Update on COVID-19 Diagnostic Testing
06-24-20

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• Situation Update
• Abbott ID NOW survey
• FDA EUA updates
• WSLH Testing update
• SEOC supplies
• Reporting
• Q and A
Notice

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/

The WSLH does not endorse products of any kind
NORMAL PEOPLE WHEN SICK

PEOPLE WITH CORONAVIRUS: I AM GOING ON AN ADVENTURE
Global Impact

Johns Hopkins University Global Coronavirus Tracking:
https://gisanddata.maps.arcgis.com/apps/opsdashboard/index.html#/bda7594740fd40299423467b48e9ecf6
New hot spots

https://ourworldindata.org/grapher/biweekly-growth-covid-cases
### Coronavirus death estimate vs. other causes of death

<table>
<thead>
<tr>
<th>Cause</th>
<th>Estimated Deaths</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart disease</td>
<td>647,457</td>
</tr>
<tr>
<td>Cancer</td>
<td>599,108</td>
</tr>
<tr>
<td>Coronavirus deaths (Trump est.)</td>
<td>100,000 - 240,000 (est.)</td>
</tr>
<tr>
<td>Accidents (unintentional injuries)</td>
<td>169,936</td>
</tr>
<tr>
<td>Chronic lower respiratory diseases</td>
<td>160,201</td>
</tr>
<tr>
<td>Stroke (cerebrovascular diseases)</td>
<td>146,383</td>
</tr>
<tr>
<td>Alzheimer’s disease</td>
<td>121,404</td>
</tr>
<tr>
<td>Diabetes</td>
<td>83,564</td>
</tr>
<tr>
<td>Influenza/Pneumonia</td>
<td>55,672</td>
</tr>
<tr>
<td>Nephritis, nephrotic syndrome and..</td>
<td>50,633</td>
</tr>
<tr>
<td>Intentional self-harm (suicide)</td>
<td>47,173</td>
</tr>
<tr>
<td>Opioid overdose deaths</td>
<td>46,802</td>
</tr>
<tr>
<td>Traffic deaths</td>
<td>36,560</td>
</tr>
<tr>
<td>Hurricane Katrina</td>
<td>1,883</td>
</tr>
</tbody>
</table>

Source: CDC, NOAA, White House
Fatality rate

Case fatality rate of COVID-19 vs. Median Age, Jun 23, 2020

The Case Fatality Rate (CFR) is the ratio between confirmed deaths and confirmed cases. During an outbreak of a pandemic, the CFR is a poor measure of the mortality risk of the disease. We explain this in detail at OurWorldInData.org/Coronavirus. The size of the bubble corresponds to the total confirmed deaths up to that date.

COVID-19 in the US

1.5 M more cases, 20,000 more deaths
US Cases per capita

Daily case reports- US
US Hot Spots

How the number of new cases has changed in the last two weeks

- Falling
- About the same
- Rising
- Few or no cases


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New US Hot Spots

- Texas
- Arizona
- Utah
- Florida
- North Carolina
- California
Wisconsin
Wisconsin Daily Cases

[Graph showing new confirmed COVID-19 cases by date confirmed, and 7-day average]

Mobility rate

https://www.dhs.wisconsin.gov/covid-19/data.htm
WI mobility data

White House report 6/23/20
Wisconsin

**Updated: 6/23/20**

| Negative Test Results | 478,165 |
| Positive Test Results | 25,331 |
| Hospitalizations      | 3,268  |
| Deaths                | 750    |

Δ277,291
Δ9,468
Δ906
Δ233

Percent of Cases Resulting in Hospitalization: 13%
Percent of Cases Resulting in Death: 3%

Cumulative total confirmed COVID-19 cases by date confirmed

https://www.dhs.wisconsin.gov/outbreaks/index.htm
SEOC Survey

PLEASE, Update the SEOC Survey!

