

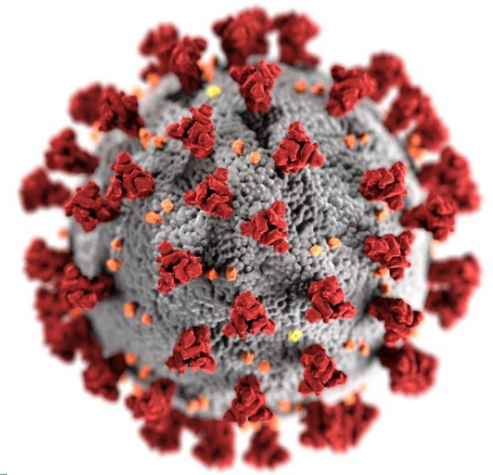
COVID-19 Update - Pandemic Status, Infection Prevention, and Rapid Point of Care Testing

Medical Society of Virginia and
Virginia Department of Health
Webinar

November 6, 2020

Background and Pandemic Update

Emergence and Spread of COVID-19



Emergence

- Identified in Wuhan, China in December 2019
- Caused by the virus SARS-CoV-2

Global Spread

- A travel-related case of COVID-19 was first reported in the U.S. on January 21, 2020
- WHO declared COVID-19 a global pandemic on March 11, 2020

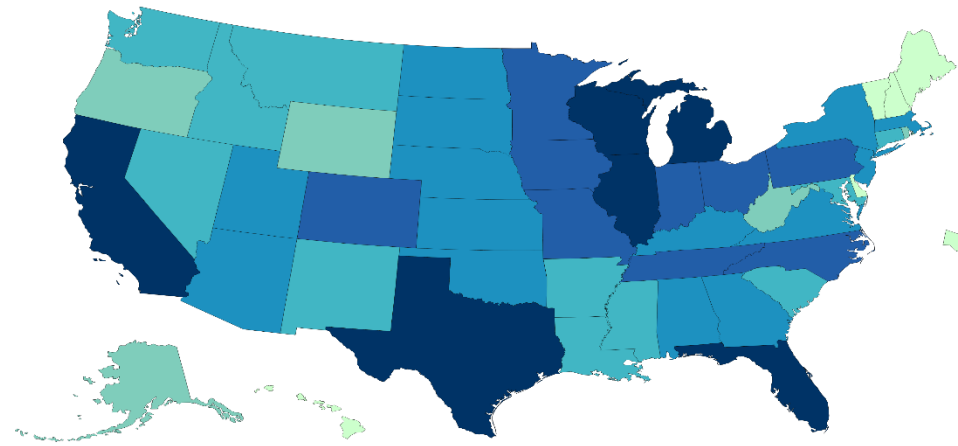
As of November 4, 2020, WHO Dashboard reports more than
47 million cases
and
1.2 million deaths
globally
due to COVID-19

COVID-19 Cases and Deaths in the US as of November 4, 2020 (CDC Data)

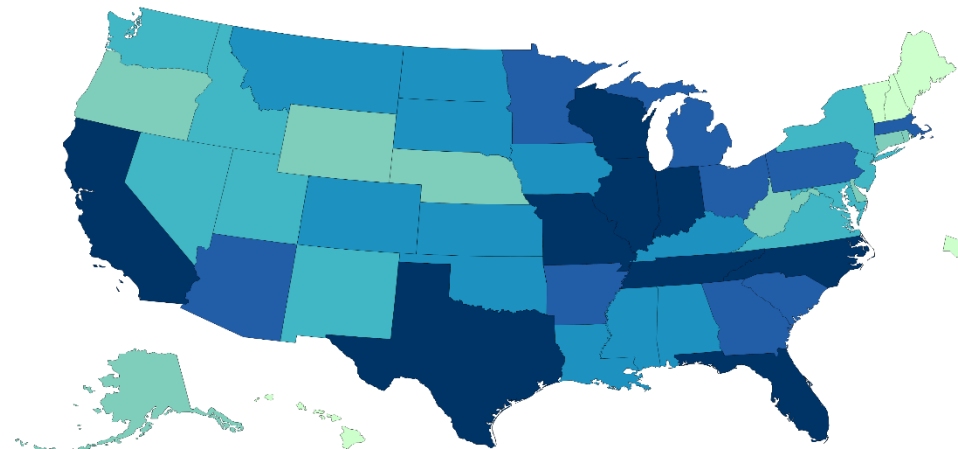
Total Reported Cases:
9,357,245
(88,427 New Cases)

