



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



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

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- Situation Update
- WSLH testing update
 - New PIF
- Clinical lab testing update
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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/>



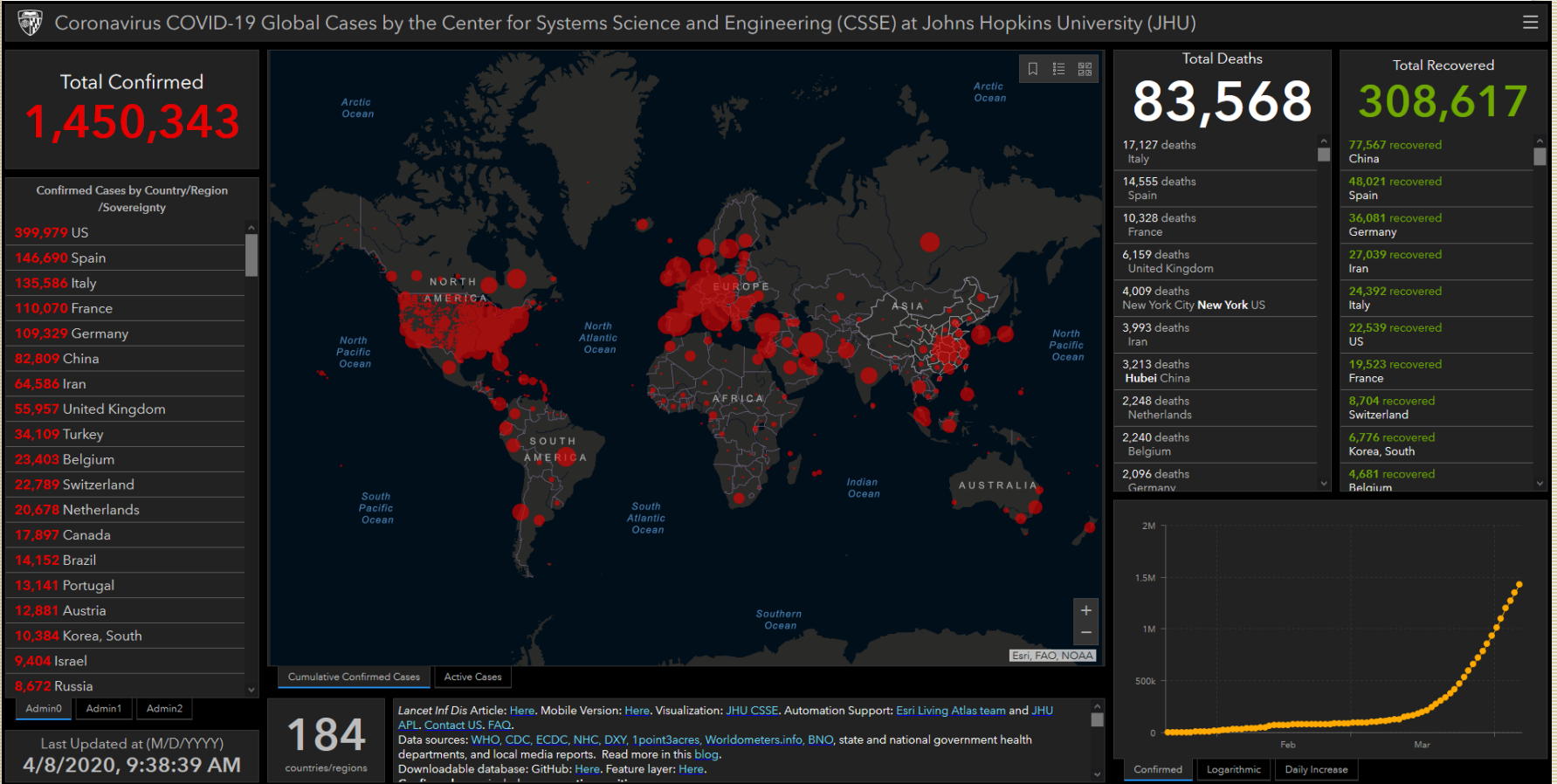
New Sriracha Hand Sanitizer

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





Global Impact

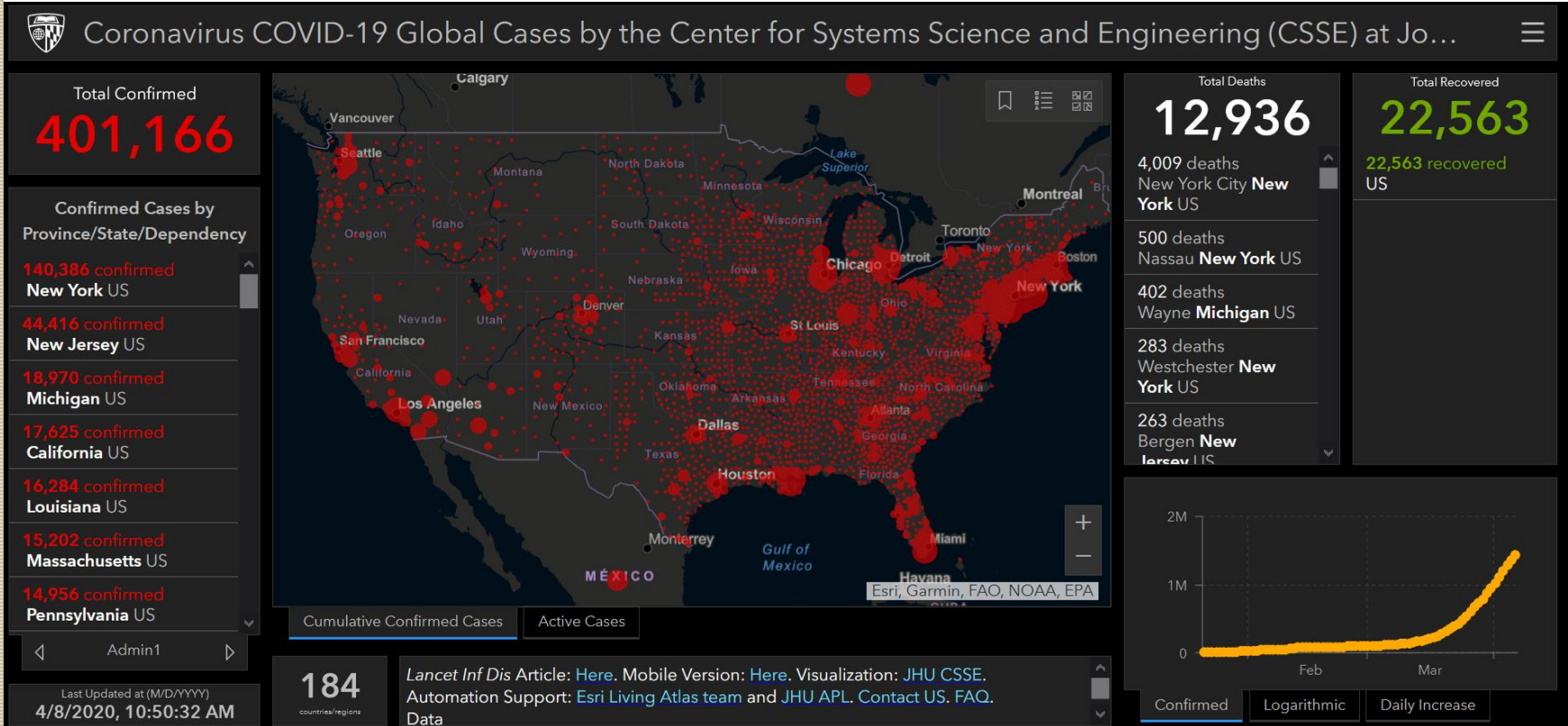


Johns Hopkins University Global Coronavirus Tracking:

