

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



Update on COVID-19 Diagnostic Testing

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- Situation Update
- WSLH testing update
- Clinical lab testing update
- 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

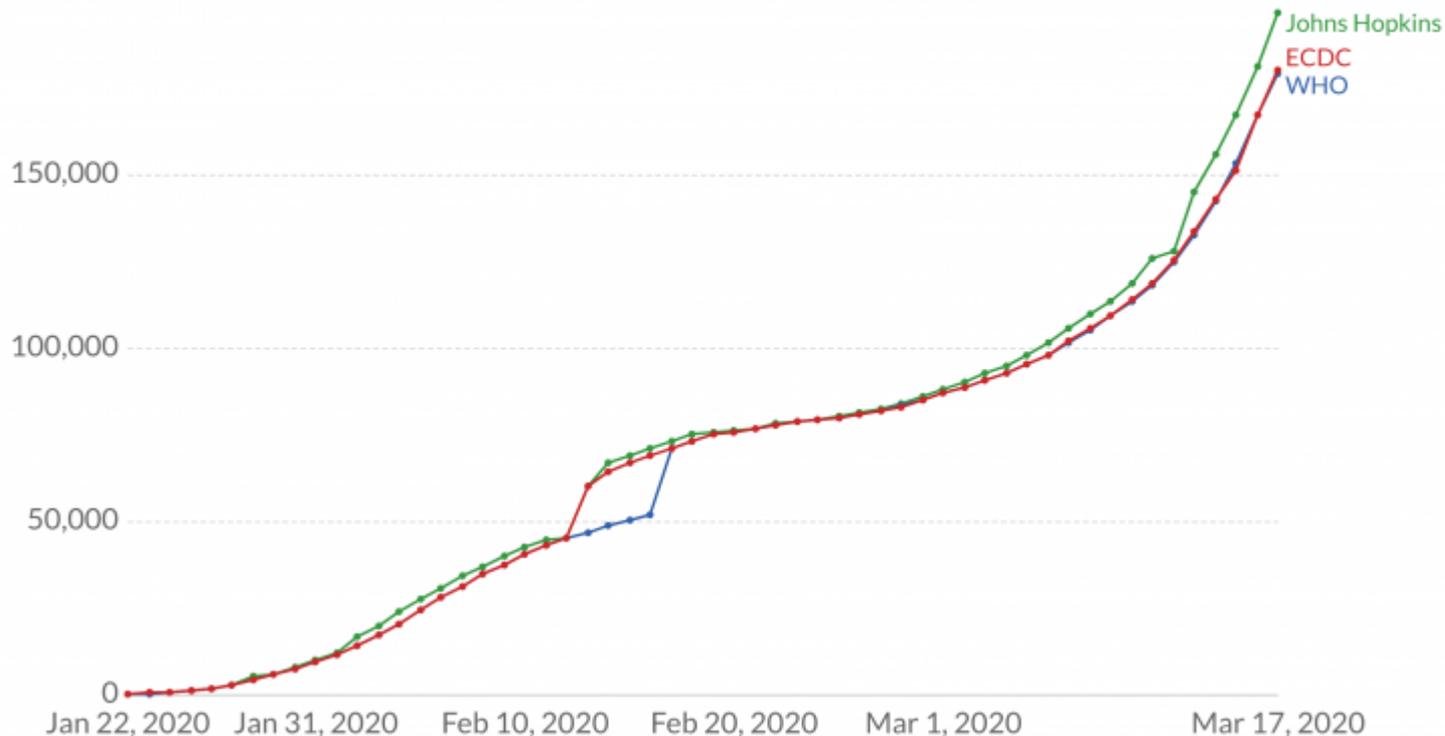


Total confirmed COVID-19 cases, by source, World

Our World
in Data

Confirmed COVID-19 cases are compared for the three main data sources:

- Johns Hopkins University;
- World Health Organization (WHO) Situation Reports;
- European Centre for Disease Prevention and Control (ECDC)