- Start testing
- Change in testing methods
- Change in capacity
- To report a supply shortage
- To remove a report of a supply shortage
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https://bi.wisconsin.gov/t/COVID19_Analytics/views/LabDashboards/TestingMethods?origin=card_share_link&embed=y&isGuestRedirectFromVizportal=y
Wisconsin COVID-19 Testing Laboratories

- **Laboratories actively testing**: 68
- **Laboratories planning to test**: 26
- **Current state capacity (tests/day)**: 18,355

COVID-19 Lab Participation Rate Over Time
(last updated 6/23/2020 6:00:44 PM
updated every 15 minutes)

Data collected by voluntary reporting from public, private, and commercial laboratories in Wisconsin. All data are estimates and do not reflect actual number of tests performed in the state. Capacity is dependent on availability of test supplies and adequate staffing.

https://bi.wisconsin.gov/t/COVID19_Analytics/views/LabDashboards/PublicDashboardLabs?isGuestRedirectFromVizportal=y&embed=y
COVID-19 Testing

>500,000 total tests


*Not all labs reporting

>28,000,000 total tests

Tests/1000 people

https://ourworldindata.org/grapher/full-list-cumulative-total-tests-per-thousand
Community Test Sites

- Many locations across the state
- If your healthcare system would like to be on the map go to the website to fill out a short survey

https://www.dhs.wisconsin.gov/covid-19/testing.htm
False Positives

- Can happen to anybody
- Common causes: contamination, sample mix up, test variability
- Monitor:
  - Negative controls
  - Performing wipe tests to check for contamination
  - Monitor for clusters (high pos next to low pos)
  - Quality checks in automated systems
- Actions:
  - Re-test from the original specimen
  - If issue is identified, consider re-testing every specimen within a run
  - Follow-up with clinician/patient
FDA updates

- **85 Molecular tests**
  - 9 EUAs with Home collection
  - 4 can be done with a CLIA waiver
- **37 LDTs**
  - 100’s submitted
- **21 Serology tests**
- **1 Antigen test**

Cue COVID-19 Test

“Lab in a box”
- CLIA Waived
- 25 minutes
- Direct nasal swab (no VTM)
- Results and instructions on your cellphone
- Currently requires supervision by a medical professional

- LOD 20 copies/swab

<table>
<thead>
<tr>
<th>Institutional Standard of Care EUA SARS-CoV-2 Test</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<tr>
<td>Cue COVID-19 Test</td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

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New kind of COVID test

Illumina receives first EUA for a sequencing-based COVID-19 diagnostic test

- Current EUA is for use with specimen that have been manually extracted with Qiagen spin columns
- Only on the NovaSeq
- Could test 3072 samples at once and provide sequence
- High complexity
- LOD 1 copy/uL

<table>
<thead>
<tr>
<th>EUA RT-PCR Comparator</th>
<th>Positive</th>
<th>Negative</th>
<th>Invalid</th>
<th>% agreement (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>53</td>
<td>1⁴</td>
<td>0</td>
<td>98.1% (90.2-99.7%)</td>
</tr>
<tr>
<td>Negative</td>
<td>1⁴</td>
<td>38</td>
<td>1²</td>
<td>97.4% (86.8-99.5%)</td>
</tr>
</tbody>
</table>

⁴ Root cause analysis revealed labeling error.
² One invalid specimen was excluded from analysis.
EUA Revoked

The FDA recently announced that the Chembio DPP™ COVID-19 IgM/IgG System SARS-CoV-2 antibody test no longer has Emergency Use Authorization (EUA).

“due to performance concerns with the accuracy of the test”

Patients tested by WSLH

• Public Health Investigations as directed by state or local public health (includes Outbreaks)
• Hospitalized patient with COVID-19 symptoms
• Patient with COVID-19 symptoms for whom rapid diagnosis is needed to inform infection control practices (e.g. labor and delivery, dialysis, aerosol-generating procedures, etc.)
• Resident of a long-term care facility with COVID-19 symptoms
• Resident in a jail, prison, or other congregate setting with COVID-19 symptoms
• Health care worker or first Responder (e.g. fire, EMS, police) with COVID-19 symptoms
• Essential staff in high consequence congregate settings (e.g. prisons or jails) with COVID-19 symptoms
• Utility workers (water, sewer, gas, electric, power, distribution of raw materials, oil and biofuel refining) with COVID-19 symptoms
• Underserved populations with poor access to testing (e.g., underinsured, patients at Federally Qualified Health Centers, homeless patients, migrant workers, etc.) with COVID-19 symptoms
• Post-mortem testing for a person with COVID-19 symptoms prior to death who died of unknown causes and where results would influence infection control interventions at a facility or inform a public health response

*All testing for COVID-19 is fee exempt at WSLH
Acceptable Specimen Types

- **Recommended:** Nasopharyngeal (NP) swab in viral transport media (VTM)
- Oropharyngeal (OP) swabs in VTM
- Sputum or other lower respiratory specimen such as bronchoalveolar lavage (BAL) or aspirate. (Induction of sputum is not indicated) (Does not need VTM)
- Nasal swabs in VTM are acceptable if no other specimen types are available.
- For postmortem testing, collect an NP swab in viral transport media (VTM). If autopsy is performed also swab the bronchioles of each lung and place in a single VTM tube.