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



COVID-19 in the US



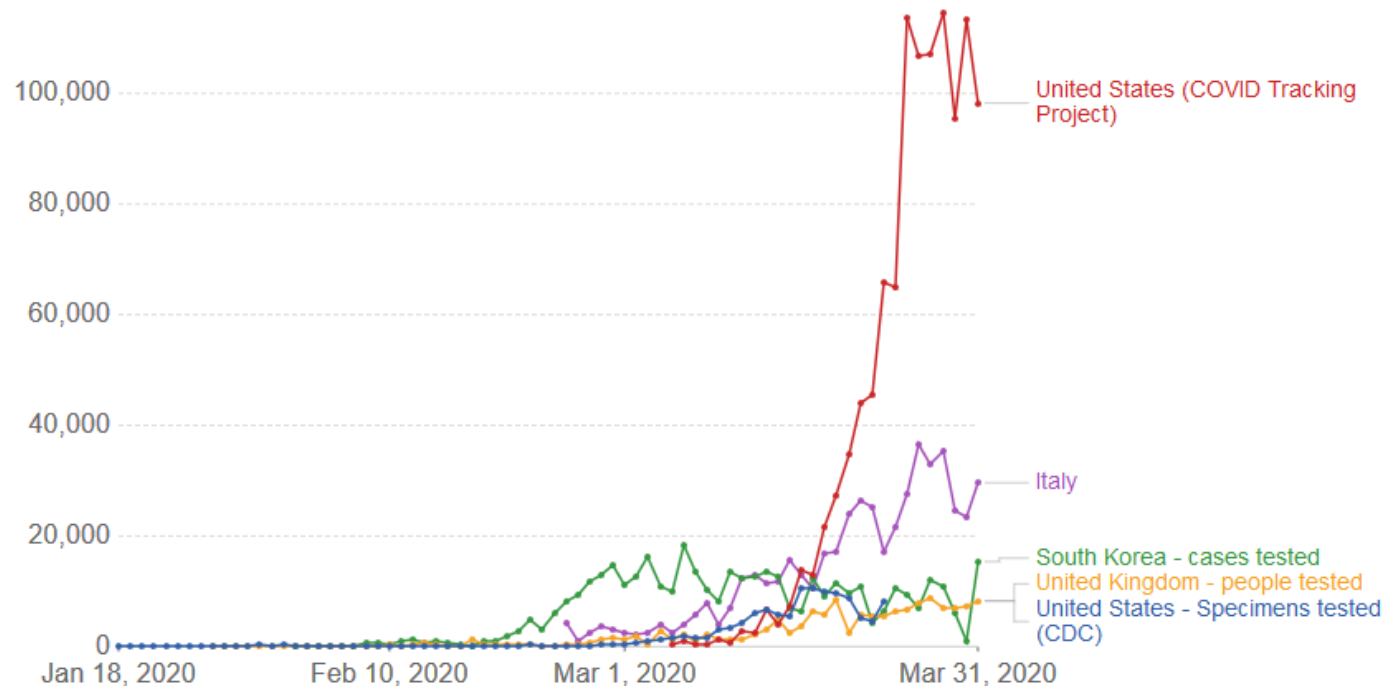


The US is doing a lot of testing

COVID-19 tests per day

Our World
in Data

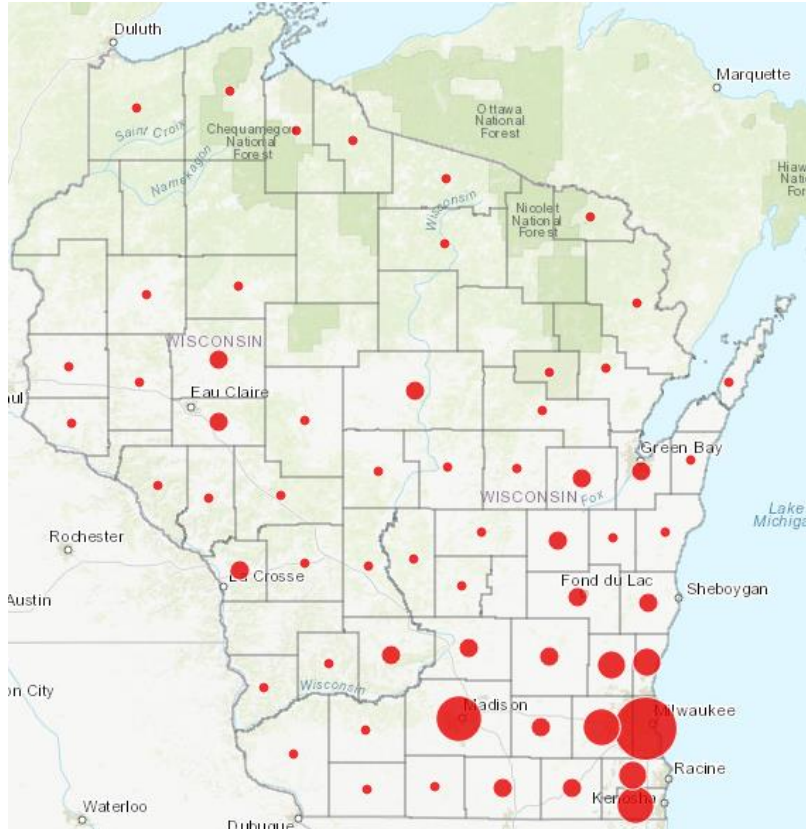
Comparisons across the series are compromised for several reasons.
See note below for more information about the series for the US and South Korea.
For the UK and Italy only limited descriptions of the data are provided by the sources.