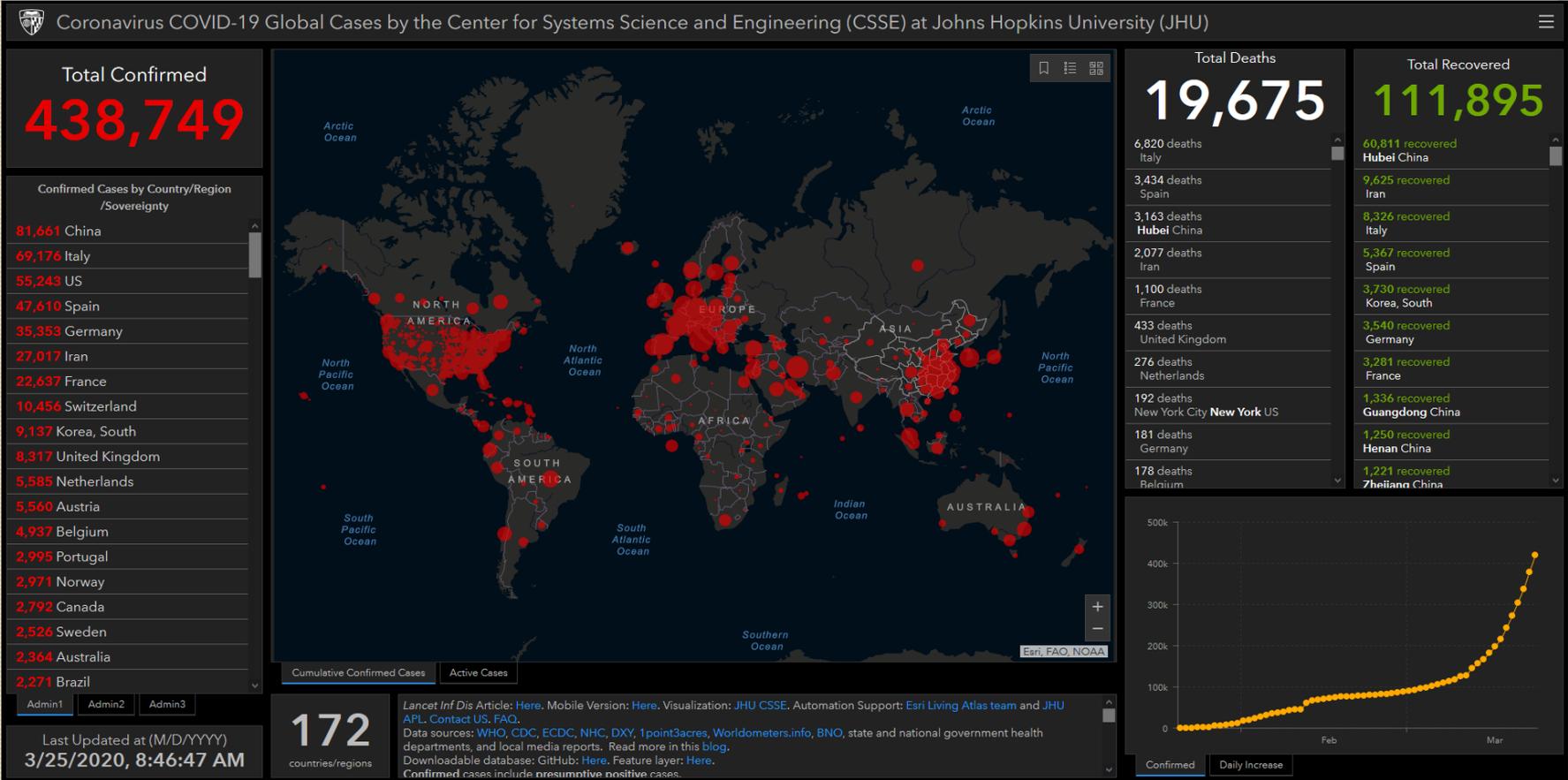
Source: Johns Hopkins (2020); WHO COVID-2019 Situation Reports; ECDC (2020)

Note: The number of confirmed cases is lower than the number of total cases. The main reason for this is limited testing.

