constraint)
55,276*	26,560*	52%

* Approximately one-third of all labs reported. Extrapolated to 100% of labs, the academic testing capacity would be ~150,000 tests per day, if supply constraints were addressed.

UPDATED Appendix – July 30, 2020:

Review of common supply constraints as reported by in-house academic labs* as of May 29, 2020:

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Not an Issue	14%	14%	30%	45%	30%
N/A	5%	73%	3%	11%	14%

Testing Capacity (tests/day, if fully supplied)	Actual Testing (tests/day, using available supplies)	Unmet Testing Capacity (testing ability not used duet to supply constraint)
55,276*	26,560*	52%

* Academic labs from 20 states reported, representing approximately one-third of all in-house labs (different state and lab mix than July 30th data). Extrapolated to 100% of labs, the current academic testing capacity would be ~150,000 tests per day, if supply constraints were addressed. (Note: This capacity is based on single sample runs; not pooled testing. No academic labs reported that they are currently performing pooled testing, but 36% of respondents are working toward doing pooled testing for diagnosis and screening.) This subset of academic labs reported conducting an estimated total of 559,024 diagnostic assay tests to-date (as of May 19th).

Review of common supply constraints as reported by in-house academic labs* as of July 30, 2020:

Supply Issue?	Reagents/ Cartridges	CDC Test Kits	Swabs	Vials	Viral Transport Media
Constant	67%	6%	8%	16%	39%
Intermittent	30%	3%	60%	45%	33%
Not an Issue	3%	18%	27%	31%	0%
N/A	0%	73%	5%	8%	28%

Note: In an open text field, 30% also reported pipette tips are a major supply issue.

Testing Capacity (tests/day, if fully supplied)	Actual Testing (tests/day, using available supplies)	Unmet Testing Capacity (testing ability not used duet to supply constraint)
92,428*	41,315*	55.3%

* Academic labs from 23 states reported, representing approximately one-third of all in-house labs (different state and lab mix than May 29th data). Extrapolated to 100% of labs, the current academic testing capacity would be ~275,000 tests per day, if supply constraints were addressed. (Note: This capacity is based on single sample runs; not pooled testing. No academic labs reported that they are currently performing pooled testing, but 50% of respondents are working toward doing pooled testing for diagnosis and screening.) This subset of academic labs reported conducting an estimated total of 2,343,564 diagnostic assay tests to-date (as of July 27th).