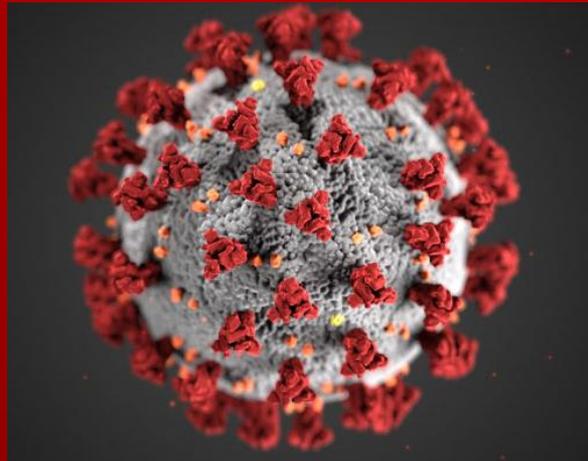


**Wisconsin State
Laboratory of Hygiene**
UNIVERSITY OF WISCONSIN-MADISON



Update on COVID-19 Diagnostic Testing

03-13-20



Dr. Alana Sterkel

PhD, D(ABMM), SM(ASCP)^{CM}

Assistant Director

Communicable Disease Division

Wisconsin State laboratory of Hygiene

Erin Bowles

BS, MT(ASCP)

WCLN Network Coordinator

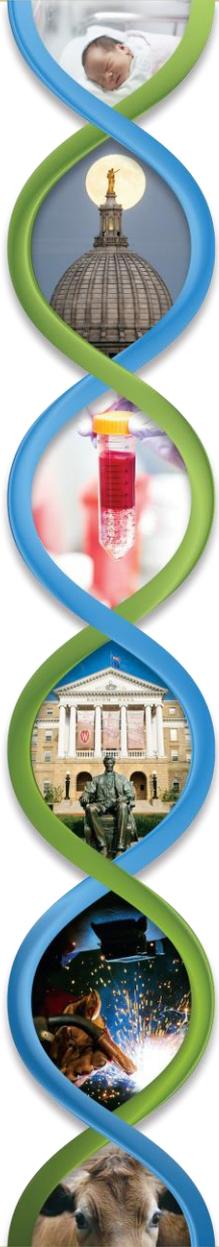
Communicable Disease Division

Wisconsin State laboratory of Hygiene



Contents

- COVID-19 background and current stats
- Efforts to contain the spread
- Testing guidance
- Who's testing
- Lab developed tests
- Testing at WSLH
- Specimen criteria
- Packaging and Shipping
- Result Reporting
- Biosafety
- Q&A





Important!

All of this information is accurate as of now.
Guidance is **rapidly** changing! Please refer to
our website for the latest guidance.