CC BY



Global Impact

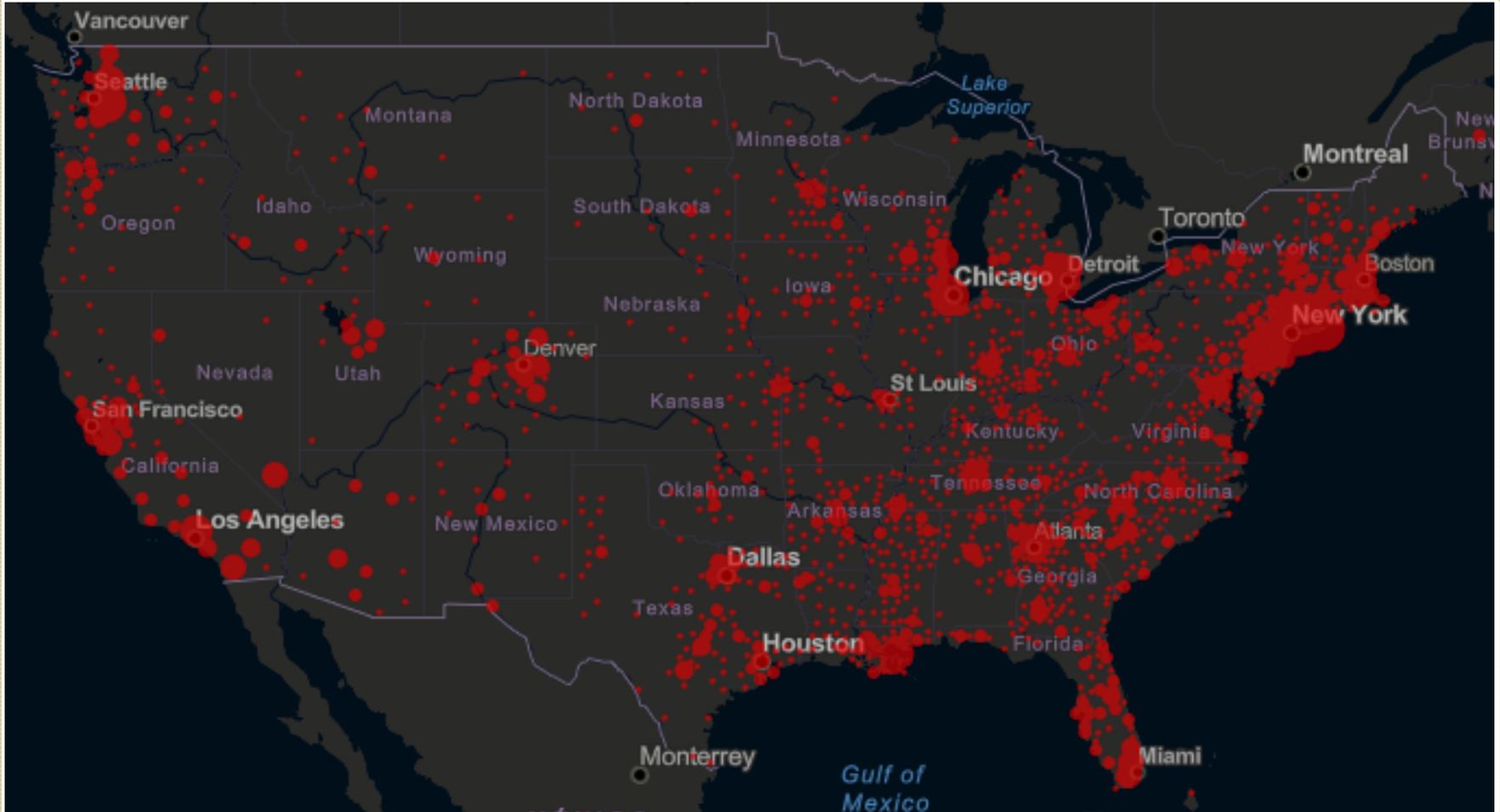


[Johns Hopkins University Global Coronavirus Tracking:](#)

