



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



Update on COVID-19 Diagnostic Testing 06-24-20

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WCLN Network Coordinator

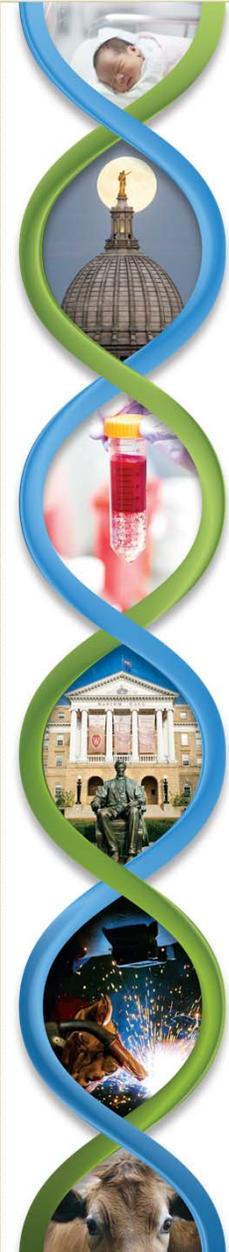
Communicable Disease Division

Wisconsin State Laboratory of Hygiene



Contents

- Situation Update
- Abbott ID NOW survey
- FDA EUA updates
- WSLH Testing update
- SEOC supplies
- Reporting
- 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/>

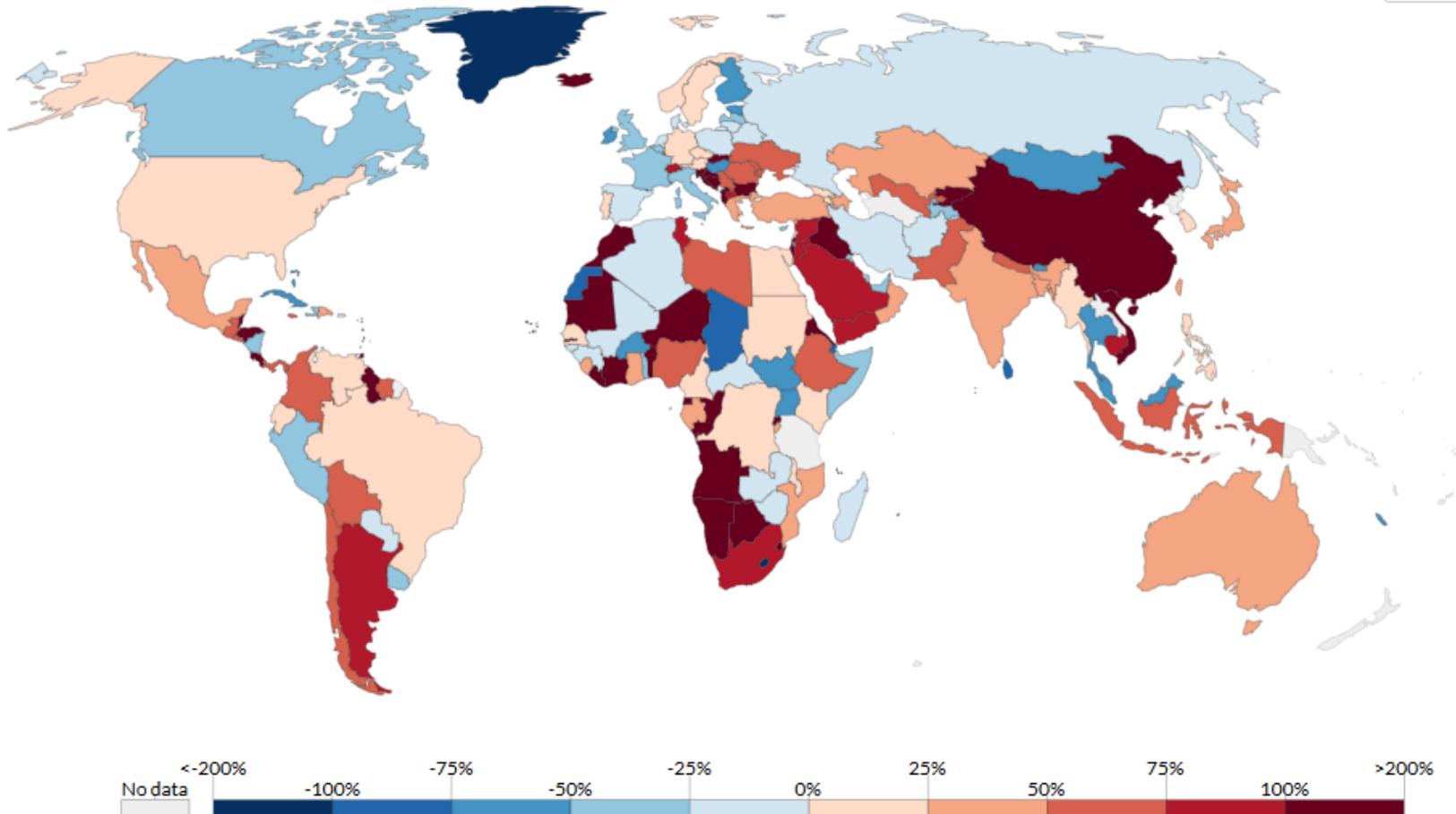
The WSLH does not endorse products of any kind





New hot spots

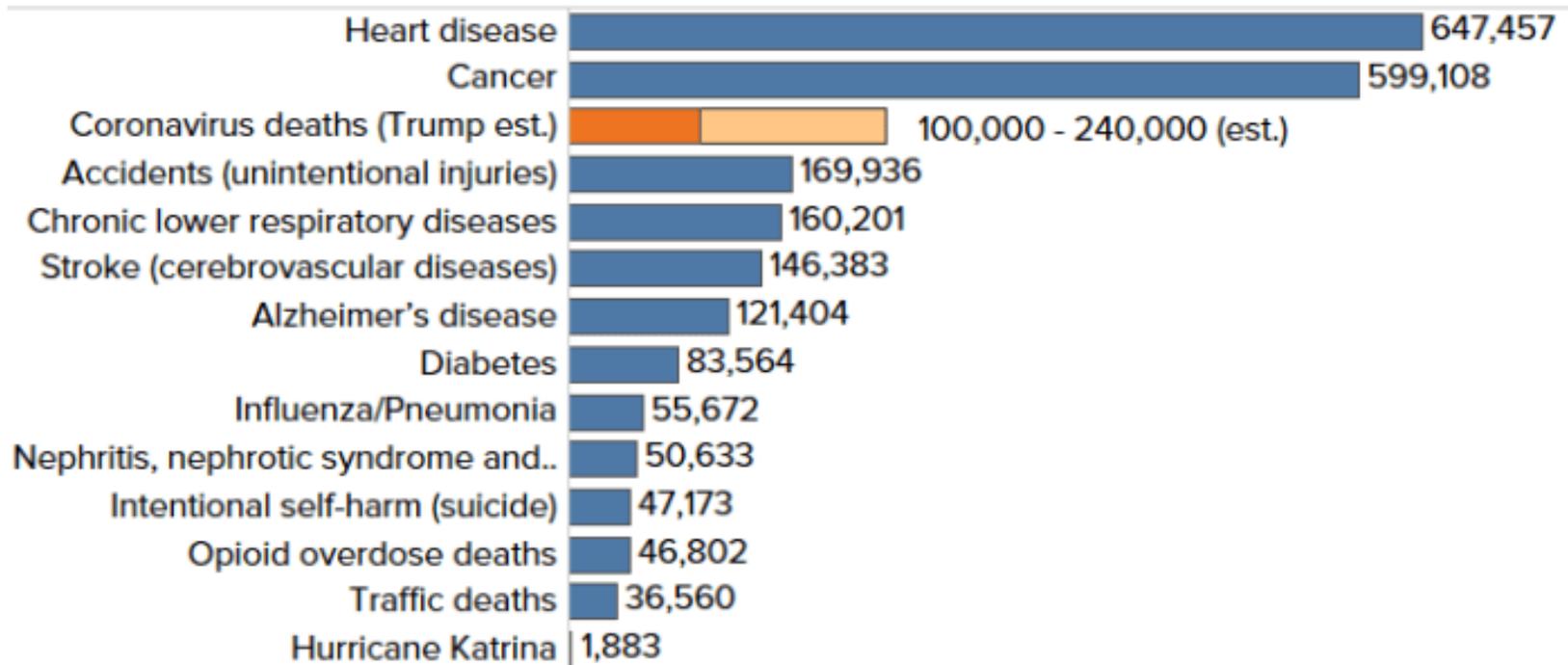
World



<https://ourworldindata.org/grapher/biweekly-growth-covid-cases>



Coronavirus death estimate vs. other causes of death



SOURCE: CDC, NOAA, White House





Fatality rate

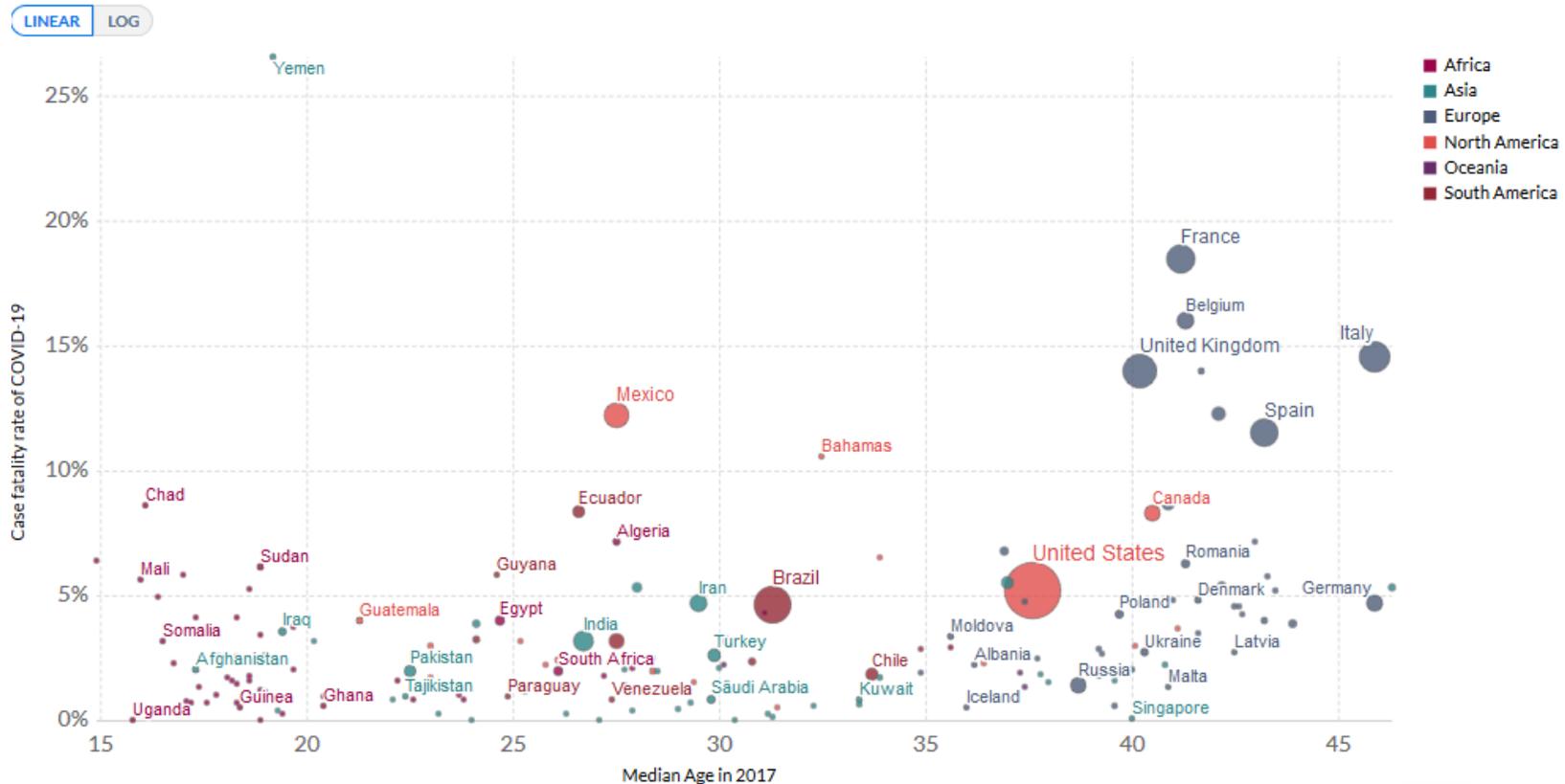
Case fatality rate of COVID-19 vs. Median Age, Jun 23, 2020