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



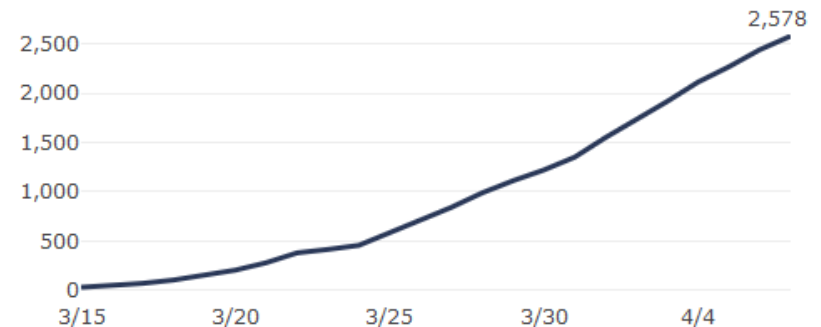
Wisconsin



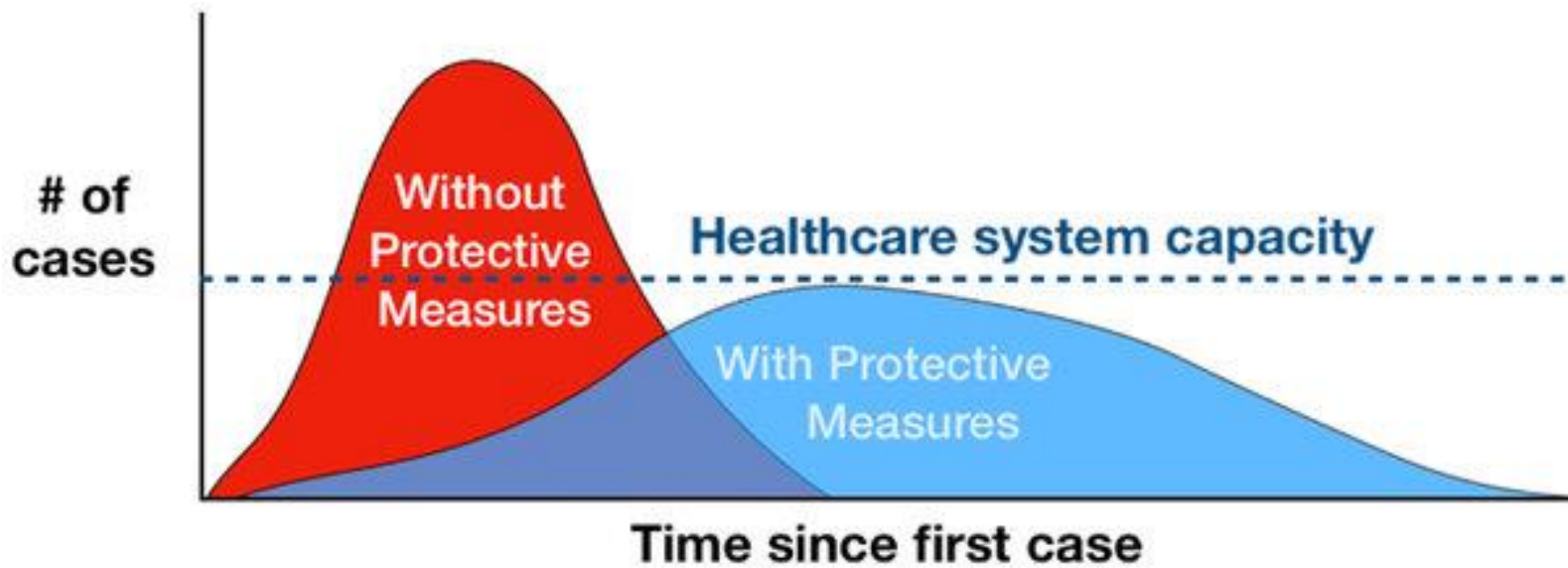
Wisconsin COVID-19 summary

Status	Number (%) of People as of 4/7/2020
Negative Test Result	28,512
Positive Test Result	2,578
Hospitalizations	745 (29%)
Deaths	92

Updated: 4/7/2020



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

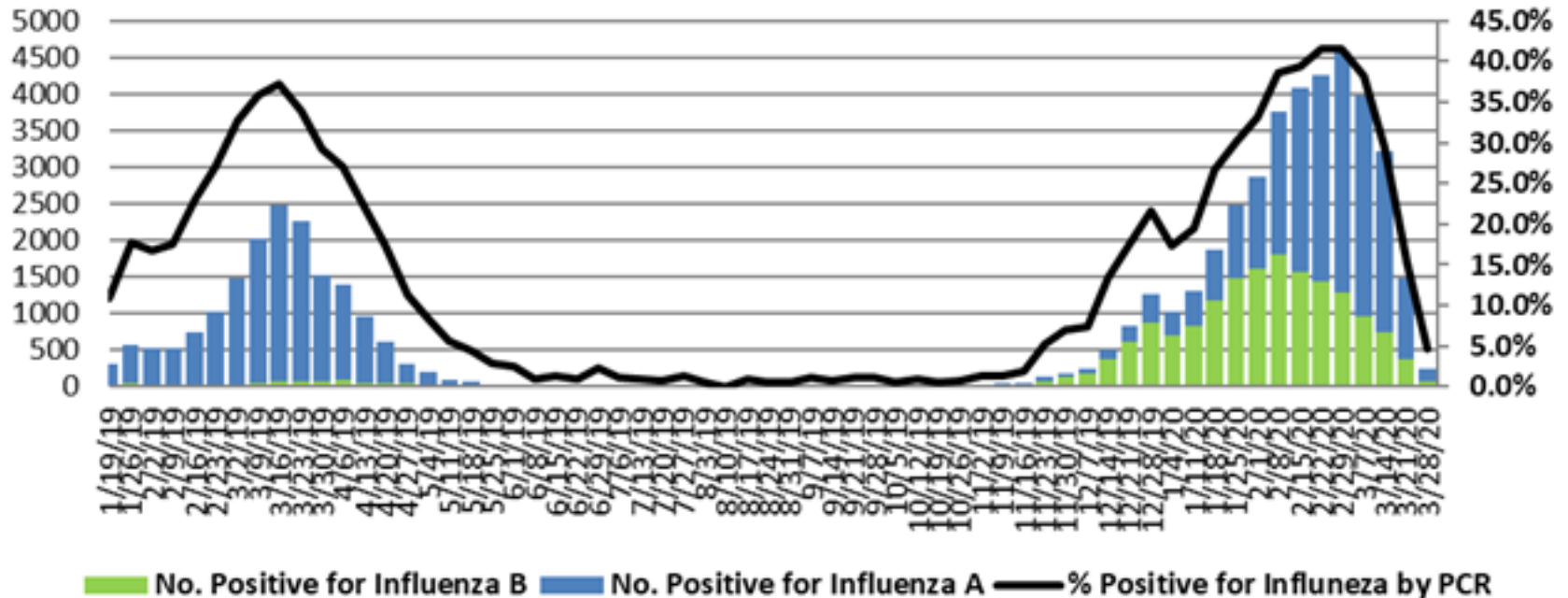


Adapted from CDC / The Economist



Distancing Works!

