

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



Update on COVID-19 Diagnostic Testing

04-01-20

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WCLN Network Coordinator

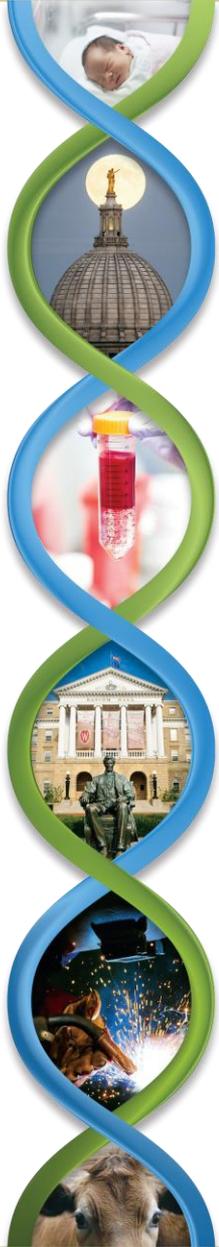
Communicable Disease Division

Wisconsin State Laboratory of Hygiene



Contents

- Situation Update
- WSLH testing update
- Clinical lab testing update
- Q and A



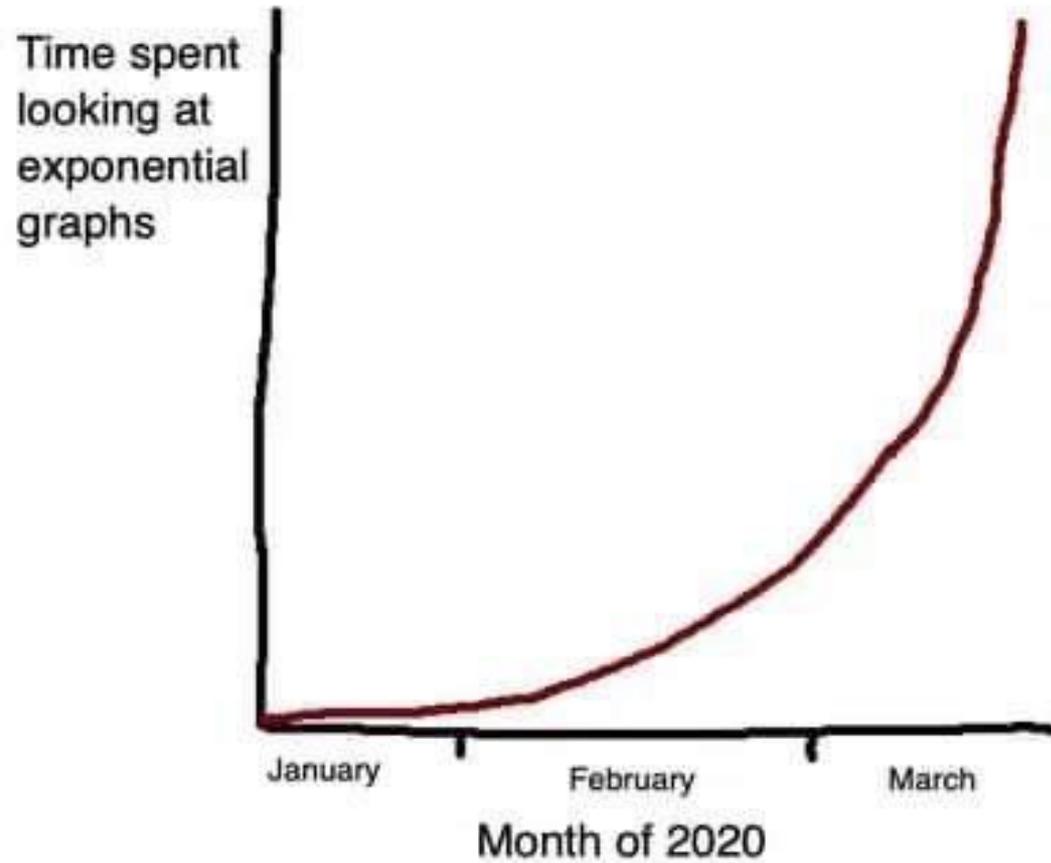


Warning

This information is subject to rapid change.

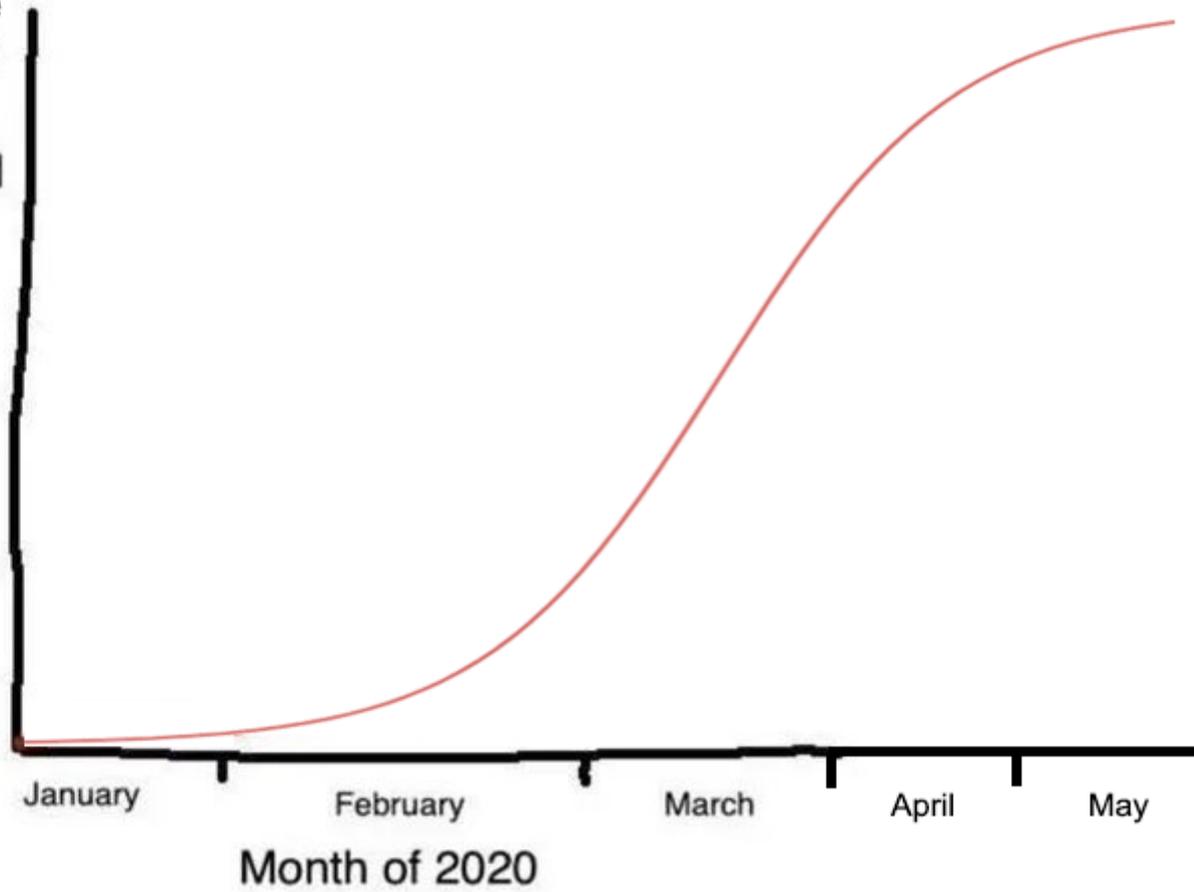
Please refer to our webpage for the most up to date guidance

