Update on COVID-19 Diagnostic Testing
04-08-20

Dr. Alana Sterkel
PhD, D(ABMM), SM(ASCP)\textsuperscript{CM}
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
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• Situation Update

• WSLH testing update
  • New PIF

• Clinical lab testing update
  • Survey Results
  • Help from the SEOC
  • National Result Reporting

• 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/
New Siracha Hand Sanitizer

not only will it kill germs but it will stop you touching your eyes, face and other places a second time
Global Impact

Johns Hopkins University Global Coronavirus Tracking: https://gisanddata.maps.arcgis.com/apps/opsdashboard/index.html#/bda7594740fd40299423467b48e9ecf6
COVID-19 in the US
The US is doing a lot of testing

COVID-19 tests per day

Comparisons across the series are compromised for several reasons. See note below for more information about the series for the US and South Korea. For the UK and Italy only limited descriptions of the data are provided by the sources.

Source: US: CDC, COVID Tracking Project; South Korea: KCDC; UK: PHE/DHSC; Italy: Ministero della Salute
Note: *Cases tested* is equivalent to the number of people tested. The COVID Testing Project aggregates figures for the number of tests and the number of people tested as reported by US states. US CDC figures do not include private labs; COVID Testing Project figures do so partially. OurWorldInData.org/coronavirus • CC BY
Wisconsin

Wisconsin COVID-19 summary

<table>
<thead>
<tr>
<th>Status</th>
<th>Number (% of People as of 4/7/2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative Test Result</td>
<td>28,512</td>
</tr>
<tr>
<td>Positive Test Result</td>
<td>2,578</td>
</tr>
<tr>
<td>Hospitalizations</td>
<td>745 (29%)</td>
</tr>
<tr>
<td>Deaths</td>
<td>92</td>
</tr>
</tbody>
</table>

Updated: 4/7/2020

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

% Positive for Influenza by PCR (Wisconsin), Week Ending March 28, 2020
WISCONSIN LABORATORY SURVEILLANCE FOR RESPIRATORY VIRUSES BY PCR

Trends in respiratory virus activity by PCR

Illness Continues to Rise

ILI activity trend analysis

Week ending

12/15 1/5 1/26 2/16 3/8 3/29

Average % ILI

0% 1% 2% 3% 4% 5% 6% 7%

Baseline

Threshold

3-week moving average (average % ILI)
Testing has Increased Rapidly

*Not all labs reporting

New Patient Information Form

WISCONSIN COVID-19 PATIENT INFORMATION FORM

THIS FORM MAY BE USED TO REPORT SUSPECTED CASES THAT ARE BEING TESTED FOR COVID-19 AND SUSPECT OR PROBABLE CASES WHO ARE DIAGNOSED BASED ON CLINICAL CRITERIA* WITHOUT TESTING

PATIENT DEMOGRAPHICS
FIRST NAME: ______________________ LAST NAME: ______________________ DATE OF BIRTH: ______/____/____
GENDER: M F OTHER UNKNOWN
ADDRESS: ____________________________________________________________
CITY: ________________________________________________________________
STATE: ______________________ ZIP: ______________________ COUNTY: __________
PHONE 1: ______________________ PHONE 2: ______________________ EMAIL: ______________________

REPORTING FACILITY
NAME: ______________________ PERSON REPORTING: ______________________ PHONE: ______________________

SPECIMEN AND CLINICAL INFORMATION
ONSET DATE: __________ SYMPTOMS: ______________________
☐ ASYMPTOMATIC - DHS does not recommend testing asymptomatic individuals at this time

COLLECTION DATE: __________ SPECIMEN TYPE: DNP COP DP/P or SPUTUM BAL FLUID

*SYMPTOMS OF COVID-19 MAY INCLUDE FEVER, COUGH, SHORTNESS OF BREATH, MYALGIA OR OTHER NONSPECIFIC SYMPTOMS; TESTING DECISIONS FOR PATIENTS WITH MILD ILLNESS SHOULD BE BASED ON CLINICIAN JUDGMENT

☐ A: PATIENT IS BEING TESTED AT A PUBLIC HEALTH LABORATORY

Specimens may be sent to the Wisconsin State Laboratory of Hygiene or the Milwaukee health department laboratory if they have one of the priority criteria listed below. If equivalent or more rapid turnaround is available through a private or commercial lab providers are encouraged to use these options.

Criteria for testing at WSLH or MHDH, please check all that apply:
☐ Isolated case of patient with COVID-19 symptoms
☐ Patient under 20 years old
☐ Patient with rapid case progression and/or high-risk features
☐ Patient hospitalized
☐ Patient with severe respiratory symptoms
☐ Patient with exposure to essential workers or essential workers
☐ Patient whose hospitalization status, inpatient, or their community setting is not reportable

☐ B: PATIENT IS BEING TESTED AT ANY OTHER LABORATORY

Patients that do not qualify for testing at WSLH or MHDH, but for whom testing is being requested by the healthcare provider, should be tested by a private or commercial laboratory.