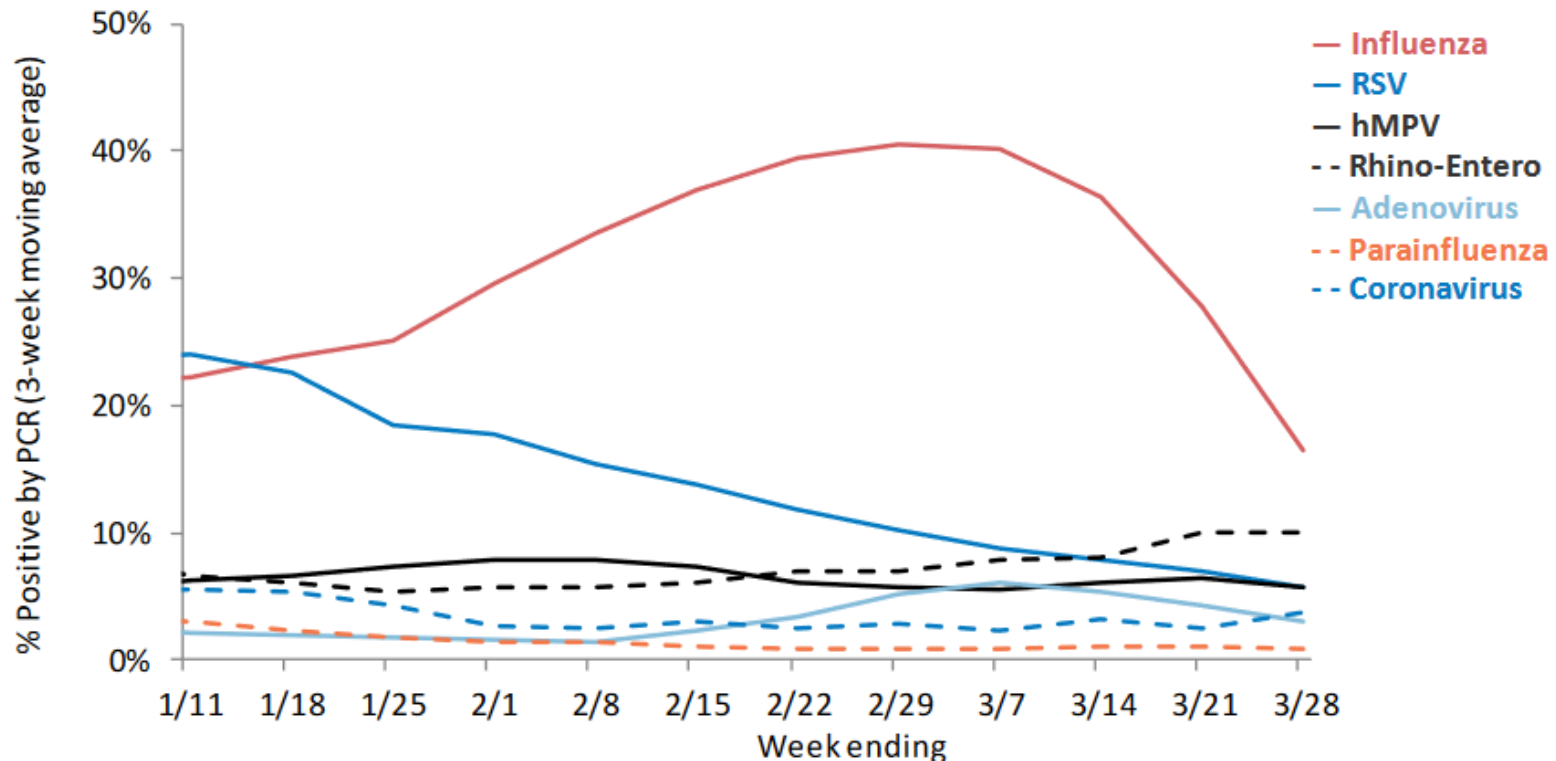
% Positive for Influenza by PCR (Wisconsin), Week Ending March 28, 2020