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



Pandemic Declaration

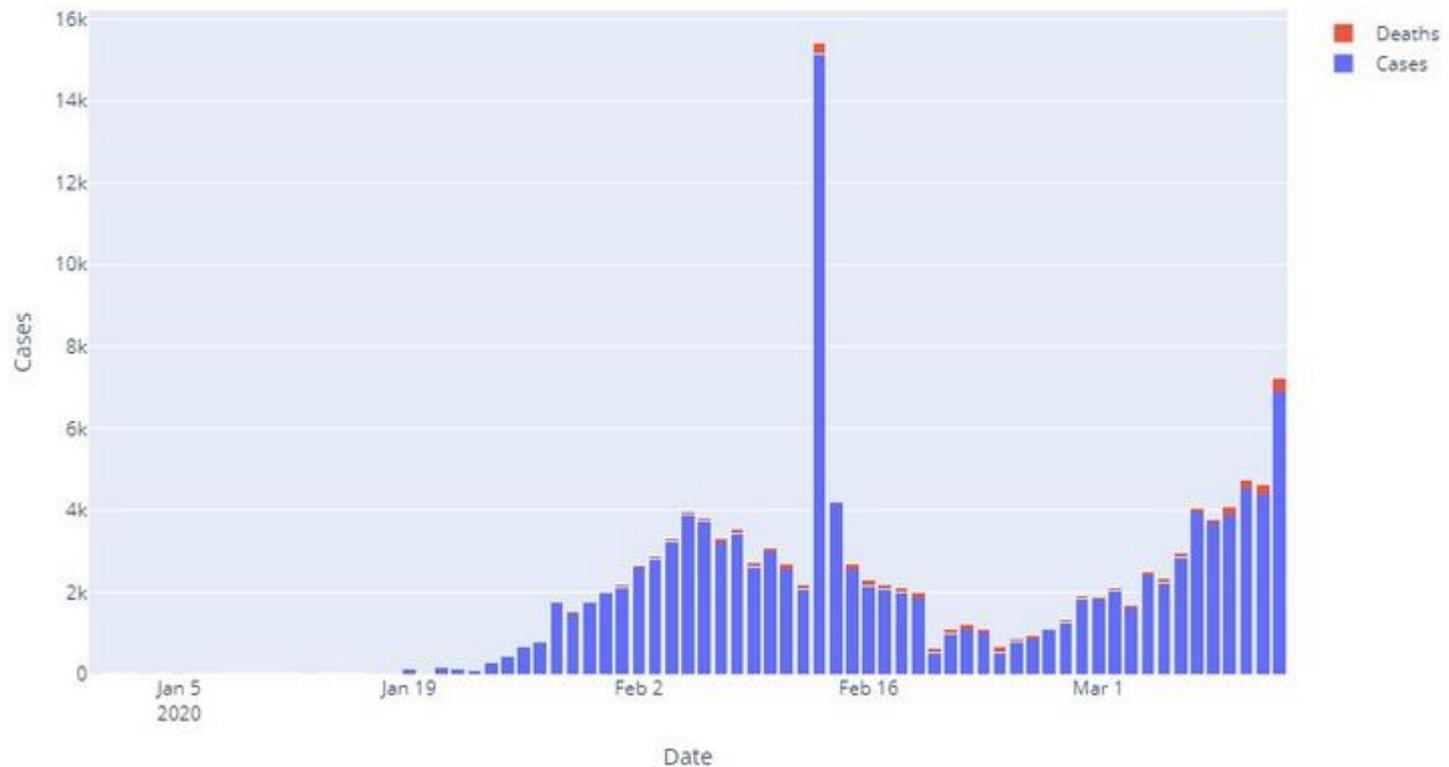
- WHO declares a Pandemic Wednesday
- Wisconsin declares state of emergency yesterday





