

Congress of the United States
Washington, DC 20515

March 19, 2020

Dr. Stephen M. Hahn
Commissioner
U.S. Food & Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

Dear FDA Commissioner Hahn:

We write with extremely urgent concerns about the availability of reagents and other coronavirus (COVID-19) testing supplies at labs throughout the state of Wisconsin. We are hearing from hospitals across the state who are facing extreme challenges due to the lack of supply of reagents, swabs, and other supplies available to process collected specimens in labs across Wisconsin. We ask you to work with the Wisconsin Department of Health Services as they are working to ensure the state of Wisconsin has the supplies necessary to meet testing capacities at state laboratories, hospitals, commercial labs, and academic medical centers.

In response to recommendations from the federal government that hospitals ramp up testing, nearly every hospital and health system in Wisconsin has increased their ability to test by setting up curbside or other forms of rapid testing. However, the overall supply chain is not keeping up with either patient demand or testing capacity.

The Wisconsin State Laboratory of Hygiene (WSLH) and Milwaukee Health Department Laboratory (MHDL) have reported in the enclosed memo that "the number of specimens being received during the week of March 16, 2020 far exceeds their daily capacity." The memo goes on to say "WSLH & MHDL has a finite number of reagents and supplies available for this testing, and WSLH received 800 samples on March 16, 2020 and more than 1,000 just in the morning on March 17th. The nationwide supply chain for reagents and other testing supplies is very fragile as more laboratories begin testing."

For this reason, these labs are deciding to first process only the highest priority patients, meaning many patients will see significant delays in obtaining test results. Instead of rapid turnaround in test results, patients are waiting up to, and sometimes more than, a week to see results.

We have several hospitals that have already set up their own labs, and more are scheduled to come online in the coming days. However, they are unable to obtain the equipment and supplies necessary to complete testing, leaving a significant amount of untapped capacity.

This testing bottleneck is creating dire consequences for our hospitals and their staff. Importantly, these delays only increase the risk of COVID-19 spread. Further, they also have serious implications for the provision of health care as health care workers pulled out of the workforce may need to wait days for test results.

While we are extremely grateful for the expedited approval FDA has given laboratories and testing suppliers, **Wisconsin needs your help NOW to make sure the supply chain can keep up with our ability to test the public.** To assist with this, we need to know as soon as possible:

- What steps FDA is taking to ensure an adequate supply of reagents and other supplies.
- More information about FDA's efforts to distribute limited testing supplies to the different entities that are performing COVID-19 testing in Wisconsin, including commercial reference laboratories and state health labs, academic medical centers, and other entities in order to ensure that testing can continue as efficiently as possible.
- We have heard that suppliers may be redirecting supplies originally slated to go to Wisconsin to other states that have a higher number of confirmed COVID-19 cases or with larger population concentrations. If this is happening, what is the process by which this gets decided?

Our ability to monitor the spread of COVID-19 and effectively respond to this pandemic depends on adequate supplies to meet the expanding need to test patients. Thank you for your ongoing efforts.

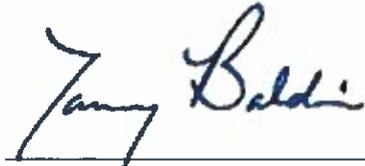
Sincerely,



Ron Kind
Member of Congress



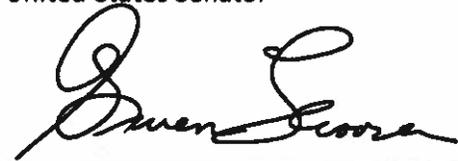
Ron Johnson
United States Senator



Tammy Baldwin
United States Senator



F. James Sensenbrenner, Jr.
Member of Congress



Gwen Moore
Member of Congress



Mark Pocan
Member of Congress



Glenn Grothman
Member of Congress



Mike Gallagher
Member of Congress



Bryan Steil
Member of Congress



Date: March 17, 2020

BCD 2020-09

To: Wisconsin Local Health Officers, Tribal Health Officials, Infection Preventionists, and Health Care Providers

From: Ryan Westergaard, MD, PhD, MPH
Chief Medical Officer and State Epidemiologist for Communicable Diseases

Urgent Update – Prioritization of COVID-19 Testing for Hospitalized Patients
The Wisconsin State Laboratory of Hygiene and City of Milwaukee Health Department
Laboratory can no Longer Process Low Priority Tests in a Timely Manner

PLEASE DISTRIBUTE WIDELY

Main Message:

Although the Wisconsin State Laboratory of Hygiene (WSLH) and the Milwaukee Health Department Laboratory (MHDL) have significantly increased their capacity for COVID-19 testing, the number of specimens being received during the week of March 16, 2020 far exceeds their daily capacity.