WISCONSIN LABORATORY SURVEILLANCE FOR RESPIRATORY VIRUSES BY PCR

Trends in respiratory virus activity by PCR

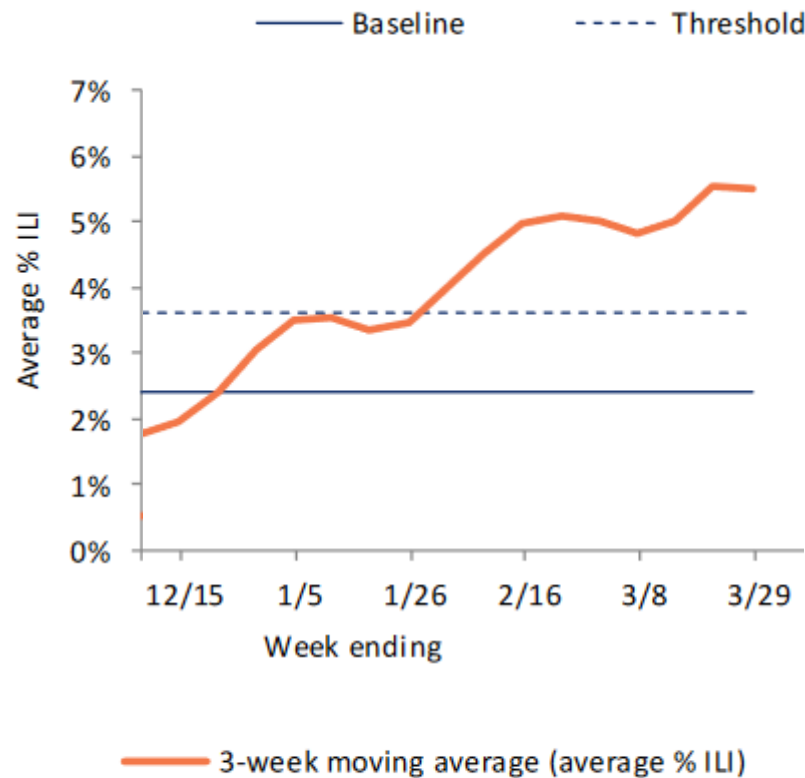


<https://www.dhs.wisconsin.gov/publications/p02346.pdf>



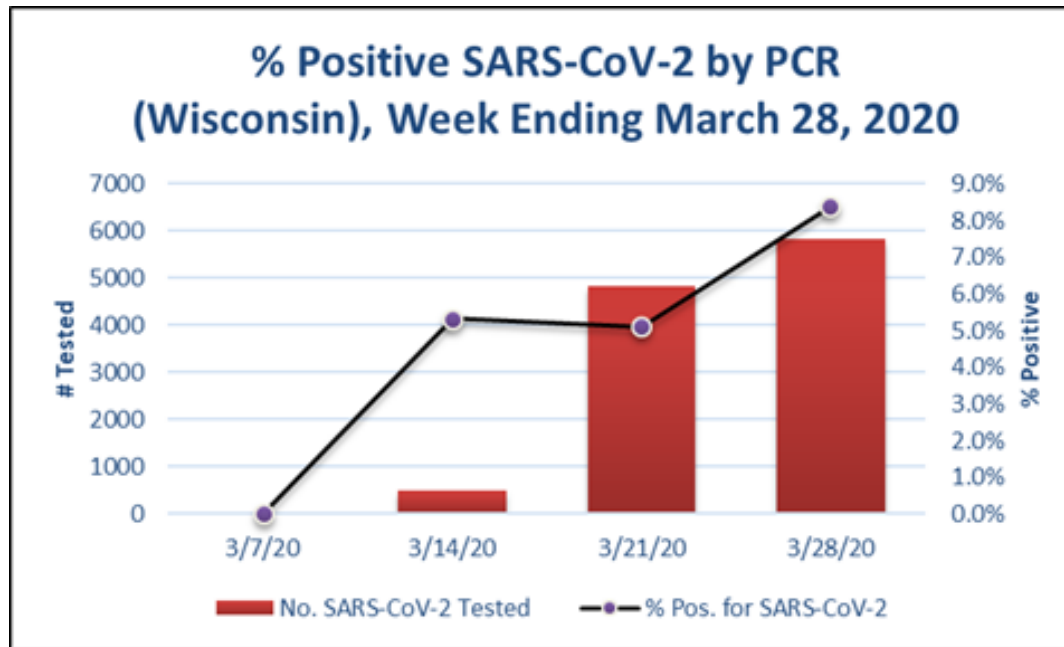
Illness Continues to Rise

ILI activity trend analysis





Testing has Increased Rapidly



*Not all labs reporting

<http://www.surveygizmo.com/s3/389222/Wisconsin-Laboratory-Surveillance-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: NP OP NNP/OP 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 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 MDHL, 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 \(#4105\)](#)

B: PATIENT IS BEING TESTED AT ANY OTHER LABORATORY

Patients that do not qualify for testing at WSLH or MDHL, 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.

DHS HAN 4/7/20
<https://content.govdelivery.com/accounts/WIDHS/bulletins/28569e9>



Approved for Testing at Public Health Labs

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Other Testing and Reporting

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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>



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>



Wisconsin State Laboratory of Hygiene

Facility Testing Status **Actively Testing** ▾

Do you have a backlog of tests? **NO** ▾

Facility Testing Start Date **3/2/2020**

Are you experiencing reagent/supply shortages that will lead to an imminent stop in testing? **NO**

If you are experiencing a shortage, what are you missing?

Current Capacity (tests per day)

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

Available
Accula
Aries
BDMax
BioFire
Cobas
Diasorin
easyMAG
ePlex
GeneXpert



Chosen
EMAG
EZ1
MagnaPure LC
Manual Extraction
Qiacube

Future Capacity (tests per day)

Future test methods (choose all that apply)

Available
Accula
Aries
BDMax
BioFire
Cobas
Diasorin
EMAG
ePlex
EZ1



Chosen
easyMAG
GeneXpert
KingFisher
Panther Fusion

Other testing methods?

