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)


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

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%

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%

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
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.

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

<table>
<thead>
<tr>
<th>Reference Extracted RT-PCR assay</th>
<th>Sofia SARS Antigen FIA Assay</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>POS</strong></td>
<td>29</td>
</tr>
<tr>
<td><strong>NEG</strong></td>
<td>1</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>30</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>29</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>30</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>209</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Statistic</th>
<th>Value</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity</td>
<td>96.67%</td>
<td>82.78% to 99.92%</td>
</tr>
<tr>
<td>Specificity</td>
<td>100.00%</td>
<td>97.96% to 100.00%</td>
</tr>
<tr>
<td>Disease prevalence (*)</td>
<td>14.35%</td>
<td>9.90% to 19.85%</td>
</tr>
<tr>
<td>Positive Predictive Value (*)</td>
<td>100.00%</td>
<td></td>
</tr>
<tr>
<td>Negative Predictive Value (*)</td>
<td>99.44%</td>
<td>96.30% to 99.92%</td>
</tr>
<tr>
<td>Accuracy (*)</td>
<td>99.52%</td>
<td>97.36% to 99.99%</td>
</tr>
</tbody>
</table>

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<thead>
<tr>
<th>Statistic</th>
<th>Value</th>
<th>95% CI</th>
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</thead>
<tbody>
<tr>
<td>Sensitivity</td>
<td>60.47%</td>
<td>44.41% to 75.02%</td>
</tr>
<tr>
<td>Specificity</td>
<td>99.82%</td>
<td>99.00% to 100.00%</td>
</tr>
<tr>
<td>Disease prevalence (*)</td>
<td>7.20%</td>
<td>5.26% to 9.58%</td>
</tr>
<tr>
<td>Positive Predictive Value (*)</td>
<td>96.30%</td>
<td>78.33% to 99.47%</td>
</tr>
<tr>
<td>Negative Predictive Value (*)</td>
<td>97.02%</td>
<td>95.74% to 97.92%</td>
</tr>
<tr>
<td>Accuracy (*)</td>
<td>96.98%</td>
<td>95.28% to 98.20%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Antigen results</th>
<th>PCR results</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Positive</strong></td>
<td><strong>negative</strong></td>
</tr>
<tr>
<td>Positive</td>
<td>26</td>
</tr>
<tr>
<td>Negative</td>
<td>17</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>43</td>
</tr>
</tbody>
</table>

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.

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<thead>
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<th>Statistic</th>
<th>Value</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity</td>
<td>97.14%</td>
<td>85.08% to 99.93%</td>
</tr>
<tr>
<td>Specificity</td>
<td>98.51%</td>
<td>91.96% to 99.96%</td>
</tr>
<tr>
<td>Disease prevalence (*)</td>
<td>34.31%</td>
<td>25.19% to 44.37%</td>
</tr>
<tr>
<td>Positive Predictive Value (*)</td>
<td>97.14%</td>
<td>82.92% to 99.58%</td>
</tr>
<tr>
<td>Negative Predictive Value (*)</td>
<td>98.51%</td>
<td>90.53% to 99.78%</td>
</tr>
<tr>
<td>Accuracy (*)</td>
<td>98.04%</td>
<td>93.10% to 99.76%</td>
</tr>
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Days Since Symptom Onset | Cumulative RT-PCR Positive (+) | Cumulative BinaxNOW COVID-19 Ag Card Positive (+) | PPA | 95% Confidence Interval |
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<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>4</td>
<td>4</td>
<td>100.0%</td>
<td>39.8% to 100.0%</td>
</tr>
<tr>
<td>2</td>
<td>10</td>
<td>10</td>
<td>100.0%</td>
<td>69.2% to 100.0%</td>
</tr>
<tr>
<td>3</td>
<td>15</td>
<td>15</td>
<td>100.0%</td>
<td>78.2% to 100.0%</td>
</tr>
<tr>
<td>4</td>
<td>18</td>
<td>18</td>
<td>100.0%</td>
<td>81.5% to 100.0%</td>
</tr>
<tr>
<td>5</td>
<td>23</td>
<td>22</td>
<td>95.7%</td>
<td>78.1% to 99.9%</td>
</tr>
<tr>
<td>6</td>
<td>27</td>
<td>26</td>
<td>96.3%</td>
<td>81.0% to 99.9%</td>
</tr>
<tr>
<td>7</td>
<td>35</td>
<td>34</td>
<td>97.1%</td>
<td>85.1% to 99.9%</td>
</tr>
</tbody>
</table>
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

<table>
<thead>
<tr>
<th>Test Result</th>
<th>Person being Tested</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Symptomatic Person</strong>&lt;br&gt;(test as close to symptom onset as possible and as recommended by manufacturer)</td>
<td>Asymptomatic Person with Close Contact to a known COVID-19 case</td>
</tr>
<tr>
<td><strong>Positive</strong>&lt;br&gt;• Current infection&lt;br&gt;• Prompt isolation until no longer contagious by symptom-based strategy</td>
<td>• Current infection&lt;br&gt;• Prompt isolation until no longer contagious by time-based strategy</td>
</tr>
<tr>
<td><strong>Negative</strong>&lt;br&gt;• No antigens were detected&lt;br&gt;• Confirm negative antigen result with a PCR test done in a high-complexity CLIA-certified laboratory**&lt;br&gt;• Prompt isolation while awaiting confirmatory test result</td>
<td>• No antigens were detected&lt;br&gt;• Close contacts who test negative must still complete 14 days of quarantine.&lt;br&gt;• Obtain COVID-19 PCR test if person develops symptoms</td>
</tr>
</tbody>
</table>
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](https://www.cms.gov), 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](https://www.fda.gov).
VDH Interim COVID-19 Antigen Testing Recommendations - Locations Online


Key Resources

2. VDH homepage: www.vdh.virginia.gov
Thank you for your attention!

Questions and Discussion
Supplementary Slides
# VDH COVID-19 Molecular Testing Algorithm

**November 5, 2020**

## Algorithm:

1. **Test for COVID-19**: While test results are pending, patient should isolate.

