Update on COVID-19 Diagnostic Testing
04-29-20

Dr. Allen Bateman
PhD, MPH, D(ABMM)
Assistant Director
Communicable Disease Division
Wisconsin State Laboratory of Hygiene

Erin Bowles
MT(ASCP)
WCLN Network Coordinator
Communicable Disease Division
Wisconsin State Laboratory of Hygiene
Contents

• Situation Update
• Survey update
• COVID-19 potpourri
• 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 any products
A moment of humor

https://xkcd.com/2287/
Global Impact

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

<table>
<thead>
<tr>
<th>State</th>
<th>Cases</th>
<th>Per 100,000 People</th>
<th>Deaths</th>
<th>Per 100,000 People</th>
<th>Case Growth Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>New York</td>
<td>292,027</td>
<td>1,501</td>
<td>17,303</td>
<td>89</td>
<td>Slower</td>
</tr>
<tr>
<td>New Jersey</td>
<td>111,188</td>
<td>1,252</td>
<td>6,044</td>
<td>68</td>
<td>Faster</td>
</tr>
<tr>
<td>Massachusetts</td>
<td>56,462</td>
<td>819</td>
<td>3,003</td>
<td>44</td>
<td>Faster</td>
</tr>
<tr>
<td>Illinois</td>
<td>45,883</td>
<td>362</td>
<td>1,992</td>
<td>16</td>
<td>Slower</td>
</tr>
<tr>
<td>California</td>
<td>45,189</td>
<td>114</td>
<td>1,800</td>
<td>5</td>
<td>Faster</td>
</tr>
<tr>
<td>Pennsylvania</td>
<td>43,189</td>
<td>337</td>
<td>1,946</td>
<td>15</td>
<td>Faster</td>
</tr>
<tr>
<td>Michigan</td>
<td>38,190</td>
<td>382</td>
<td>3,406</td>
<td>34</td>
<td>Faster</td>
</tr>
<tr>
<td>Wisconsin</td>
<td>6,081</td>
<td>104</td>
<td>281</td>
<td>5</td>
<td>Faster</td>
</tr>
</tbody>
</table>

COVIDView

U.S. State and Local Public Health Laboratories Reporting to CDC:
Number of Specimens Tested and Percent Positive for SARS-CoV-2
March 1, 2020 - April 18, 2020

Percentage of Visits for Influenza-Like Illness (ILI) Reported by
the U.S. Outpatient Influenza-like Illness Surveillance Network (ILINet),
Weekly National Summary, September 29, 2019 - April 18, 2020

COVIDView

NSSP: Percentage of Visits for Influenza-Like Illness (ILI) and COVID-19-Like Illness to Emergency Departments
Weekly National Summary, September 29, 2019 - April 18, 2020

NCHS Mortality Reporting System:
Pneumonia, Influenza and COVID-19 Mortality
Data through the week ending April 18, 2020, as of April 23, 2020
Wisconsin

Number of newly reported COVID-19 cases, by day, and 7-day average (last 14 days)

https://www.dhs.wisconsin.gov/covid-19/data.htm
# Survey Results

<table>
<thead>
<tr>
<th>Laboratories actively testing</th>
<th>Laboratories planning to test</th>
<th>Current state capacity (tests/day)</th>
</tr>
</thead>
<tbody>
<tr>
<td>50</td>
<td>37</td>
<td>11,040</td>
</tr>
</tbody>
</table>

**COVID-19 Testing Capacity Over Time**

Last updated 4/28/2020 2:15:26 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/PublicDashboard?origin=card_share_link&embed=y&isGuestRedirectFromVizportal=y
Reminder to Update the Survey

• First time to check for accuracy
• Update when there is a change in testing
  • Start testing for the first time
  • Add or change testing methods
  • Increase or decrease in testing capacity
  • Report major reagent/supply limitations
    • Collection kits
    • Testing components
  • Remove a shortage report

https://covidlabsurvey.wi.gov
### What Tests are Being Used?

#### Active Test Methods Statewide

<table>
<thead>
<tr>
<th>Method</th>
<th>BDMax</th>
<th>EZ1</th>
<th>EMAG</th>
<th>KingFisher</th>
</tr>
</thead>
<tbody>
<tr>
<td>GeneXpert 36</td>
<td>6</td>
<td>4</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>ID Now 6</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MagnaPure LC 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Manual Extraction 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diasorin 5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Qiacube 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>Oth</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pan</td>
<td>Pan</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Current and Planned Methods

<table>
<thead>
<tr>
<th>Method</th>
<th>BDMax</th>
<th>Diasorin</th>
<th>EZ1</th>
<th>KingFisher</th>
</tr>
</thead>
<tbody>
<tr>
<td>GeneXpert 72</td>
<td>7</td>
<td></td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>ID Now 24</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Panther Fusion 4</td>
<td></td>
<td></td>
<td>easy</td>
<td></td>
</tr>
<tr>
<td>BioFire 17</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EMAG 3</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

[Link to dataset](https://bi.wisconsin.gov/t/COVID19_Analytics/views/LabDashboards/TestingMethods?origin=card_share_link&embed=y&isGuestRedirectFromVizportal=y)
What are the Challenges?

