



**Wisconsin State
Laboratory of Hygiene**
UNIVERSITY OF WISCONSIN-MADISON



Update on COVID-19 Diagnostic Testing

04-15-20

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Contents

- Situation Update
- Survey update
- Testing options update
- Guest speakers from DHS
- Data 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/>



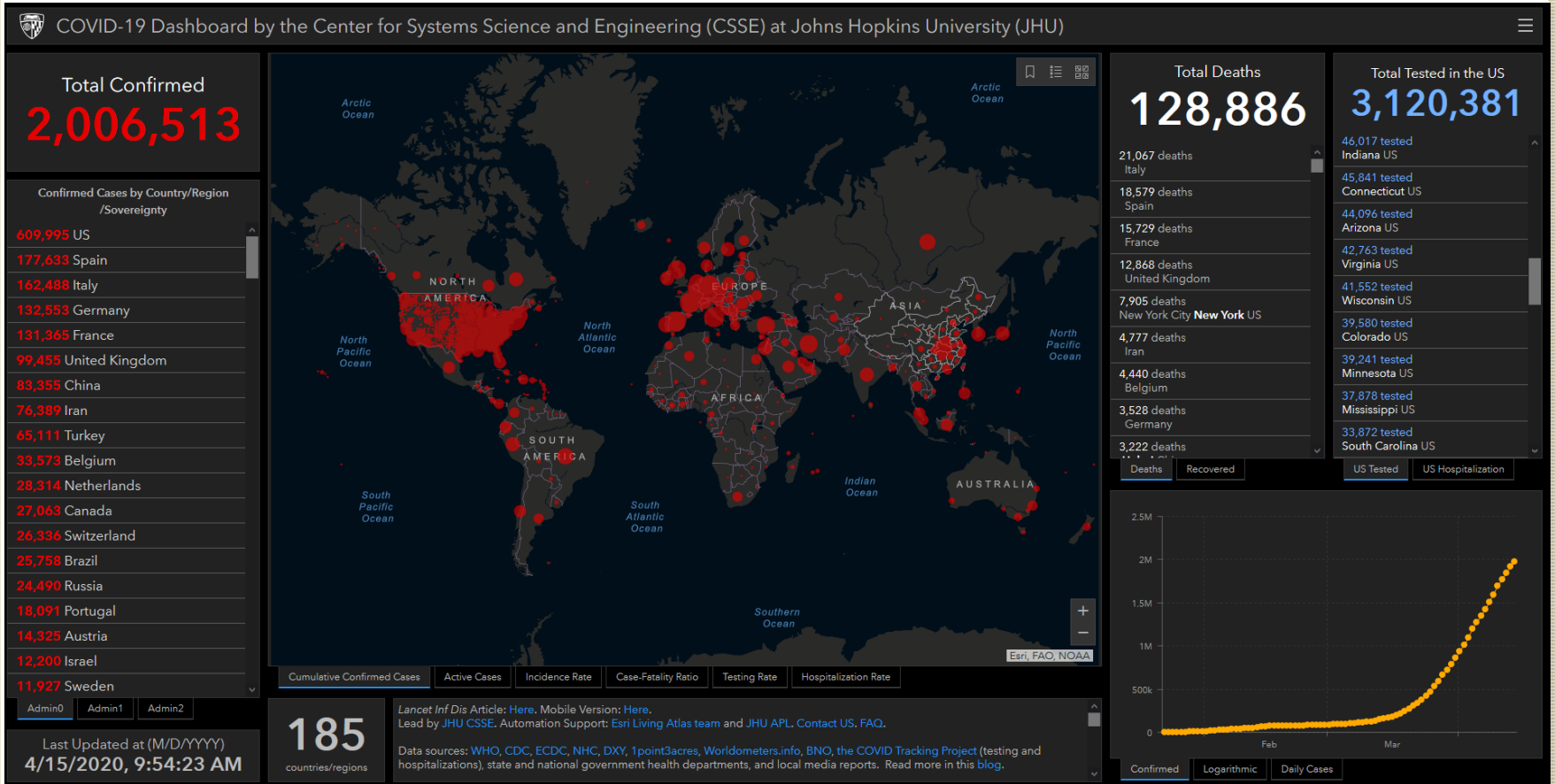
Fight Coronavirus!

Eat five cloves of garlic every day. It does absolutely nothing, but keeps everyone else at a safe distance.





Global Impact



Johns Hopkins University Global Coronavirus Tracking:

<https://gisanddata.maps.arcgis.com/apps/opsdashboard/index.html#/bda7594740fd40299423467b48e9ecf6>



COVID-19 in the US

COVID-19 Dashboard by the Center for Systems Science and Engineering (CSSE) at Johns Hopkins University (JHU)