The Case Fatality Rate (CFR) is the ratio between confirmed deaths and confirmed cases.

During an outbreak of a pandemic the CFR is a poor measure of the mortality risk of the disease. We explain this in detail at [OurWorldInData.org/Coronavirus](https://ourworldindata.org/coronavirus)

The size of the bubble corresponds to the total confirmed deaths up to that date.

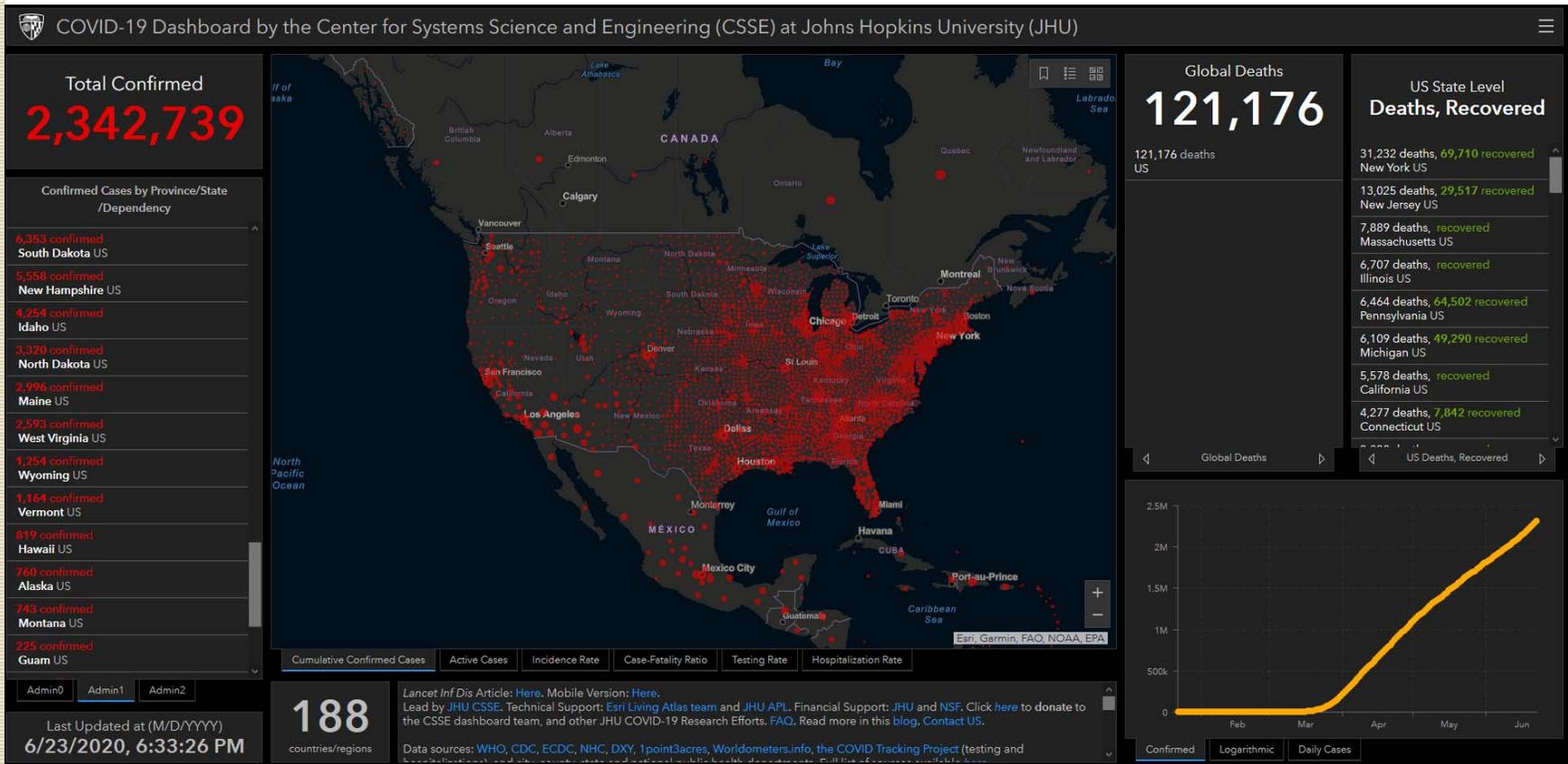
Our World
in Data



<https://ourworldindata.org/grapher/case-fatality-rate-of-covid-19-vs-median-age>