Save

Cancel



Survey Results

Lab Stats

Number of active labs

14

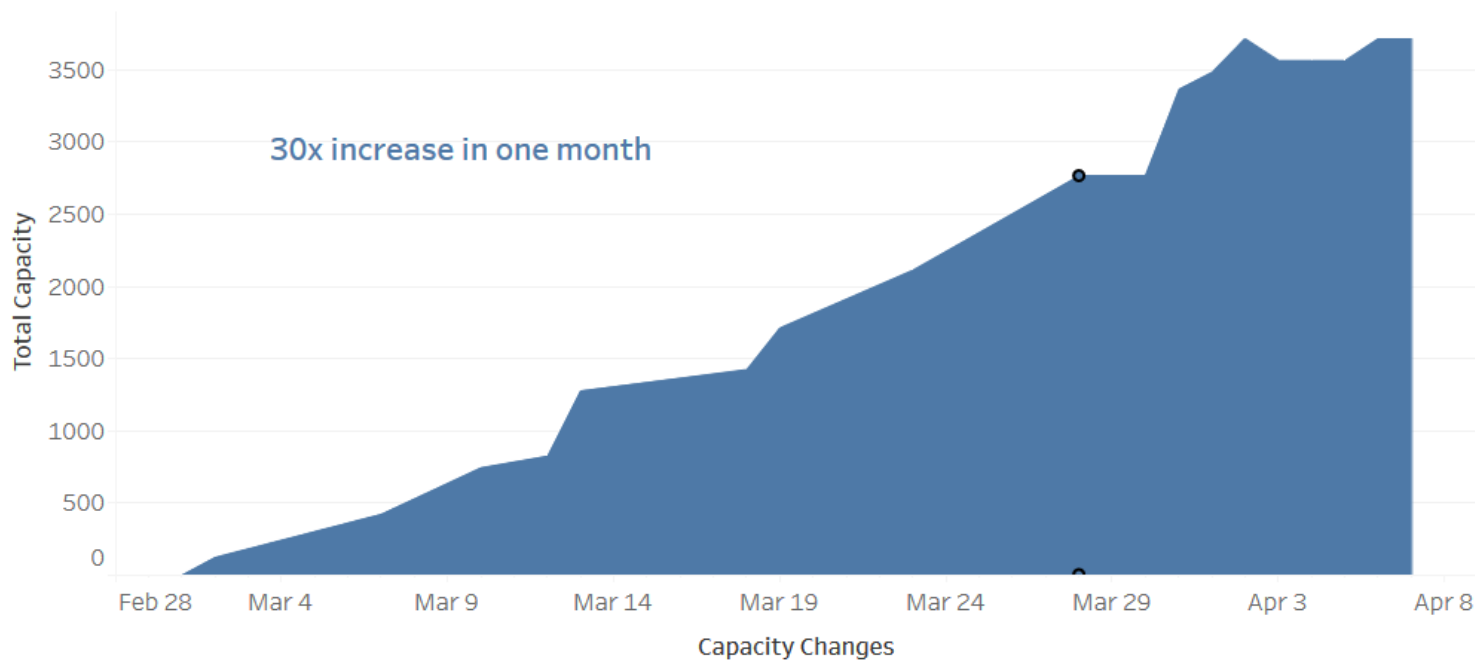
Number of planned labs

44

Current Daily Testing Capacity

3,623

Capacity Growth Over Time

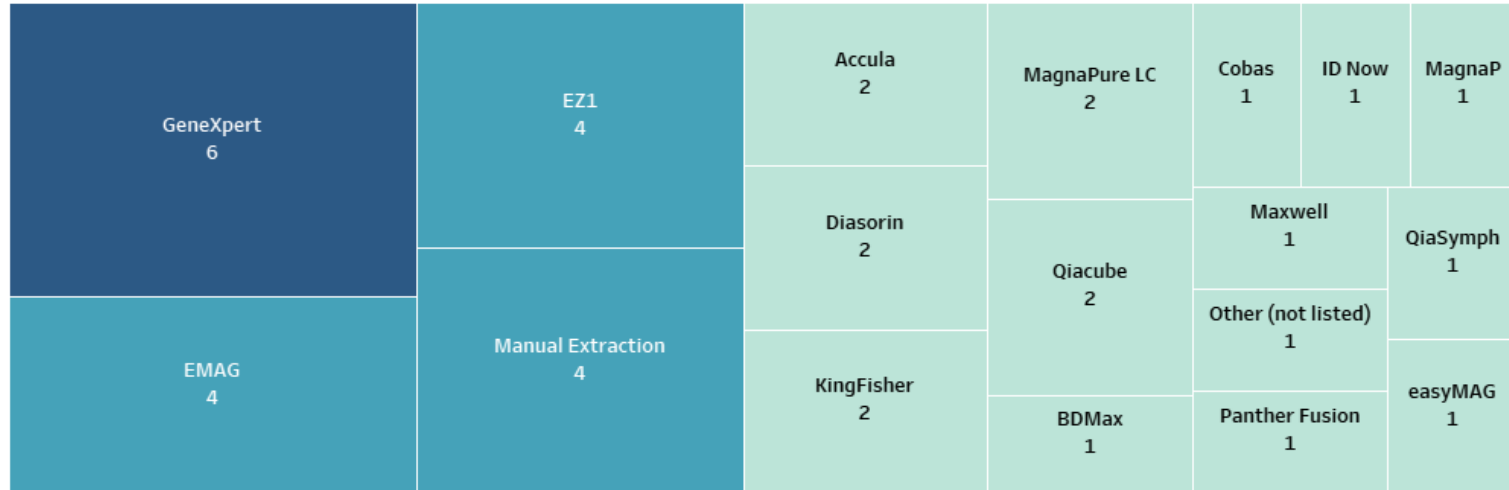


Test capacity per day does not equate to patients tested per day. This data is based on laboratory internal assessments and planning for future testing. All data are estimates and do not reflect actual test volumes. Capacity is limited by fragile test supply availability.