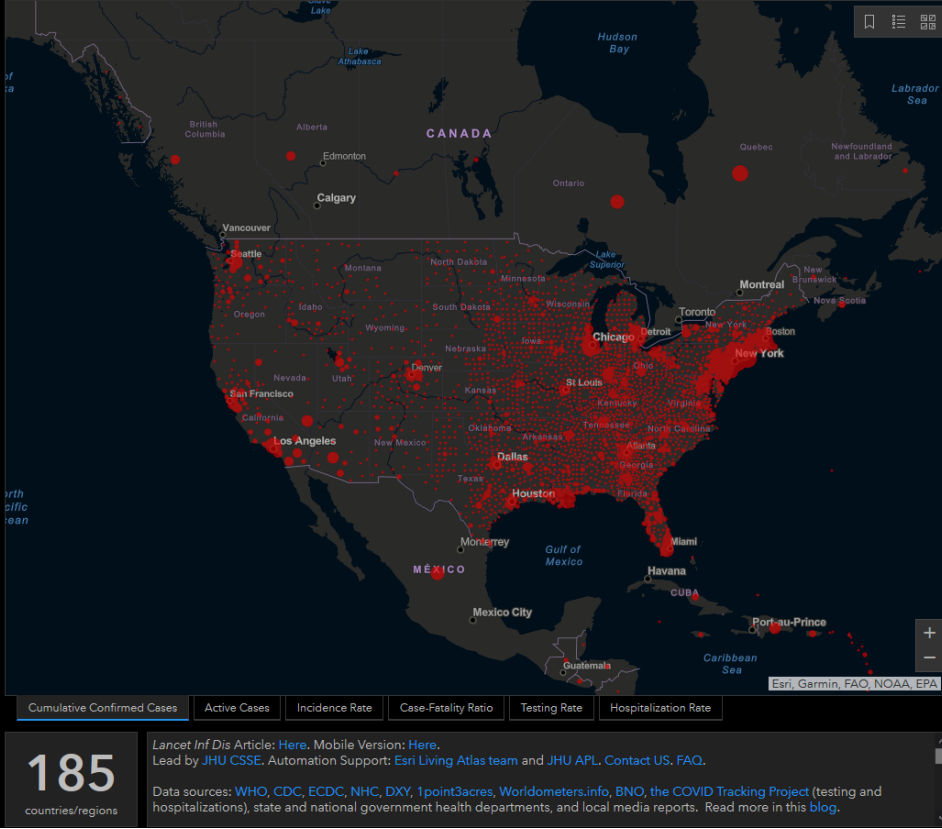
Total Confirmed
609,995

Confirmed Cases by Province/State /Dependency

- 283,377 confirmed New York US
- 68,824 confirmed New Jersey US
- 28,163 confirmed Massachusetts US
- 27,001 confirmed Michigan US
- 25,779 confirmed California US
- 25,591 confirmed Pennsylvania US
- 23,248 confirmed Illinois US
- 21,628 confirmed Florida US
- 21,518 confirmed Louisiana US
- 15,343 confirmed Texas US
- 14,578 confirmed Georgia US
- 13,989 confirmed Connecticut US
- 10,886 confirmed Washington US

Admin0 Admin1 Admin2

Last Updated at (M/D/YYYY)
4/15/2020, 9:54:23 AM



Total Deaths
26,069

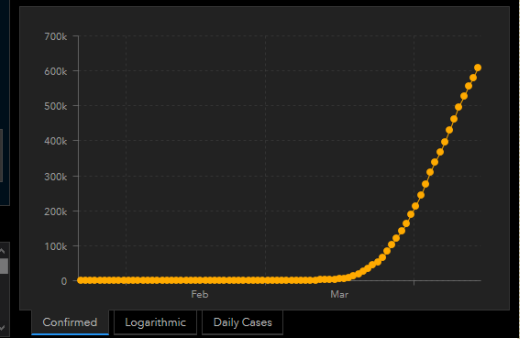
- 7,905 deaths New York City New York US
- 1,001 deaths Nassau New York US
- 820 deaths Wayne Michigan US
- 608 deaths Suffolk New York US
- 596 deaths Westchester New York US
- 577 deaths Cook Illinois US
- 550 deaths Bergen New Jersey US
- 535 deaths Essex New Jersey US
- 366 deaths

Deaths Recovered

Total Tested in the US
3,120,381

- 46,017 tested Indiana US
- 45,841 tested Connecticut US
- 44,096 tested Arizona US
- 42,763 tested Virginia US
- 41,552 tested Wisconsin US
- 39,580 tested Colorado US
- 39,241 tested Minnesota US
- 37,878 tested Mississippi US
- 33,872 tested South Carolina US