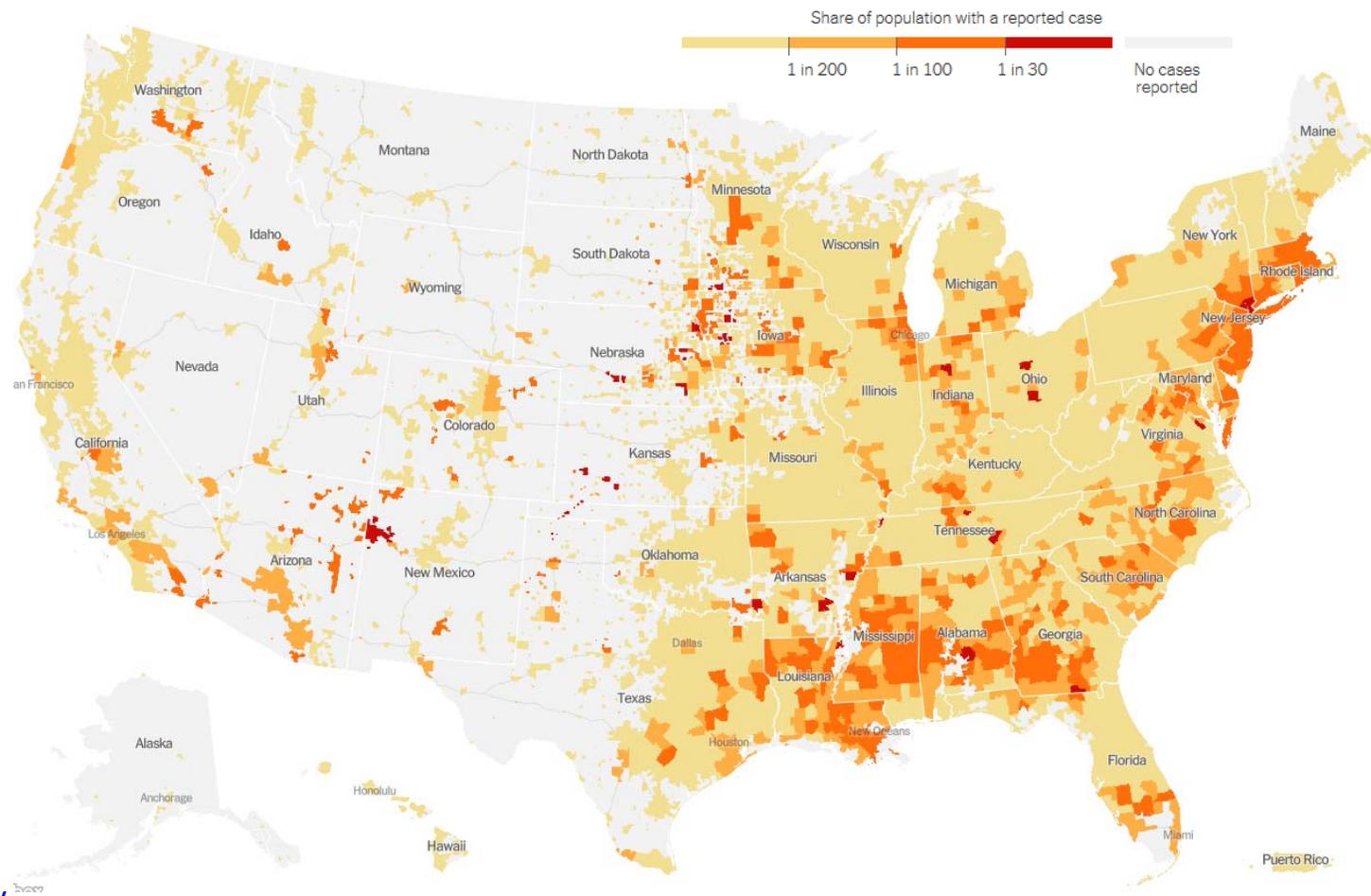


COVID-19 in the US





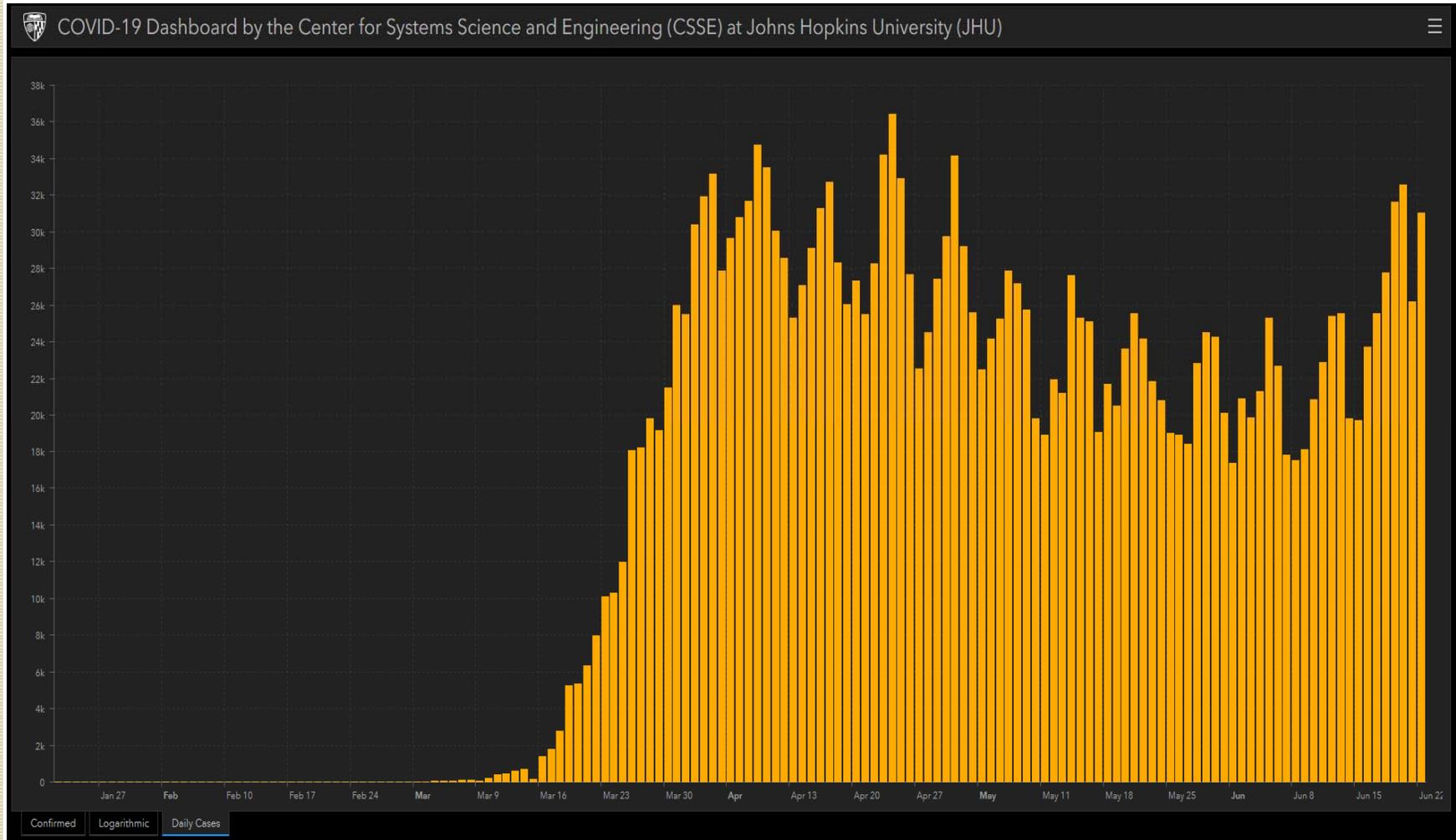
US Cases per capita



<https://www.nytimes.com/interactive/2020/us/coronavirus-us-cases.html>



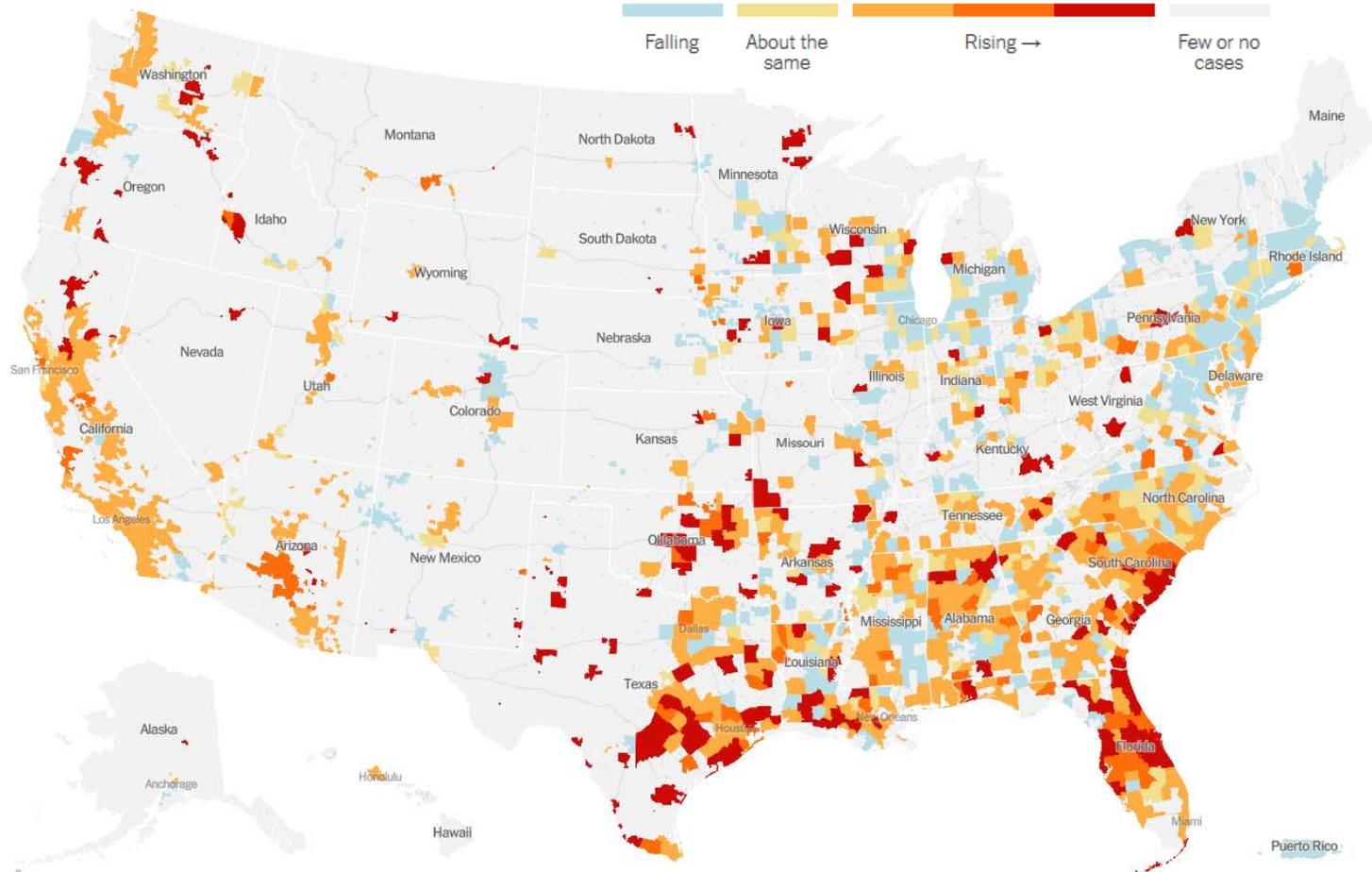
Daily case reports- US





US Hot Spots

How the number of new cases has changed in the last two weeks



<https://www.nytimes.com/interactive/2020/us/coronavirus-us-cases.html>

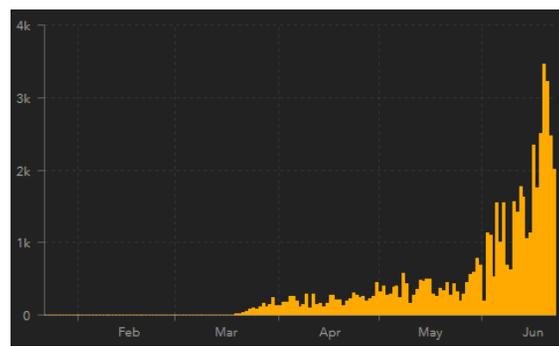


New US Hot Spots

Texas



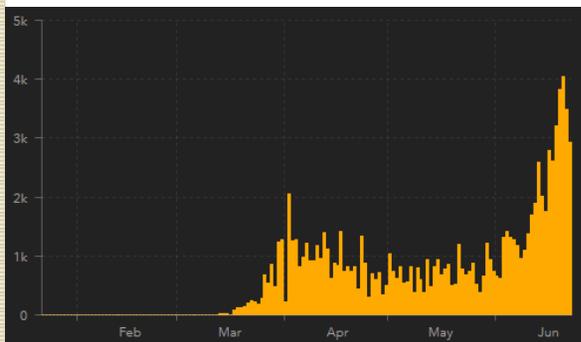
Arizona



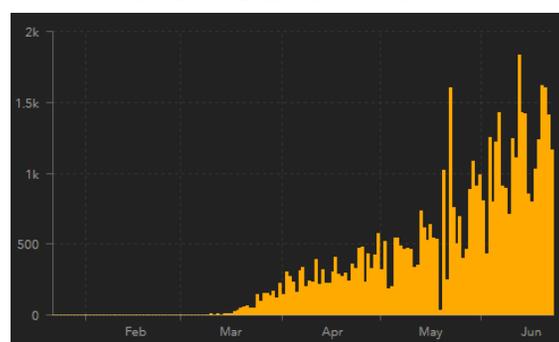
Utah



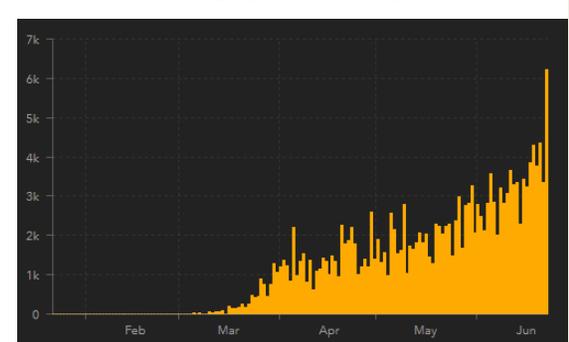
Florida



North Carolina



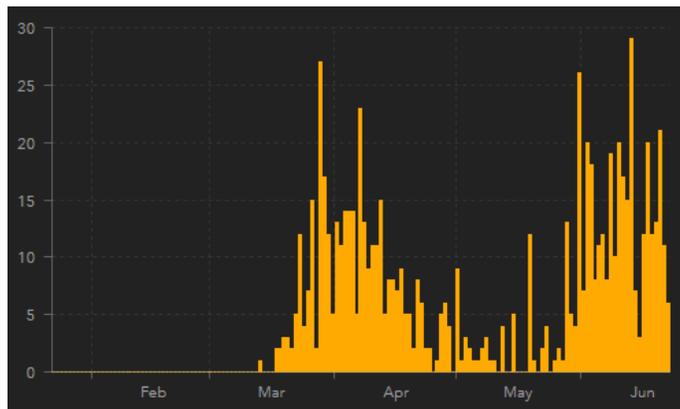
California