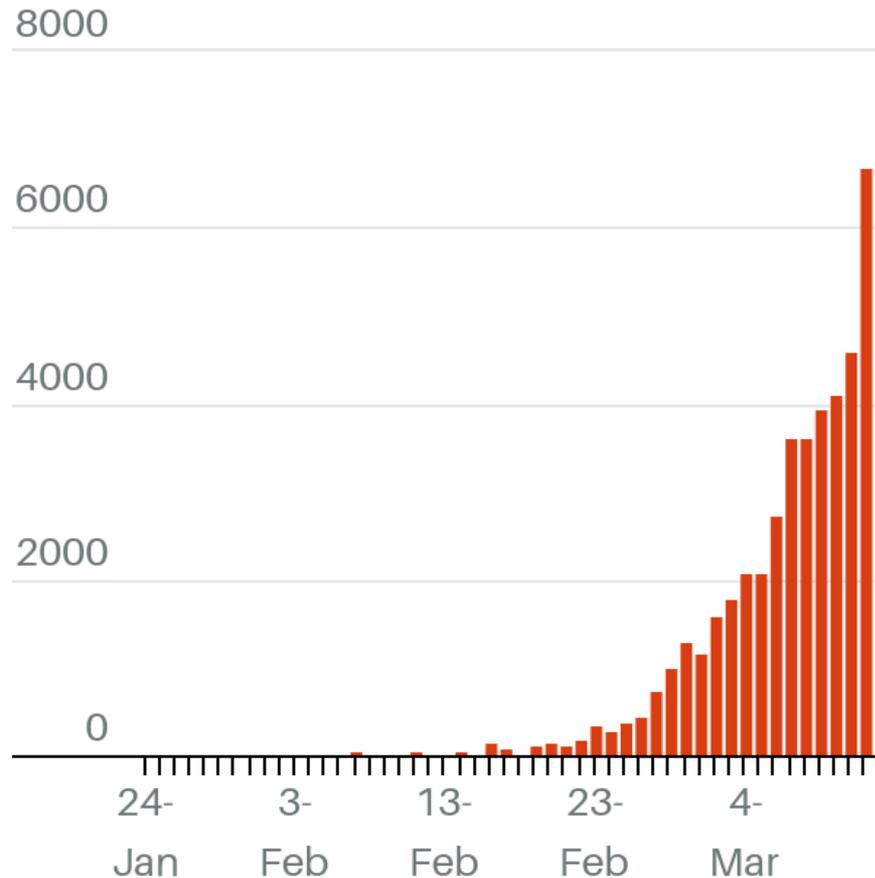
Watching the Pandemic Develop

Daily COVID-19 diagnoses and deaths





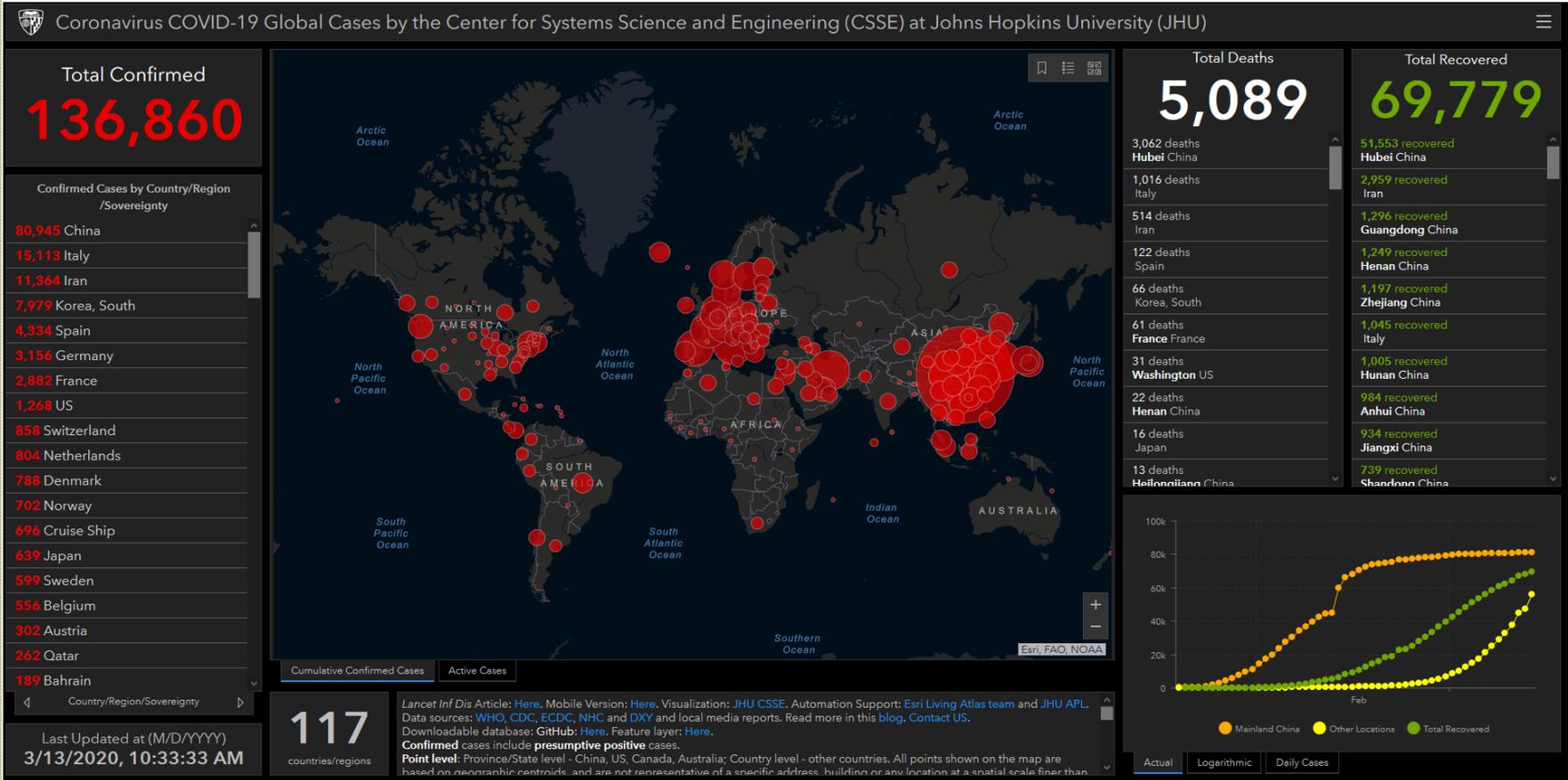
Daily New Coronavirus Cases Reported Outside of China