US Tested US Hospitalization

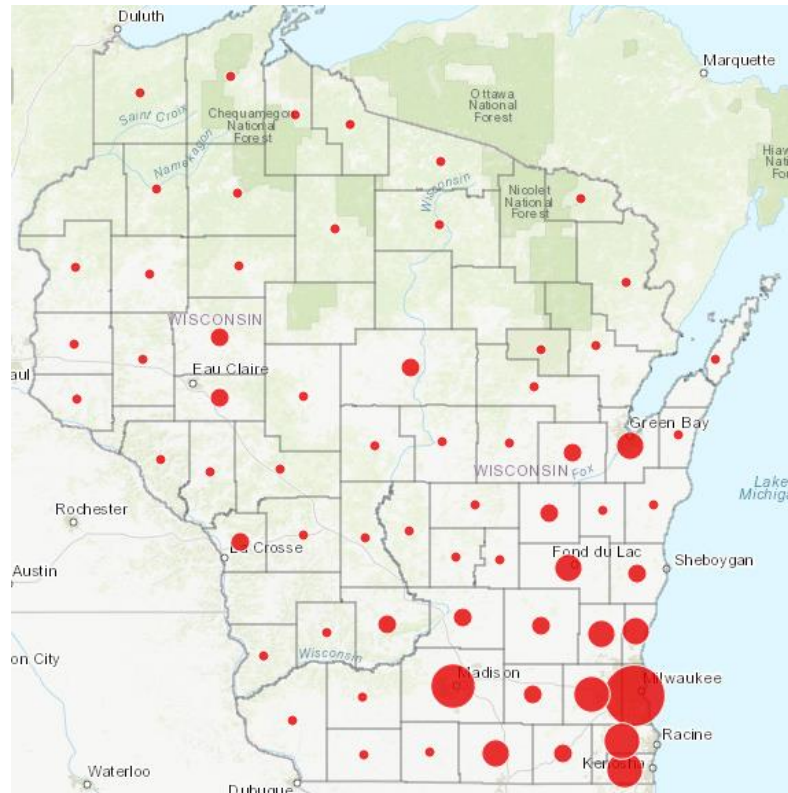




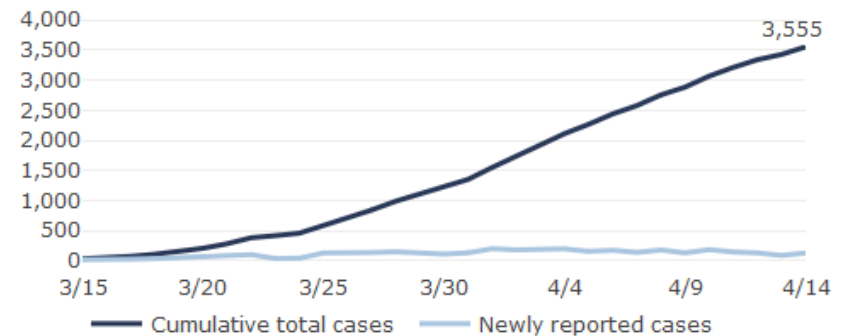
Wisconsin

Wisconsin COVID-19 Test Results

Status	Number (%) of People as of 4/14/2020
Negative Test Result	37,997
Positive Test Result	3,555
Hospitalizations	1049 (30%)
Deaths	170



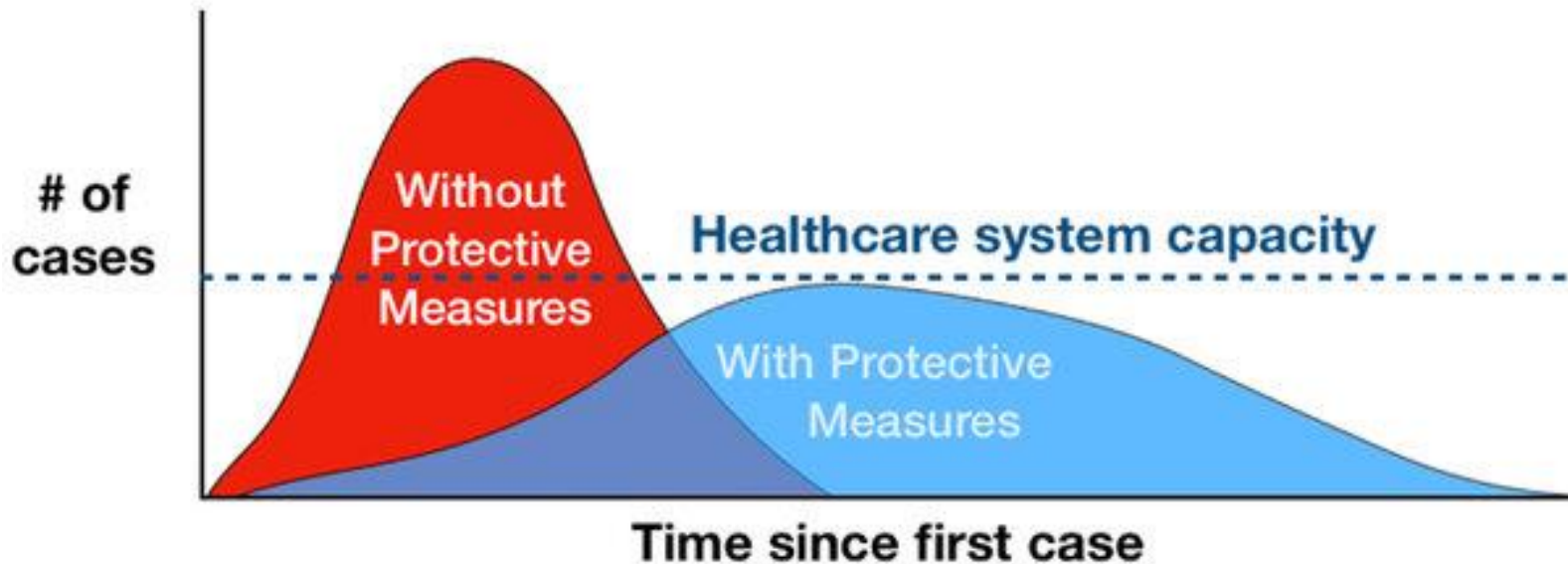
Updated: 4/14/2020



<https://www.dhs.wisconsin.gov/outbreaks/index.htm>



Flattening the Curve



Adapted from CDC / The Economist



Distancing Works!