<table>
<thead>
<tr>
<th># of reports</th>
<th>Problems</th>
</tr>
</thead>
<tbody>
<tr>
<td>45</td>
<td>GeneXpert cartridges</td>
</tr>
<tr>
<td>17</td>
<td>Collections Kits (NP swab and/or VTM)</td>
</tr>
<tr>
<td>13 / 2</td>
<td>Abbott ID Now cartridges / instruments</td>
</tr>
<tr>
<td>11</td>
<td>BioFire supplies</td>
</tr>
<tr>
<td>4</td>
<td>EMAG/EasyMAG supplies</td>
</tr>
<tr>
<td>4</td>
<td>BD Max supplies</td>
</tr>
<tr>
<td>1</td>
<td>PPE</td>
</tr>
</tbody>
</table>

*Please continue to submit these updates!
Wisconsin Reference Laboratories

In addition to national reference labs, Wisconsin laboratories that accept outside specimens for PCR testing include:

**Coppe Laboratories**  
Phone: 262-574-0701  
Email: info@coppelabs.com  
Webpage: www.coppelabs.com

**Exact Sciences**  
Phone: 844-570-9730  
Email: COVIDCustomerAccountSet-up@exactsciences.com

**Midwest Respiratory Virus Program**  
Dr. Kelly Henrickson  
Phone: 262-391-3993  
Email: khenrick@mcw.edu and henrickson@aol.com

**Wisconsin Diagnostic Laboratories**  
Phone: 414-702-0401  
Email: SChristel@wisconsindiagnostic.com  
Webpage: https://www.wisconsindiagnostic.com/healthcare_providers/work_with_us/
Ordering Supplies from
SEOC Distribution Center

NEW - SEOC Web Portal Available Now:
https://covid19supplies.wi.gov/Testing

- For clinical laboratorians and hospital system medical professionals
- For local public health large outbreaks (>50 specimens collected)
- Order swabs and viral transport media for COVID-19 testing
  - Commercial Kits: specimen collection materials including commercial M4 room temperature stable viral transport media (VTM) and a nasopharyngeal (NP) swab. *NOTE*: these are currently in very limited supply.
  - Cold Kits: specimen collection materials including VTM (CDC protocol) and an FDA approved NP swab. *NOTE*: materials require refrigerated storage.
  - Exact Sciences Kits: specimen collection materials including room temperature stable saline and a nasal swab. *NOTE*: Supplies intended for testing performed at Exact Sciences. For more information go to: Exact Sciences. Public Health approved fee exempt testing available.
  - Swab Only: NP swab alone, FDA approved.
  - VTM Only: CDC protocol VTM. *NOTE*: materials require refrigerated storage.
Ordering Supplies from WSLH Clinical Orders Department

Call WSLH Clinical Orders M-F between 7:45 AM and 2:45 PM to request supplies at 800-862-1088

• For local public health
  • Order small numbers of collection kits (6 or 12)
  • Order packaging and shipping supplies

• For clinical labs
  • Order packaging and shipping supplies
  • Order WSLH Requisition (A) Form 4105

• Leave a message if call outside of listed hours
  • Facility name, address, supply requested and # needed
  • If requesting small order of VTM, can you store at 2-8°C
  • WSLH will fill the orders we can and triage to SEOC those we are unable to fill
Specimen Types for PCR

- Validated at WSLH (other labs may differ)
  - Nasopharyngeal (NP)
  - Oropharyngeal (OP)
  - Sputum
  - BAL

- CDC/FDA Preferred: NP
- CDC/FDA acceptable alternatives: OP, mid-turbinate swab, anterior nares (nasal swab)


- FDA: “More data are necessary on the validity of buccal swabs, saliva specimens, or other specimen types. ”

- Don’t forget about flu and other respiratory pathogens!
## New FDA EUA Assays

<table>
<thead>
<tr>
<th>Date EUA Issued</th>
<th>Manufacturer</th>
<th>Diagnostic (Letter of Authorization)</th>
<th>Technology</th>
</tr>
</thead>
<tbody>
<tr>
<td>04/27/2020</td>
<td>SEASUN BIOMATERIALS</td>
<td>U-TOP COVID-19 Detection Kit</td>
<td>Molecular</td>
</tr>
<tr>
<td>04/26/2020</td>
<td>Abbott Laboratories Inc.</td>
<td>SARS-CoV-2 IgG assay</td>
<td>Serology IgG only</td>
</tr>
<tr>
<td>04/24/2020</td>
<td>DiaSorin Inc.</td>
<td>LIAISON SARS-CoV-2 S1/S2 IgG</td>
<td>Serology IgG only</td>
</tr>
<tr>
<td>04/24/2020</td>
<td>Ortho-Clinical Diagnostics, Inc.</td>
<td>VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Reagent Pack</td>
<td>Serology IgG only</td>
</tr>
<tr>
<td>04/24/2020</td>
<td>Autobio Diagnostics Co. Ltd.</td>
<td>Anti-SARS-CoV-2 Rapid Test</td>
<td>Serology IgM and IgG</td>
</tr>
<tr>
<td>04/23/2020</td>
<td>SD Biosensor, Inc.</td>
<td>STANDARD M nCoV Real-Time Detection Kit</td>
<td>Molecular</td>
</tr>
</tbody>
</table>

• 838 positives included in this analysis
• Shifted lower than influenza Ct values
• 25% have a Ct <20
“The current antibody testing landscape is varied and clinically unverified, and these tests should not be used as the sole test for diagnostic decisions. Further, until more evidence about protective immunity is available, serology results should not be used to make staffing decisions or decisions regarding the need for personal protective equipment.”

“Some FDA-authorized COVID-19 antibody tests are estimated to have 96-98% specificity, which would mean that a positive test result is more likely a false-positive result than a true positive result if the prevalence is 5% or less.”
Next COVID-19 webinar: in 2 weeks?
Please Type Your Questions in the Question Box!