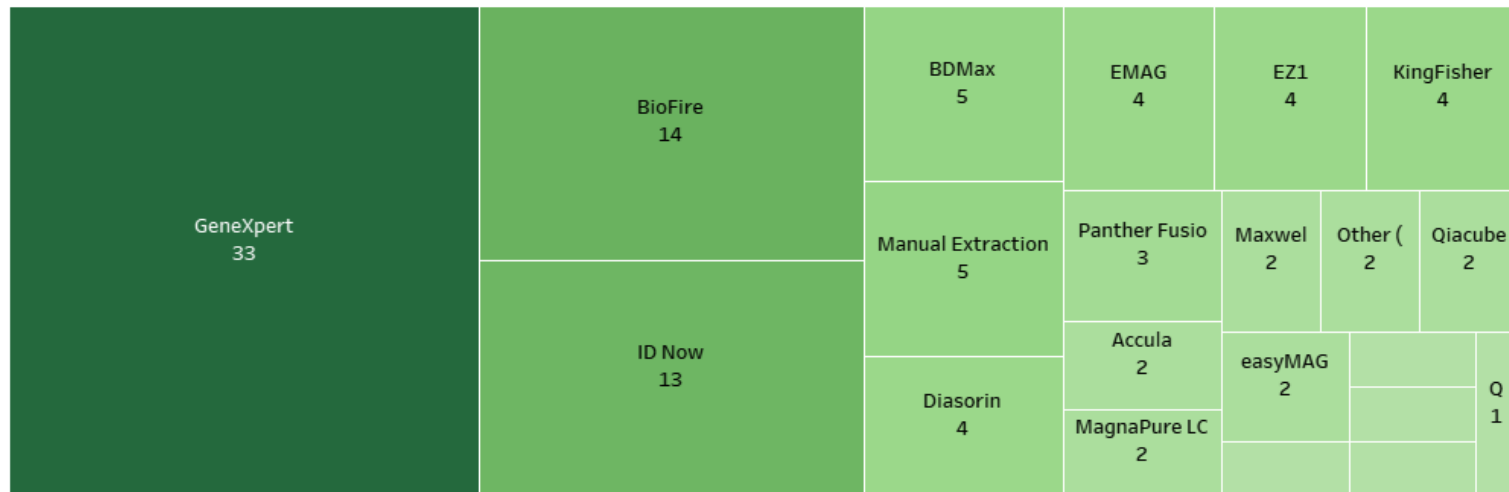


What Tests are Being Used?

Active Test Methods Statewide



Current and Planned Methods





What are the Challenges?

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

*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 (2-8°C) prior to use
- Can be use 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:

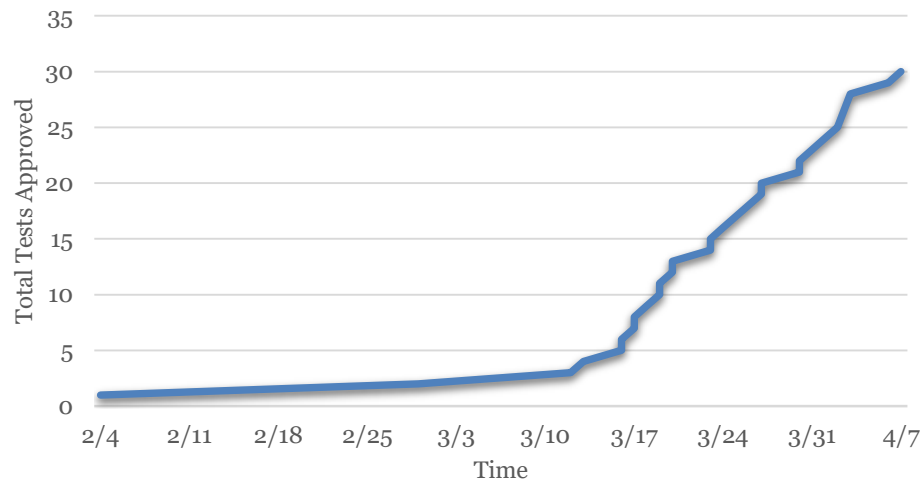
- Your facility/healthcare system
- Shipping Address
- Current testing capacity
- # needed
- If you can store these at 2-8 C

Requests will be fulfilled as supplies allow



FDA EUA Tests

FDA authorization of COVID-19 EUA tests



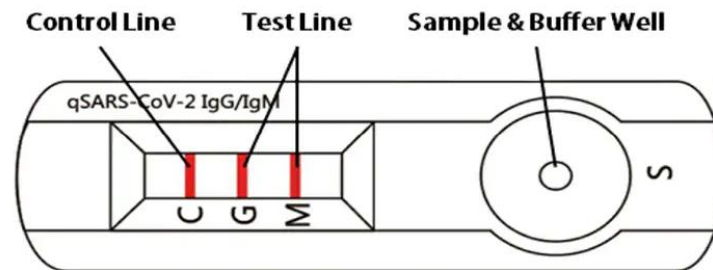
*8 new since last week

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



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?

NAAT (PCR or molecular)

- **Stand alone-** Confirmatory for COVID-19
- **Early detection-** Positives are first detected at symptom onset or possibly slightly before
- Can be fast or slow (5 minutes - 6 hours)
- **Sensitive-** The gold standard in COVID-19 detection
- **Specific-** only detects COVID-19

Serology (antibody)

- These tests cannot be used alone to diagnose a patient.
- Positives are first detected between 3-14 days after symptom onset
- **Rapid** (usually minutes)
- Variable detection, even on the same patient
- May have false positives from other coronaviruses or from other patient factors



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.)
9. Real-Time Fluorescent RT-PCR Kit for Detecting SARS-2019-nCoV (BGI Genomics Co. Ltd)
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

BioMeriux

- 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.)
- **MagPlex 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

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

THE VICE PRESIDENT
WASHINGTON

March 29, 2020

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.



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!