Total Reported Deaths:
231,988
(1,095 New Deaths)

<https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html>



Cases
reported to
CDC in the 7
days before
Nov 4, 2020



Deaths
reported to
CDC in the 7
days before
Nov 4, 2020

COVID-19 Cases and Deaths in Virginia as of November 5, 2020 (Va Data)

Total Cases:

187,202

Total Hospitalizations:

12,865

Total Deaths:

3,688

<https://www.vdh.virginia.gov/coronavirus/covid-19-daily-dashboard/>

Select Measure
(Affects Map and Bar Chart)

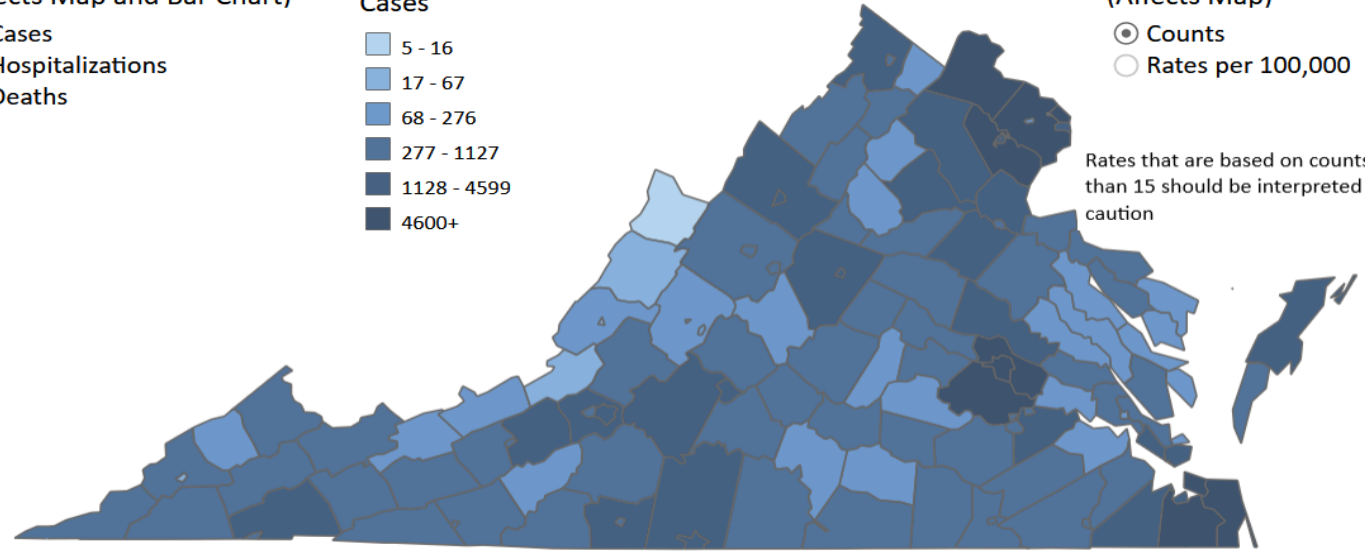
- ☒ Cases
- ☐ Hospitalizations
- ☐ Deaths

Counts of
Cases

- 5 - 16
- 17 - 67
- 68 - 276
- 277 - 1127
- 1128 - 4599
- 4600+

Select Counts or Rates
(Affects Map)

- ☒ Counts
- ☐ Rates per 100,000



Select Measure
(Affects Map and Bar Chart)