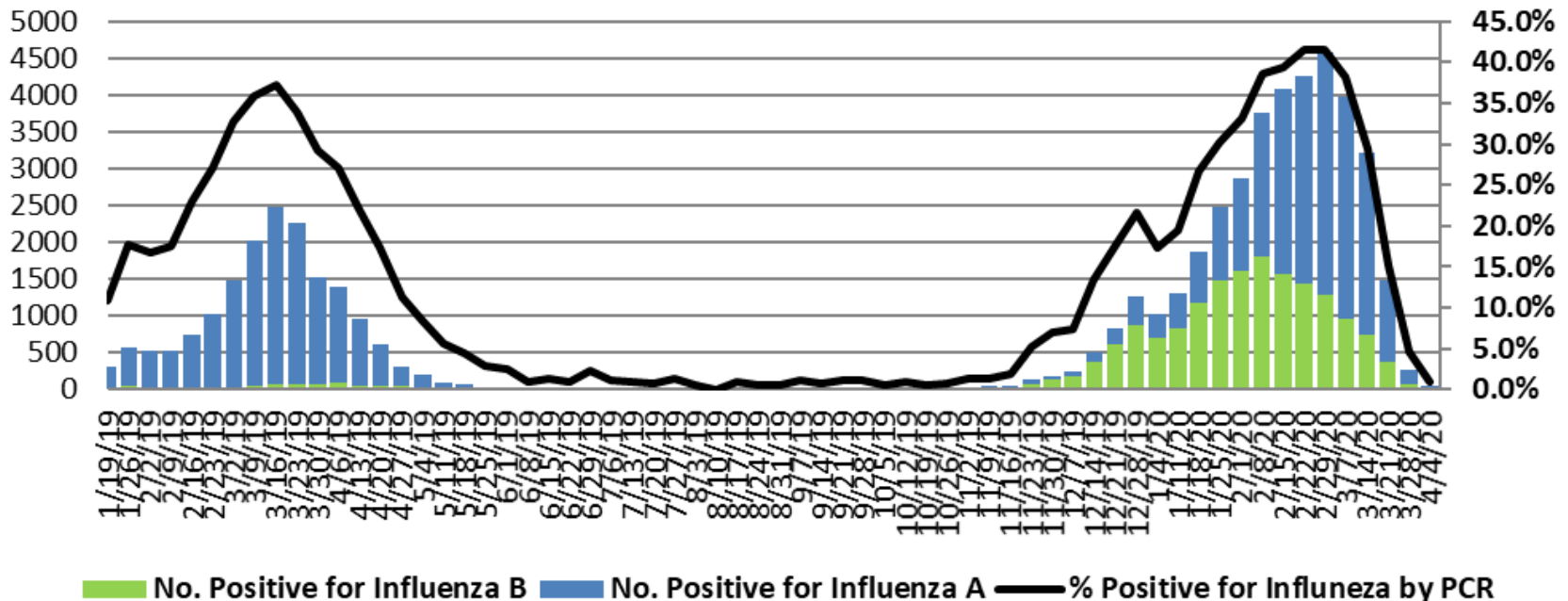


<https://www.dhs.wisconsin.gov/news/releases/041420.htm>



Distancing Works!

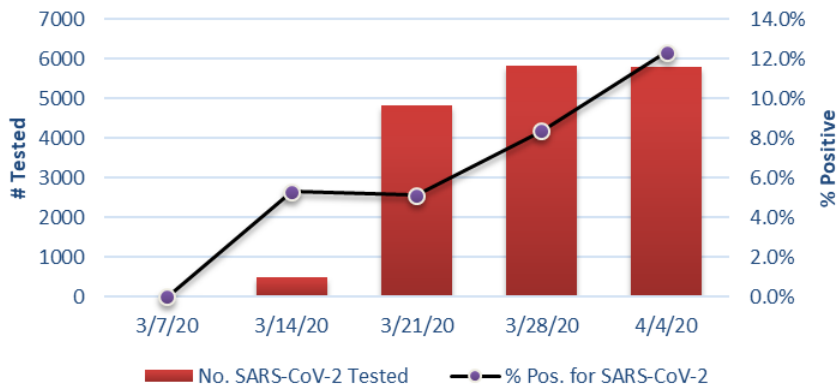
% Positive for Influenza by PCR (Wisconsin), Week Ending April 4, 2020





COVID-19 Testing

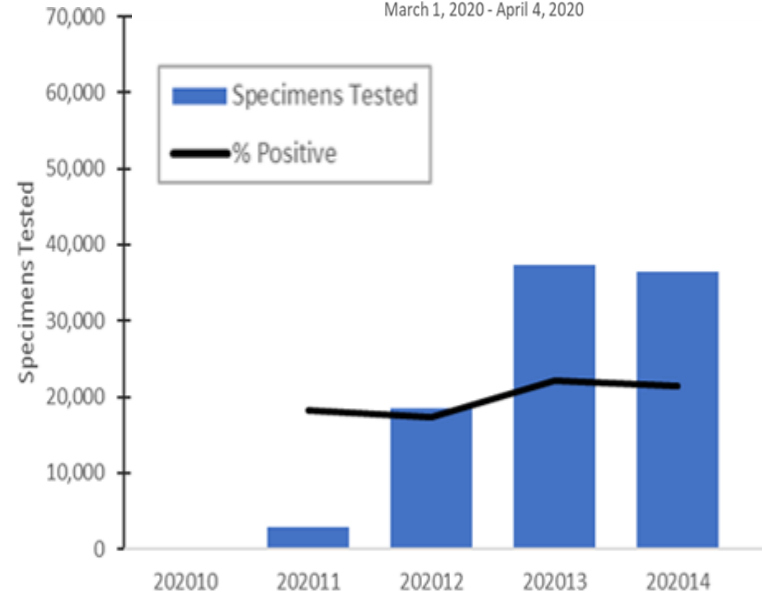
% Positive SARS-CoV-2 by PCR (Wisconsin), Week Ending April 4, 2020



<http://www.surveymoz.com/s3/389222/Wisconsin-Laboratory-Surveillance-Reporting>

*Not all labs reporting

U.S. Clinical Laboratories Reporting to the National Respiratory and Enteric Virus Surveillance System:
Number of Specimens Tested and Percent Positive for SARS-CoV-2
March 1, 2020 - April 4, 2020