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



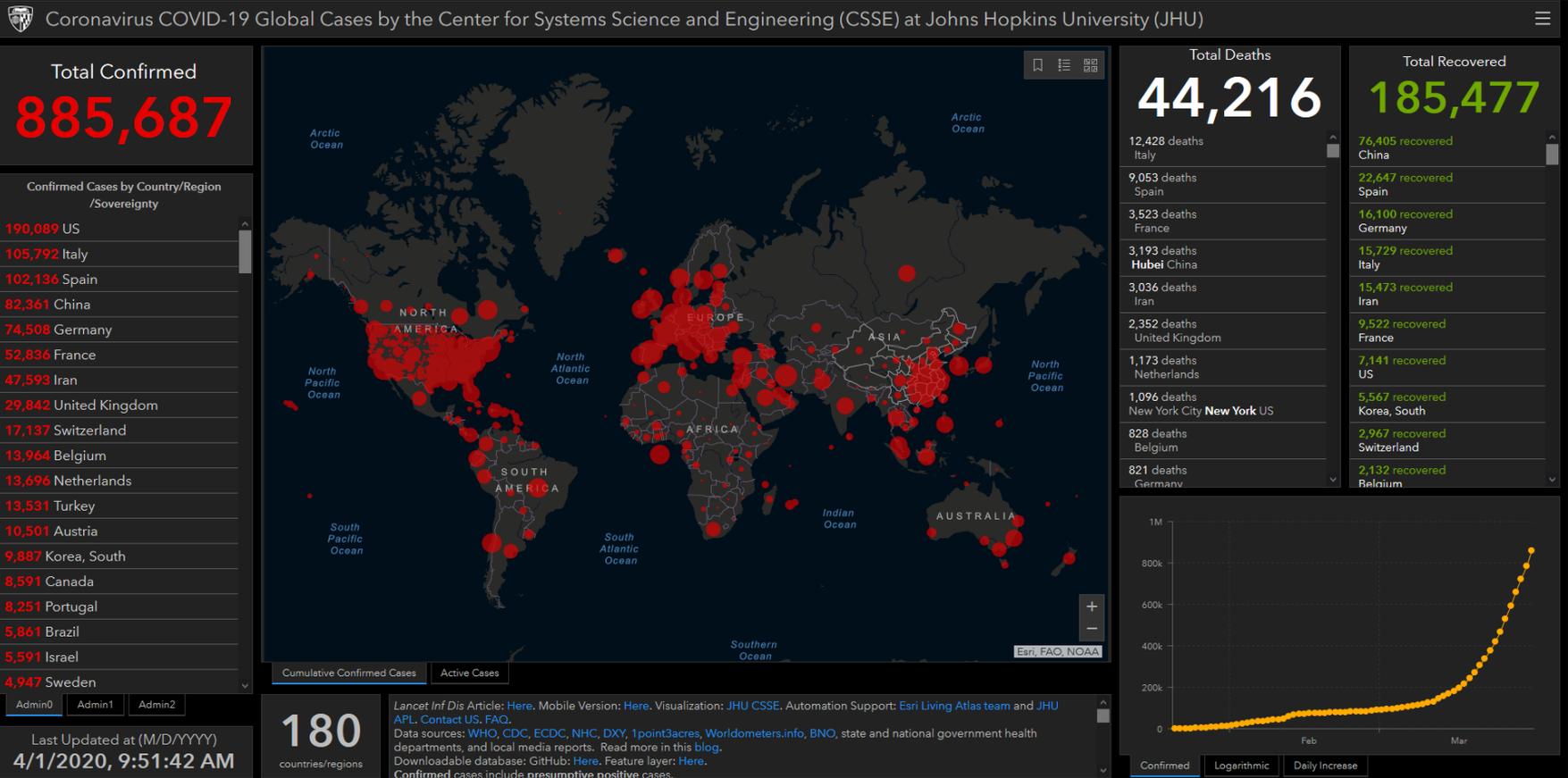


Cumulative
Time spent
looking at
exponential
graphs





Global Impact

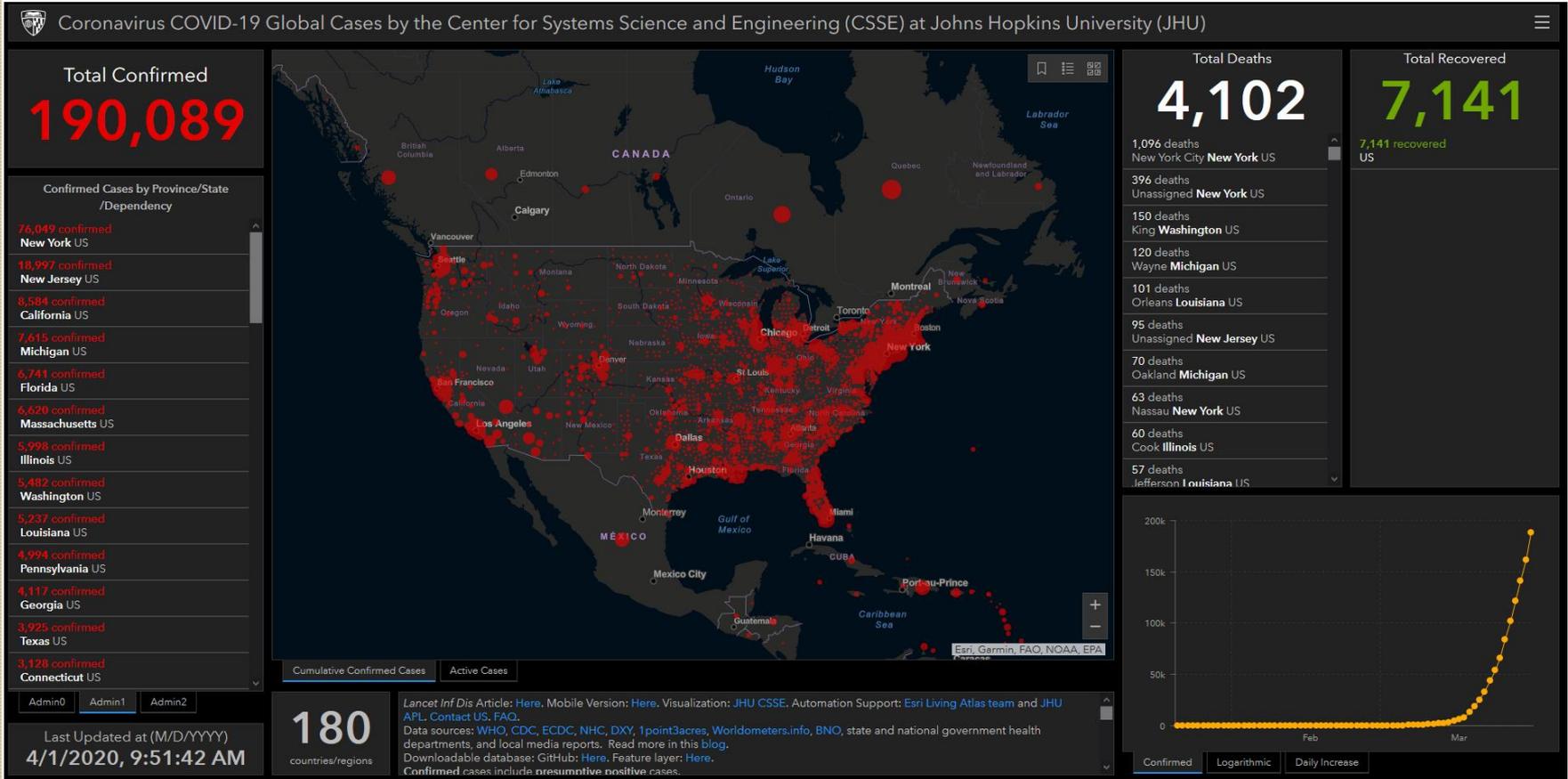


[Johns Hopkins University Global Coronavirus Tracking:](#)