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

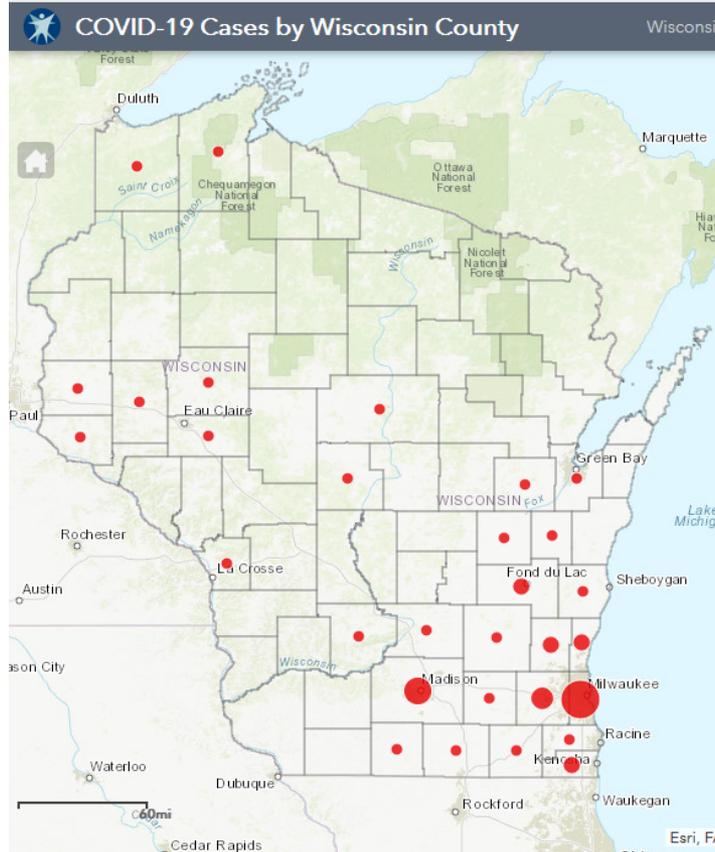


COVID-19 in the US





Wisconsin



Test Results	Number of People as of 3/24/2020
Negative	8237
Positive	457
Deaths	5