Source: World Health Organization Situation Reports



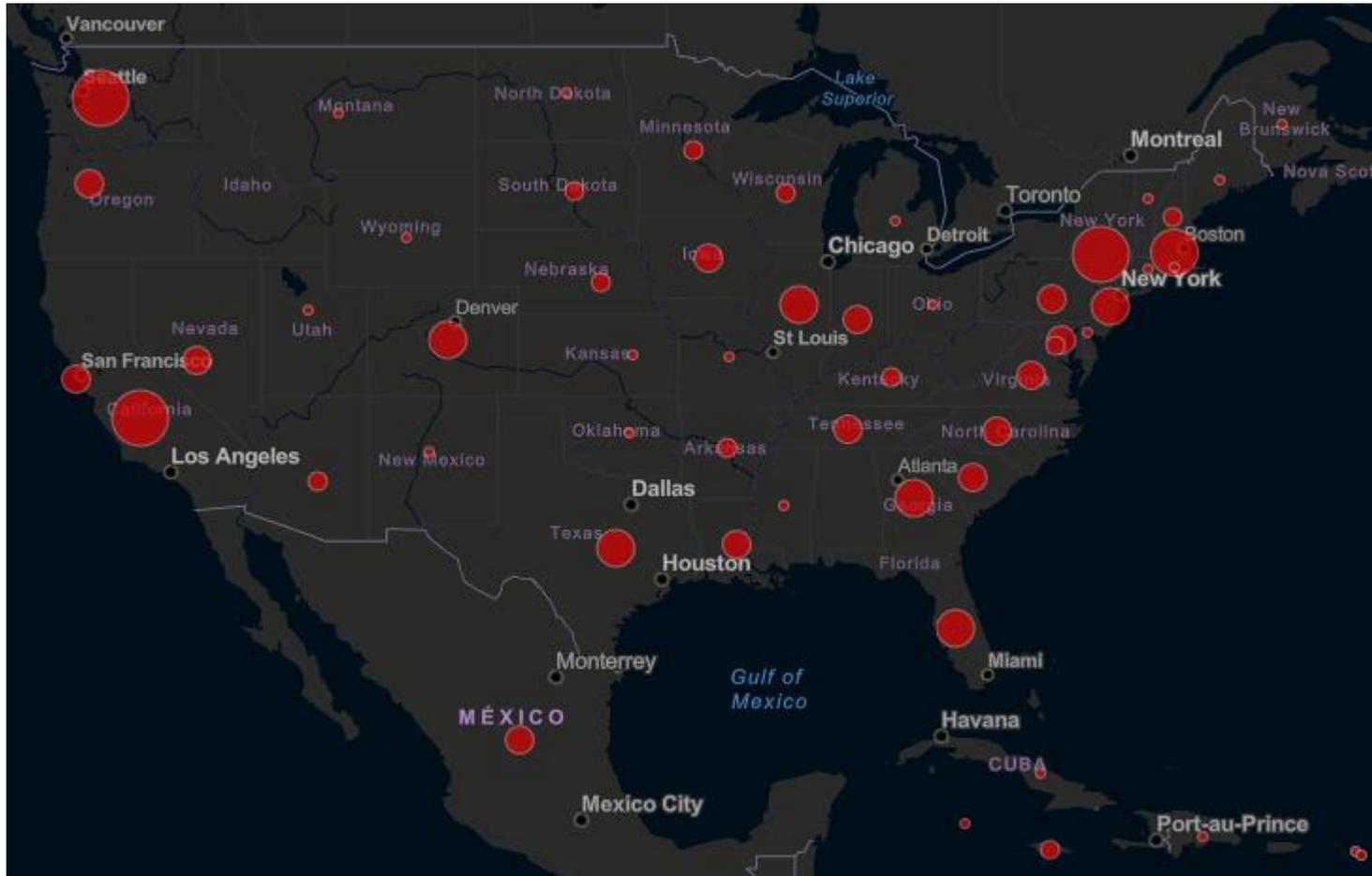
Global Impact



[Johns Hopkins University Global Coronavirus Tracking: https://gisanddata.maps.arcgis.com/apps/opsdashboard/index.html#/bda7594740fd40299423467b48e9ecf6](https://gisanddata.maps.arcgis.com/apps/opsdashboard/index.html#/bda7594740fd40299423467b48e9ecf6)