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

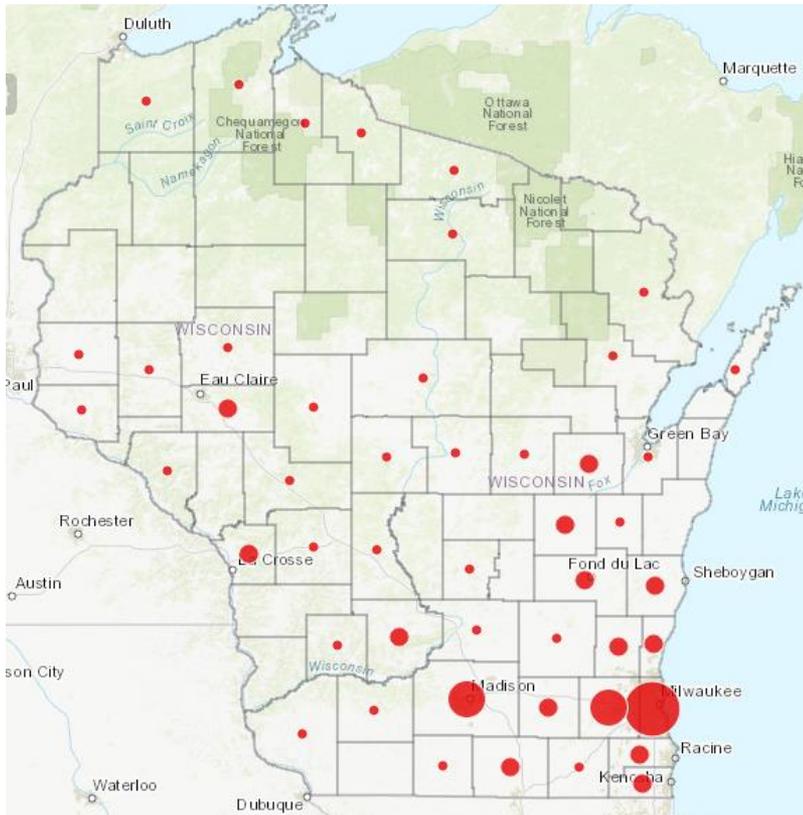


COVID-19 in the US





Wisconsin

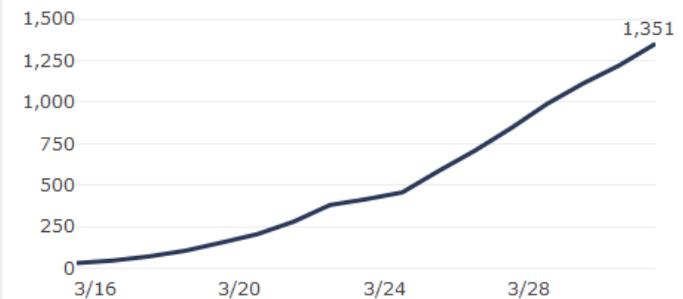


Wisconsin COVID-19 Test Results

Test Results	Number of People as of 3/31/2020
Negative	17,375
Positive	1,351
Deaths	16