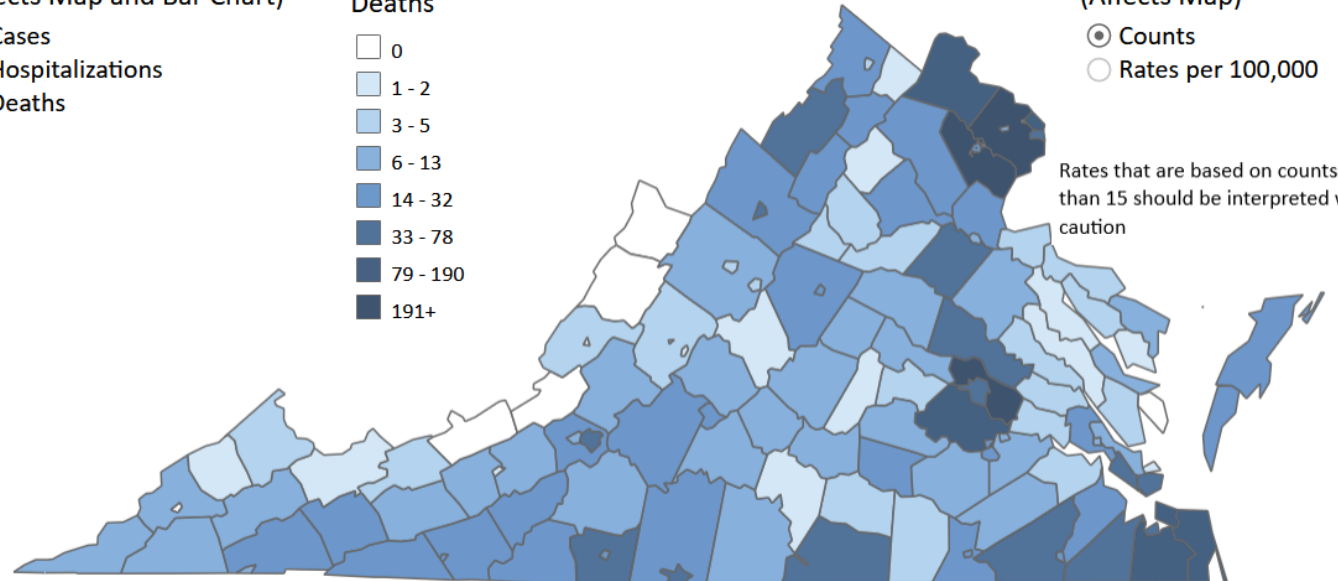
- ☐ Cases
- ☐ Hospitalizations
- ☒ Deaths

Counts of
Deaths

- 0
- 1 - 2
- 3 - 5
- 6 - 13
- 14 - 32
- 33 - 78
- 79 - 190
- 191+

Select Counts or Rates
(Affects Map)

- ☒ Counts
- ☐ Rates per 100,000



COVID-19 Testing Totals Nationally as of November 4, 2020 *(CDC Data)*

Total Tests Reported:

152,599,729

Positive Tests Reported:

11,198,066

% of Positive Tests: **7.3%**

<https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/testing-in-us.html>

COVID-19 Testing Totals and Trends New Cases in Virginia as of November 5, 2020 (*Va Data*)

Testing Encounters
Total:

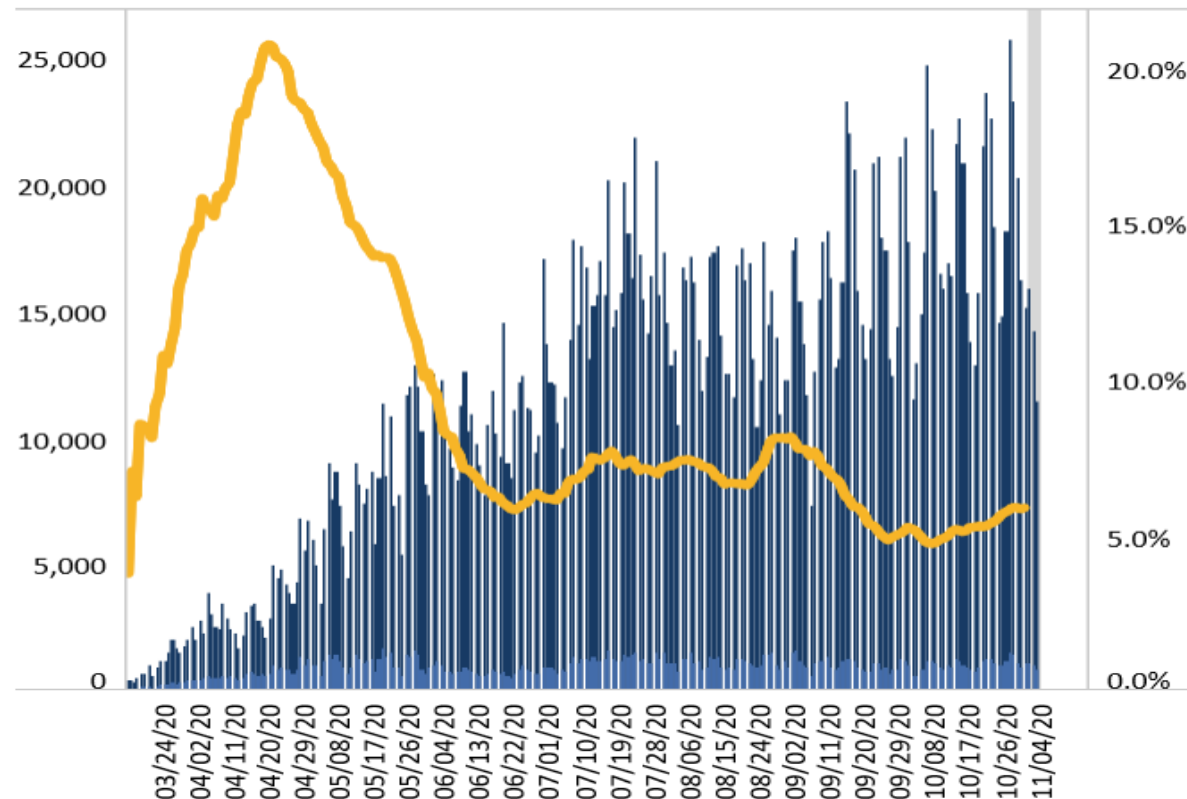
2,719,206

Current 7-day
Positivity Rate Total:
5.8%

<https://www.vdh.virginia.gov/coronavirus/covid-19-daily-dashboard/>

Number of Cases by Date of Symptom Onset - Virginia:

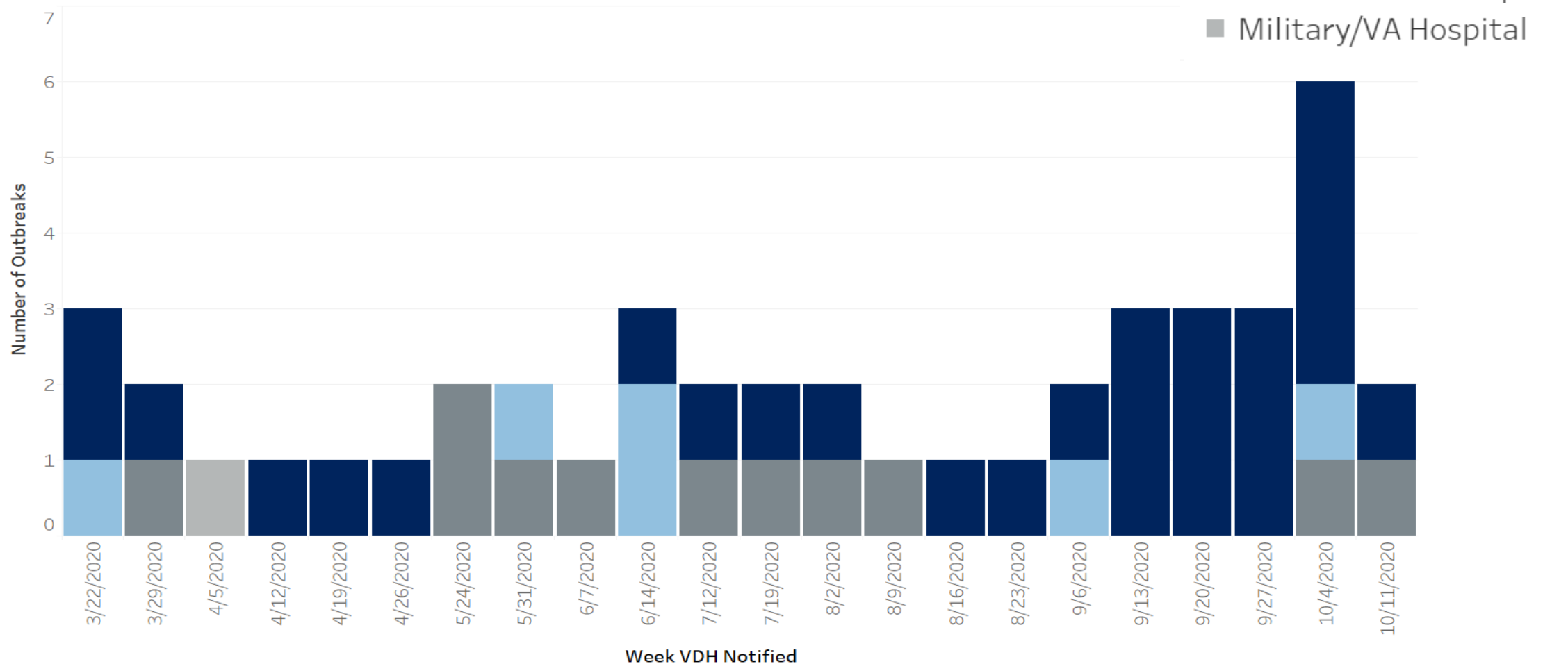
Number of Testing Encounters, Number of Positive Testing Encounters, and Percent Positivity** by Lab Report Date - All Health Districts, PCR Only