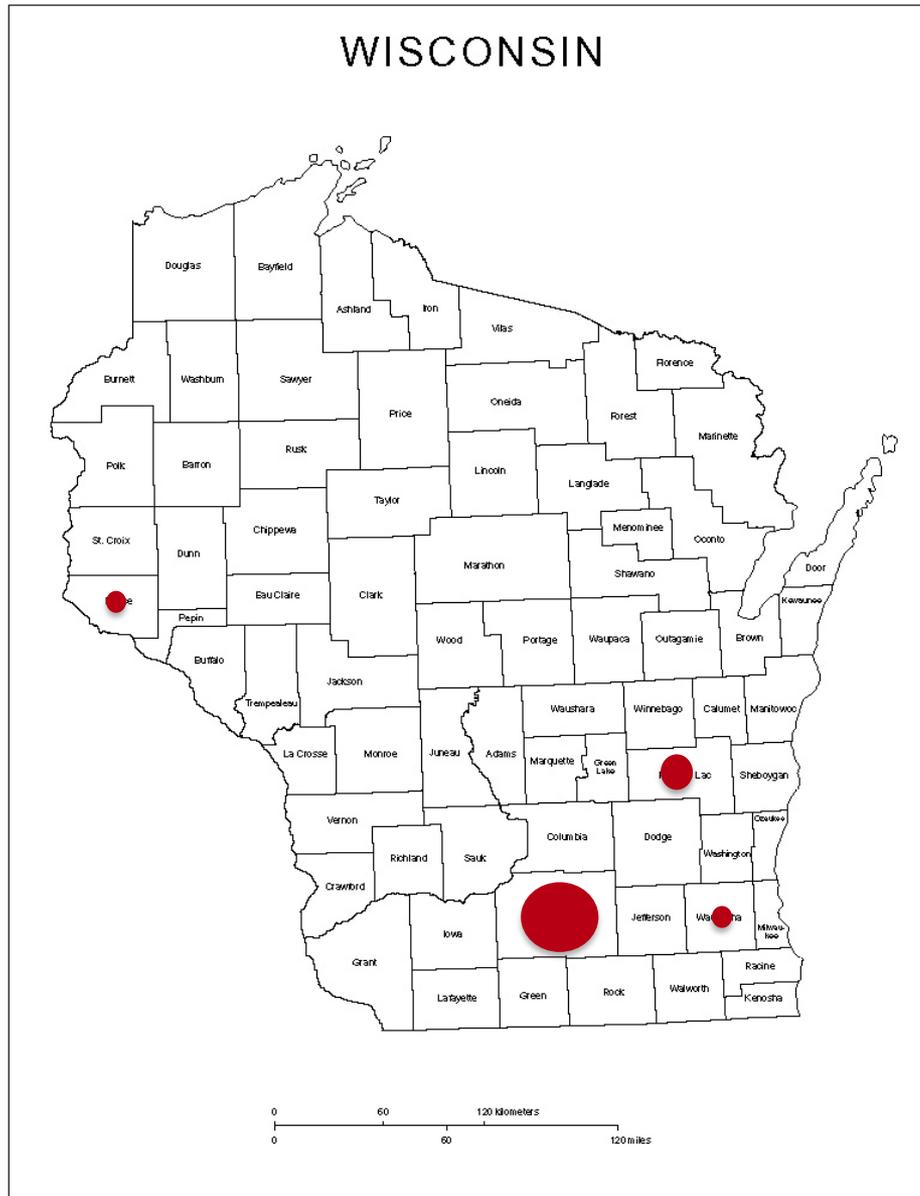


COVID-19 in the US





WISCONSIN





Wisconsin

- 8 people have tested positive in Wisconsin
- 7 in the past week
- 1 from February has recovered