*If VTM is unavailable UTM, Amies, or sterile RNAse free Saline or PBS may be substituted.

**Collection Kits and shipping supplies available for free from WSLH or SEOC (large orders)**
[https://covid19supplies.wi.gov/Testing](https://covid19supplies.wi.gov/Testing)

*PIF no longer required for submission*
Future Testing Changes at WSLH

• Planning to bring on a COVID/Flu multiplex in preparation for the coming flu season
  • We will use a new CDC multiplex assay
  • COVID-19/Flu tests in development on several platforms including BioFire, Cepheid, others
• Panther TMA
• Cepheid GeneXpert
Resources

Contact Information:
CDD Customer Service: 1-800-862-1013
Clinical Orders: 1-800-862-1088
Emergency Pager: 1-608-263-3280
Gold Cross Courier: 1-715-839-9989

Free Gold Cross Courier
Order by NOON for same-day pick-up for NEXT DAY delivery (7 days a week)

CDD Customer Service Hours:
• Monday-Friday: 7:45 AM – 4:30 PM
• Saturday: 7:45 AM - 12:30 PM

CDD Specimen Receiving Hours:
• Monday-Friday: 6:00 AM – 4:30 PM
• Saturday: 6:30 AM - 12:30 PM
• Sunday: 9:00 AM - 12:30 PM

Results
• Results reported within 48 hours of receipt in the lab to the submitter and WEDSS
• All positives phoned to the submitter immediately

WSLH COVID-19 Website
http://www.slh.wisc.edu/clinical/diseases/covid-19/
SEOC Supplies

- Allocation to all states by FEMA
- Not all supplies are usable
  - Primestore MTM (Cyanide gas)
  - FillaKit PBS (Non-sterile production)
- Some supplies available to order on the Web portal (nasal swabs)
- Mix of supplies too variable for the web portal (saline and nasal swabs)
  - Look for a WCLN message next week with order options
Local Collection Kits

Stable stored at room temp for 12 weeks and counting!

Package inserts for WVDL and Gentueri updated on WSLH webpage
New Survey – Abbott ID NOW

- The Wisconsin SEOC has put together a survey to learn about how Abbott ID NOW testing is being used.
- The SEOC has been allocated a limited number of Abbott ID NOW COVID-19 test reagents. They would like to distribute these reagents as equitably as possible to interested laboratories that have the ID NOW instrument.
- If you use this platform, please complete this survey as fully as possible whether you want to receive test kits or not.
- Completion of the survey does not guarantee your laboratory will receive these supplies.
- The number of test reagents distributed is dependent on how many laboratories express interest.
- You may not charge anyone for these test reagents.
- Supplies are very limited and it is unknown if Wisconsin will receive further allotments.
- Complete by this Friday (6/26/20)

Short duration of immunity after SARS-CoV-2 infection?

IgG levels and neutralizing antibodies in a high proportion of individuals who recovered from SARS-CoV-2 infection start to decrease within 2–3 months after infection.

https://www.nature.com/articles/s41591-020-0965-6.pdf
July 4\textsuperscript{th} Holiday Observance

Please note the following plans for our hours of operation for WSLH CDD Specimen Receipt and Customer Service. \textbf{WSLH is observing the holiday on Sunday, July 5\textsuperscript{th} and will be closed.}

<table>
<thead>
<tr>
<th>DATE</th>
<th>WSLH CDD 2601 Agriculture Drive Specimen Receiving</th>
<th>WSLH CDD 2601 Agriculture Drive Customer Service</th>
<th>Gold Cross Transport</th>
</tr>
</thead>
<tbody>
<tr>
<td>Friday, July 3, 2020</td>
<td>6:00 AM – 4:30 PM</td>
<td>7:45 AM – 4:30 PM</td>
<td>Schedule Friday by noon for Friday pick-up with Saturday delivery</td>
</tr>
<tr>
<td>Saturday, July 4, 2020</td>
<td>6:30 AM – 12:30 PM</td>
<td>7:45 AM – 12:30 PM</td>
<td>Schedule Saturday by noon for Saturday pick-up with Monday delivery</td>
</tr>
<tr>
<td>Sunday, July 5, 2020</td>
<td>CLOSED</td>
<td>CLOSED</td>
<td>Schedule Sunday by noon for Sunday pick-up with Monday delivery</td>
</tr>
<tr>
<td>Monday, July 6, 2020</td>
<td>6:00 AM – 4:30 PM</td>
<td>7:45 AM – 4:30 PM</td>
<td>Schedule Monday by noon for Monday pick-up with Tuesday delivery</td>
</tr>
</tbody>
</table>
New - DHS COVID-19 Activity Level Data Dashboard