Providers should use their clinical judgment and refer to the priority criteria for testing patients with suspected COVID-19 infection for additional guidance on overall testing priorities.

If the patient is being tested at a lab other than a PM, but would meet criteria for testing, please indicate the applicable priority criteria above. This information may be of use to public health agencies and other laboratories.

☐ C: PATIENT IS A SUSPECTED OR PROBABLE CASE WHO IS NOT BEING TESTED AT THIS TIME

Individuals should be reported as probable cases if they meet either of the criteria below (please check one):
☐ An illness with clinically compatible symptoms of COVID-19 infection who was in close contact with a confirmed COVID-19 case and has no other known etiology for the clinical illness
☐ An illness with clinically compatible symptoms of COVID-19 infection who was a member of a cluster of illnesses where at least one member is a confirmed case, and has no other known etiology for the clinical illness

DHS HAN 4/7/20 https://content.govdelivery.com/accounts/WIDHS/bulletins/28569e9
**Approved for Testing at Public Health Labs**

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**SYMPTOMS OF COVID-19 MAY INCLUDE FEVER, COUGH, SHORTNESS OF BREATH, MYALGIA OR OTHER NONSPECIFIC SYMPTOMS; TESTING DECISIONS FOR PATIENTS WITH MILD ILLNESS SHOULD BE BASED ON CLINICIAN JUDGEMENT**

☐ A: PATIENT IS BEING TESTED AT A PUBLIC HEALTH LABORATORY

Specimens may be sent to the Wisconsin State Laboratory of Hygiene or the Milwaukee Health Department Laboratory if they have one of the priority criteria listed below. If equivalent or more rapid turn-around is available through an in-house or commercial lab providers are encouraged to use these other options.

Criteria for testing at WSLH or MDHL, please check ALL that apply:

- ☐ Hospitalized patient with COVID-19 symptoms
- ☐ Admit Date: __________________________
- ☐ Please also indicate if the patient is in ICU or on a ventilator: ☐ ICU  ☐ Ventilator
- ☐ 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
- ☐ Post-mortem testing for a person with COVID-19 symptoms prior to death OR who died of unknown causes AND where results would influence infection control interventions at a facility or inform a public health response

**WHEN SUBMITTING SPECIMENS TO THE WSLH AND MHDL, THIS PATIENT INFORMATION FORM MUST BE ACCOMPANIED BY THE APPROPRIATE REQUISITION FORM:**

Milwaukee Health Department Laboratory: Microbiology Requisition H-455
Wisconsin State Laboratory of Hygiene: CDD Requisition Form A (#4105)
Other Testing and Reporting

☐ B: PATIENT IS BEING TESTED AT ANY OTHER LABORATORY

Patients that do not qualify for testing at WSLH or MHDL, but for whom testing is being requested by the healthcare provider, should be tested by in-house or commercial laboratories.

Providers should use their clinical judgement and are advised to refer to the CDC Priorities for Testing Patients with Suspected COVID-19 Infection for additional guidance on overall testing priorities.

If the patient is being tested at a lab other than a PHL, but would meet criteria for PHL testing, please indicate the applicable priority criteria above. This information may be of use to public health agencies and other laboratories.

☐ C: PATIENT IS A SUSPECTED OR PROBABLE CASE WHO IS NOT BEING TESTED AT THIS TIME

Individuals should be reported as probable cases if they meet either of the criteria below (please check one):

☐ An illness with clinically compatible symptoms of COVID-19 infection who was a close contact with a confirmed COVID-19 case, and has no other known etiology for the clinical illness.

☐ An illness with clinically compatible symptoms of COVID-19 infection who was a member of a cluster of illnesses where at least one member is a confirmed case, and has no other known etiology for the clinical illness.

☐ An illness with clinically compatible symptoms of COVID-19 infection who was a close contact with another probable COVID-19 case, and has no other known etiology for the clinical illness.