Test Results	Number of People
Negative	84
Positive	7
Positive: Recovered	1

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



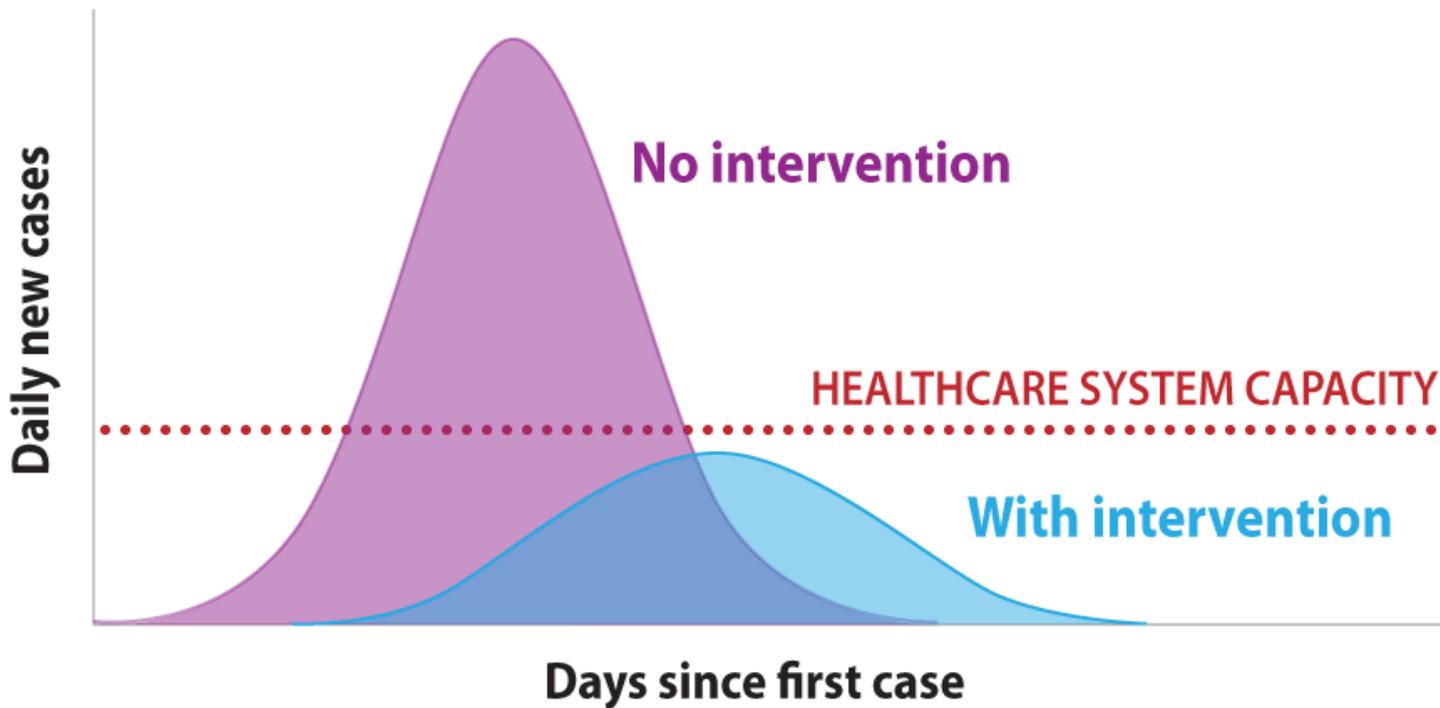
Social Distancing

- DHS recommended canceling events that will draw more than 250 people
- March Sadness (Basketball games cancelled)
- Disney closed
- Non-essential travel discouraged or banned
- Conferences **cancelled**
 - WCLN Technical Conference on April 7th
- Colleges moving to remote learning
- Grade schools closing in other states



FLATTENING THE CURVE

A look at the importance of slowing the spread of a virus, so that the rate of infection doesn't outpace the resources to fight against it.



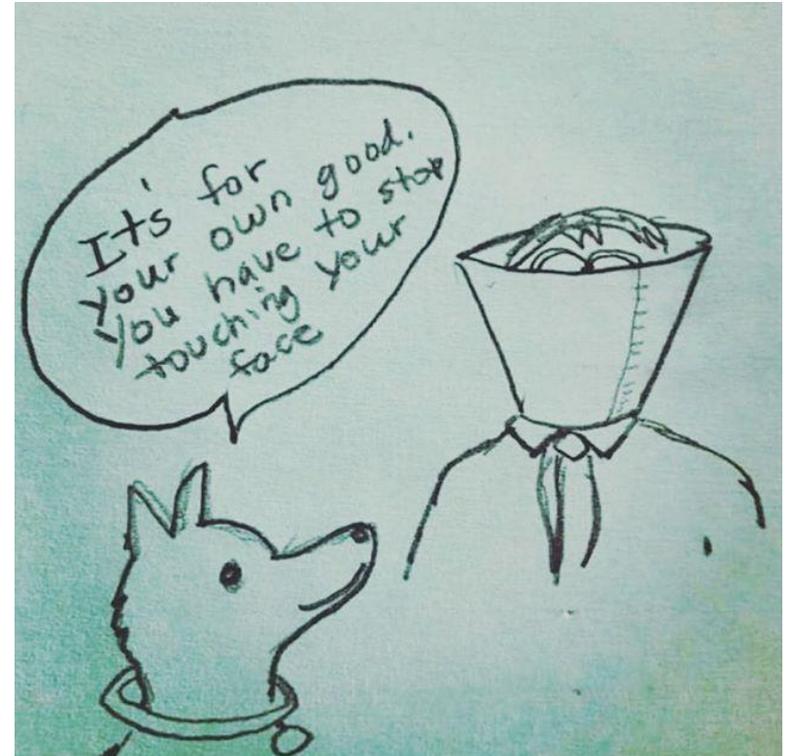
SOURCE: CDC

THE CANADIAN PRESS



What You Can Do

- Regular hand washing
- Don't touch your face
- Foot taps instead of handshakes
- Avoid travel
- Avoid social gatherings





Who should get tested?