<https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html>



Survey tool



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--

Select your lab

<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 components

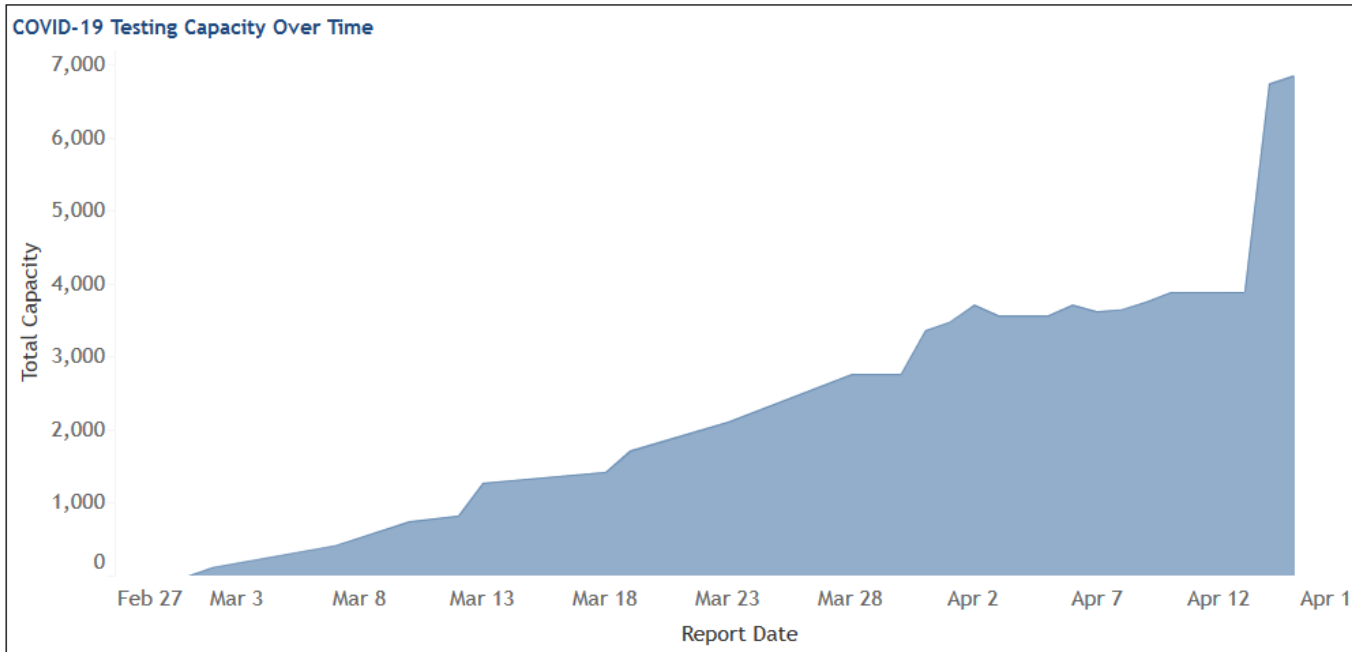
<https://covidlabsurvey.wi.gov>



Survey Results

Wisconsin COVID-19 Laboratory Testing Capacity

Laboratories actively testing 27	Laboratories planning to test 37	Current state capacity (tests/day) 6,853
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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



Testing in Wisconsin

Lab type	Capacity (tests/day)
Public Health Labs	450
Clinical Labs	3353
Commercial Labs	3050
Total	6743



Wisconsin Labs Accepting Outside Specimen for Testing

Public Health Labs

- Wisconsin State Laboratory of Hygiene
- Milwaukee Health Department Laboratory

Commercial/Large Clinical Labs

- Exact Sciences
- Wisconsin Diagnostic Laboratories
- Coppe Laboratories



Lab Data Sharing

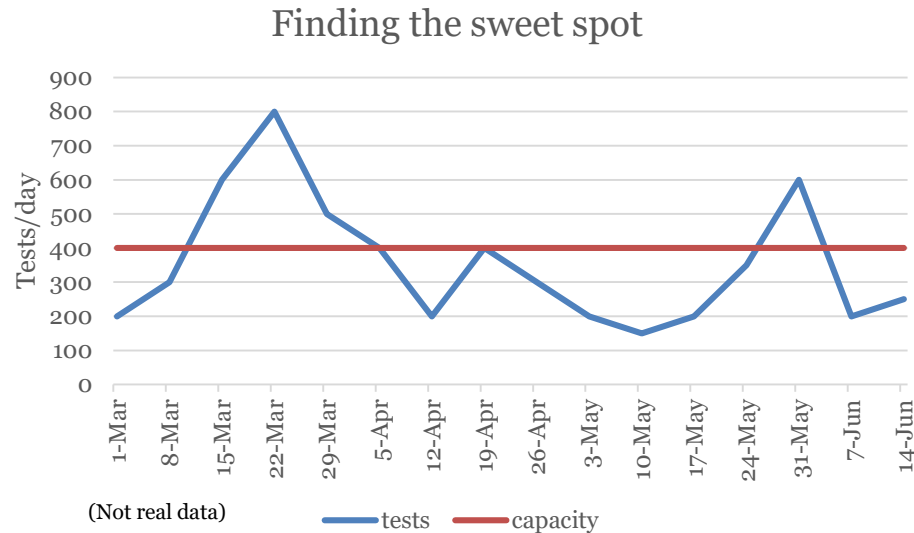
What do you think?

Should we publically share a list of all labs currently testing for COVID-19?

Answer in the comments section, on the listserv, or by email.



Why aren't we testing at capacity?



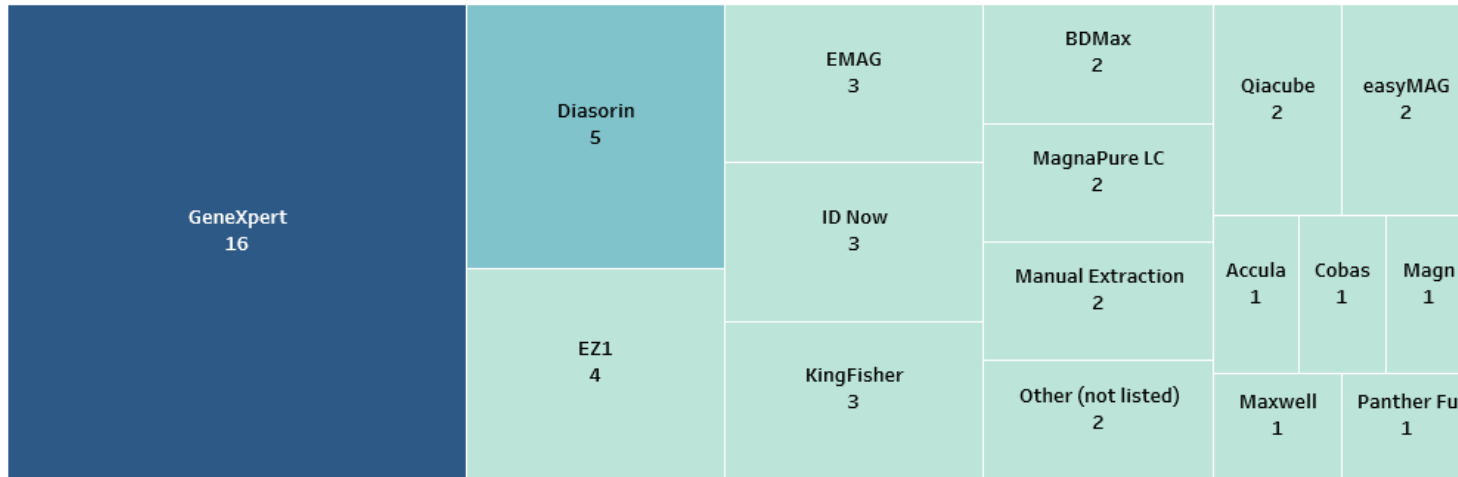
*Need to communicate with Clinicians what you lab is able to handle

