Update on COVID-19 Diagnostic Testing
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Contents

• Update on current cases
• Change is test prioritization
• Start performing COVID-19 testing in your lab
• 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/
Watching the Pandemic Develop
Global Impact

Johns Hopkins University Global Coronavirus Tracking:
https://gisanddata.maps.arcgis.com/apps/opsdashboard/index.html#/bda7594740fd40299423467b48e9ecf6
COVID-19 in the US
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>1038</td>
</tr>
<tr>
<td>Positive</td>
<td>72</td>
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</table>

https://www.dhs.wisconsin.gov/outbreaks/index.htm
Social Distancing

- Gatherings of 10 or more people prohibited
- Non-essential travel discouraged or banned
- Many employees working from home
- Colleges moving to remote learning for whole semester
- Schools closed
Samples for Testing

- **Recommended**: NP swab alone in VTM
  - If VTM is unavailable UTM, Amies, or RNAse free Saline may be substituted.
- NP/OP swabs, with both swabs placed in a single tube of VTM
  - If VTM is unavailable UTM, Amies, or RNAse free Saline may be substituted
- Sputum or other lower respiratory specimen such as bronchoalveolar lavage or aspirate. (Induction of sputum is not indicated)
  - Does not need VTM
- Postmortem- combined NP/OP described above and bronchial swabs if autopsy is performed. Follow CDC Postmortem testing guidance. (Not in triage list, call DHS for approval)

Testing Triage has Begun

The volume of specimens submitted to the WSLH has exceeded our sustainable capacity resulting in our need to triage specimens. Due to the fragility of the supply chain of testing components, and in order to protect our ability to provide testing for the most critically ill, the Wisconsin Department of Health Services released a memo with updated guidelines for providers to prioritize hospitalized patients to be tested for COVID-19.

## Risk Prioritization

### Tier One:
- Patient is critically ill and receiving ICU level care with unexplained viral pneumonia or respiratory failure
- OR - Patient is hospitalized (non-ICU) with fever or signs and symptoms of lower respiratory tract illness (cough, shortness of breath) AND either of the following high risk conditions:
  - Known exposure to a laboratory-confirmed COVID-19 patient
  - Travel to an area where sustained community transmission has been identified

### Tier Two:
- Hospitalized (non-ICU) patients and long-term care residents with unexplained fever AND signs/symptoms of a lower respiratory tract illness
- OR - Health care workers with unexplained fever AND signs/symptoms of a lower-respiratory tract illness, regardless of hospitalization

### Tier Three:
- 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 - Health care workers with mild upper respiratory symptoms (rhinorrhea, congestion, sore throat) without fever

### Tier Four:
- 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

*Please include a copy of this form with the Rec form when submitting samples*
Lower Priority Samples

- Will be frozen to maintain stability
- Will likely be forwarded to other labs for testing
- Will likely exceed the 1-2 day turnaround time

- We will send messaging if a sample is deemed lower priority
- Notify us if you want samples returned
- Please avoid sending in lower priority samples
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
  - LabCorp, University of Washington, Mayo
  - Many Clinical Labs bringing on testing
Options for testing in your lab

- Commercial EUA tests
- Lab Developed Test (LDT)
## FDA EUA Tests

* Does not require submission to the FDA to use these tests!!!

<table>
<thead>
<tr>
<th>In Vitro Diagnostic Product</th>
<th>Date of EUA Issuance</th>
<th>Letter of Authorization</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>March 15, 2020 (reissuance)</td>
<td></td>
</tr>
<tr>
<td>New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel (Wadsworth Center, NYSDOH)</td>
<td>February 29, 2020 (initial issuance)</td>
<td>Letter of Authorization (PDF, 312 KB)</td>
</tr>
<tr>
<td></td>
<td>March 10, 2020 (reissuance)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>March 15, 2020 (amendments granted)</td>
<td>Letter Granting EUA Amendment(s), March 15, 2020 (PDF, 63 KB)</td>
</tr>
<tr>
<td>cobas SARS-CoV-2 (ROCHE)</td>
<td>March 12, 2020</td>
<td>Letter of Authorization (PDF, 111 KB)</td>
</tr>
<tr>
<td>Panther Fusion SARS-CoV-2 (Hologic, Inc.)</td>
<td>March 16, 2020</td>
<td>Letter of Authorization (PDF, 290 KB)</td>
</tr>
<tr>
<td>COVID-19 RT-PCR Test (Laboratory Corporation of America)</td>
<td>March 16, 2020</td>
<td>Letter of Authorization (PDF, 296 KB)</td>
</tr>
<tr>
<td>Lyra SARS-CoV-2 Assay (Quidel Corp.)</td>
<td>March 17, 2020</td>
<td>Letter of Authorization (PDF, 294 KB)</td>
</tr>
<tr>
<td>Quest SARS-CoV-2 rRT-PCR (Quest Diagnostics Infectious Disease, Inc.)</td>
<td>March 17, 2020</td>
<td>Letter of Authorization (PDF, 297 KB)</td>
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</tbody>
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Other EUAs coming soon

- Cephied- GeneXpert (this week?)
- BioMerieux- Biofire
- BD- Max (next week?)
- Promega
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
  - Develop your own COVID-19 assay
  - Use CDC’s protocol with your own reagents
  - Use Commercial RUO assay (with no EUA)
Are you planning to test?

• Survey coming soon in a WCLN message!
  • When will you start testing?
  • What method(s) will you use?
  • What patient types will you test?
  • What is your expected capacity?

• Please post on the WCLN listserv if you are experiencing any supply shortages.
New CPT Code

Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])

87635

“Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)(Coronavirus disease [COVID-19]), amplified probe technique”

* WSLH Testing is fee exempt
Questions?

Please type your questions in the question box.