Cumulative total COVID-19 cases by date confirmed

Updated: 3/31/2020



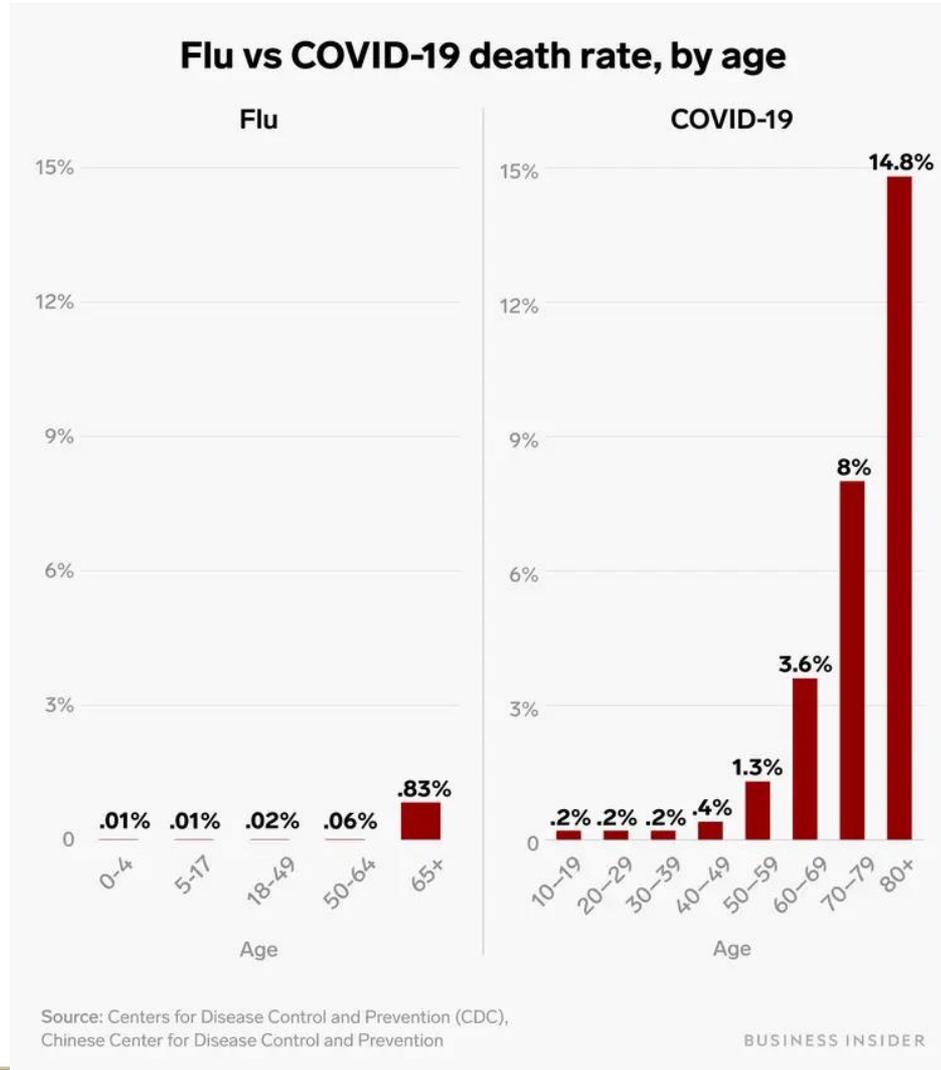
<https://www.dhs.wisconsin.gov/outbreaks/index.htm>



Social Distancing

- “Safer at Home” plan still in place
- All non-essential businesses closed

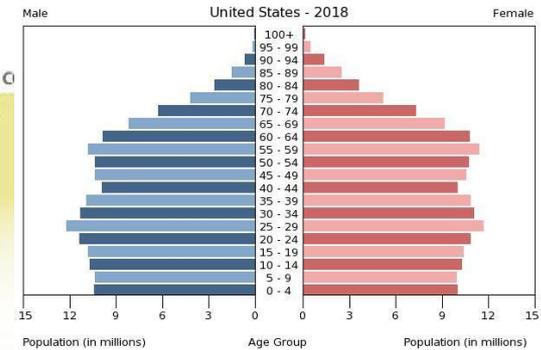
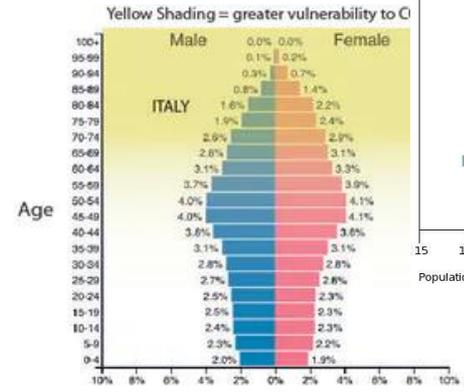
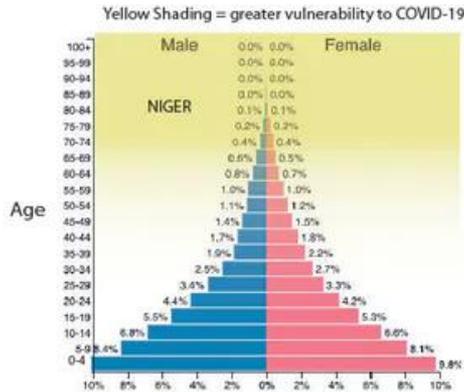
Older People are at Greatest Risk