- Not everyone with the sniffles!
 - This would overwhelm our healthcare system
- Those who are ill, but not at high risk or in urgent need of care are encouraged to self isolate until symptoms resolve.
 - Don't go to work, school, church, basketball games, or on cruises!

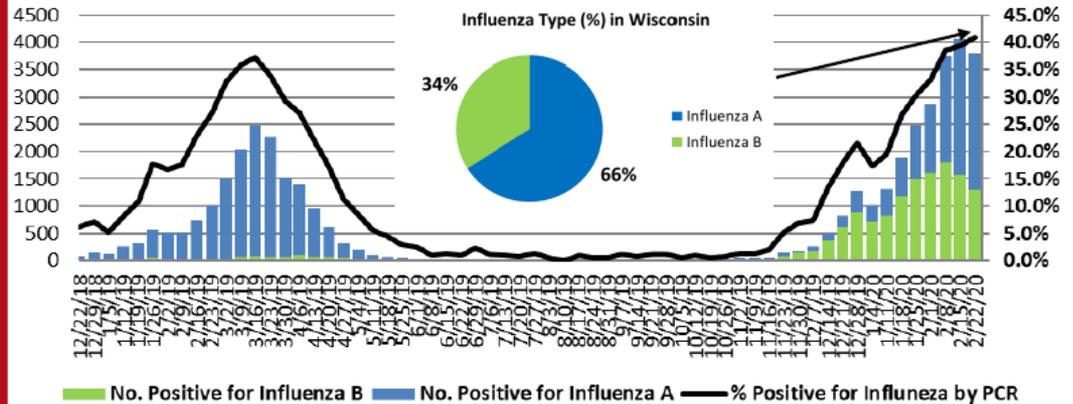


COVID's not the only thing going around

Week Ending February 22, 2020

Resp. Pathogen PCR	# Tested	% Positive
Influenza	9,266	40.8
RSV	2,223	10.3↓
Rinovirus/ Enterovirus	605	8.6
Human metapneumovirus	642	5.5
Adenovirus	43	4.7
Parainfluenza	622	<1
Seasonal coronaviruses	43	0
<i>B. pertussis</i>	415	<1

% Positive for Influenza by PCR (Wisconsin), Week Ending February 22, 2020





Who should get tested?

CDC guidance as of March 9th

- **Hospitalized patients** who have signs and symptoms compatible with COVID-19 in order to inform decisions **related to infection control**.
- Other symptomatic individuals such as, **older adults** and individuals with **chronic medical conditions** and/or an **immunocompromised** state that may put them at higher risk for poor outcomes (e.g., diabetes, heart disease, receiving immunosuppressive medications, chronic lung disease, chronic kidney disease).
- Any persons including healthcare personnel, who within 14 days of **symptom** onset had **close contact** with a suspect or laboratory-confirmed COVID-19 patient, or who have a **history of travel** from affected geographic areas (see below) within 14 days of their symptom onset.



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
 - Quest, LabCorp, ARUP, University of Washington, (Mayo Clinic coming soon)
- Many Clinical Labs bringing on LDTs



Options for testing in your lab

- Test with an FDA EUA assay
 - CDC's EUA test in public health labs only
 - Commercial EUA tests
 - Coming soon, not yet available
 - Promega, Cepheid, Biofire, Thermo-Fisher





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 for LDT
 - Develop your own COVID-19 assay
 - Use CDC's protocol with your own reagents
 - Use Commercial RUO assay (with no EUA)
 - Use a CE Mark assay from overseas



What do you need for an LDT?

- Accuracy
 - 30 positive (Can use spiked samples)
 - 30 negative
- Limit of Detection (LoD)
 - 3 replicates per concentration
 - 20 replicates at the limit (precision)
- Cross Reactivity
 - Test against other common oral flora

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



Testing at WSLH





Can you test at WSLH?

- We can provide COVID-19 testing
- Due to the high volume of testing and limited reagents, please send samples for low risk individuals to commercial labs or test in-house.
- We have expanded our hours to meet the increasing need for testing



Specimens

Recommended:

- **NEW** - Collect NP only and place in a tube of VTM or UTM
 - No calcium alginate swabs or wooden shafts

Additional:

- Both NP and OP swabs placed in a single tube of VTM or UTM
- Patients with productive cough – sputum, BAL, tracheal aspirate

Post-Mortem:

- Both NP and OP swabs placed in a single tube of VTM or UTM
- Bronchial swabs from each lung



Rejection Criteria

The following will be rejected:

- Swab not submitted in VTM liquid (dry swab)
- Specimen without 2 patient identifiers
- Specimen received at room temperature
 - No cold packs or dry ice
- Unfrozen specimen received after 72 hrs. of collection
- Specimen that has totally leaked out of the tube into the secondary container

REJECTED



What Else Do We Need With a Specimen?