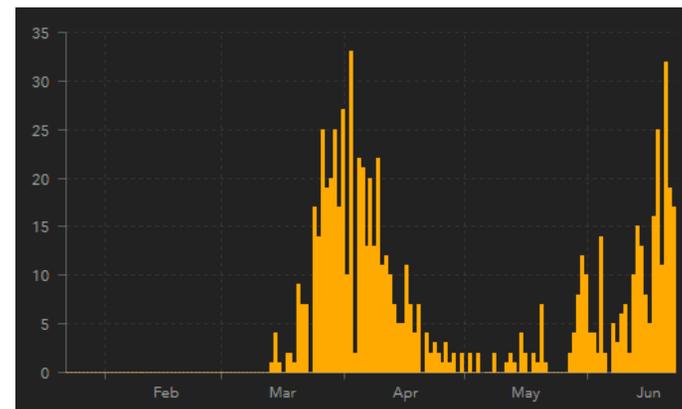


Second Waves

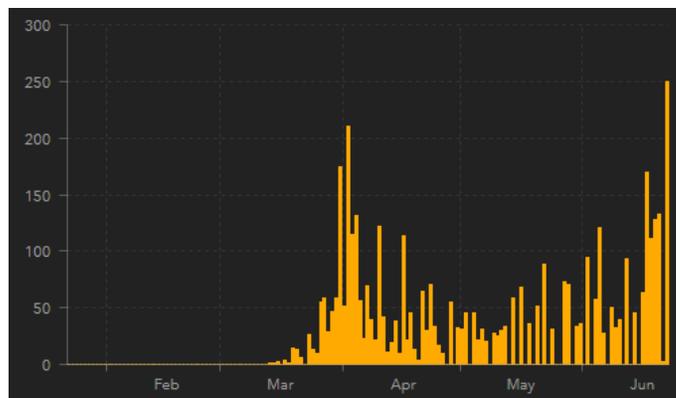
Alaska



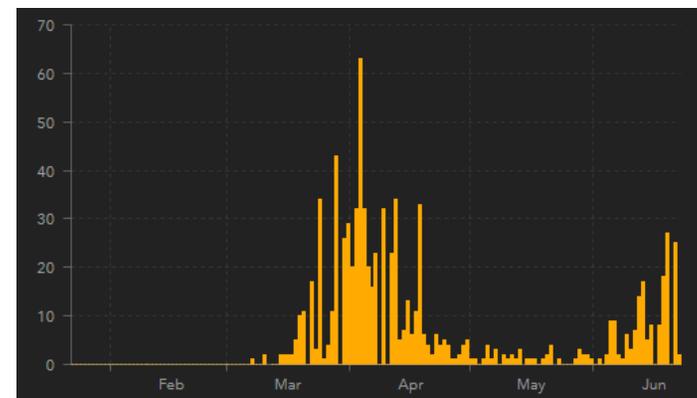
Montana



Idaho

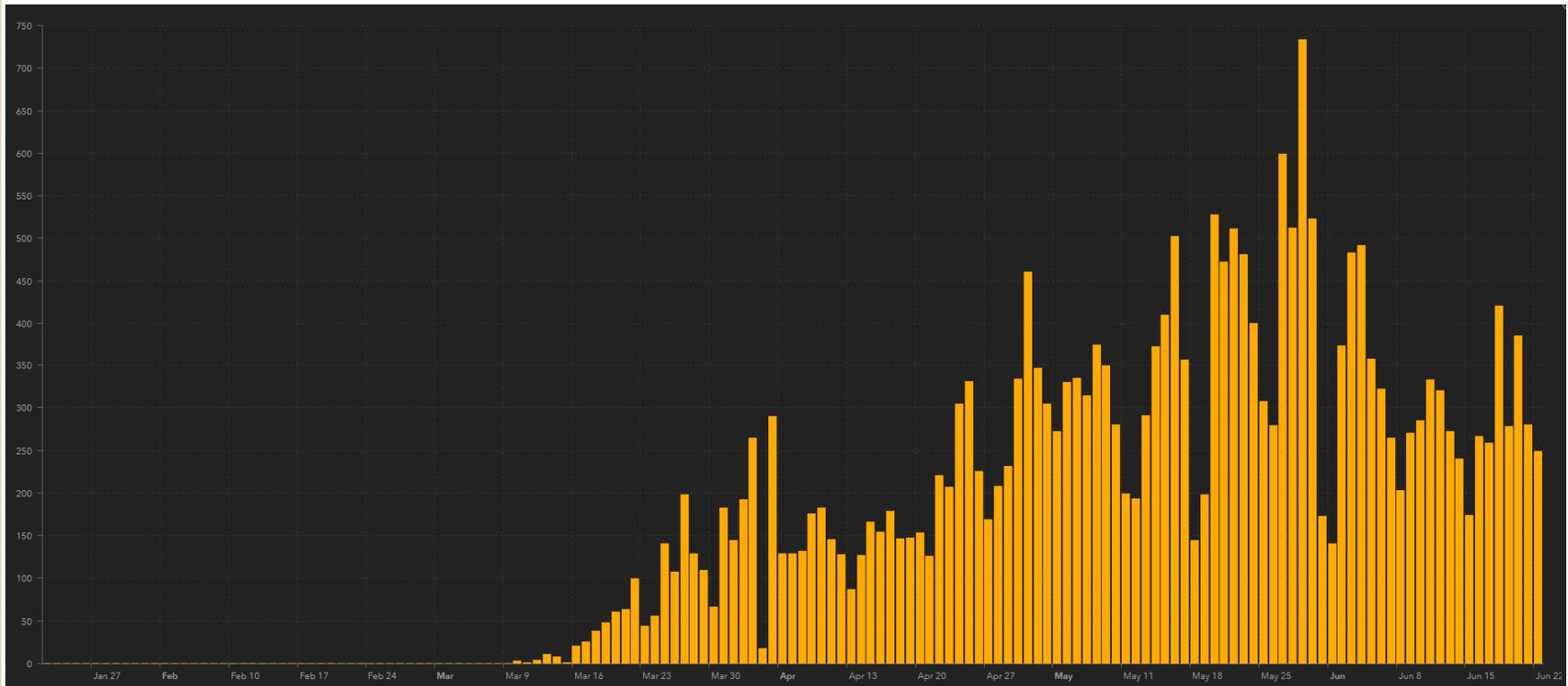


Hawaii





Wisconsin

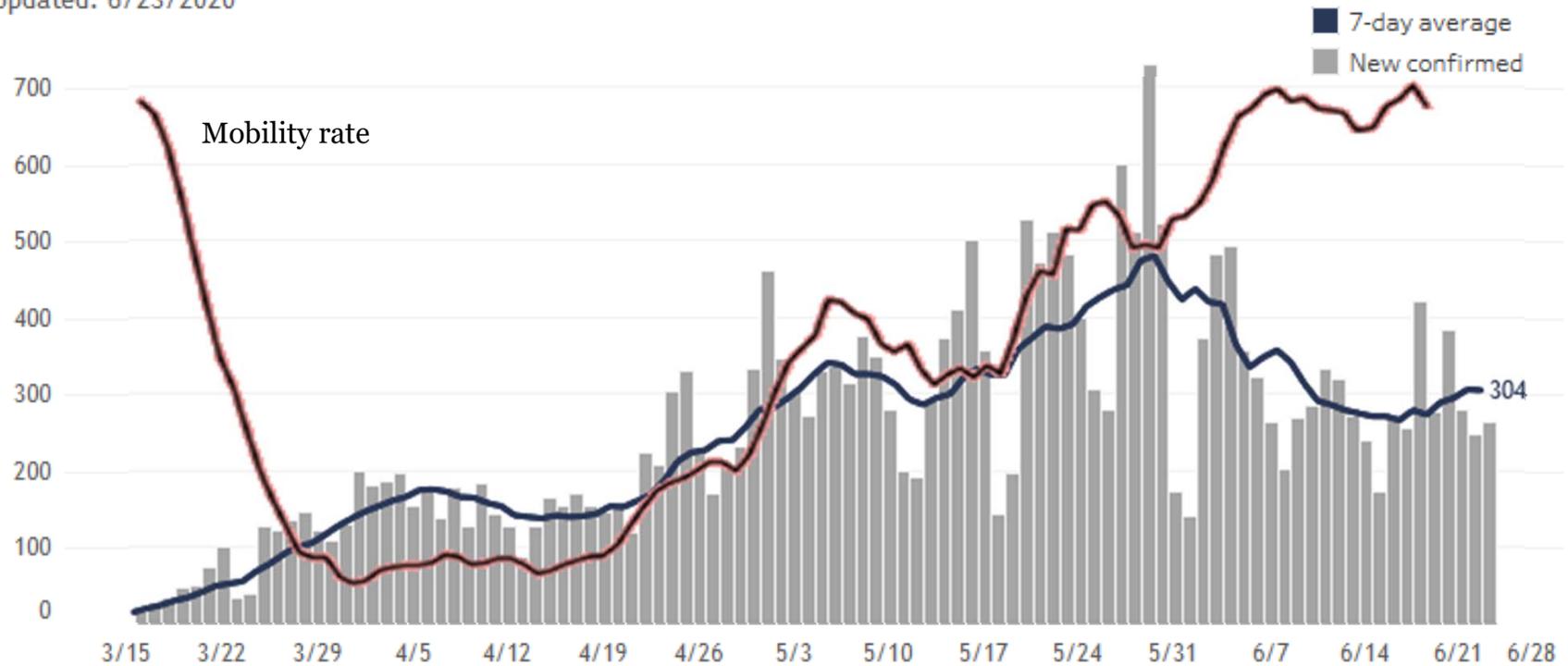




Wisconsin Daily Cases

New confirmed COVID-19 cases by date confirmed, and 7-day average

Updated: 6/23/2020



<https://www.dhs.wisconsin.gov/covid-19/data.htm>



WI mobility data



White House report 6/23/20



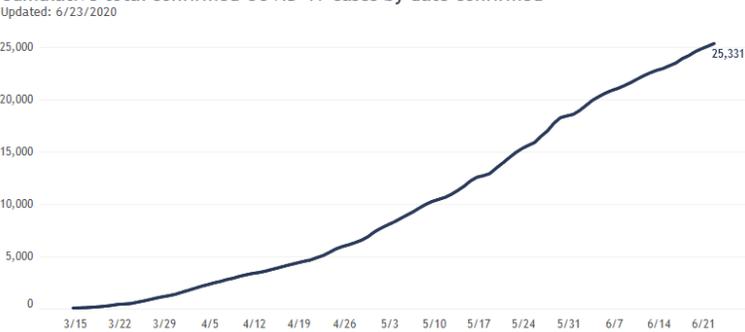
Wisconsin

Updated: 6/23/20

Negative Test Results	478,165	$\Delta 277,291$
Positive Test Results	25,331	$\Delta 9,468$
Hospitalizations	3,268	$\Delta 906$
Deaths	750	$\Delta 233$