Infection Prevention and Control (IPC)

Medical Facility COVID-19 Outbreaks*

by Facility Type and Week VDH Notified



Data from Virginia Outbreak Surveillance System
Updated 10/19/2020

*At least two lab-confirmed cases are required to classify an outbreak as confirmed.

Patterns recognized during recent hospital and outpatient COVID-19 outbreaks

- Relaxed adherence to recommended infection prevention and control (IPC) practices
 - PPE usage
 - Physical distancing in break rooms
 - Social distancing before/after work
- Return of furloughed staff who were not trained in COVID-19 IPC practices
- Relaxed visitation guidelines
- Return of sick or exposed HCP

What should hospitals and clinics do?

- Enforce social distancing between staff in common areas like break rooms and cafeterias
- Routinely continue to educate staff on the proper use of PPE
 - See guidance for [PPE for aerosol generating procedures](#)
 - CDC emphasizes that staff should not be extending use or reusing PPE if supplies have been restored
- Implement enhanced infection prevention and control rounds
 - Monitor and validate PPE and hand hygiene compliance on COVID and non-COVID units
 - On non-COVID units, ensure products used for environmental cleaning are effective against MDROs.

What should hospitals and clinics do? (continued)

- Review employee health policies
 - Follow CDC [return-to-work criteria](#) for HCP
 - Follow VDH [guidance](#) for managing exposed, asymptomatic HCP
- Continue to implement universal source control (masks) for staff, patients, and visitors
- Continue to Screen and monitor staff for signs/symptoms of COVID-19
- Review visitation policies to ensure that visitors and non-essential personnel are screened and educated on IPC practices
- Evaluate the process of transferring information regarding a patient's COVID-19 status to other facilities
- Immediately notify the local health department when a suspected outbreak is occurring

Infection Prevention and Control (IPC) Strategies

- **Must remain vigilant about IPC measures**
- Ensure adequate supplies of PPE such as masks, gowns, gloves, hand soap, alcohol-based hand sanitizer, face shields
- Use PPE appropriately - see CDC document [Using Personal Protective Equipment](#) - has excellent infographics about PPE
- If needed, obtain N95 respirators - wearing a respirator requires medical clearance and fit testing initially and annually

Does wearing glasses protect HCPs from getting Covid-19?

- In a [study](#) published September 16, in JAMA Ophthalmology, the authors conclude that wearing eyeglasses more than 8 hours per day may be protective against SARS-CoV-2 infection
- They hypothesize this may be due to eyeglasses acting as a barrier that reduces the frequency with which people touch their eyes.
- From an epidemiological perspective, we must be careful to avoid inferring a causal relationship from a single observational study.
- CDC reports that protective eyewear (e.g., safety glasses, trauma glasses) with gaps between glasses and the face likely do not protect eyes from all splashes and sprays.

Rapid Point of Care (POC) Testing

Case

54 yo female with mild hypertension is in for her medication check.

- She heard that someone at work was positive for COVID-19.
- She does not know who but wants to get tested before she goes to see her 80 yo mother for the holiday.
- Should she get tested today?
- Should she get tested before travel?
- Which test should she use and does it matter?

Epidemiologic testing

- Find the infectious cases to limit further spread of the virus and subsequent cases
 - High risk situations for secondary cases to occur
 - Find infectious asymptomatic individuals with high risk exposure
 - Testing in asymptomatic as surveillance

Diagnostic testing

- Find patients who are infected to assess if their symptoms can be attributed to a SARS-CoV-2 infection
 - Patients with symptoms which can be placed in the context of a positive test

Which test to use depends on many factors several of which are not scientific

- 158 PCR and 7 antigen diagnostic assays with FDA Emergency Use Authorization (EUA)
- None have FDA approval
- The majority detect SARS-CoV-2 RNA (antigen in upper respiratory specimens)
- Variables
 - Availability
 - Turn around time
 - Specimen type
 - Performance



Abbott



Cepheid



480 x 350

Bloomberg.com

The antigen tests have all been approved on very few symptomatic cases and real world data is coming