- Too many samples and we get a back log
- Too few samples and it's wasted resources
- Can't control what gets submitted

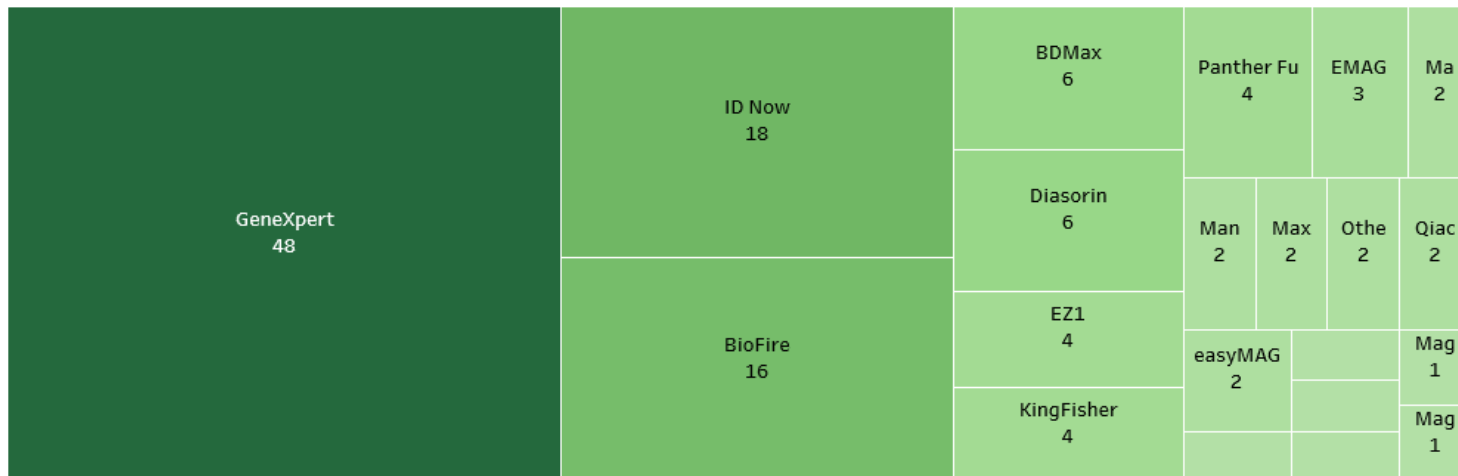


What Tests are Being Used?

Active Test Methods Statewide



Current and Planned Methods





What are the Challenges?

# of reports	Problems
25	Experiencing supply shortages
23	GeneXpert cartridges
12	Backlog of specimen
14	Collections Kits (NP swab and/or VTM)
10	Abbott ID Now cartridges
6	BioFire supplies
3	EMAG/EasyMAG supplies
1	PPE
1	BD Max supplies
1	Testing for Tier 3 and 4 patients
1	Reagents
1	ID Now instruments
1	Shipping supplies

*Please continue to submit these updates!



How has your data helped?

- State Distribution Center now open for COVID-19 collection kits
- Has informed on broadening guidance for testing
- Letters from the Governor being drafted to Cepheid, BioFire, and BioMerieux



SEOC has Collection Kits

- 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

- M4 Remel VTM kits with a single NP swab
 - Locally produced VTM kits (CDC protocol)
 - NP swabs alone (FDA approved) **(Monday)**
-
- Call the WSLH Clinical Orders Department
1-800-862-1088
Mon-Fri 7:45 AM – 2:45 PM



Local 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 yet been evaluated for detection of other pathogens
- Requires refrigeration (2-8°C) 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

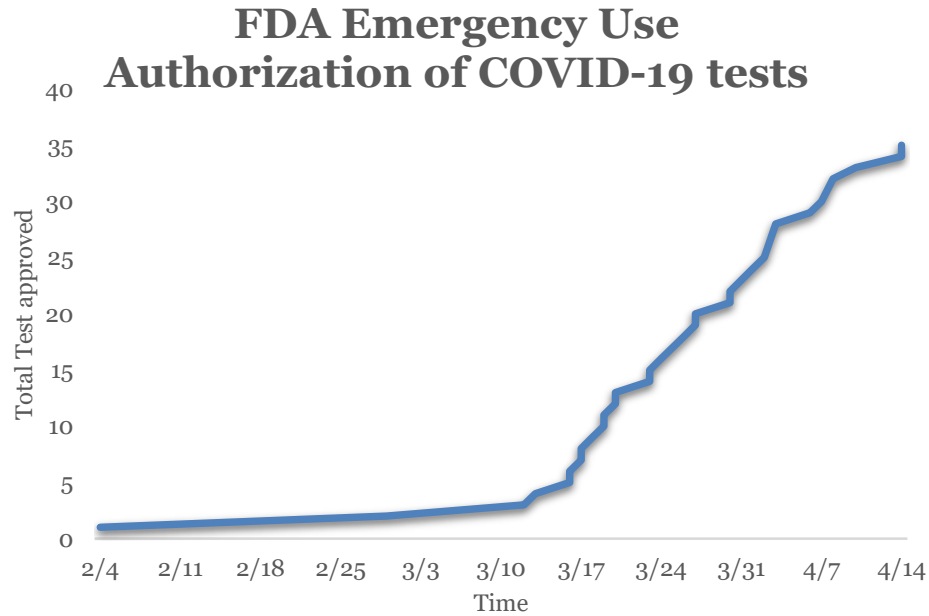


Need Validation Samples?