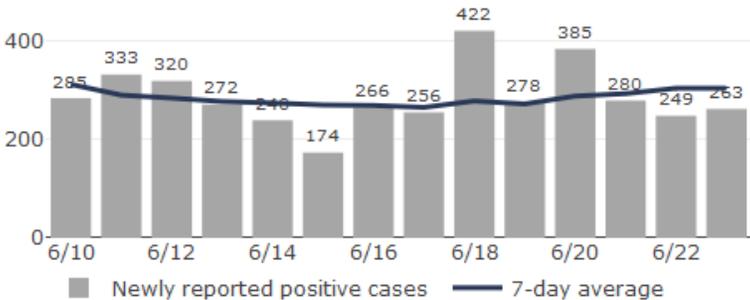
Percent of Cases Resulting in Hospitalization: 13%
 Percent of Cases Resulting in Death: 3%

Cumulative total confirmed COVID-19 cases by date confirmed

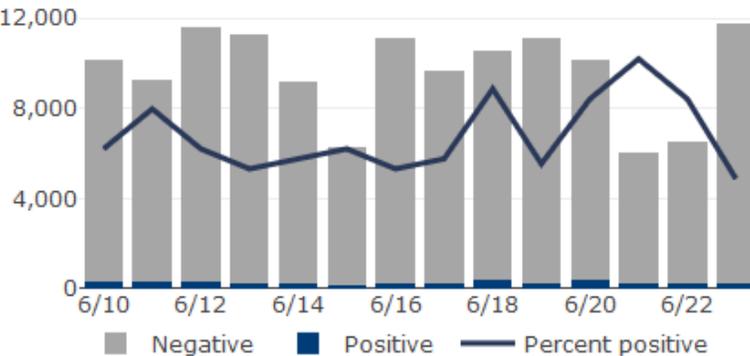


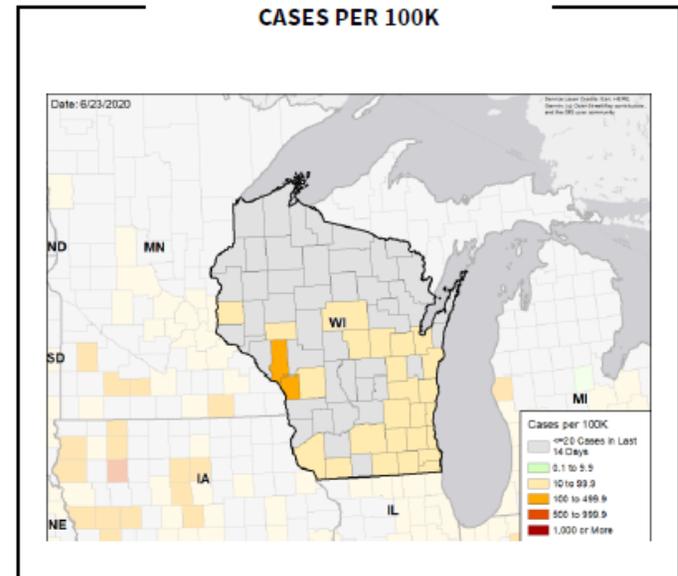
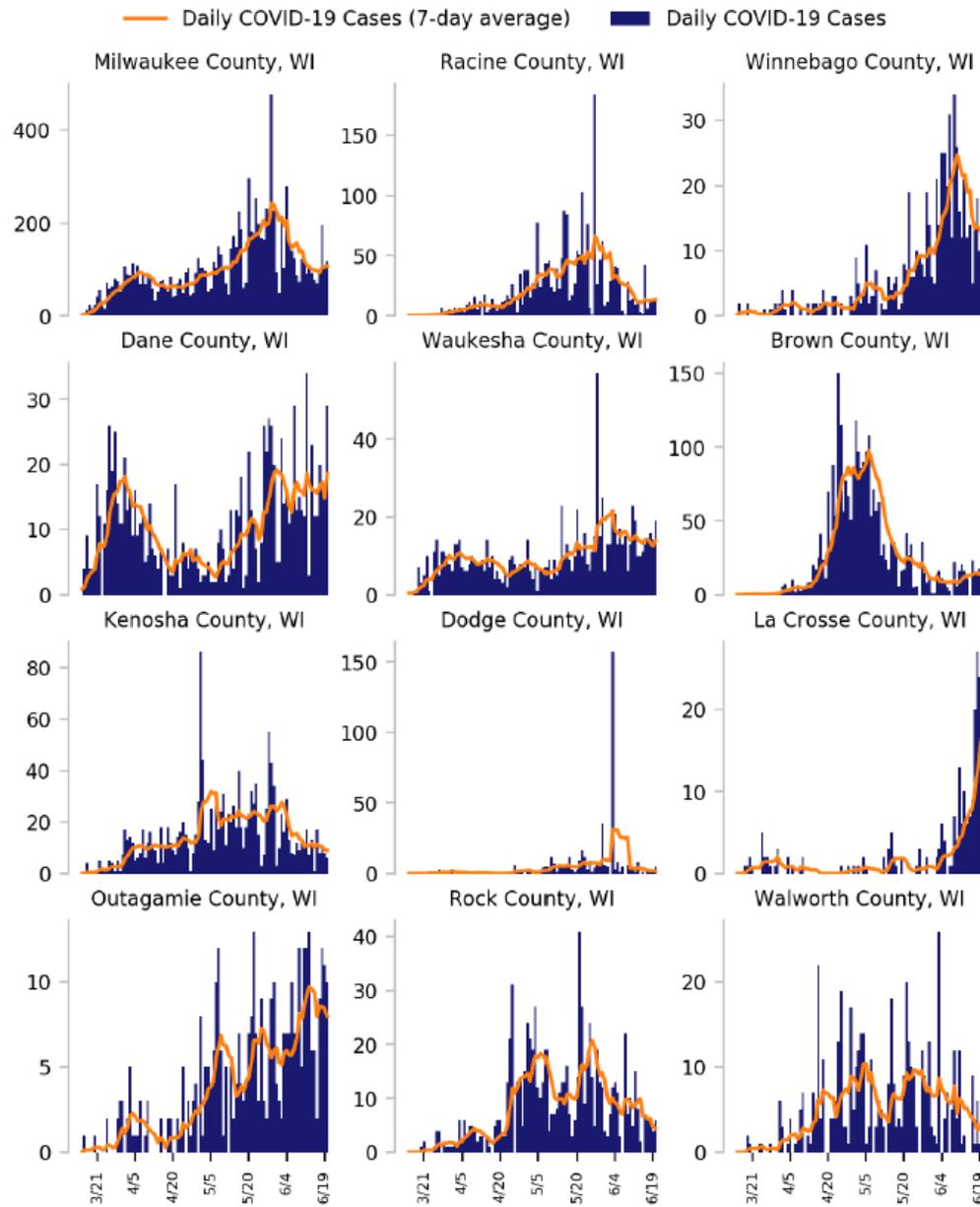
<https://www.dhs.wisconsin.gov/outbreaks/index.htm>

Updated: 6/23/2020



Updated: 6/23/2020





White House report 6/23/20



SEOC Survey

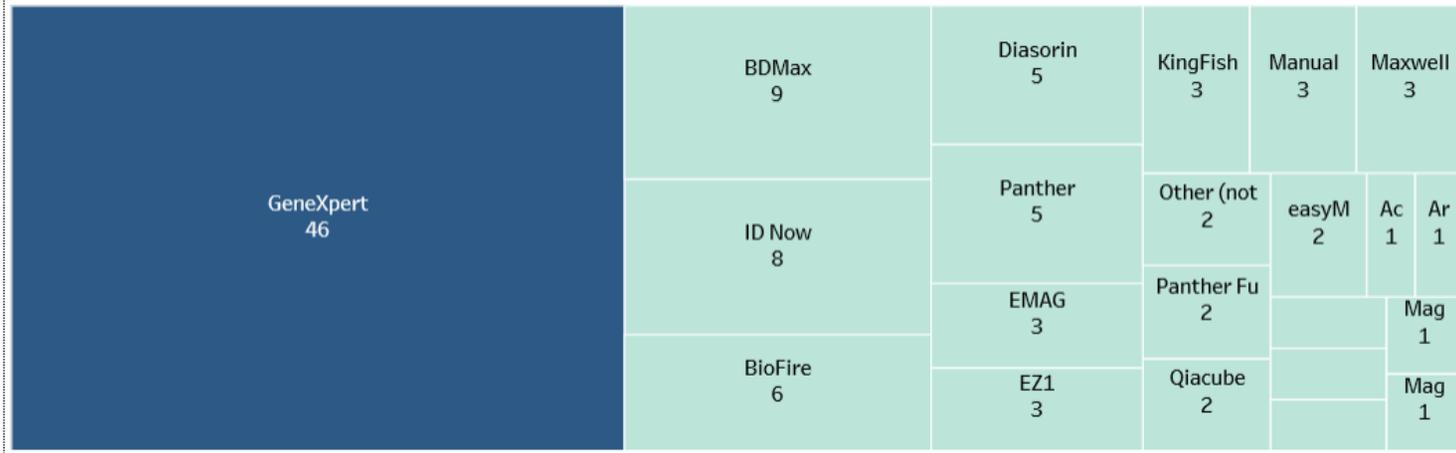
PLEASE, Update the SEOC Survey!