For FDA Emergency Use Authorization of the Quidel Sofia antigen test, 209 symptomatic patients were tested

Reference Extracted RT-PCR assay				
Sofia SARS Antigen FIA Assay		POS	NEG	Total
	POS	29	0	29
	NEG	1	179	180
	Total	30	179	209

University of Virginia just completed a validation of the Quidel Sofia and the performance was different in symptomatic university students

PCR results				
Antigen results		Positive	negative	Total
	Positive	26	1	27
	Negative	17	553	570
	Total	43	554	597

Statistic	Value	95% CI
Sensitivity	96.67%	82.78% to 99.92%
Specificity	100.00%	97.96% to 100.00%
Disease prevalence (*)	14.35%	9.90% to 19.85%
Positive Predictive Value (*)	100.00%	
Negative Predictive Value (*)	99.44%	96.30% to 99.92%
Accuracy (*)	99.52%	97.36% to 99.99%

Statistic	Value	95% CI
Sensitivity	60.47%	44.41% to 75.02%
Specificity	99.82%	99.00% to 100.00%
Disease prevalence (*)	7.20%	5.26% to 9.58%
Positive Predictive Value (*)	96.30%	78.33% to 99.47%
Negative Predictive Value (*)	97.02%	95.74% to 97.92%
Accuracy (*)	96.98%	95.28% to 98.20%

Work led by Melinda Poulter, Lindsay Bazydlo and Meredith Hayden

The federal government purchased 150 million to increase test availability

Nucleocapsid protein from nasal swab is the antigen tested



BinaxNOW™ COVID-19 Ag Card Performance within 7 days of symptom onset against the Comparator Method

BinaxNOW™ COVID-19 Ag Card	Comparator Method		
	Positive	Negative	Total
Positive	34	1	35
Negative	1	66	67
Total	35	67	102
Positive Agreement: 34/35 97.1% (95% CI: 85.1% - 99.9%)			
Negative Agreement: 66/67 98.5% (95% CI: 92.0% - 100%)			

Statistic	Value	95% CI
Sensitivity	97.14%	85.08% to 99.93%
Specificity	98.51%	91.96% to 99.96%
Disease prevalence (*)	34.31%	25.19% to 44.37%
Positive Predictive Value (*)	97.14%	82.92% to 99.58%
Negative Predictive Value (*)	98.51%	90.53% to 99.78%
Accuracy (*)	98.04%	93.10% to 99.76%

Days Since Symptom Onset	Cumulative RT-PCR Positive (+)	Cumulative BinaxNOW COVID-19 Ag Card Positive (+)	PPA	95 % Confidence Interval	
1	4	4	100.0%	39.8%	100.0%
2	10	10	100.0%	69.2%	100.0%
3	15	15	100.0%	78.2%	100.0%
4	18	18	100.0%	81.5%	100.0%
5	23	22	95.7%	78.1%	99.9%
6	27	26	96.3%	81.0%	99.9%
7	35	34	97.1%	85.1%	99.9%

VDH Interim COVID-19 Antigen Testing Recommendations

VDH Interim Covid-19 Antigen Testing Recommendations - General Information

- All currently available rapid POC antigen tests are Rx only - need to have a medical provider's order
- Facility performing test must have a CLIA certificate of accreditation or CLIA certificate of waiver
- Facility performing test must have someone designated as Lab Director
- Staff performing test must be trained to do so - it is recommended they complete manufacturer's training program
- All test results must be reported to VDH within 24 hours

Interim COVID-19 Antigen Testing Recommendations

Test Result	Person being Tested		
	Symptomatic Person <i>(test as close to symptom onset as possible and as recommended by manufacturer)</i>	Asymptomatic Person with Close Contact[#] to a known COVID-19 case	Asymptomatic Person without Close Contact[#] to a known COVID-19 case
Positive	<ul style="list-style-type: none"> • Current infection • Prompt isolation until no longer contagious by symptom-based strategy 	<ul style="list-style-type: none"> • Current infection • Prompt isolation until no longer contagious by time-based strategy 	<ul style="list-style-type: none"> • Presumptive current infection • Prompt isolation while awaiting confirmatory test result • Confirm positive result with a PCR test done in a high-complexity CLIA-certified laboratory^{†*} • Patients with positive confirmatory test should isolate until no longer contagious by time-based strategy
Negative	<ul style="list-style-type: none"> • No antigens were detected • Confirm negative antigen result with a PCR test done in a high-complexity CLIA-certified laboratory[†] • Prompt isolation while awaiting confirmatory test result 	<ul style="list-style-type: none"> • No antigens were detected • Close contacts who test negative must still complete 14 days of quarantine. • Obtain COVID-19 PCR test if person develops symptoms 	<ul style="list-style-type: none"> • No antigens were detected • No additional case follow-up necessary • Reinforce prevention measures

