



March 16, 2020

Secretary-Designee Andrea Palm
WI Department of Health Services
1 W. Wilson St.
Madison, WI 53703

Dear Secretary Palm,

This memo is an update (as of March 16, 2020 at 12:30 PM) on testing for the COVID-19 virus at the Wisconsin State Laboratory of Hygiene (WSLH). From March 2 – March 15, 2020, the WSLH has been running the CDC-developed PCR test for the COVID-19 virus.

Status Report – Activities through March 15

The WSLH target turnaround time (time to results) is defined as 1-2 days from receipt of specimen in the laboratory. This is a standard turnaround time for this type of PCR test, and is consistent with the stated turnaround time of CDC, other state public health laboratories, and national commercial reference laboratories. WSLH has consistently met this timeframe; to date, >99% of tests are resulted within 1-2 days.

WSLH initially stated a capacity of testing 100 samples per day, which WSLH could meet without substantially altering normal operations. The number of specimens was 50 – 100 per day until late last week. On Friday, March 13 WSLH received >300 specimens, and on Saturday, March 14 WSLH received almost 300 more. WSLH immediately scaled up, tested all day on Saturday and Sunday, and continued to meet the 1-2 day turnaround time. WSLH rapidly scaled up to meet the demand, and has met the demand up to this point.

By extending hours and staffing, WSLH can currently test 300-400 samples per day – CONTINGENT on an adequate supply chain for reagents and other testing supplies. WSLH is also actively working to continue to scale up. This involves daily communication with the FDA, CDC, and commercial manufacturers to identify larger throughput instruments and to investigate changing the CDC's test to be more efficient by multiplexing (putting all targets into one well rather than separate wells).

WSLH will be testing 7 days per week for the foreseeable future. WSLH is also aware of the need for reliable specimen shipping over the weekend, and is working to identify options for Sunday delivery of specimens. Once WSLH learns of Sunday delivery options this information will be shared widely.

Short Term Plans Moving Forward - Next one to two weeks

In addition to scaling up internally, WSLH is working daily with large Wisconsin clinical laboratories to help these laboratories bring on their own lab-developed tests for the COVID-19 virus. As of March 16, two large Wisconsin clinical laboratories are offering this testing, and five additional laboratories are working toward onboarding testing. The WSLH expects these additional five to be online in the coming 1-3 weeks. These large laboratories will substantially increase the testing capacity in Wisconsin.



Long Term Plans and Planning for Further Increased Capacity

Another substantial increase in testing capacity will occur once manufacturers get their tests approved and manufactured to scale. There are 60-80 laboratories in Wisconsin that can run these commercially-available, sample-to-answer tests. These laboratories are located throughout the state, in hospitals and clinics. FDA approvals for these commercial tests are likely in the coming weeks. The WSLH anticipates that approval and manufacturing scale-up of these commercial tests will take 1-2 months; therefore, in approximately 2 months the WSLH anticipates that COVID PCR testing capability and capacity will be equivalent to influenza PCR testing in Wisconsin. Finally, as a further contingency WSLH is investigating investing in testing platforms that might allow even higher testing throughout to further augment state testing capacity.

Current Issues that need to be addressed with DHS and/or State of Wisconsin Assistance

1) Sample Prioritization

WSLH needs assistance from DHS to determine which specimens are high priority. Specimen numbers are expected to continue to increase, and reagents and supplies for this test are limited. WSLH needs to ensure that high-priority patients receive prompt results. WSLH needs assistance in the form of further guidance from DHS to hospitals/healthcare providers about specimen priority and/or a DHS epidemiologist on-site at the WSLH to help with triage/prioritization.

2) Supply Chain

Many of the reagents and supplies are on backorder or only a limited amount is available. WSLH orders as much as we can as often as we can and requests assistance from DHS in ensuring that necessary supplies and reagents are available at WSLH.

3) Sample Transport

WSLH contracts with a statewide courier, Gold Cross, for delivery Monday-Saturday at 12:30 PM. To minimize the effect of shipping time on total time to results, courier availability for Sunday delivery is now needed. WSLH is exploring options for this with Gold Cross, but DHS assistance may be needed to coordinate Sunday specimen deliveries. WSLH emergency preparedness staff are actively engaged with State and National Guard partners to investigate options for filling this gap.

Background Material

1) Definition of Test Kits

The CDC-developed PCR is a test system, with many different reagents and supplies. The ‘test kit’ that has been discussed in the media is actually the specific reagents (primers and probes) that makes the test a COVID-19 PCR test rather than influenza PCR test or measles PCR test. Many other reagents and supplies also go into this test system. Supply chains for these reagents and supplies are currently stressed, and reagent availability is a limiting factor to testing.

2) Drive-through sampling

‘Drive-through-testing’ is actually ‘drive-through sampling.’ After the swab sample is taken, it is sent to a laboratory for testing. The term ‘test kit’ in this setting is referring to a sampling kit.

Sincerely,

A handwritten signature in black ink, appearing to read "James J. Schauer". The signature is fluid and cursive, with the first name "James" and last name "Schauer" clearly distinguishable.

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cc: Chancellor Blank, Dean Golden, WSLH Board