- Start testing
- Change in testing methods
- Change in capacity
- To report a supply shortage
- To remove a report of a supply shortage

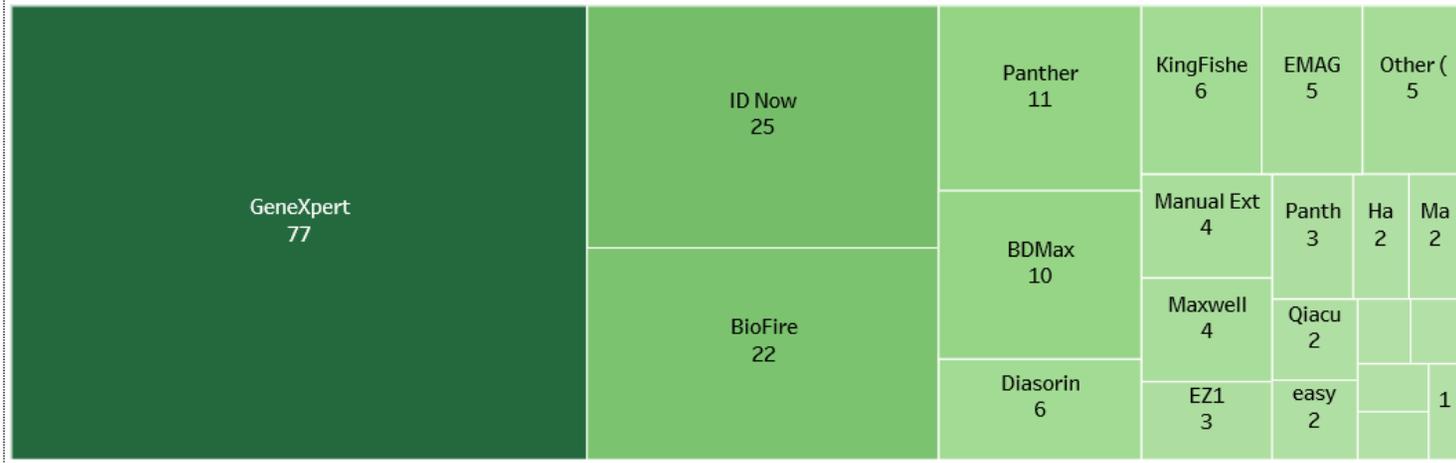


Wisconsin Clinical Laboratory COVID-19 Test Methods

Active Test Methods Statewide



Current and Planned Methods



https://bi.wisconsin.gov/t/COVID19_Analytics/views/LabDashboards/TestingMethods?:origin=card_share_link&:embed=y&:isGuestRedirectFromVizportal=y



Wisconsin COVID-19 Molecular Testing Capacity

Laboratories actively testing

68

Laboratories planning to test

26

Current state capacity (tests/day)

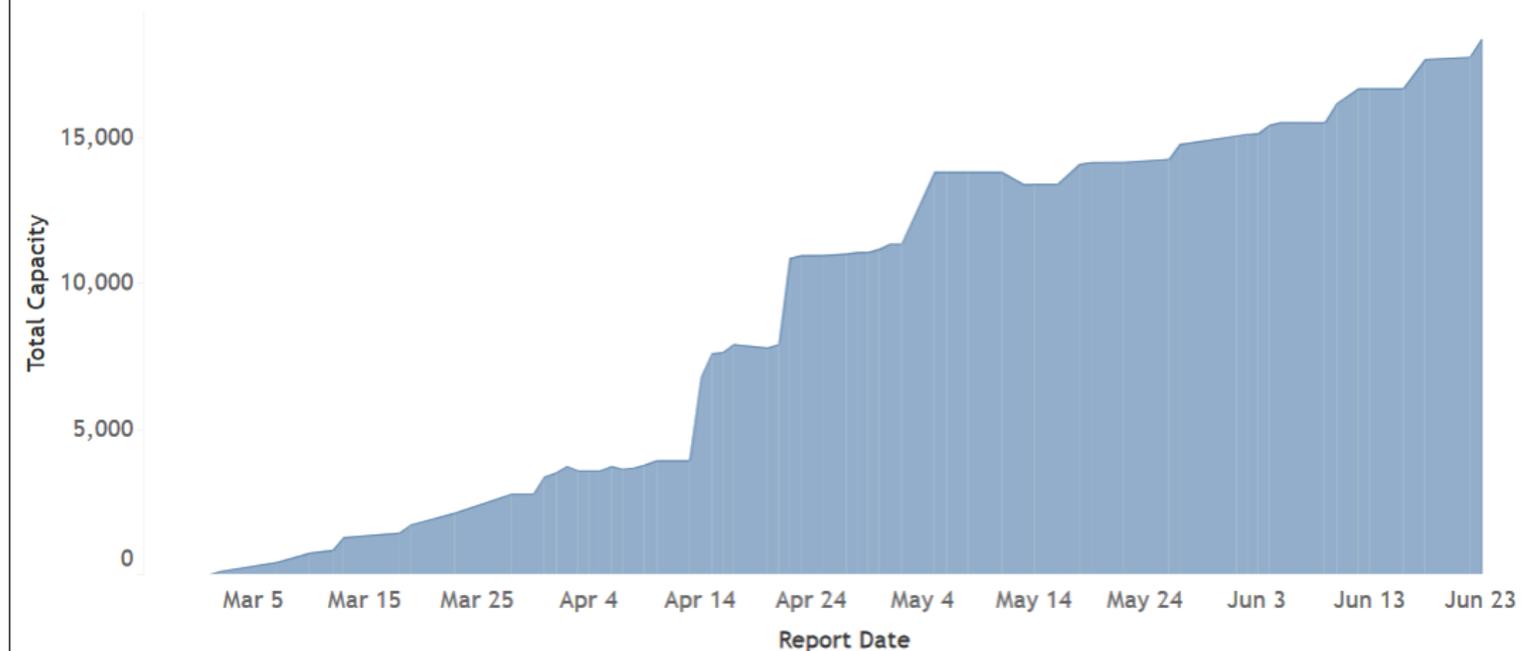
Last Updated: 6/23/2020 5:00:44 PM

18,355

COVID-19 Testing Capacity Over Time

last updated 6/23/2020 5:00:43 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



Wisconsin COVID-19 Testing Laboratories

Laboratories actively testing

68

Laboratories planning to test

26

Current state capacity (tests/day)

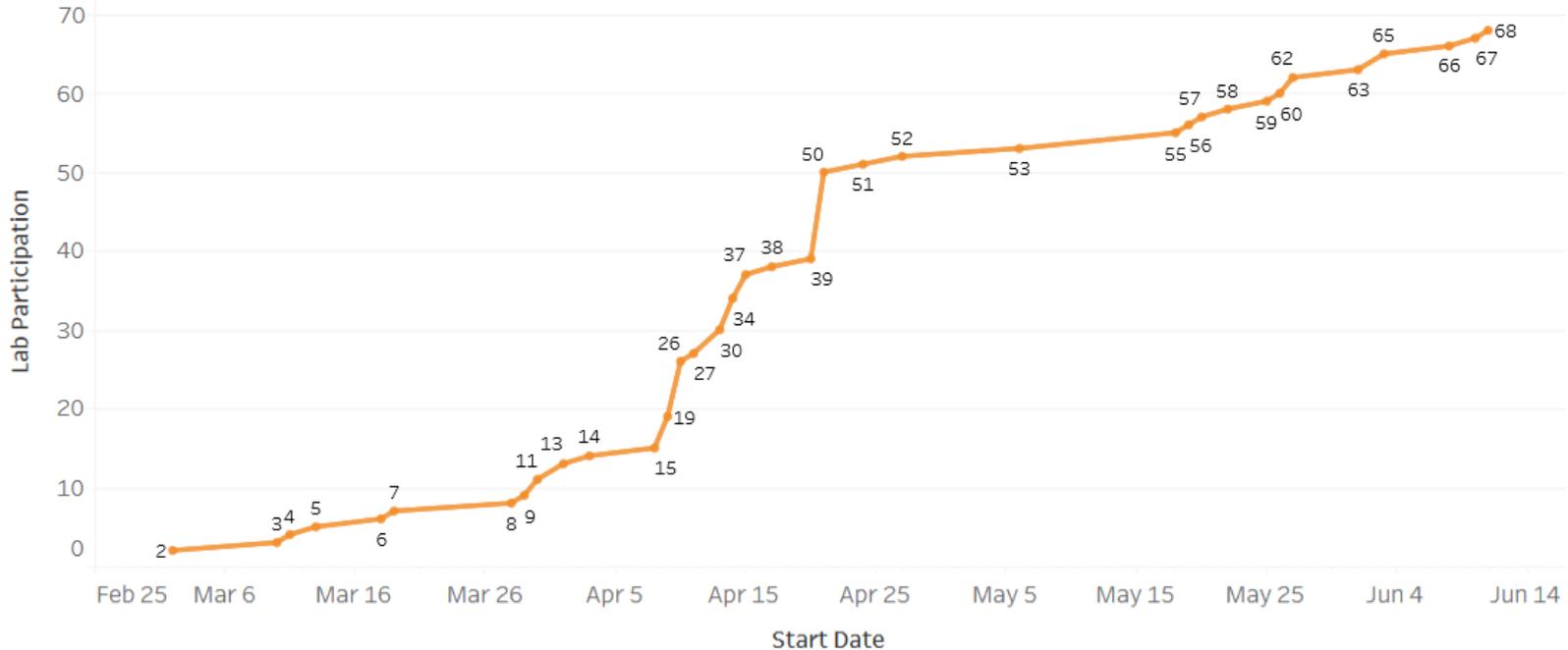
Last Updated: 6/23/2020 6:00:45 PM

18,355

COVID-19 Lab Participation Rate Over Time

last updated 6/23/2020 6:00:44 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

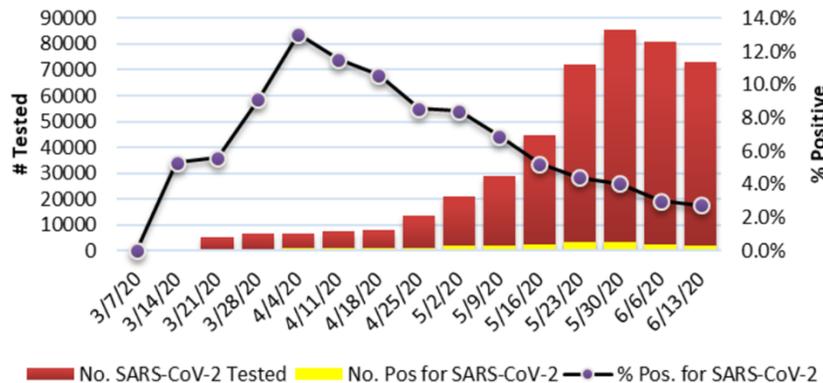
https://bi.wisconsin.gov/t/COVID19_Analytics/views/LabDashboards/PublicDashboardLabs?isGuestRedirectFromVizportal=y&embed=y