- 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



FDA EUA Tests



***3 new since last week**

<https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#2019-ncov>



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.)
9. Real-Time Fluorescent RT-PCR Kit for Detecting SARS-2019-nCoV (BGI Genomics Co. Ltd)
10. COV-19 IDx assay (Ipsium 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)
15. QuantiVirus SARS-CoV-2 Test kit (DiaCarta, Inc)
16. iAMP COVID-19 Detection Kit (Atila BioSystems, Inc.)



Sample to Answer

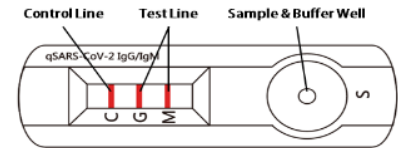
1. **Cobas SARS-CoV-2** (Roche)
2. **Panther Fusion SARS-CoV-2** (Hologic, Inc.)
3. **Simplexa COVID-19 Direct** (Diasorin Molecular, LLC)
4. **ePlex SARS-CoV-2** (GenMark Diagnostics, Inc.)
5. **Xpert Xpress SARS-CoV-2 test** (Cepheid)
6. **BioFire COVID-19 test** (BioFire Defense, LLC)
7. **Accula SARS-Cov-2 Test** (Mesa Biotech Inc.)
8. **ID NOW COVID-19** (Abbott Diagnostics Scarborough, Inc.)
9. **MagPix NxTAG CoV Extended panel** (Luminex Molecular Diagnostics, Inc.)
10. **QIAstat-Dx Respiratory SARS-CoV-2 Panel** (QIAGEN GmbH)
11. **BD MAX BioGX SARS-CoV-2 Reagents** (Becton, Dickinson & Company (BD))
12. **ARIES SARS-CoV-2 Assay** (Luminex Corporation)
13. **BD MAX BD SARS-CoV-2 Reagents** (Becton, Dickinson & Company)





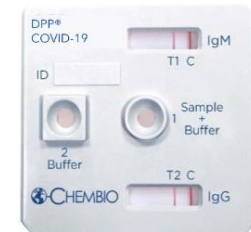
Serology Tests

- qSARS-CoV-2 IgG/IgM Rapid Test (Cellex Inc.)
 - Lateral flow- Serum or Plasma



- VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack (Ortho Clinical Diagnostics, Inc.)
 - Traditional ELISA (HRP) using Serum or Plasma

- DPP COVID-19 IgM/IgG System (Chembio Diagnostic System, Inc.)
 - Fingerstick Whole Blood, Venous Whole Blood, Serum and Plasma





Beware false claims

- “While more than 70 companies have notified the FDA they have serology tests available for use, some are falsely claiming their tests have been approved.”- FDA
- “The FDA will take appropriate action against firms making false claims or marketing tests that are not accurate and reliable”- FDA
- Currently NO approved in-home testing

FDA list of Current COVID-19 EUAs:

<https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>

Symptom Monitoring

All health care organizations should develop and implement procedures for evaluating health care workers for symptoms of respiratory illness before every shift involving direct patient care.

Monitoring may be performed by designated staff at the facility or by employees themselves with allowances for documentation of the symptoms screen to supervisors (e.g. via text, email or other methods).

Staff who develop symptoms while at work should be instructed to don a face mask, notify their supervisor, and leave work for the day.

Symptom Monitoring

The purpose of self-monitoring is to identify illness early and encourage self-isolation at home to reduce the potential of transmission to co-workers and patients.

Monitoring should include temperature monitoring and query for symptoms of COVID-19 like illness which include any of the following:

- ✓ measured temperature $>100.0F^*$ (37.8C) or subjective fever
- ✓ new or worsening cough
- ✓ new or worsening shortness of breath
- ✓ sore throat
- ✓ myalgia

*CDC recommends fever cutoffs are different in its guidance for the healthcare workers. This is done to recognize illness early.

Health care worker illnesses

Health care workers should not report to work when ill, even if they only have mild symptoms that would not normally cause them to miss work.

If a worker tests positive for COVID-19, they should follow standard isolation and release recommendations for person's diagnosed with COVID-19.

- ✓ **they must remain isolated for a minimum of 7 days from the date of symptom onset, and**
- ✓ **they must be free of fever and others symptoms of acute illness for at least 3 days.**

What should I do if I am diagnosed with COVID-19?

Being diagnosed with COVID-19 can mean that you had a positive lab test or a doctor told you that you had COVID-19. If either of these situations occurred, you should practice **self-isolation** and **self-monitoring** in order to protect yourself and your community from COVID-19. You should follow these recommendations for **at least 7 days since symptoms first began AND for at least 3 days after symptoms resolve**.

Self-Isolation: For at least 7 days since symptoms first began AND for at least 3 days after symptoms resolve



Stay home (or other location approved by public health). This means do not go to work, school, or public areas. If you need medical care, it is important you follow the instructions below.



Separate yourself from other people and animals in your home. As much as possible, you should stay in a specific room and away from other people in your home. If possible, you should use a separate bathroom.

Other people who you live with or had close contact with, starting 2 days before you were sick and while you were sick, should now stay home (self-quarantine) and watch for symptoms for 14 days after their last close contact with you.



Avoid sharing personal household items. You should not share dishes, drinking glasses, eating utensils, towels, or bedding with other people in your home. After using these items, they should be washed thoroughly with soap and water.



Wash your hands often and practice good hygiene.



Wear a facemask if you need to be around other people and **cover your mouth and nose with a tissue** when you cough and sneeze.



