Update on COVID-19 Diagnostic Testing

04-01-20

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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/
Time spent looking at exponential graphs

Month of 2020

January
February
March
Cumulative Time spent looking at exponential graphs

Month of 2020

January February March April May
Global Impact

Johns Hopkins University Global Coronavirus Tracking: https://gisanddata.maps.arcgis.com/apps/opsdashboard/index.html#bda7594740fd40299423467b48e9ecf6
COVID-19 in the US
Wisconsin

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

Flu vs COVID-19 death rate, by age

Source: Centers for Disease Control and Prevention (CDC), Chinese Center for Disease Control and Prevention
Why some countries have a higher death rate

[Charts and graphs showing population pyramids and projected fatal COVID-19 cases for different countries.]
Adapted from CDC / The Economist
Distancing Works!

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

Influenza Type (%) in Wisconsin

- 25%
- 75%

No. Positive for Influenza B  No. Positive for Influenza A  % Positive for Influenza by PCR
New Priority Form

**PLEASE SELECT ALL THAT APPLY BELOW TO DETERMINE TEST PRIORITY**

<table>
<thead>
<tr>
<th>TIER ONE:</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Patients who are critically ill and receiving ICU level care with unexplained viral pneumonia or respiratory failure</td>
</tr>
<tr>
<td>-OR-</td>
</tr>
<tr>
<td>□ 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.</td>
</tr>
<tr>
<td>-OR-</td>
</tr>
<tr>
<td>□ 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</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>TIER TWO:</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Hospitalized (non-ICU) patients with unexplained fever AND signs/symptoms of acute respiratory illness</td>
</tr>
<tr>
<td>-OR-</td>
</tr>
<tr>
<td>□ Health care workers or first responders with unexplained fever AND signs/symptoms of acute respiratory illness, regardless of hospitalization</td>
</tr>
<tr>
<td>-OR-</td>
</tr>
<tr>
<td>□ Essential staff in high consequence congregate settings (e.g. correctional officers) with unexplained fever AND signs/symptoms of acute respiratory illness, regardless of hospitalization</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>TIER THREE: TESTING OF TIER THREE SPECIMENS WILL NOT BE PERFORMED AT WSLH OR MHDL</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ 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 &gt;50, immunocompromised hosts among others</td>
</tr>
<tr>
<td>-OR-</td>
</tr>
<tr>
<td>□ Health care workers with acute respiratory symptoms (e.g. rhinorhea, congestion, sore throat, cough) without fever</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>TIER FOUR: TESTING OF TIER FOUR SPECIMENS WILL NOT BE PERFORMED AT WSLH OR MHDL</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Other patients, as directed by public health or infection control authorities (e.g. community surveillance or public health investigations)</td>
</tr>
</tbody>
</table>

**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
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 publicly 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
What it asks
What it asks
### What it asks

**Do you have a backlog of tests?**

- NO
- YES
- NO
What it asks
What it asks

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?

Current Capacity (tests per day)

Available
- Accula
- Aries
- BDMax
- BioFire
- Cobas
- Diascorin
- easyMAG
- eMax
- GeneXpert

Other testing methods?

Future Capacity (tests per day)

Available
- Accula
- Aries
- BDMax
- BioFire
- Cobas
- Diascorin
- easyMAG
- eMax
- EZ1
- MagnaPure LC
- Manual Extraction
- QiaCube

Future test methods (choose all that apply)

Available
- easyMAG
- GeneXpert
- KingFisher
- Panther Fusion

Choose
- EZ1
- EZ2
- MagnaPure LC
- Manual Extraction
- QiaCube

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**
- **YES**
  - **NO**

**Current Capacity (tests per day)**

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

<table>
<thead>
<tr>
<th>Available</th>
<th>Chosen</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accula</td>
<td>EMAG</td>
</tr>
<tr>
<td>Aries</td>
<td>EZ1</td>
</tr>
<tr>
<td>BDMax</td>
<td>MagnaPure LC</td>
</tr>
<tr>
<td>BioFire</td>
<td>Manual Extraction</td>
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<tr>
<td>Cobas</td>
<td>Qiacube</td>
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<tr>
<td>Diasorin</td>
<td></td>
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<tr>
<td>easyMAG</td>
<td></td>
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<tr>
<td>ePlex</td>
<td></td>
</tr>
<tr>
<td>GeneXpert</td>
<td></td>
</tr>
</tbody>
</table>

**Other testing methods?**

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**Wisconsin State Laboratory of Hygiene - University of Wisconsin**
What it asks
What it asks
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

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.)
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)
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)

*6 new since last week


WISCONSIN STATE LABORATORY OF HYGIENE - UNIVERSITY OF WISCONSIN
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.)
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.)
- **QIAsstat-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

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-hhscovid-diagnostics-tf@fema.dhs.gov

• 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!