Patients being diagnosed with COVID-19 who will not be tested should be reported to the patient’s local health department.
How to Use the new PIF

• Must be submitted along with specimens when testing at a public health lab only

• May be used within a facility
• May be used to report to public health

• Patients that do not meet this criteria may still benefit from testing and you are encouraged to provide testing in-house or at a reference laboratory
SEOC Survey

• Created by the State Emergency Operations Center (SEOC) Specimen Collection and Laboratory Capacity workgroup
• Will be used to help labs!
  • Identify shortages and find solutions
  • Inform on State purchasing of testing supplies
  • Inform on allocation of State purchased supplies
  • Inform on government requests for state prioritization of testing supplies

https://covidlabsurvey.wi.gov
When to Use 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 kits
    - Testing components

https://covidlabsurvey.wi.gov
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 publically 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

https://covidlabsurvey.wi.gov
Survey Results

Lab Stats

<table>
<thead>
<tr>
<th>Number of active labs</th>
<th>Number of planned labs</th>
<th>Current Daily Testing Capacity</th>
</tr>
</thead>
<tbody>
<tr>
<td>14</td>
<td>44</td>
<td>3,623</td>
</tr>
</tbody>
</table>

Capacity Growth Over Time

30x increase in one month

Test capacity per day does not equate to patients tested per day. This data is based on laboratory internal assessments and planning for future testing. All data are estimates and do not reflect actual test volumes. Capacity is limited by fragile test supply availability.
### What Tests are Being Used?

#### Active Test Methods Statewide

<table>
<thead>
<tr>
<th>Method</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>GeneXpert</td>
<td>6</td>
</tr>
<tr>
<td>Accula</td>
<td>2</td>
</tr>
<tr>
<td>EZ1</td>
<td>4</td>
</tr>
<tr>
<td>Manual Extraction</td>
<td>4</td>
</tr>
<tr>
<td>KingFisher</td>
<td>2</td>
</tr>
<tr>
<td>EMAG</td>
<td>4</td>
</tr>
<tr>
<td>MagnaP</td>
<td>1</td>
</tr>
<tr>
<td>MagnaPure LC</td>
<td>2</td>
</tr>
<tr>
<td>Cobas</td>
<td>1</td>
</tr>
<tr>
<td>ID Now</td>
<td>1</td>
</tr>
<tr>
<td>Maxwell</td>
<td>1</td>
</tr>
<tr>
<td>QiaSymph</td>
<td>1</td>
</tr>
<tr>
<td>Other (not listed)</td>
<td>1</td>
</tr>
<tr>
<td>easyMAG</td>
<td>1</td>
</tr>
<tr>
<td>Panther Fusion</td>
<td>1</td>
</tr>
</tbody>
</table>

#### Current and Planned Methods

<table>
<thead>
<tr>
<th>Method</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>GeneXpert</td>
<td>33</td>
</tr>
<tr>
<td>BioFire</td>
<td>14</td>
</tr>
<tr>
<td>Manual Extraction</td>
<td>5</td>
</tr>
<tr>
<td>ID Now</td>
<td>13</td>
</tr>
<tr>
<td>EMAG</td>
<td>4</td>
</tr>
<tr>
<td>EZ1</td>
<td>4</td>
</tr>
<tr>
<td>KingFisher</td>
<td>4</td>
</tr>
<tr>
<td>BDMAX</td>
<td>2</td>
</tr>
<tr>
<td>Panther Fusion</td>
<td>3</td>
</tr>
<tr>
<td>Maxwel</td>
<td>2</td>
</tr>
<tr>
<td>Other</td>
<td>2</td>
</tr>
<tr>
<td>QiaCube</td>
<td>2</td>
</tr>
<tr>
<td>Accula</td>
<td>2</td>
</tr>
<tr>
<td>easyMAG</td>
<td>1</td>
</tr>
<tr>
<td>MagnaPure LC</td>
<td>2</td>
</tr>
<tr>
<td>QiaSymph</td>
<td>1</td>
</tr>
<tr>
<td>Other (not listed)</td>
<td>1</td>
</tr>
</tbody>
</table>
# What are the Challenges?

<table>
<thead>
<tr>
<th># of reports</th>
<th>Problems</th>
</tr>
</thead>
<tbody>
<tr>
<td>11</td>
<td>Collections Kits (NP swab and/or VTM)</td>
</tr>
<tr>
<td>10</td>
<td>Backlog of specimen</td>
</tr>
<tr>
<td>9</td>
<td>GeneXpert cartridges</td>
</tr>
<tr>
<td>6</td>
<td>Abbott ID Now cartridges</td>
</tr>
<tr>
<td>2</td>
<td>EMAG/EasyMAG supplies</td>
</tr>
<tr>
<td>2</td>
<td>BioFire supplies</td>
</tr>
<tr>
<td>1</td>
<td>BD Max supplies</td>
</tr>
<tr>
<td>1</td>
<td>Aries supplies</td>
</tr>
<tr>
<td>1</td>
<td>Testing for Tier 3 and 4 patients</td>
</tr>
</tbody>
</table>

*Please continue to submit these updates!
SEOC to Help With Collection Kits

The SEOC is working to make emergency supplies available to medical systems throughout Wisconsin

• Available at no charge
• Quantities limited, available on allocation
• Intended to allow continuity of testing
• NOT intended to replace current supply streams
Available for Order Monday

- Very limited M4 Remel kits
- Locally produced VTM kits (CDC protocol)
- NP swabs alone (FDA approved)