Postpone all non-essential medical appointments until you are out of isolation. If you have an essential appointment during the isolation period, please tell your local health department who will help coordinate the visit.

Self-Monitoring



If you have a thermometer, measure your temperature twice a day, once in the morning and once at night. Otherwise watch for symptoms of fever like feeling hot, chills or sweats.



Watch for a worsening **cough** or **difficulty breathing**.

If your symptoms get worse or you have difficulty breathing:

Contact your doctor. Do not use public transportation, ride-sharing, or taxis.

If you need emergency medical attention any time during the self-isolation period, call 911 and let them know that you were diagnosed with COVID-19.



COVID-19: Isolation release times



Bureau of Communicable Diseases
Department of Health Services

I have been
diagnosed with
COVID-19

Isolation
release



Be well* for 3 days

AND

At least 7 days
since symptoms
began

REMEMBER: If you have other people living in your home, you should isolate yourself from them.

*free of fever, productive cough, and other symptoms of respiratory infection

P-02632 (03/2020)

COVID-19: Quarantine release times



Bureau of Communicable Diseases
Department of Health Services

**I have had close
contact with
someone
diagnosed with
COVID-19**

Quarantine
release



14 days after
your last
contact with
the sick person



If you get sick, please follow the guidance in the [“What should I do if I was tested for COVID-19 and awaiting results?” one-pager](#)

P-02634 (3/2020)

Public health lab priorities

- **Hospitalized** patients with COVID-19 symptoms
- **Patients 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.)
- **Residents of a long-term care** facility with COVID-19 symptoms
- **Residents in a jail, prison, or other congregate setting** with COVID-19 symptoms
- **Health care workers or first responders** (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 generation, distribution and production of raw materials; oil and biofuel refining)



Reporting Results Daily to HHS

“hospitals may be relieved from reporting directly to the Federal Government if they receive a written release from the State stating that the State will collect the data from the hospitals and take over Federal reporting responsibilities.”

“States must first receive written certification from their FEMA Regional Administrator affirming that the State has an established, functioning data reporting stream to the Federal Government that is delivering all of the information below at the appropriate daily (or higher) frequency.”

The State is evaluating WEDSS data for it's ability to meet federal requirements. The State intends to pursue FEMA certification.

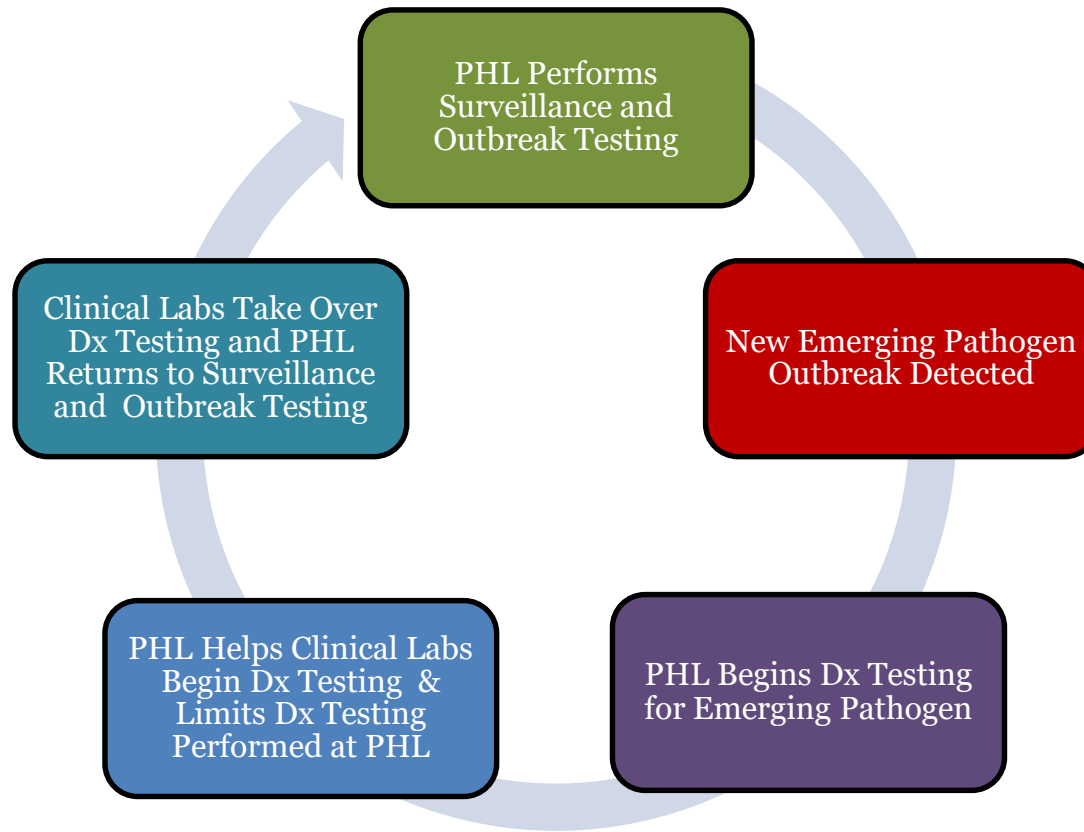


Common Problems With Paperwork

- Problems with CDD Requisition (A) Form 4105:
 - 3 Most Common Pieces of Missing Information:
 - Date of birth
 - Date of Collection
 - Site of collection
 - Remove perforated edge of form
 - Only submit the top (white) copy with specimen
 - Retain the 2nd (yellow) copy for your records
- Missing PIF



Outbreak Response Cycle



- Cycle is working exactly as it is supposed to.



Please Type Your Questions in the
Question Box!





References

Analytical sensitivity and efficiency comparisons of SARS-COV-2 qRT-PCR assays

<https://www.medrxiv.org/content/10.1101/2020.03.30.20048108v1.full.pdf>