COVID-19 Testing

>500,000 total tests

% Positive SARS-CoV-2 by PCR (Wisconsin), Week Ending June 13, 2020

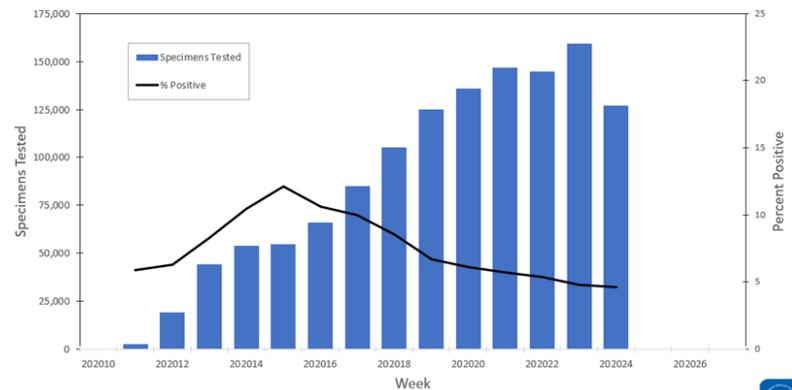


<http://www.surveymoz.com/s3/389222/Wisconsin-Laboratory-Surveillance-Reporting>

*Not all labs reporting

>28,000,000 total tests

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 8, 2020 - June 13, 2020

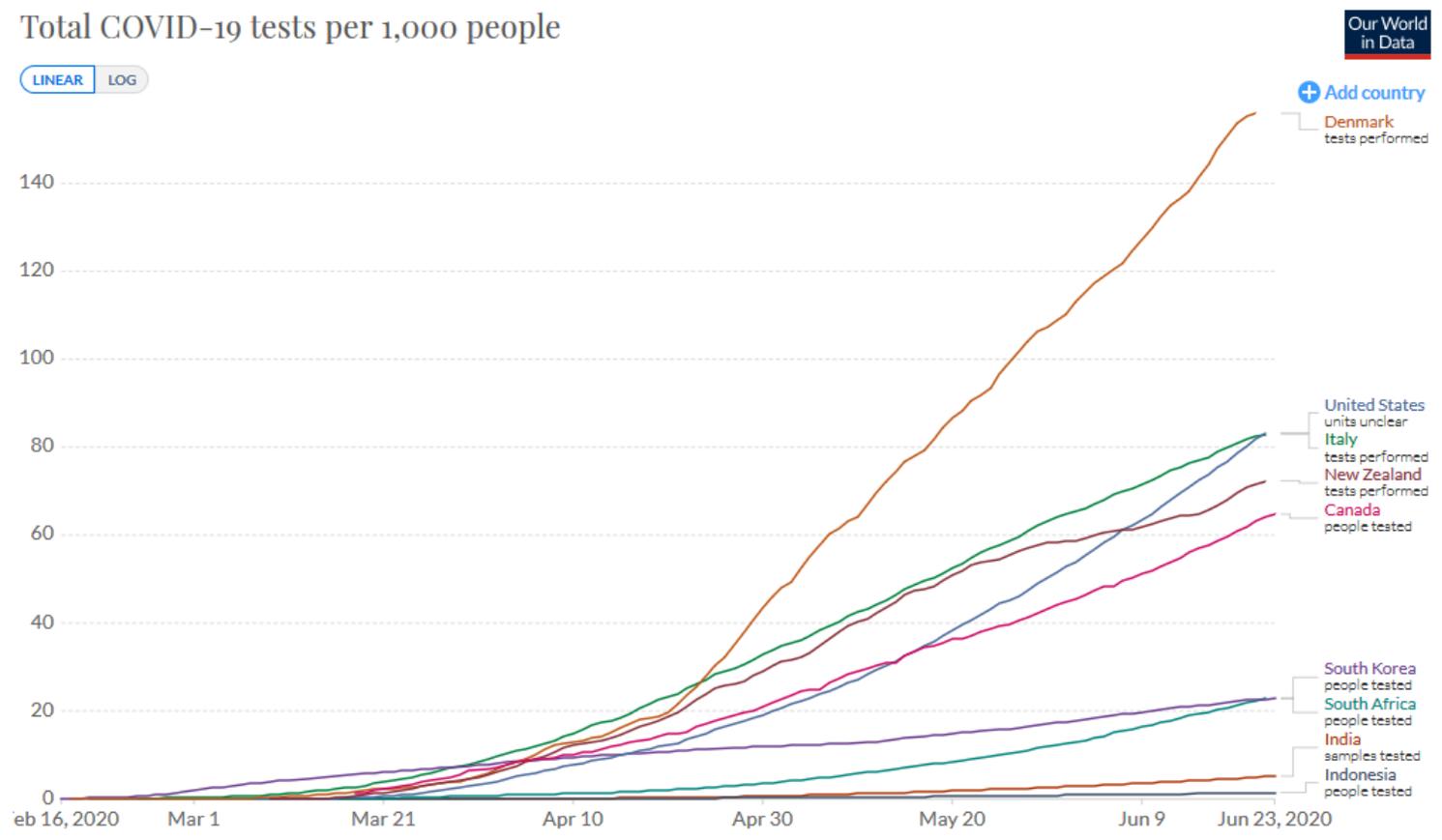


<https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html>





Tests/1000 people



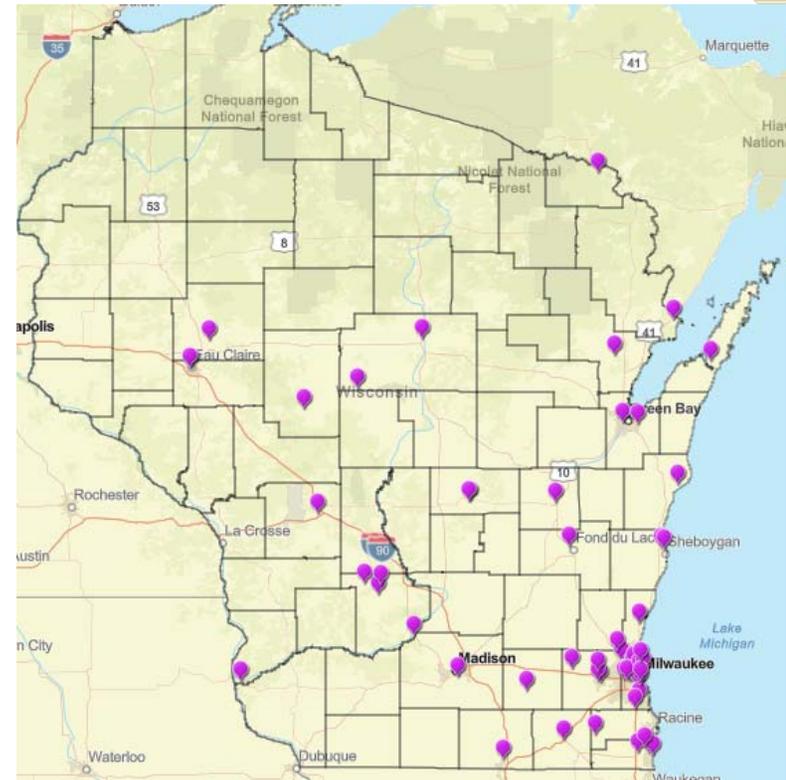
Source: Official sources collated by Our World in Data
Note: Comparisons of testing data across countries are affected by differences in the way the data are reported. Details can be found at our Testing Dataset page.
OurWorldInData.org/coronavirus • CC BY

<https://ourworldindata.org/grapher/full-list-cumulative-total-tests-per-thousand>



Community Test Sites

- Many locations across the state
- If your healthcare system would like to be on the map go to the website to fill out a short survey



<https://www.dhs.wisconsin.gov/covid-19/testing.htm>



False Positives

- Can happen to anybody
- Common causes: contamination, sample mix up, test variability
- Monitor:
 - Negative controls
 - Performing wipe tests to check for contamination
 - Monitor for clusters (high pos next to low pos)
 - Quality checks in automated systems
- Actions:
 - Re-test from the original specimen
 - If issue is identified, consider re-testing every specimen within a run
 - Follow-up with clinician/patient



FDA updates

- 85 Molecular tests
 - 9 EUAs with Home collection
 - 4 can be done with a CLIA waiver
- 37 LDTs
 - 100's submitted
- 21 Serology tests
- 1 Antigen test

<https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas>



Cue COVID-19 Test

“Lab in a box”

- CLIA Waived
- 25 minutes
- Direct nasal swab (no VTM)
- Results and instructions on your cellphone
- Currently requires supervision by a medical professional



- LOD 20 copies/swab

		Institutional Standard of Care EUA SARS-CoV-2 Test	
		Positive	Negative
Cue COVID-19 Test	Positive	6	3
	Negative	0	35



New kind of COVID test

ILLUMINA RECEIVES FIRST EUA FOR A SEQUENCING-BASED COVID-19 DIAGNOSTIC TEST

- Current EUA is for use with specimen that have been manually extracted with Qiagen spin columns
- Only on the NovaSeq
- Could test 3072 samples at once and provide sequence
- High complexity
- LOD 1 copy/uL

EUA RT-PCR Comparator	Illumina COVIDSeq Test Results (NP Swabs)			
	Positive	Negative	Invalid	% agreement (95% CI)
Positive	53	1 ¹	0	98.1% (90.2-99.7%)
Negative	1 ¹	38	1 ²	97.4% (86.8-99.5%)

¹ Root cause analysis revealed labeling error.

² One invalid specimen was excluded from analysis.



EUA Revoked

The FDA recently announced that the **Chembio DPP™ COVID-19 IgM/IgG System SARS-CoV-2 antibody test** no longer has Emergency Use Authorization (EUA).

“due to performance concerns with the accuracy of the test”

<https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-revokes-emergency-use-authorization-chembio-antibody-test>



Patients tested by WSLH

- Public Health Investigations as directed by state or local public health (includes Outbreaks)
- Hospitalized patient with COVID-19 symptoms
- 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
- Utility workers (water, sewer, gas, electric, power, distribution of raw materials, oil and biofuel refining) with COVID-19 symptoms
- Underserved populations with poor access to testing (e.g., underinsured, patients at Federally Qualified Health Centers, homeless patients, migrant workers, etc.) with COVID-19 symptoms
- Post-mortem testing for a person with COVID-19 symptoms prior to death who died of unknown causes and where results would influence infection control interventions at a facility or inform a public health response

***All testing for COVID-19 is fee exempt at WSLH**



Acceptable Specimen Types

- **Recommended:** Nasopharyngeal (NP) swab in viral transport media (VTM)
- Oropharyngeal (OP) swabs in VTM
- Sputum or other lower respiratory specimen such as bronchoalveolar lavage (BAL) or aspirate. (Induction of sputum is not indicated) (Does not need VTM)
- Nasal swabs in VTM are acceptable if no other specimen types are available.
- For postmortem testing, collect an NP swab in viral transport media (VTM). If autopsy is performed also swab the bronchioles of each lung and place in a single VTM tube.

*If VTM is unavailable UTM, Amies, or sterile RNase free Saline or PBS may be substituted.

Collection Kits and shipping supplies available for free from WSLH or SEOC (large orders)

<https://covid19supplies.wi.gov/Testing>

*PIF no longer required for submission



Future Testing Changes at WSLH

- Planning to bring on a COVID/Flu multiplex in preparation for the coming flu season
 - We will use a new CDC multiplex assay
 - COVID-19/Flu tests in development on several platforms including BioFire, Cepheid, others
- Panther TMA
- Cepheid GeneXpert



Resources

Contact Information:

CDD Customer Service: 1-800-862-1013

Clinical Orders: 1-800-862-1088

Emergency Pager: 1-608-263-3280

Gold Cross Courier: 1-715-839-9989

Free Gold Cross Courier

Order by NOON for same-day pick-up for NEXT DAY delivery (7 days a week)

WSLH COVID-19 Website

<http://www.slh.wisc.edu/clinical/diseases/covid-19/>

CDD Customer Service Hours:

- Monday-Friday: 7:45 AM – 4:30 PM
- Saturday: 7:45 AM - 12:30 PM

CDD Specimen Receiving Hours:

- Monday-Friday: 6:00 AM – 4:30 PM
- Saturday: 6:30 AM - 12:30 PM
- Sunday: 9:00 AM - 12:30 PM

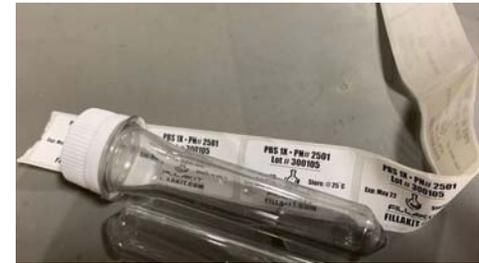
Results

- Results reported **within 48 hours** of receipt in the lab to the submitter and WEDSS
- All positives phoned to the submitter immediately



SEOC Supplies

- Allocation to all states by FEMA
- Not all supplies are usable
 - Primestore MTM (Cyanide gas)
 - FillaKit PBS (Non-sterile production)
- Some supplies available to order on the Web portal (nasal swabs)
- Mix of supplies too variable for the web portal (saline and nasal swabs)
 - Look for a WCLN message next week with order options





Local Collection Kits

Stable stored at room temp for
12 weeks
and counting!