<https://www.dhs.wisconsin.gov/outbreaks/index.htm>



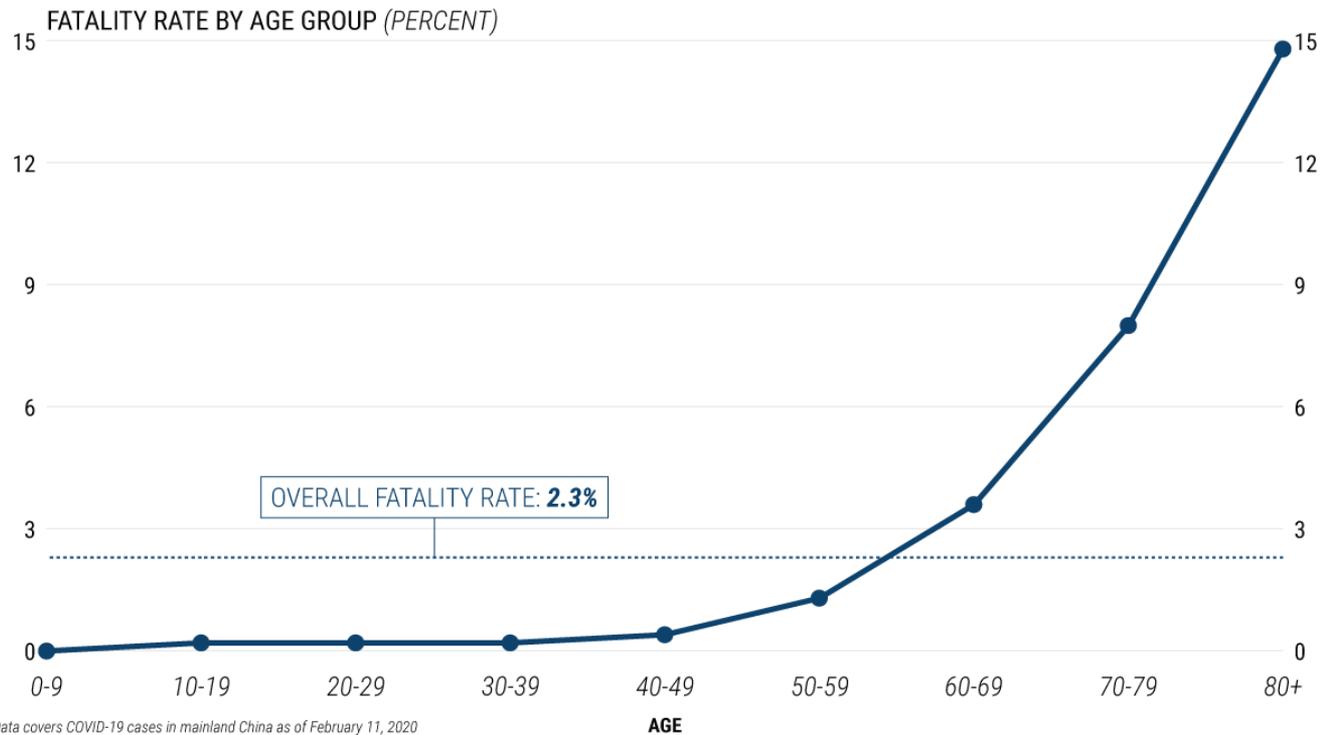
Social Distancing

- “Safer at Home” plan issued yesterday
- All non-essential businesses closed



Older People are at Greatest Risk

COVID-19: *Fatality Rate*





Testing and Resulting for the Public

The WSLH does NOT

- Clinically evaluate patients
- Swab patients
- Report results directly to patients
- Accept sample submitted directly by patients

Please do not give the labs phone number out to patients. They need to speak to their healthcare provider.



Resulting

- The WSLH **will call all positive results** to the submitter
- All results will be report electronically or by Fax to the submitting lab
- All results will be reported to WEDSS
- We are no longer calling positives to public health



Samples for Testing

- **Recommended:** NP swab alone in VTM
- NP/OP swabs, with both swabs placed in a single tube of VTM
- Sputum or other lower respiratory specimen such as bronchoalveolar lavage or aspirate. (Induction of sputum is not indicated)
- 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>



What if I don't have VTM?

1. **VTM**
2. **UTM**
3. **Amies**
4. **Saline-** Molecular grade Phosphate Buffered Saline (PBS)



What if I don't have an NP swab?

Upper Respiratory

1. NP swab
2. NP/OP
3. OP

Lower Respiratory

1. Sputum
2. BAL
3. Trachial Aspirate
4. Mini BAL



COVID-19 Survey

Survey results are being compiled. We now have data from 41 labs related to COVID-19 testing. Please complete the survey if you have not done so already!

This data is being shared with state officials to help inform on needs that could be fulfilled through state and federal routes.

- PPE request yesterday
- VTM kits and test supplies requested today



Testing Triage is in Place

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 WSLH is only testing high priority patients based on the Wisconsin Department of Health Services guidelines

<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 Sample

Due to the sudden change in submission guidance, testing requests for lower priority specimen received prior to 3/21/20 were honored.

- Specimen were sent to the Mayo Clinic
- No charge to the submitter
- Results expected by Thursday
- **One time only!**



Lower Priority Samples

- Due to reagent limitations lower priority (Tier 3 and below) specimen will not be tested at WSLH.
- A “Not Performed” result will be sent to the submitting laboratory
- They will be frozen to maintain stability
- Call Customer Service if you want samples returned or to cancel testing
- Seek other labs or in-house testing for these patients
- Please do not submit lower priority specimen, they will not be tested or sent out again



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, ARUP, and Quest
 - Clinical Labs now testing!
 - 8 so far with 33+ more planning



Testing Options

- Send to a reference lab
- Commercial EUA tests in-house
- Lab Developed Test (LDT) in-house