Examples of populations or circumstances where antigen testing could be considered

- Symptomatic individual(s) in whom COVID-19 is suspected, particularly within seven days of symptom onset
- Asymptomatic individual(s) with close contact to someone with known COVID-19. Ideally, testing should occur approximately one week after the last known exposure.
- Symptomatic and asymptomatic residents and staff in congregate settings (e.g., nursing homes or similar settings) where less frequent, highly sensitive tests such as PCR tests are not available or subject to prolonged turnaround times (> 48 hours).
 - Outbreak situation
 - Per [CMS regulations](#), routine serial testing (using antigen or PCR) of nursing home staff
- Asymptomatic people who are NOT close contacts to a known COVID-19 case, in settings where a highly sensitive test is not feasible or turnaround times are excessive.
 - The [FDA has commented on this issue](#).

VDH Interim COVID-19 Antigen Testing Recommendations - Locations Online

- Health Professionals - www.vdh.virginia.gov/coronavirus/antigen-testing-recommendations/
- Testing, Laboratory, and Therapeutics - see <https://www.vdh.virginia.gov/coronavirus/antigen-testing-recommendations/>

Key Resources

1. CDC COVID-19 website: www.cdc.gov/coronavirus/2019-nCoV/index.html - see latest updates at bottom of homepage
2. VDH homepage: www.vdh.virginia.gov
3. VDH COVID-19 webpage for healthcare professionals: www.vdh.virginia.gov/coronavirus/health-professionals
4. Locate COVID-19 test sites in Virginia: www.vdh.virginia.gov/coronavirus/covid-19-testing/covid-19-testing-sites
5. CDC Overview of Testing for SARS-CoV-2: www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html
6. Clinical Tips for Healthcare Providers on COVID-19 Patient Care: www.cdc.gov/coronavirus/2019-ncov/downloads/hcp/fs-ten-clinical-tips.pdf
7. CDC Using Personal Protective Equipment: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/using-ppe.html>
8. VDH Interim COVID-19 Antigen Testing Recommendations: <https://www.vdh.virginia.gov/coronavirus/antigen-testing-recommendations/>
9. VDH COVID-19 Testing Algorithms for Health Care Providers: <https://www.vdh.virginia.gov/content/uploads/sites/182/2020/05/COVID-19-Testing-Algorithm.pdf> - please note there are two algorithms - one for molecular testing and one for antigen testing

Thank you for your attention!