The following must accompany the specimen:

- WSLH Requisition Form A – Needed by WSLH
 - Write COVID-19 in the “Other”
 - Write the indicators for priority testing in the “Other” section
- PUI Form – Needed by CDC
 - Helps the WSLH prioritize specimen testing

Enter into WEDSS: Reportable Condition

- Electronically, or Manually
- Required by State Statute



Storage

- If it 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





Transport

Gold Cross Courier:

- Provided free by WSLH
- M-F must call by noon for pick-up that day with delivery the following day
- No pick up on Sat. or Sun. unless scheduled by WSLH for urgent specimens requested by WDPH
 - **DO NOT CALL GOLD CROSS FOR A STAT PICK-UP**
- If you miss the noon cut-off for pick-up on Friday, you will need to freeze specimen and order a pick-up for Monday with delivery on Tuesday
- **You can utilize other commercial or in-house courier or delivery service at your expense**
 - WSLH only open for receipt of specimens Sat. until 12:30 PM
 - WSLH not open for receipt of specimens Sun.



Packaging

Package as UN3373 Biological Substance, Category B:

- Must be triple packaged
- Primary container - make sure cap is on straight and is shut tight
- Secondary container (sealed biohazard bag) must be leak proof and sift proof
 - Must be 95kPA if shipping by air
 - Cushioning and absorbent must be inside
 - **Do not** place paperwork inside with specimen
 - If shipping multiple specimens, bag each separately
- Tertiary outer container must be rigid
 - Place paperwork in outer container
 - Can submit multiple specimens in container



Labeling

Package as UN3373 Biological Substance, Category B:

- Must have UN3373 label
- Must have proper shipping name: Biological Substance, Category B
 - **DO NOT** write suspect or possible COVID-19
- If shipping on dry ice, must have UN 1845 dry ice label
 - Must write dry ice and the # of lbs. of dry ice in the box
- Must have name and phone of responsible person
 - Person must be available during normal business hours
 - This is who will be called if a problem with the package during transport
- Must have shipper and consignee addresses.
- **DO NOT** tape all the edges of the box to totally seal it



Reporting Results

- **The WSLH will call all positive results as they are considered a critical value :**
 - Called to the submitting laboratory
 - Submitting laboratory is responsible for notifying the clinician
 - Called to WDPH
 - WDPH will notify the local jurisdiction
- **Negative results**
 - Are automatically entered into WEDSS
 - Are reported to the submitting lab as per your usual method or receiving result from the WSLH
- **Available within 1-2 business days of receipt**
- **Please limit calls for results if possible**



Contacting the WSLH

You can help us by using the appropriate method to contact us.

- WSLH Customer Service: 800-862-1013
 - Use for questions, results, M-F 7:45 AM – 4:30 PM
- WSLH Supplies: 800-862-1088
 - Use to order collection supplies or WSLH requisition Form A
- WSLH Emergency Pager: 608-263-3280
 - Use for emergencies after hours, weekends, and holidays. (e.g. Possible terrorism event, DPH approved urgent transport)



Biosafety Considerations

Need to do your own risk assessment:

- Identify hazards – not just micro but entire lab
 - Assess the facility design,
 - Assess the testing you are performing
 - Assess the people performing the testing
 - Determine likelihood and consequences of hazards
- Determine level of risk are you comfortable with
- Determine and implement mitigation steps to lower risk to the acceptable level
- Continually re-assess and make adjustments



Biosafety Guidance

CDC Interim Laboratory Biosafety Guidelines

- <https://www.cdc.gov/coronavirus/2019-nCoV/lab/lab-biosafety-guidelines.html>

Specimen Collection:

- Standard precautions: gloves, lab coat, eye protection,
- Droplet isolation: N95 respirator, closed front gown, double gloves

Specimen Processing & Testing:

- Work in a certified biosafety cabinet – especially for aerosols
- Use covered centrifuge buckets – load and unload in a BSC
- For procedure outside a BSC use eye and face protection (mask, goggles/safety glasses, face shield) and other physical barriers (splash shield)
- Use EPA registered disinfectants effective against coronaviruses
- Follow routine practices and procedures for management of laboratory waste.



Please Type Your Questions in the
Question Box!

