Update on COVID-19 Diagnostic Testing

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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

- Cases
- Deaths

Date:
- Jan 5, 2020
- Jan 19
- Feb 2
- Feb 16
- Mar 1
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
COVID-19 in the US
Wisconsin

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

Wisconsin COVID-19 Test Results

<table>
<thead>
<tr>
<th>Test Results</th>
<th>Number of People</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative</td>
<td>84</td>
</tr>
<tr>
<td>Positive</td>
<td>7</td>
</tr>
<tr>
<td>Positive: Recovered</td>
<td>1</td>
</tr>
</tbody>
</table>

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.
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

<table>
<thead>
<tr>
<th>Resp. Pathogen PCR</th>
<th># Tested</th>
<th>% Positive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Influenza</td>
<td>9,266</td>
<td>40.8</td>
</tr>
<tr>
<td>RSV</td>
<td>2,223</td>
<td>10.3 ↓</td>
</tr>
<tr>
<td>Rinovirus/ Enterovirus</td>
<td>605</td>
<td>8.6</td>
</tr>
<tr>
<td>Human metapneumovirus</td>
<td>642</td>
<td>5.5</td>
</tr>
<tr>
<td>Adenovirus</td>
<td>43</td>
<td>4.7</td>
</tr>
<tr>
<td>Parainfluenza</td>
<td>622</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Seasonal coronaviruses</td>
<td>43</td>
<td>0</td>
</tr>
<tr>
<td>B. pertussis</td>
<td>415</td>
<td>&lt;1</td>
</tr>
</tbody>
</table>
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](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](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


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!