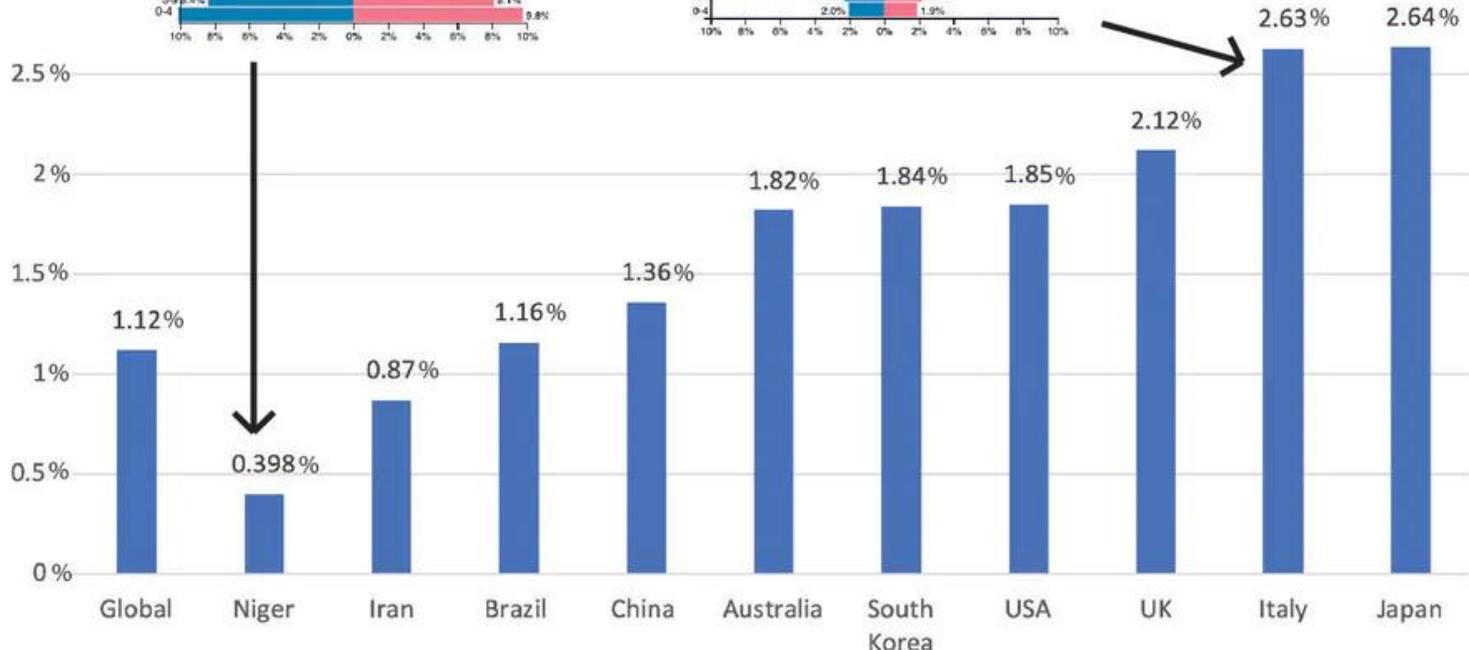


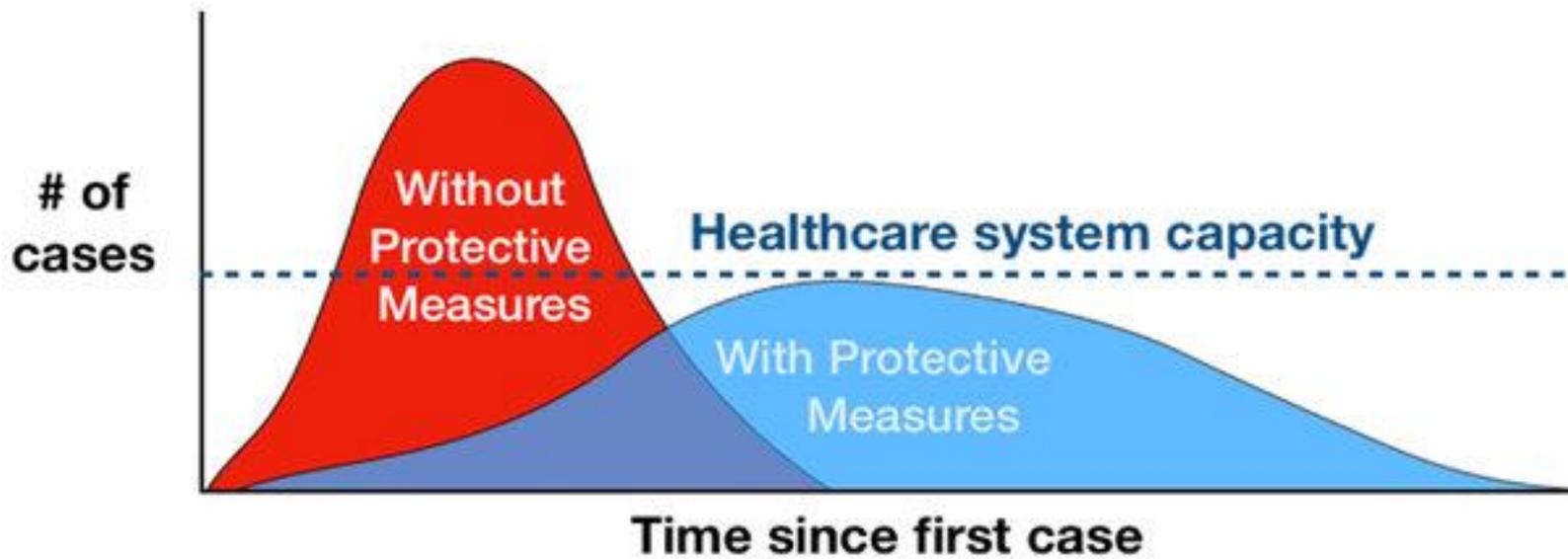
Why some countries have a higher death rate

POPULATION PYRAMID (age structure of population)



PROJECTED FATAL COVID-19 CASES (CFR*)