- Call the WSLH Clinical Orders Department
  1-800-862-1088
  Mon-Fri 7:45 AM – 4:30 PM
SEOC VTM Kits

- Comes as a “kit” with an NP swab
- Evaluated by WSLH
  - Sterility
  - COVID-19 stability under CDC Assay requirements
  - Contamination by human and COVID-19 nucleic acid
  - Has not been evaluated for detection of other pathogens
- Requires refrigeration (2-8ºC) prior to use
- Can be used for testing at any laboratory that accepts NP swabs in VTM (not limited to WSLH testing)
- May need additional validation in your facility (Director Discretion)
To order VTM from SEOC

What they need from you:

• Your facility/healthcare system
• Shipping Address
• Current testing capacity
• # needed
• If you can store these at 2-8 C

Requests will be fulfilled as supplies allow
FDA EUA Tests

FDA authorization of COVID-19 EUA tests

*8 new since last week

Serology Testing

- Many new IgM and IgG tests flooding the market
- FDA has given their first EUA (Cellex, Inc.)
  - Requires use in a CLIA setting
- At this time WSLH discourages the use of these tests for diagnosis of COVID-19
## What’s the Difference?

<table>
<thead>
<tr>
<th>NAAT (PCR or molecular)</th>
<th>Serology (antibody)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Stand alone</strong> - Confirmatory for COVID-19</td>
<td>These tests cannot be used alone to diagnose a patient.</td>
</tr>
<tr>
<td><strong>Early detection</strong> - Positives are first detected at symptom onset or possibly slightly before</td>
<td>Positives are first detected between 3-14 days after symptom onset</td>
</tr>
<tr>
<td>Can be fast or slow (5 minutes - 6 hours)</td>
<td><strong>Rapid</strong> (usually minutes)</td>
</tr>
<tr>
<td><strong>Sensitive</strong> - The gold standard in COVID-19 detection</td>
<td>Variable detection, even on the same patient</td>
</tr>
<tr>
<td><strong>Specific</strong> - only detects COVID-19</td>
<td>May have false positives from other coronaviruses or from other patient factors</td>
</tr>
</tbody>
</table>
Serology FAQ

Q: Can these tests be used to diagnose patients?
A: No, they cannot substitute a molecular test

Q: Can these be used to get people back to work?
A: A positive results does not necessarily equal immune status

Q: Can these tests be used to end lockdown?
A: Maybe, a high quality test could be used to as a part of national surveillance to asses the proportion of the population that has been exposed to the virus.
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.)
10. COV-19 IDx assay (Ipsum Diagnostics, LLC)
11. ScienCell SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit (ScienCell Research Laboratories)
12. Logix Smart Coronavirus Disease 2019 (COVID-19) Kit (Co-Diagnostics, Inc.)
13. Gnomegen COVID-19 RT-Digital PCR Detection Kit (Gnomegen LLC)
14. Smart Detect SARS-CoV-2 rRT-PCR Kit (InBios International, Inc)
Extraction Methods

Roche
• MagNa Pure LC
• MagNa Pure Compact
• MagNa Pure 96
• MagNa Pure 24

BioMerieux
• EMAG
• easyMAG

Qiagen
• EZ1
• Manual Extraction (Qiagen kits)
• QiaCube

ThermoFisher
• KingFisher

Promega
• Maxwell
Large High Capacity Instruments

- **cobas** SARS-CoV-2 (Roche)

- **Panther** Fusion SARS-CoV-2 (Hologic, Inc.)

- **BD MAX** BioGX SARS-CoV-2 Reagents (Becton, Dickinson & Company (BD))
Sample to Answer Medium Instruments

- **Xpert** Xpress SARS-CoV-2 test (Cepheid)
- **ePlex** SARS-CoV-2 (GenMark Diagnostics, Inc.)
- **MagPix** NxTAG CoV Extended panel (Luminex Molecular Diagnostics, Inc.)
- **QIAstat-Dx** Respiratory SARS-CoV-2 Panel (QIAGEN GmbH)
- **ARIES** SARS-CoV-2 Assay (Luminex Corporation)
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.)
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
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.

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**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
CDC Working With State Health Departments

• CDC is investigating whether they can collect aggregate data from with the State Health Departments rather than having clinical labs report to HHS directly

• WSLH is working with WDHS to discern if required data can be pulled from WEDSS and reported to CDC

• Clinical labs must ensure:
  • All suspect patients with orders for COVID-19 are promptly being entered into WEDSS when testing it ordered
  • All test results of COVID-19 testing performed in your laboratory must be promptly reported to WEDSS, either automatically via **ELR**, or manually via **WLR**.
  • Clinical labs performing COVID-19 testing should report the number tested and the number positive to the WSLH weekly along with your other surveillance data.
Please Type Your Questions in the Question Box!