In order to avoid depleting the reagents and supplies for testing, DHS is working with WSLH and MHDL to use the reagents and supplies to test the specimens from the highest priority patients. Both public health laboratories will test high-priority specimens (Tier 1 and 2 in table below), and DHS, in coordination with WSLH and MHDL, will identify laboratories in the state and country to send the lower priority specimens to for testing. The lower priority specimens will have a longer time to result.

To allow DHS and WSLH & MHDL to triage the specimens, submitters **MUST** include the new DHS COVID-19 triage form with the specimen and requisition form.

Summary

The Wisconsin State Laboratory of Hygiene (WSLH) has increased capacity for COVID-19 testing. The WSLH is:

- Testing 7 days/week and significantly expanded work hours each day
- Can test **up to 400 specimens per day**
- Can report results on priority specimens 1-2 days **after receipt** of the specimen at WSLH

The Milwaukee Health Department Laboratory (MHDL) has increased capacity for COVID-19 testing. The MHDL is:

- Testing 7 days/week and significantly expanded work hours each day
- Can test **up to 150 specimens per day**
- Can report results on priority specimens 1-2 days **after receipt** of the specimen at WSLH

However, WSLH & MHDL has a finite number of reagents and supplies available for this testing, and WSLH received 700 samples on March 16, 2020 and more than 450 just in the morning on March 17th. The nationwide supply chain for reagents and other testing supplies is very fragile as more laboratories begin testing.

With the increased number of cases of COVID-19 reported nationally and the growing likelihood of widespread community transmission in all areas of the country, the number of people requiring testing for COVID-19 is increasing significantly. Priority should therefore be given to the testing of specimens from patients for whom a timely diagnosis is most urgent.

Clinicians may make decisions to test patients for COVID-19 based on their clinical judgment, but at this time, providers are urged to prioritize testing for hospitalized patients for whom timely diagnosis of COVID-19 is critical to inform management decisions. **Going forward, DHS and WSLH & MHDL will only test Tier 1 and Tier 2 specimens (see table below). Healthcare providers should begin identifying alternate laboratories for testing lower priority specimens.**

It should be emphasized to patients and providers that there is no role for testing asymptomatic individuals. Testing should be reserved for making a diagnosis of COVID-19 in patients suspected of having the disease, in order to inform clinical management and infection control decisions.

Testing is NOT recommended for patients with mild, upper respiratory symptoms, except in limited circumstances. Patients without significant comorbidities, and who are not health care workers, should not be tested if they have mild illnesses for which they would not normally seek medical care. It should be recommended that these patients self-isolate at home until their symptoms improve.

Testing should be prioritized based on clinical criteria. Based on recommendations from the Infectious Disease Society of America, DHS and the Wisconsin State Laboratory of Hygiene (WSLH) have established criteria for prioritizing laboratory specimens, as shown in Table 1. In situations when the volume of tests requested exceeds the capacity for processing all specimens with a standard turn-around time of 1-2 days, WSLH will prioritize specimens in the Tier 1 and Tier 2 categories.

The CDC-developed Person Under investigation (PUI) form is no longer required to be completed or submitted at the time of testing. In its place, a new form containing limited patient information, and a designation of the priority level for the patient. A copy of the form is attached to this memo in the memo library.

Contacts

Please contact DHSResponse@dhs.wisconsin.gov with all questions. A team of DHS staff is monitoring the inbox. We will use the incoming questions to update our FAQs and guidance.

Table 1. Priority levels for COVID-19 testing.

Tier One:
<ul style="list-style-type: none"> • Patient is critically ill and receiving ICU level care with unexplained viral pneumonia or respiratory failure
-OR-
<ul style="list-style-type: none"> • Patient is hospitalized (non-ICU) with fever or signs and symptoms of lower respiratory tract illness (cough, shortness of breath) AND <u>either</u> of the following high risk conditions: <ul style="list-style-type: none"> ○ Known exposure to a laboratory-confirmed COVID-19 patient ○ Travel to an area where sustained community transmission has been identified
Tier Two:
<ul style="list-style-type: none"> • Hospitalized (non-ICU) patients and long-term care residents with unexplained fever AND signs/symptoms of a lower respiratory tract illness
-OR-
<ul style="list-style-type: none"> • Health care workers with unexplained fever AND signs/symptoms of a lower-respiratory tract illness, regardless of hospitalization
Tier Three:
<ul style="list-style-type: none"> • Patient is in an outpatient setting and meets <u>criteria for influenza testing</u>. This includes individuals with co-morbid conditions including diabetes, COPD, congestive heart failure, age >50, immunocompromised hosts among others
-OR-
<ul style="list-style-type: none"> • Health care workers with mild upper respiratory symptoms (rhinorrhea, congestion, sore throat) without fever
Tier Four:
<ul style="list-style-type: none"> • Other patients, as directed by public health or infection control authorities (e.g. community surveillance or public health investigations)
Do NOT Test
Patients without symptoms
Patients with mild upper respiratory symptoms only who are not health care workers