

Dear Co-Chairs Roblan and Holvey, and Members of the Joint Special Committee on Coronavirus Response,

Thank you for all the work you are doing for our State on this Special Committee. I am a registered lobbyist, but writing this email personally, with information from other sources and those expert on testing. As you know, the U.S. has struggled from a shortage of available testing that has drastically altered our response to the coronavirus. Countries with rapid testing responses have minimized transmission, shortened the duration of the epidemic, and avoided the large scale quarantines that have already begun to devastate the economy here.

The story of how the U.S. failed to provide adequate testing capabilities has been widely told, but that story has so far focused only on the lack of testing kits. The FDA has attempted to minimize bureaucratic interference in the process of developing those tests by accelerating Emergency Use Authorizations and also by delegating authority over test validation to the states themselves. There is now reason to believe that large commercial test manufacturers will begin producing tests in adequate numbers within the next couple of weeks.

There has been very little attention paid to the question of laboratory capacity for running these tests. Only CLIA-certified clinical laboratories are permitted to perform them. In Oregon this likely includes just a few hospital labs, the state public health lab, and a very small number of commercial labs. It does not appear that anyone has quantified the capacity these labs have all together, but it is almost certainly inadequate. Current tests in Oregon hospitals, when there are test kits available, still take five days to return results. This is shocking and inexcusable in this emergency. Commercial labs that do routine genetic or agricultural testing often contain the machines necessary to run coronavirus tests (they're called qPCR machines), and can guarantee turnaround times under 24 hours. The test itself only takes 4 hrs to run. There is huge unused qPCR testing capacity in most states, but these labs are not certified under CLIA, the clinical lab certification program.

There are very good reasons for clinical labs to be held to the CLIA standards. Most of those reasons don't concern the technology around running such tests — they have to do with collecting samples, handling personal data, and reporting patient results appropriately. But there is no good reason why this excess testing capacity shouldn't be utilized. There is a huge push at the federal level to minimize regulatory hurdles to expanding testing. The states are now empowered to make whatever decisions they need to in this case, and federal requirements (as well as consequences for violating them) are being regularly waived.

In California, where they are beginning to feel this pressure sooner than Oregon, this issue has already been raised (<https://blogs.berkeley.edu/2020/03/16/academic-labs-can-help-u-s-ramp-up-coronavirus-testing/>) and the CDPH has now arranged for private and academic labs to perform testing simply by allowing them to partner with a CLIA-certified lab that can handle the patient reporting. Workarounds like this are not natural for state health departments. The FDA may have made quite a mistake by failing to realize that by delegating authority over testing to the states it was actually delegating that authority to overburdened state health agencies that are absolutely unqualified to generate new regulatory pathways on the fly.

Allowing clinical labs to contract out some of their testing work to non-clinical labs with high qPCR throughput is something the OHA could do easily. But if Oregon does not arrange for that quickly it's very possible that the OHA will be unable to even structure that indirect level of CLIA oversight. If the need for testing ramps up by orders of magnitude — and it will — it's rapidly going to seem bizarre to protest against even the most unregulated forms of testing. Unregulated testing could be disastrous.

Recommendations:

The OHA should be directed to make sure that the state of Oregon can do the coronavirus testing it needs in the next few months. The steps to take are relatively simple, but require immediate leadership, planning and focus:

- 1. Quantify the amount of testing capacity in Oregon. There currently seems to be no idea of the capacity.*
- 2. Good epidemiological measures are powered by information, and we have almost no information about how widespread this coronavirus is in Oregon, because almost no one is allowed to get tested. The notion that we shouldn't bother with testing is a reaction to the lack of available testing. It shouldn't be what drives our planning. The current approach by OHA with limited testing availability is to require a physician to order a test for a patient with symptoms. Of course, it is important for sick patients and their caregivers to know whether they have the coronavirus. The current approach assumes that everyone should stay inside and assume they are infected-whether they are totally asymptomatic or clearly showing signs of COVID 19 illness. With testing, our state could transition from the current approach to an approach that identifies all people with coronavirus, including the asymptomatic carriers, to isolate them and those they have been in contact with. This approach could greatly shorten the period of time required for shelter in place for everyone.*
- 3. Make a plan to acquire the tests and staff the administration of the tests once available. There currently does not appear to be a plan. How many people should be tested? When? Testing for health care workers, hospital personnel, essential service workers and their child care providers could be prioritized. Grocery store workers and others in contact with the public could also receive tests once they are available. There is a protocol in place now, but it has been completely shaped by the lack of testing capacity.*
- 4. Make sure we have the tests available to carry out that plan under close to worse-case scenarios. The OHA is still depending on the CDC to provide it with reagents. The large test manufacturers are ramping up production, but if Oregon does not take steps to enable large purchases there is no guarantee that any of them will come to this state.*
- 5. Make sure that we have adequate lab testing capacity to run all the tests we're projected to need, or more. There must be money appropriated to acquire the tests, administer the tests and run the tests in the Special Session. This must be done now, while there's still a chance for testing capacity that provides the safety and public protections of CLIA-compliant testing.*

Thank you for your consideration of this request. Thank you for your public service in these challenging and heartbreaking times.

Sincerely,

Lisa

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