FDA EUA Tests

1. CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel (CDC)
2. Cobas SARS-CoV-2 (Roche)
3. TaqPath COVID-19 Combo Kit (Thermo Fisher Scientific, Inc.)
4. Panther Fusion SARS-CoV-2 (Hologic, Inc.)
5. Lyra SARS-CoV-2 Assay (Quidel Corp.)
6. Abbott RealTime Sars-CoV-2 Assay (Abbott Molecular)
7. Simplexa COVID-19 Direct (Diasorin Molecular, LLC)
8. ePlex SARS-CoV-2 (GenMark Diagnostics, Inc.)
9. Primerdesign Ltd COVID-19 genesig Real-Time PCR (Primerdesign Ltd)
10. Xpert Xpress SARS-CoV-2 test (Cepheid)
11. BioFire COVID-19 test (BioFire Defense, LLC)
12. Accula SARS-Cov-2 Test (Mesa Biotech Inc.)
13. Coronavirus Nucleic Acid Detection Kit (PerkinElmer)

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

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



Traditional Molecular Methods

Extraction followed by PCR

1. CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel (CDC)
2. TaqPath COVID-19 Combo Kit (Thermo Fisher Scientific, Inc.)
3. Lyra SARS-CoV-2 Assay (Quidel Corp.)
4. Primerdesign Ltd COVID-19 genesig Real-Time PCR (Primerdesign Ltd)
5. Abbott RealTime Sars-CoV-2 Assay (Abbott Molecular)
6. Coronavirus Nucleic Acid Detection Kit (PerkinElmer)



Sample to answer- Large Instruments

1. cobas SARS-CoV-2 (Roche)



2. Panther Fusion SARS-CoV-2 (Hologic, Inc.)



3. ePlex SARS-CoV-2 (GenMark Diagnostics, Inc.)





Sample to answer- Small Instruments

- Simplexa COVID-19 Direct (Diasorin Molecular, LLC)
- Xpert Xpress SARS-CoV-2 test (Cepheid)
- BioFire COVID-19 test (BioFire Defense, LLC)
- Accula SARS-Cov-2 Test (Mesa Biotech Inc.)





Other EUAs coming soon

- BD- Max
- Promega PCR and Extraction Reagents
- Bruker



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 Commercial RUO assay (with no EUA)
 - Modify an existing EUA
- Current LDTs require an another EUA testing lab to confirm your first results, WSLH can do this for you.
 - Please notify me (Alana Sterkel) if you submit these
 - Write in “COVID-19 Confirmatory” in the Rec A form



Need Validation Samples?

- WSLH is able to provide a panel of de-identified, residual specimen to aid in validation
- Contact Customer service (1-800-862-1013) or Al Bateman to request a panel



If you are Testing

- Please post on the WCLN listserv if you are experiencing any supply shortages. Others may be able to help
- Please notify WSLH when you go live or if you have changes in testing.
- Please report all results to in the normal flu reporting spreadsheet



New COVID- 19 CPT Code

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

87635

* WSLH Testing is fee exempt



Transport and Specimen Receipt

Gold Cross Courier Transport:

- Provided free by WSLH
- 7 days a week must call by noon for pick-up that day with delivery the following day. Call 715-839-9989
 - **DO NOT wait until the last minute to call for a pick-up**
 - **DO NOT call Gold Cross for a STAT pick-up**
 - **STAT pick-up is approved and arranged by State Epidemiologists.**
- You can utilize other commercial or in-house courier or delivery services at your expense

Specimen Receipt:

- WSLH only open for receipt of specimens Sat. 6:00 AM – 4:30 PM and Sun. 9:00 AM - 4:30 PM



Proper Storage and Shipping

- If will be received within 72 hrs. at WSLH, store at 2-8°C
 - Transport on chilled cold packs
- If won't be received within 72 hrs, store frozen at -70°C
 - Transport on plenty of dry ice
- Don't expect Gold Cross to refrigerate or freeze for you.





Packaging and Shipping

NEW – Package and Shipping Biological Substance, Category B Specimens

- New pictorial guidance posted to help you package a COVID-19 specimen correctly.
- The link is found on the COVID-19 web page in the “Packaging and Shipping” section. It is listed as “Instructions for shipping”





Listserv



- Please use the WCLN Listserv:
 - Ask general questions
 - Communicate issues to the WSLH
 - Report shortages of supplies
 - Performance issues with testing
 - Communicate with each other
- Here is the link to WCLN Listserv web page to register:

<http://www.slh.wisc.edu/wcln-surveillance/wcln/wcln-listserv/>



Please Type Your Questions in the
Question Box!