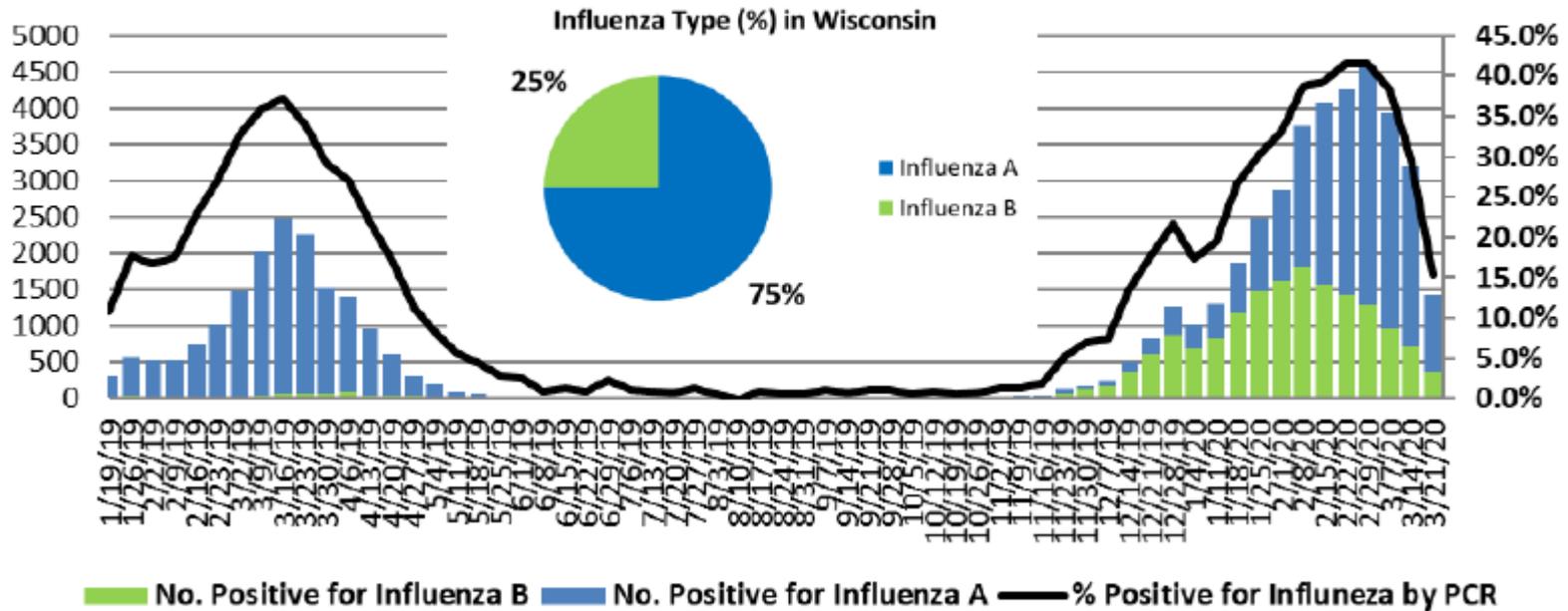


Adapted from CDC / The Economist



Distancing Works!

% Positive for Influenza by PCR (Wisconsin), Week Ending March 21, 2020





New Priority Form

PLEASE SELECT ALL THAT APPLY BELOW TO DETERMINE TEST PRIORITY

TIER ONE:
<input type="checkbox"/> Patients who are critically ill and receiving ICU level care with unexplained viral pneumonia or respiratory failure
-OR-
<input type="checkbox"/> Patients who are residents of long-term care facilities or other high consequence congregate settings (e.g. prisons or jails), with unexplained fever OR signs/symptoms of acute respiratory illness.
-OR-
<input type="checkbox"/> Post-mortem testing for people who died of unknown causes, if COVID-19 testing would influence infection control interventions or inform a public health response
TIER TWO:
<input type="checkbox"/> Hospitalized (non-ICU) patients with unexplained fever AND signs/symptoms of acute respiratory illness
-OR-
<input type="checkbox"/> Health care workers or first responders with unexplained fever AND signs/symptoms of acute respiratory illness, regardless of hospitalization
-OR-
<input type="checkbox"/> Essential staff in high consequence congregate settings (e.g. correctional officers) with unexplained fever AND signs/symptoms of acute respiratory illness, regardless of hospitalization
TIER THREE: TESTING OF TIER THREE SPECIMENS WILL <u>NOT BE PERFORMED</u> AT WSLH OR MHDL
<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 acute respiratory symptoms (e.g. rhinorrhea, congestion, sore throat, cough) without fever
TIER FOUR: TESTING OF TIER FOUR SPECIMENS WILL <u>NOT BE PERFORMED</u> AT WSLH OR MHDL
<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



Tracking Testing Capacity in the State

- State Emergency Operations Center (SEOC)
- Simple survey to track COVID-19 testing capacity
- Will be used to help labs!
 - Inform on State purchasing of testing supplies
 - Inform on allocation of state purchased supplies
 - Identify shortages and find solutions



When to Use the Survey

- First time to check for accuracy
- Only update when there is a change in testing!
 - Start testing for the first time
 - Add or change testing methods
 - Increase or decrease in capacity
 - Report reagent/supply limitations that will lead to an imminent stop in testing



Survey tool



Welcome to the SEOC Lab Capacity Reporting System

This tool is intended as a means to track testing capacity and supply needs in the State of Wisconsin. This data will be used to inform on **supply procurement strategies and resource allocation**. Individual lab information will only be viewable to Public Health Agencies. Aggregate data for the State will be publically available. Please update the information for your lab anytime there is a **significant change in testing**. This includes starting testing with a new COVID-19 assay or platform, a large change in testing capacity, or a major supply limitation affecting your ability to perform testing.

Select your lab and then press login

--Select your Lab--

Login

Select your lab



What it asks

Wisconsin State Laboratory of Hygiene

Facility Testing Status	Actively Testing	Facility Testing Start Date	3/2/2020
Do you have a backlog of tests?	NO	Are you experiencing reagent/supply shortages that will lead to an imminent stop in testing?	NO
Current Capacity (tests per day)		Future Capacity (tests per day)	
Current test methods (choose all that apply) – Double click to add	Available Accula Aries BDMax BioFire Cobas Diasorin easyMAG ePlex GeneXpert	Chosen EMAG EZ1 MagnaPure LC Manual Extraction Qiacube	Future test methods (choose all that apply)
Other testing methods?		Available Accula Aries BDMax BioFire Cobas Diasorin EMAG ePlex EZ1	Chosen easyMAG GeneXpert KingFisher Panther Fusion
		Save Cancel	



What it asks

Facility Testing Status

Do you have a backlog of tests?

