

**Wisconsin State
Laboratory of Hygiene**
UNIVERSITY OF WISCONSIN-MADISON



Update on COVID-19 Diagnostic Testing 03-18-20

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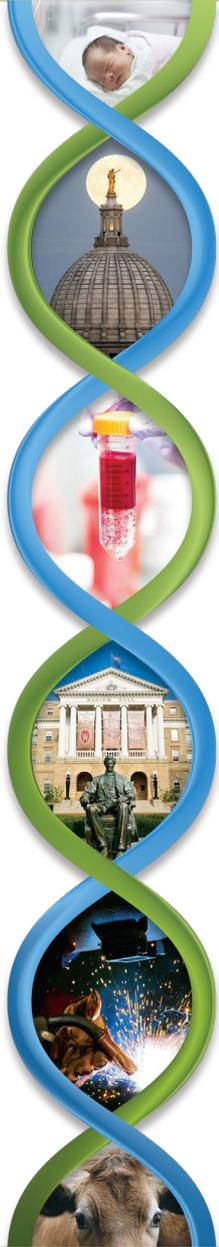
Communicable Disease Division

Wisconsin State laboratory of Hygiene



Contents

- Update on current cases
- Change in test prioritization
- Start performing COVID-19 testing in your lab
- Q and A





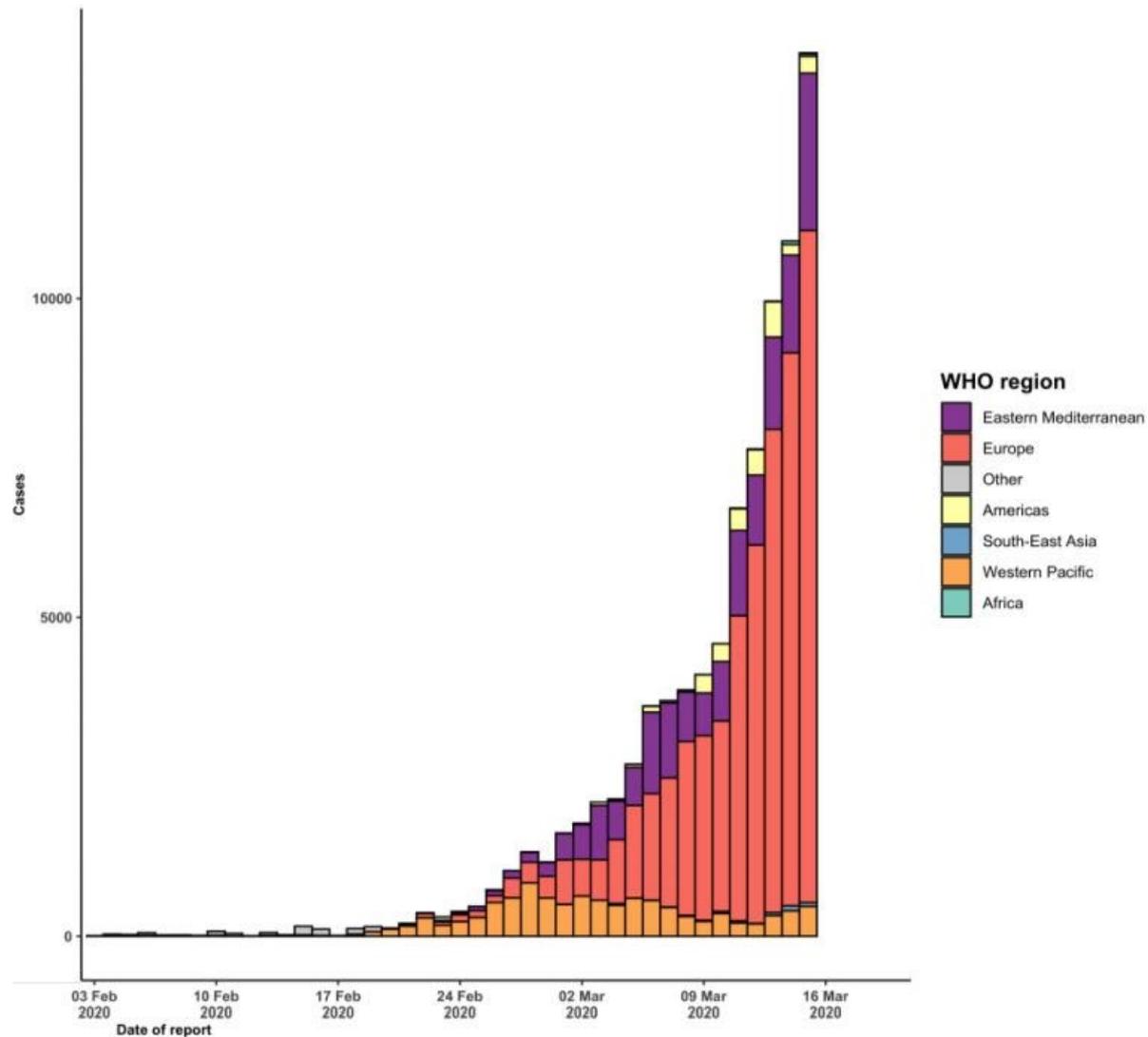
Warning

This information is subject to rapid change.

Please refer to our webpage for the most up to date guidance

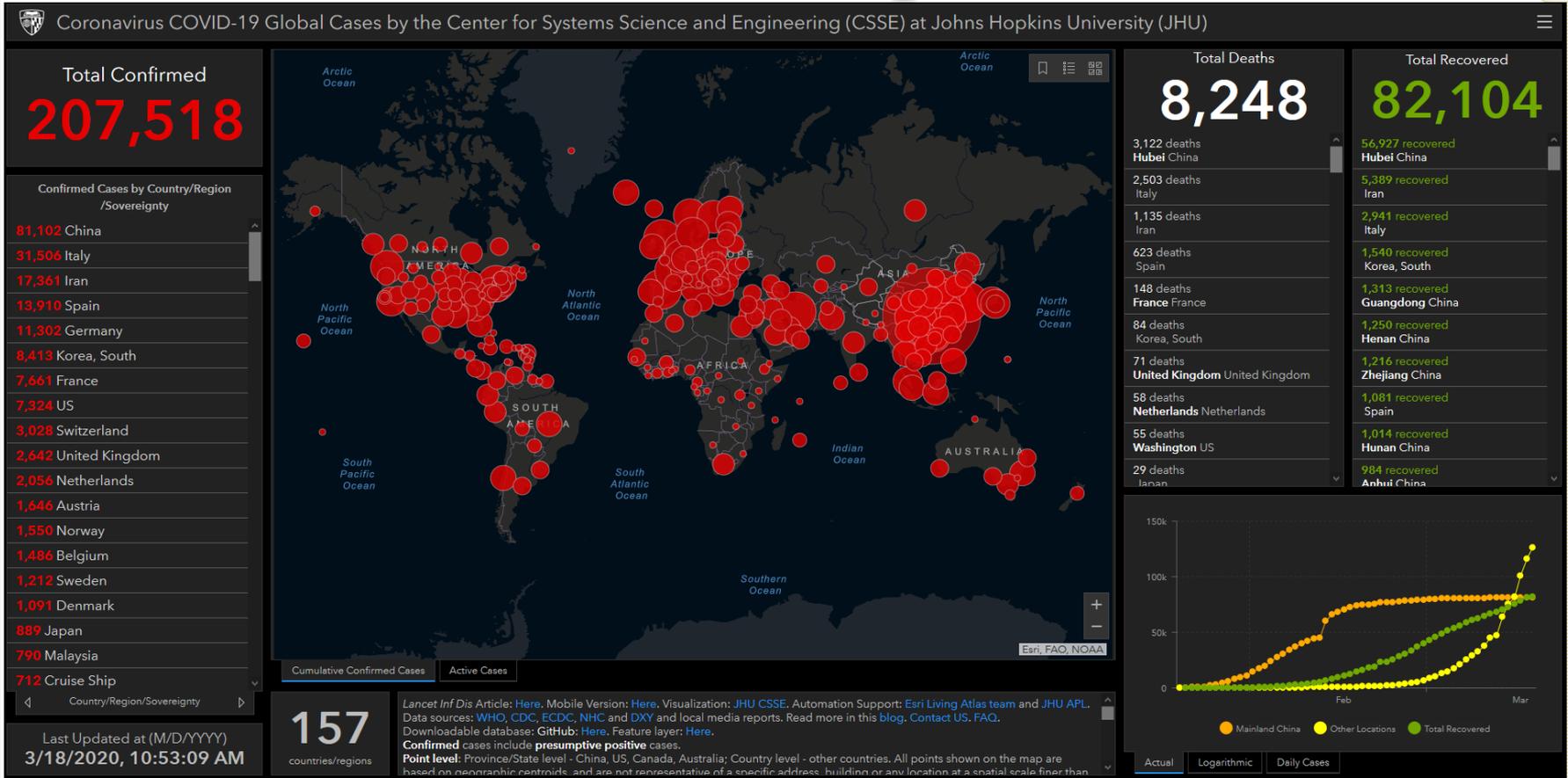
<http://www.slh.wisc.edu/clinical/diseases/covid-19/>