Questions and Discussion

Supplementary Slides

11/5/2020



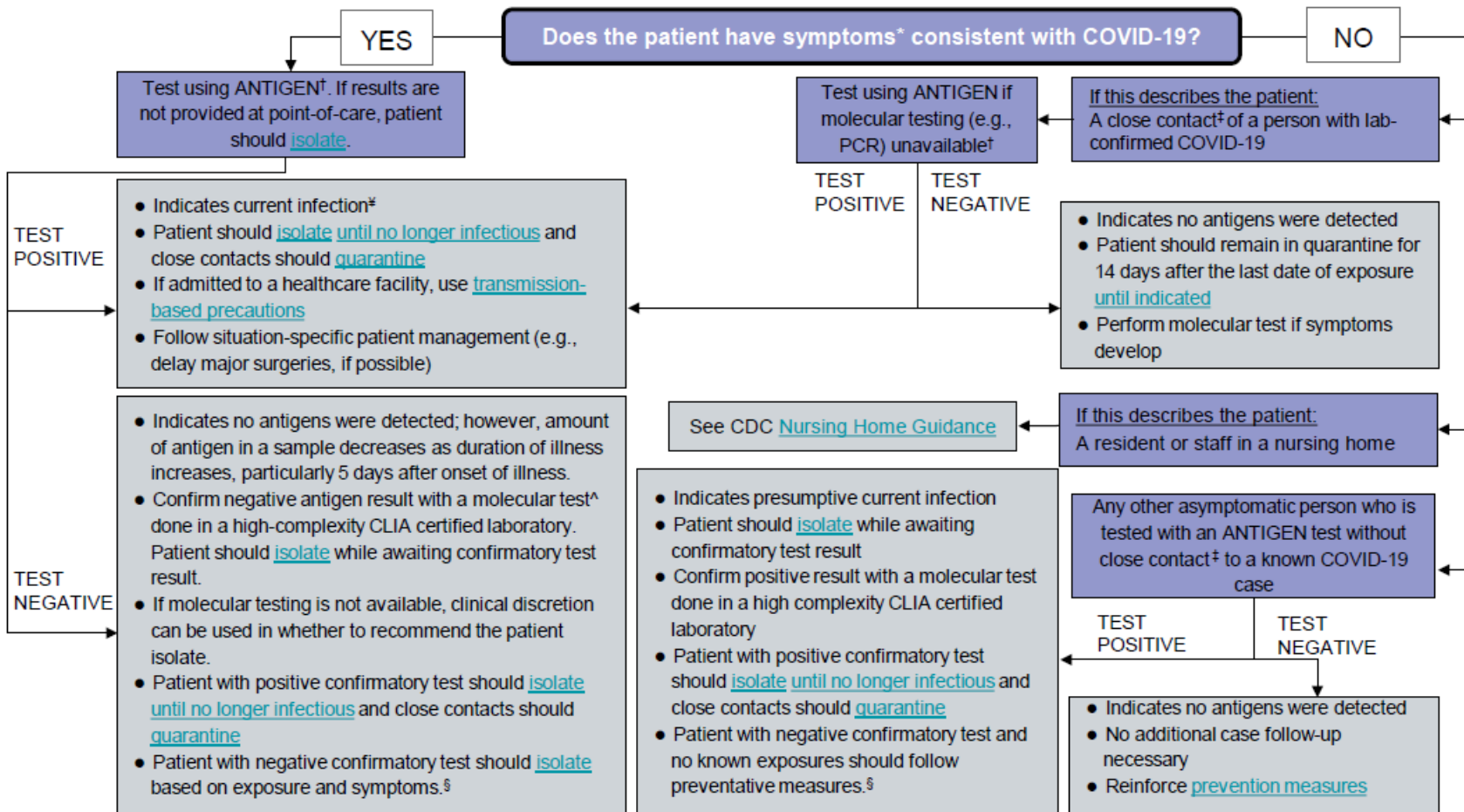
VDH COVID-19 Antigen Testing Algorithm

11/5/2020

VDH COVID-19 ANTIGEN TESTING ALGORITHM

For healthcare providers to understand who to test and what recommendations to provide based on the results

November 5, 2020



Recommendations are based on [CDC guidance](#), [VDH Guidance](#), [Infectious Diseases Society of America Guidelines on the Diagnosis of COVID-19](#), [APHL's Considerations for Implementation of SARS-CoV-2 Rapid Antigen Testing](#), current [FDA Emergency Use Authorizations](#) for available tests, and [FDA FAQ](#).

* COVID-19 patients may present with a variety of [symptoms](#).

† Point-of-care (POC) tests must be performed at a CLIA-certified laboratory or testing site. More information can be found on the [VDH Office of Licensure and Certification website](#). All results (positive and negative) must be [reported to VDH](#) within 24 hours. If there is a known exposure, it is reasonable to test approximately one week after exposure based on the average incubation period and available evidence to date. If testing is not readily available, prioritize symptomatic individuals and asymptomatic close contacts [at increased risk for severe COVID-19](#).

‡ False positives can occur, especially in low prevalence populations.

§ When confirming an antigen test result with a PCR test, the confirmatory PCR test should be performed in a high complexity CLIA certified laboratory. The follow-up specimen should be collected within 24 hours of the original test, if possible, and no more than 48 hours after the antigen test. Specimens collected more than 48 hours after the initial test may lead to discordant results.

¶ If the person had close contact with someone with COVID-19, the person should continue to quarantine until 14 days after the last known exposure. If the person did not have close contact with someone with COVID-19, the person should isolate until at least 24 hours after symptoms resolve (if symptomatic) or follow protective measures in place in the community (if asymptomatic).

‡ For COVID-19, VDH defines close contact as being within six feet of someone known to have COVID-19 for a total of 15 minutes or longer over a 24-hour period, or having exposure to respiratory secretions from an infected person (e.g., being coughed or sneezed on, sharing a drinking glass or utensils, kissing), starting from two days before the person became sick (or two days before specimen collection if asymptomatic) until the person was isolated.