Package inserts for WVDL and Gentueri updated
on WSLH webpage



New Survey – Abbott ID NOW

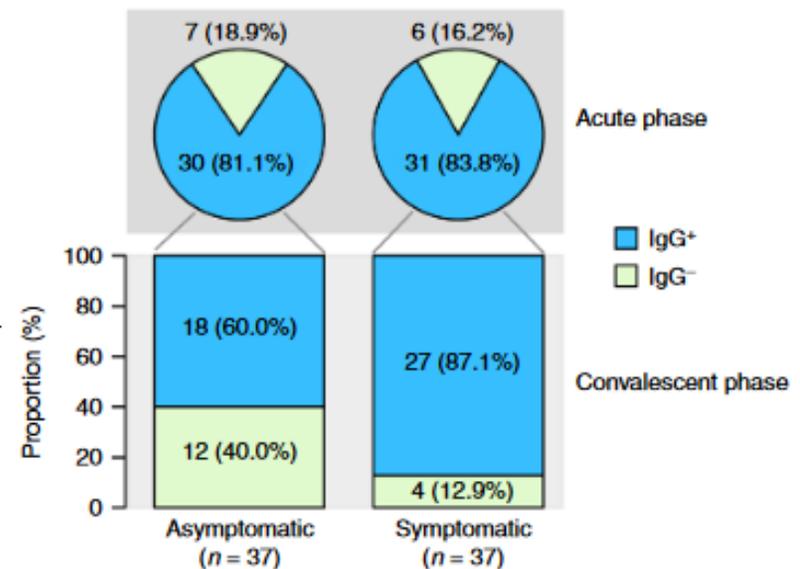
- The Wisconsin SEOC has put together a survey to learn about how Abbott ID NOW testing is being used.
- The SEOC has been allocated a limited number of Abbott ID NOW COVID-19 test reagents. They would like to distribute these reagents as equitably as possible to interested laboratories that have the ID NOW instrument
- If you use this platform, please complete this survey as fully as possible whether you want to receive test kits or not.
- Completion of the survey does not guarantee your laboratory will receive these supplies.
- The number of test reagents distributed is dependent on how many laboratories express interest.
- You may not charge anyone for these test reagents.
- Supplies are very limited and it is unknown if Wisconsin will receive further allotments.
- Complete by this Friday (6/26/20)

<https://www.surveymzmo.com/s3/5649399/Abbott-Lab-Equipment-Survey>



Short duration of immunity after SARS-CoV-2 infection?

IgG levels and neutralizing antibodies in a high proportion of individuals who recovered from SARS-CoV-2 infection start to decrease within 2–3 months after infection.



<https://www.nature.com/articles/s41591-020-0965-6.pdf>



July 4th Holiday Observance

Please note the following plans for our hours of operation for WSLH CDD Specimen Receipt and Customer Service. **WSLH is observing the holiday on Sunday, July 5th and will be closed.**

DATE	WSLH CDD 2601 Agriculture Drive Specimen Receiving	WSLH CDD 2601 Agriculture Drive Customer Service	Gold Cross Transport
Friday, July 3, 2020	6:00 AM – 4:30 PM	7:45 AM – 4:30 PM	Schedule Friday by noon for Friday pick-up with Saturday delivery
Saturday, July 4, 2020	6:30 AM – 12:30 PM	7:45 AM – 12:30 PM	Schedule Saturday by noon for Saturday pick-up with Monday delivery
Sunday, July 5, 2020	CLOSED	CLOSED	Schedule Sunday by noon for Sunday pick-up with Monday delivery
Monday, July 6, 2020	6:00 AM – 4:30 PM	7:45 AM – 4:30 PM	Schedule Monday by noon for Monday pick-up with Tuesday delivery



New - DHS COVID-19 Activity Level Data Dashboard

Consists of maps and tables that toggle between counties and Healthcare Emergency Readiness Coalition (HERC) regions.

<https://www.dhs.wisconsin.gov/covid-19/local.htm>

COVID-19 Case Indicators (last two weeks)

Updated: 6/17/2020

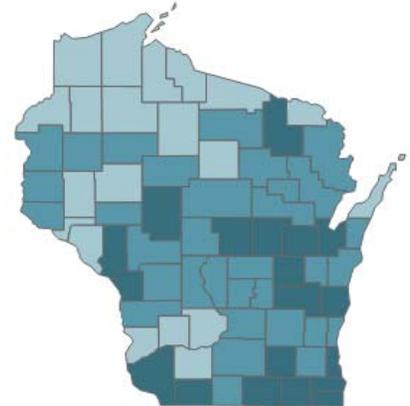
- Select Geography
- County
 - HERC Region

- COVID-19 activity level
- Low
 - Medium
 - High

COVID-19 activity level

Highlight Geography
No items highlighted

Click on a county or region on the map to filter data below.



© 2020 Mapbox © OpenStreetMap

Burden (case rate), trajectory (percent case change), and COVID-19 activity level

Geography	Count	Burden	Trajectory	Trend	Activity Level
Wisconsin	4,060	70 Moderately High	-15	▼	Medium
Adams	5	24 Moderate	N/A	↔	Medium
Ashland	1	6.3 Low	N/A	↔	Low
Barron	6	13 Moderate	N/A	↔	Medium

Reporting COVID-19 Results



NAAT Testing:

- **WEDSS** - Report **all** COVID-19 test results (positives and negatives) via ELR or WLR
- **WCLN Surveillance Data** - Report weekly the total number of positives and total number tested.
 - Combine numbers of COVID-19 testing performed in-house with numbers of COVID-19 testing performed at out-of-state reference lab
 - **Do not** include testing sent to in-state reference lab (e.g. Exact Sciences)
 - In-state reference labs report directly



Reporting COVID-19 Results

Antibody Testing:

- **WEDSS** - Report **only positive** COVID-19 test results via ELR or WLR
- **WCLN Surveillance Data** - Report weekly the total number of positives and total number tested.
 - Combine numbers of COVID-19 testing performed in-house with numbers of COVID-19 testing performed at out-of-state reference lab
 - **Do not** include testing sent to in-state reference lab (e.g. Exact Sciences)
 - In-state reference labs report directly



How to Ensure Your Specimen is Delivered to the WSLH

- Determine to which laboratory you are submitting testing
 - If planning to collect and submit more than 100 specimens at one time, please notify WSLH in advance
- Confirm the delivery location with Gold Cross dispatch when you call for a pick-up.
 - If you have specimens for both WSLH and Exact Sciences, confirm that with Gold Cross.
- DO NOT package specimens for WSLH and Exact Sciences together in the same package
 - Packaging specimens together results in testing delays while specimens are redelivered to the correct testing lab.
- Confirm with the courier who picks up the packages where they are delivering your packages

How to Ensure Your Specimen is Delivered to the WSLH (cont.)



Packaging:

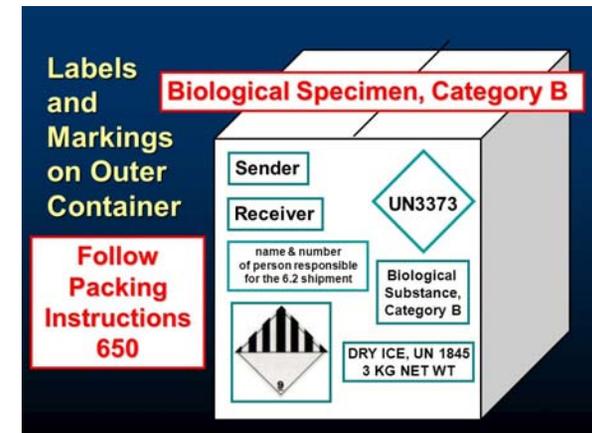
- Follow [instructions for shipping](#) *Packaging and Shipping Biological Substance, Category B Specimens* pictorial guidance document
 - Must triple package and use a shipper with a rigid outer container
 - Gold Cross **won't accept** specimens for the WSLH packaged only in a biohazard bag to put in a cooler
- If specimen is for **WSLH**, remove or cover any labels, waybills, etc. that say Exact Sciences on the shipper.
- Package specimens for **Exact Sciences** per their direction
 - Currently, Gold Cross will accept a specimen in a biohazard bag to put into a cooler

How to Ensure Your Specimen is Delivered to the WSLH (cont.)



Labeling:

- UN3373 Biological Substance, Category B label
- Dry ice label (if shipping on dry ice)
- Clearly address the package to:
Wisconsin State Laboratory of Hygiene
Communicable Disease Division
2601 Agriculture Dr.
Madison, WI 53718
- The submitter information must include:
Your laboratory name
Your laboratory address
Emergency contact name (knowledgeable about the contents)
Emergency contact phone number (answered during normal business hours)





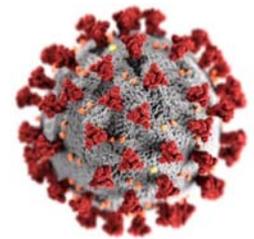
New HHS Reporting Requirements

- June 4, 2020 HHS announce new guidance that specifies what additional data must be reported to HHS by laboratories by 8/1/2020
<https://www.hhs.gov/about/news/2020/06/04/hhs-announces-new-laboratory-data-reporting-guidance-for-covid-19-testing.html>
- Changes are due to concern that COVID-19 is having a disproportionate impact on certain demographics including racial minorities and older Americans
- Mary Wedig is working with CDC and APHL to get further guidance on what additional data testing laboratories will have to provide into WEDSS via ELR or WLR.
- WSLH will notify labs what modifications need to be made once we receive further clarification.
- Contact mary.wedig@slh.wisc.edu with questions.



Moving to As Needed COVID-19 Webinars

Information is not changing as rapidly as it was at the beginning of the COVID-19 pandemic and we want to respect your time. We understand that laboratory testing is picking up and it is more difficult to make time for a webinar, therefore, we will only hold future COVID-19 webinars when we have important information, or there are significant changes we need to share with you.





Please Type Your Questions in the
Question Box!