Watching the Pandemic Develop





Global Impact



Johns Hopkins University Global Coronavirus Tracking:

<https://gisanddata.maps.arcgis.com/apps/opsdashboard/index.html#/bda7594740fd40299423467b48e9ecf6>



COVID-19 in the US





Social Distancing

- Gatherings of 10 or more people prohibited
- Non-essential travel discouraged or banned
- Many employees working from home
- Colleges moving to remote learning for whole semester
- Schools closed



Samples for Testing

- **Recommended:** NP swab alone in VTM
 - If VTM is unavailable UTM, Amies, or RNase free Saline may be substituted.
- NP/OP swabs, with both swabs placed in a single tube of VTM
 - If VTM is unavailable UTM, Amies, or RNase free Saline may be substituted
- Sputum or other lower respiratory specimen such as bronchoalveolar lavage or aspirate. (Induction of sputum is not indicated)
 - Does not need VTM
- Postmortem- combined NP/OP described above and bronchial swabs if autopsy is performed. Follow CDC Postmortem testing guidance. **(Not in triage list, call DHS for approval)**

<https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-postmortem-specimens.html>



Testing Triage has Begun

The volume of specimens submitted to the WSLH has exceeded our sustainable capacity resulting in our need to triage specimens. Due to the fragility of the supply chain of testing components, and **in order to protect our ability to provide testing for the most critically ill**, the Wisconsin Department of Health Services released a memo with updated guidelines for providers to prioritize hospitalized patients to be tested for COVID-19.

<https://www.dhs.wisconsin.gov/dph/memos/communicable-diseases/2020-09.pdf>



Risk Prioritization

High
Priority

Tier One:	
<input type="checkbox"/>	Patient is critically ill and receiving ICU level care with unexplained viral pneumonia or respiratory failure
-OR-	
<input type="checkbox"/>	Patient is hospitalized (non-ICU) with fever or signs and symptoms of lower respiratory tract illness (cough, shortness of breath) AND either 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:	
<input type="checkbox"/>	Hospitalized (non-ICU) patients and long-term care residents with unexplained fever AND signs/symptoms of a lower respiratory tract illness
-OR-	
<input type="checkbox"/>	Health care workers with unexplained fever AND signs/symptoms of a lower-respiratory tract illness, regardless of hospitalization
Tier Three:	
<input type="checkbox"/>	Patient is in an outpatient setting and meets criteria for influenza testing. This includes individuals with co-morbid conditions including diabetes, COPD, congestive heart failure, age >50, immunocompromised hosts among others
-OR-	
<input type="checkbox"/>	Health care workers with mild upper respiratory symptoms (rhinorrhea, congestion, sore throat) without fever
Tier Four:	
<input type="checkbox"/>	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