Consists of maps and tables that toggle between counties and Healthcare Emergency Readiness Coalition (HERC) regions.

https://www.dhs.wisconsin.gov/covid-19/local.htm
Reporting COVID-19 Results

NAAT Testing:

- **WEDSS** - Report all COVID-19 test results (positives and negatives) via ELR or WLR
- **WCLN Surveillance Data** - Report weekly the total number of positives and total number tested.
  - Combine numbers of COVID-19 testing performed in-house with numbers of COVID-19 testing performed at out-of-state reference lab
  - **Do not** include testing sent to in-state reference lab (e.g. Exact Sciences)
  - In-state reference labs report directly
Reporting COVID-19 Results

Antibody Testing:

- **WEDSS** - Report **only positive** COVID-19 test results via ELR or WLR
- **WCLN Surveillance Data** - Report weekly the total number of positives and total number tested.
  - Combine numbers of COVID-19 testing performed in-house with numbers of COVID-19 testing performed at out-of-state reference lab
  - **Do not** include testing sent to in-state reference lab (e.g. Exact Sciences)
  - In-state reference labs report directly
How to Ensure Your Specimen is Delivered to the WSLH

• Determine to which laboratory you are submitting testing
  • If planning to collect and submit more than 100 specimens at one time, please notify WSLH in advance

• Confirm the delivery location with Gold Cross dispatch when you call for a pick-up.
  • If you have specimens for both WSLH and Exact Sciences, confirm that with Gold Cross.

• DO NOT package specimens for WSLH and Exact Sciences together in the same package
  • Packaging specimens together results in testing delays while specimens are redelivered to the correct testing lab.

• Confirm with the courier who picks up the packages where they are delivering your packages
How to Ensure Your Specimen is Delivered to the WSLH (cont.)

Packaging:

• Follow instructions for shipping *Packaging and Shipping Biological Substance, Category B Specimens* pictorial guidance document
  - Must triple package and use a shipper with a rigid outer container
  - Gold Cross *won’t accept* specimens for the WSLH packaged only in a biohazard bag to put in a cooler
• If specimen is for WSLH, remove or cover any labels, waybills, etc. that say Exact Sciences on the shipper.
• Package specimens for Exact Sciences per their direction
  - Currently, Gold Cross will accept a specimen in a biohazard bag to put into a cooler
How to Ensure Your Specimen is Delivered to the WSLH (cont.)

Labeling:

- UN3373 Biological Substance, Category B label
- Dry ice label (if shipping on dry ice)
- Clearly address the package to:
  Wisconsin State Laboratory of Hygiene
  Communicable Disease Division
  2601 Agriculture Dr.
  Madison, WI 53718
- The submitter information must include:
  Your laboratory name
  Your laboratory address
  Emergency contact name (knowledgeable about the contents)
  Emergency contact phone number (answered during normal business hours)
New HHS Reporting Requirements

• June 4, 2020 HHS announce new guidance that specifies what additional data must be reported to HHS by laboratories by 8/1/2020

• Changes are due to concern that COVID-19 is having a disproportionate impact on certain demographics including racial minorities and older Americans

• Mary Wedig is working with CDC and APHL to get further guidance on what additional data testing laboratories will have to provide into WEDSS via ELR or WLR.

• WSLH will notify labs what modifications need to be made once we receive further clarification.

• Contact mary.wedig@slh.wisc.edu with questions.
Moving to As Needed COVID-19 Webinars

Information is not changing as rapidly as it was at the beginning of the COVID-19 pandemic and we want to respect your time. We understand that laboratory testing is picking up and it is more difficult to make time for a webinar, therefore, we will only hold future COVID-19 webinars when we have important information, or there are significant changes we need to share with you.
Please Type Your Questions in the Question Box!