- Actively Testing
- Planning to Test
- Actively Testing**
- No Current Plans

Laboratory of Hygiene

Facility Testing Start Date

Are you experiencing reagent/supply shortages that will lead to an imminent stop in testing?

If you are experiencing a shortage, what are you missing?

Future Capacity (tests per day)

Future test methods (choose all that apply)

- Available**
- Accula
 - Aries
 - BDMax
 - BioFire
 - Cobas
 - Diasorin
 - easyMAG
 - ePlex
 - GeneXpert

- Chosen**
- easyMAG
 - GeneXpert
 - KingFisher
 - Panther Fusion



What it asks

Laboratory of Hygiene

Do you have a backlog of tests?

NO

YES

NO

Double click to add

- Available
- Accula
 - Aries
 - BDMax
 - BioFire
 - Cobas
 - Diasorin
 - easyMAG
 - ePlex
 - GeneXpert



- Chosen
- EMAG
 - EZ1
 - MagnaPure LC
 - Manual Extraction
 - Qiacube

Future test methods (choose all that apply)

- Available
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 - Aries
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 - Cobas
 - Diasorin
 - EMAG
 - ePlex
 - EZ1



- Chosen
- easyMAG
 - GeneXpert
 - KingFisher
 - Panther Fusion

Other testing methods?

Save

Cancel



What it asks

Wisconsin State Laboratory of Hygiene

Facility Testing Start Date 3/2/2020

Do you have a backlog of tests?

NO

YES

NO

Current test methods (choose all that apply) – Double click to add

- Available
- Accula
 - Aries
 - BDMax
 - BioFire
 - Cobas
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- Chosen
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 - Panther Fusion

Other testing methods?

Save Cancel



What it asks

Wisconsin State Laboratory of Hygiene

Are you experiencing reagent/supply shortages that will lead to an imminent stop in testing?
If you are experiencing a shortage, what are you missing?

NO

YES

NO

Current Capacity (tests per day)

Future Capacity (tests per day)

Current test methods (choose all that apply) – Double click to add

- Available
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 - Panther Fusion

Other testing methods?

Save

Cancel



What it asks

Wisconsin State Laboratory of Hygiene

Are you experiencing reagent/supply shortages that will lead to an imminent stop in testing?

NO

If you are experiencing a shortage, what are you missing?

YES

NO

Current Capacity (tests per day)  

Current test methods (choose all that apply) –
Double click to add

- Available**
- Accula
 - Aries
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 - BioFire
 - Cobas
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 - easyMAG
 - ePlex
 - GeneXpert



- Chosen**
- EMAG
 - EZ1
 - MagnaPure LC
 - Manual Extraction
 - Qiacube

Other testing methods?



What it asks

Wisconsin State Laboratory of Hygiene

Facility Testing Status: Facility Testing Start Date:

Do you have a backlog of tests? Are you experiencing reagent/supply shortages that will lead to an imminent stop in testing?

If you are experiencing a shortage, what are you missing?

Future Capacity (tests per day)

Future test methods (choose all that apply)

Available

- Accula
- Aries
- BDMax
- BioFire
- Cobas
- Diasorin
- EMAG
- ePlex
- EZ1



Chosen

- easyMAG
- GeneXpert
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- Panther Fusion



What it asks

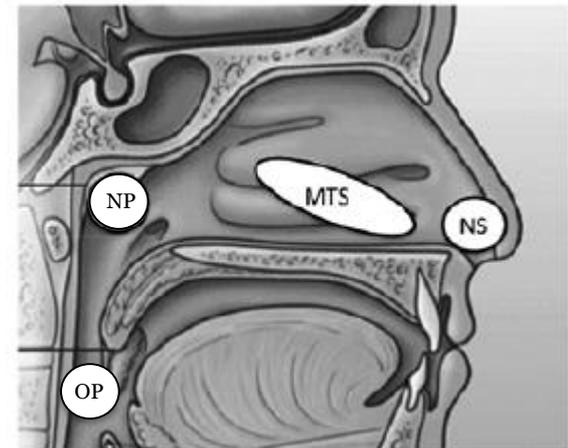
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<input type="button" value="Save"/> <input type="button" value="Cancel"/>			



What if I don't have NP swabs?

- Data from past flu studies and new data from COVID-19 studies show that the **Nasopharyngeal (NP)** swab is most likely to identify disease
- In descending order of sensitivity
 - **Oropharyngeal swab (OP)**
 - Mid-turbinate swab (MTS)
 - Nasal swab (NS)
 - Tongue
 - Saliva





Non-Commercial VTM from WSLH

- The WSLH has partnered with other labs to produce VTM using the CDC protocol.
- Comes as a “kit” with an NP swab
- Validated for sterility, stability, and nucleic acid contamination by WSLH
- Requires refrigeration (2-8° C)
- Available upon request now
 - Call the WSLH Clinical Orders Department
1-800-862-1088, Mon-Fri 7:45 AM – 4:30 PM



Serology Testing

- Many new IgM and IgG tests flooding the market
- FDA initially said they do not “intend to object to the distribution and use of serology tests”.
 - They are reconsidering this stance after strong objections from public health
- These tests are at high risk for false results which could lead to harm

<https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-provides-more-regulatory-relief-during-outbreak-continues-help>



Serology

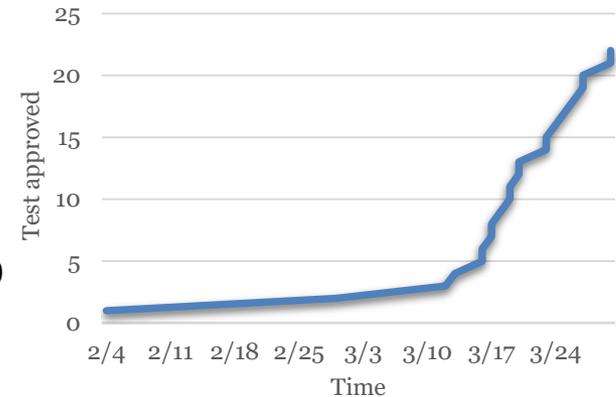
- Antibodies take multiple days longer to detect a positive than NAAT of viral RNA
- These tests cannot be used alone to diagnose a patient.
 - Positive and negative results would have to be confirmed by NAAT.
 - Would not conserve reagents.
- These tests are at high risk to cross react with other beta coronaviruses already widespread in our community.