***Please include a copy of this form with the Rec form when submitting samples**



Lower Priority Samples

- Will be frozen to maintain stability
- Will likely be forwarded to other labs for testing
- Will likely exceed the 1-2 day turnaround time

- We will send messaging if a sample is deemed lower priority
- Notify us if you want samples returned
- Please avoid sending in lower priority samples



Testing Locations

- Public Health Labs across the Country
 - Milwaukee Health Department Lab
 - Wisconsin State Laboratory of Hygiene
- Multiple commercial labs now offering COVID-19 testing
 - LabCorp, University of Washington, Mayo
 - Many Clinical Labs bringing on testing



Options for testing in your lab

- Commercial EUA tests
- Lab Developed Test (LDT)



FDA EUA Tests

*** Does not require submission to the FDA to use these tests!!!**

<i>In Vitro</i> Diagnostic Product	Date of EUA Issuance	Letter of Authorization
CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel (CDC)	February 4, 2020 (initial issuance)	Letter of Authorization (PDF, 286 KB)
	March 15, 2020 (reissuance)	
New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel (Wadsworth Center, NYSDOH)	February 29, 2020 (initial issuance)	Letter of Authorization (PDF, 312 KB)
	March 10, 2020 (reissuance)	Letter Granting EUA Amendment(s), March 15, 2020 (PDF, 63 KB)
	March 15, 2020 (amendments granted)	
cobas SARS-CoV-2 (ROCHE)	March 12, 2020	Letter of Authorization (PDF, 111 KB)
TaqPath COVID-19 Combo Kit (Thermo Fisher Scientific, Inc.)	March 13, 2020	Letter of Authorization (PDF, 105 KB)
Panther Fusion SARS-CoV-2 (Hologic, Inc.)	March 16, 2020	Letter of Authorization (PDF, 290 KB)
COVID-19 RT-PCR Test (Laboratory Corporation of America)	March 16, 2020	Letter of Authorization (PDF, 296 KB)
Lyra SARS-CoV-2 Assay (Quidel Corp.)	March 17, 2020	Letter of Authorization (PDF, 294 KB)
Quest SARS-CoV-2 rRT-PCR (Quest Diagnostics Infectious Disease, Inc.)	March 17, 2020	Letter of Authorization (PDF, 297 KB)

<https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#2019-ncov>



Other EUAs coming soon

- Cephied- GeneXpert (this week?)
- BioMerieux- Biofire
- BD- Max (next week?)
- Promega



Clinical Lab LDT

- Requires submission to the FDA for EUA
- FDA has a fast track method for CLIA labs to bring up COVID-19 testing

<https://www.fda.gov/media/135659/download>

- Options
 - Develop your own COVID-19 assay
 - Use CDC's protocol with your own reagents
 - Use Commercial RUO assay (with no EUA)



Are you planning to test?

- Survey coming soon in a WCLN message!
 - When will you start testing?
 - What method(s) will you use?
 - What patient types will you test?
 - What is your expected capacity?
- Please post on the WCLN listserv if you are experiencing any supply shortages.



New CPT Code

Severe Acute Respiratory Syndrome
Coronavirus 2 (SARS-CoV-2) (Coronavirus
disease [COVID-19])

87635

“Infectious agent detection by nucleic acid (DNA or RNA);severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)(Coronavirus disease [COVID-19]), amplified probe technique”

* WSLH Testing is fee exempt



Questions?

Please type your questions in the question box.