   - **Box A**: Indicates RNA was not detected
     - Follow situation-specific infection prevention measures
     - Negative test does not rule out the potential for future infection

   - **Box B**: Indicates current infection
     - Patient should isolate until no longer infectious and close contacts should quarantine
     - If admitted to a healthcare facility, use transmission-based precautions
     - Follow situation-specific patient management (e.g., delay major surgeries, if possible)

## Positive Test:

- **Consider testing**
  - Test for COVID-19
  - Refer to VDH Healthcare Personnel Guidance to assess and manage exposed asymptomatic healthcare personnel

## Negative Test:

- **Test for COVID-19**
  - Refer to VDH Healthcare Personnel Guidance to assess and manage exposed asymptomatic healthcare personnel

## Additional Guidance:

- If any of these describe the patient:
  - Pregnant and presenting in labor
  - Neonates born to women with confirmed or suspected COVID-19
  - Undergoing aerosol-generating procedures with limited PPE at the facility (if testing, wait within 48 hours of procedure)
  - Undergoing major time-sensitive surgery (if testing, within 48 hours of surgery)
  - Immunocompromised person being admitted to the hospital
  - Undergoing immunosuppressive procedures

- If this describes the patient:
  - A close contact of a person with lab-confirmed COVID-19
  - Exposed healthcare personnel
  - A resident or staff of a congregate setting
  - Any other asymptomatic person who was tested with a molecular test without close contact to a known COVID-19 case

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**Notes:**

1. For known specimen collection locations in Virginia, see [here](link).

2. Serology testing can be used for public health surveillance or research purposes, but is not recommended for diagnosing current COVID-19 infection or making decisions about returning to work. All COVID-19 test results (positive and negative) should be reported to VDH within 24 hours.

3. 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. Testing is not readily available for all close contacts, prioritize symptomatic close contacts or those at increased risk for severe COVID-19.

4. If the person had a known exposure to someone with COVID-19, the person should continue to quarantine until 14 days after the last known exposure. If the person did not have a known exposure to someone with COVID-19, isolation should last for at least 14 days after symptom onset (if symptomatic) or the last day of exposure in the community (if asymptomatic).

5. For COVID-19, VDH defers 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, being within three feet of the person for less than 15 minutes, or having direct skin contact with a respiratory secretions of an infected person). Testing should be offered to asymptomatic contacts within 7 days of last exposure, if possible.

6. A negative molecular test result for SARS-CoV-2 means that at the time of collection, RNA from this virus was not present in the specimen above the limit of detection.
VDH COVID-19 Antigen Testing Algorithm

11/5/2020

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

Does the patient have symptoms consistent with COVID-19?

Yes

Test using ANTIGEN if results are not provided at point-of-care, patient should isolate.

- Indicates current infection
- Patient should isolate until no longer infectious and close contacts should quarantine
- If admitted to a healthcare facility, use transmission-based precautions
- Follow situation-specific patient management (e.g., delay major surgeries, if possible)

TEST POSITIVE

- Indicates no antigens were detected; however, amount of antigen in a sample decreases as duration of illness increases, particularly 5 days after onset of illness.
- Confirm negative antigen result with a molecular test done in a high-complexity CLIA certified laboratory. Patient should isolate while awaiting confirmatory test result.
- If molecular testing is not available, clinical decision can be used in whether to recommend the patient isolate.
- Patient with positive confirmatory test should isolate until no longer infectious and close contacts should quarantine
- Patient with negative confirmatory test should isolate based on exposure and symptoms.

TEST NEGATIVE

No

Test using ANTIGEN if molecular testing (e.g., PCR) unavailable.

If this describes the patient:

- A close contact of a person with lab-confirmed COVID-19

TEST POSITIVE

- Indicates no antigens were detected
- Patient should remain in quarantine for 14 days after the last date of exposure until indicated
- Perform molecular test if symptoms develop

TEST NEGATIVE

- Any other asymptomatic person who is tested with an ANTIGEN test without close contact and is not a known COVID-19 case

TEST POSITIVE

- Indicates no antigens were detected
- No additional case follow-up necessary
- Reinforce prevention measures

See CDC Nursing Home Guidance

Recommendations are based on CDC guidance, VDH guidance, Infectious Disease Society of America Guidelines on the Diagnosis of COVID-19, APIC’s Considerations for Implementation of SARS-CoV-2 Rapid Antigen Testing, current FDA Emergency Use Authorizations for available tests, and FDA FAQs.

* 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.

§ Asymptomatic individuals have been isolated following exposure to a known COVID-19 case, including close contacts who have been isolated for 14 days from last exposure to a known COVID-19 case and individuals who are asymptomatic and have been exposed to someone known to have COVID-19 for a total of 15 minutes or longer over a 24-hour period, or having exposure to respiratory aerosols 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.