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)
14. AvellinoCoV2 test (Avellino Lab USA, Inc.)
15. Real-Time Fluorescent RT-PCR Kit for Detecting SARS-2019-nCoV (BGI Genomics Co. Ltd)
16. ID NOW COVID-19 (Abbott Diagnostics Scarborough, Inc.)
17. NxTAG CoV Extended panel (Luminex Molecular Diagnostics, Inc.)
18. NeuMoDx SARS-CoV-2 Assay (NeuMoDx Molecular, Inc.)
19. QIAstat-Dx Respiratory SARS-CoV-2 Panel (QIAGEN GmbH)

FDA approval of COVID-19 tests



*6 new since last week



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)
7. NeuMoDx SARS-CoV-2 Assay (NeuMoDx Molecular, Inc.)
8. AvellinoCoV2 test (Avellino Lab USA, Inc.)
9. Real-Time Fluorescent RT-PCR Kit for Detecting SARS-2019-nCoV (BGI Genomics Co. Ltd)



Large High Capacity Instruments

- **cobas SARS-CoV-2**
(Roche)



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





Sample to Answer Medium Instruments

- **Xpert Xpress SARS-CoV-2 test** (Cepheid)
- **ePlex SARS-CoV-2** (GenMark Diagnostics, Inc.)
- **NxTAG CoV Extended panel** (Luminex Molecular Diagnostics, Inc.)
- **QIAstat-Dx Respiratory SARS-CoV-2 Panel** (QIAGEN GmbH)





Sample to Answer Small Instruments

- **Simplexa COVID-19 Direct**
(Diasorin Molecular, LLC)



- **BioFire COVID-19 test**
(BioFire Defense, LLC)

- **ID NOW COVID-19** (Abbott
Diagnostics Scarborough, Inc.)



- **Accula SARS-Cov-2 Test**
(Mesa Biotech Inc.)





Other EUAs coming soon

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



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
- WSLH is able to provide confirmatory testing for labs doing an NAAT LDT

Letter from Vice President Pence



Request for COVID-19 Test Result Reporting:

- Data needed by FEMA and CDC to support their efforts to support states and localities respond to the virus
- Empowered by Coronavirus Aid, Relief and Economic Security (CARES) Act signed into law 3/27/20 by President Trump

THE VICE PRESIDENT
WASHINGTON

March 29, 2020

Dear Hospital Administrator:

On behalf of President Trump and the White House Coronavirus Task Force, I want to extend my gratitude for your tireless efforts to provide healthcare to Americans during this unprecedented pandemic. Your hospital is on the frontlines of America's response, each day providing lifesaving treatment for patients. Your efforts are indispensable, and the Trump Administration values them deeply.

The Coronavirus Task Force continues to take aggressive and proactive steps to address the COVID-19 pandemic as the health and safety of the American people remain a top priority. FEMA is coordinating the full Federal response along with the Department of Health and Human Services (HHS) to ensure State, local, tribal, and territorial governments receive the supplies and support they need, including medical supplies. This is truly a whole-of-government response that is Locally executed, State managed, and Federally supported.

As you know, partnership is essential as we work together to address the COVID-19 pandemic. To that end, we are requesting your assistance with reporting data that is critical for epidemiological surveillance and public health decision making. We understand that you may already be reporting to your State, but the data is needed at the federal level to support FEMA and the Centers for Disease Control and Prevention (CDC) in their efforts to support states and localities in addressing and responding to the virus.

At the President's direction, we are requesting that all hospitals report the following information to HHS:

1. COVID-19 Test Result Reporting

- a. We are requesting that all hospitals report data on COVID-19 testing performed in your Academic/University/Hospital "in-house" laboratories. ***If all of your COVID-19 testing is sent out to private labs and performed by one of the commercial laboratories on the list below, you do not need to report using this spreadsheet.***
 - i. ***Commercial laboratories:*** LabCorp, BioReference Laboratories, Quest Diagnostics, Mayo Clinic Laboratories, and ARUP Laboratories.
- b. ***Reporting Instructions:*** We request that all data for COVID-19 testing completed at "in-house" laboratories or a laboratory not listed above be ***reported*** using the attached spreadsheet.



Form to report data

COVID-19 Test Result Reporting:

- Hospital labs asked to report data on COVID-19 testing performed in-house daily by 5:00 PM to HHS at: fema-hscovid-diagnostics-tf@fema.dhs.gov

Date: XXX									
Data Element	New Diagnostic Tests Ordered/Received	Cumulative Diagnostic Tests Ordered/Received	New Tests Resulted	Cumulative Specimens Rejected*	Cumulative Tests Performed	New Positive COVID-19 Tests	Cumulative Positive COVID-19 Tests	Percent Positive among Newly Resulted Tests	Cumulative Percent Positive among Resulted Tests
Definition	<i>Midnight to midnight cutoff, tests ordered on previous date queried</i>	<i>All tests ordered to date.</i>	<i>Midnight to midnight cutoff, test results released on previous date queried</i>	<i>All specimens rejected for testing to date</i>	<i>All tests with results released to date</i>	<i>Midnight to midnight cutoff, positive test results released on previous date queried</i>	<i>All positive test results released to date</i>	<i># of new positive test results released / # of total new tests released for previous date queried</i>	<i># of total positive results to released date / # of total tests results released to date</i>
Enter State									
Enter County									

- CDC is trying to find a way to make this least burdensome on the labs – **stay tuned!**



Requests for Influenza Testing

- Receiving hand-written requests on WSLH Requisition Form A to do influenza testing if negative for COVID-19
- Please **Do Not** request influenza testing!
 - WSLH doesn't offer diagnostic Influenza
 - WSLH only performs Influenza surveillance testing



Listserv



- Please use the WCLN Listserv:
 - Ask general questions
 - Communicate issues to the WSLH
 - Performance issues with testing
 - Communicate with each other
 - Share useful tips
- 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!

