COVID-19 Testing

Medical Society of Virginia and Virginia Department of Health Webinar

July 31, 2020
Objectives

• Overview and Current Status of COVID-19
• Updated CDC and VDH Guidance on Who Should be Tested
• COVID-19 Testing Information and Interpretation
• VDH COVID-19 Testing Algorithm
• Useful resources
Background/Epidemiologic 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

The WHO Situation Report from July 28, 2020 reported over 16 million cases and 650 thousand deaths globally due to COVID-19
COVID-19 Cases and Deaths in the US as of July 28, 2020 (CDC Data)

Total Reported Cases: 4,280,135 (54,448 New Cases)

Total Reported Deaths: 147,672 (1,126 New Deaths)

COVID-19 Cases and Deaths in Virginia as of July 28, 2020 (VA Data)

Total Cases: 86,994
Total Hospitalizations: 7,686
Total Deaths: 2,095

COVID-19 Testing Totals and Trends in New Cases Nationally as of July 28, 2020 (CDC Data)

- **Total Tests Reported:** 52,942,145
- **Positive Tests Reported:** 5,046,506
- **% of Positive Tests:** 10%


The following chart shows the number of new COVID-19 cases reported each day in the U.S. since the beginning of the outbreak. Hover over the bars to see the number of new cases by day.

COVID-19 Testing Totals and Trends New Cases in Virginia as of July 28, 2020 (VA Data)

Testing Encounters Total:
1,157,924

Current 7-day Positivity Rate Total:
7.5%

CDC COVID-19 Testing Guidance
CDC Testing Guidance *(Last updated July 17, 2020)*

Describes five populations for which SARS-CoV-2 testing with **viral tests** (i.e., nucleic acid or antigen tests) is appropriate:

1. **Individuals with signs or symptoms** consistent with COVID-19
2. Asymptomatic individuals with **recent known or suspected exposure** to SARS-CoV-2 to control transmission
3. Asymptomatic individuals without known or suspected exposure to SARS-CoV-2 for **early identification in special settings**
5. Individuals being tested for purposes of **public health surveillance** for SARS-CoV-2

Updated CDC Guidance on Discontinuation of Transmission-Based Precautions *(Last updated July 17, 2020)*

A test-based strategy is no longer recommended *(except for rare situations)* because, in the majority of cases, it results in prolonged isolation of patients who continue to shed detectable SARS-CoV-2 RNA but are no longer infectious.

**Symptom-Based Strategy for Discontinuing Transmission-Based Precautions.**

- Patients with mild to moderate illness who are not severely immunocompromised:
  - At least 10 days have passed since symptoms first appeared and
  - At least 24 hours have passed since last fever without the use of fever-reducing medications and
  - Symptoms (e.g., cough, shortness of breath) have improved

- Patients with severe to critical illness or who are severely immunocompromised\(^1\):
  - At least 20 days have passed since symptoms first appeared and
  - At least 24 hours have passed since last fever without the use of fever-reducing medications and
  - Symptoms (e.g., cough, shortness of breath) have improved

[1](https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-hospitalized-patients.html#definitions)
Testing of HCP can be considered in four situations:

1. Testing HCP with signs or symptoms consistent with COVID-19
2. Testing asymptomatic HCP with known or suspected exposure* to SARS-CoV-2
3. Testing asymptomatic HCP without known or suspected exposure to SARS-CoV-2 for early identification in special settings (e.g., nursing homes)
4. Testing HCP who have been diagnosed with SARS-CoV-2 infection to determine when they are no longer infectious (See HCP Return to Work for recent updates)

*Exposure Personal Protective Equipment Used

HCP who had prolonged close contact with a patient, visitor, or HCP with confirmed COVID-19

- HCP not wearing a respirator or facemask
- HCP not wearing eye protection if the person with COVID-19 was not wearing a cloth face covering or facemask
- HCP not wearing all recommended PPE (i.e., gown, gloves, eye protection, respirator) while performing an aerosol-generating procedure


VDH Testing Guidance
VDH Testing Guidance

- Test all patients with symptoms consistent with COVID-19:
  - These include fever or chills, cough, dyspnea, fatigue, myalgias, headache, new loss of taste or smell, sore throat, congestion or runny nose, nausea, vomiting or diarrhea
  - Older adults may present with delirium, confusion or falls
  - Children often present with similar symptoms, but milder
  - Multisystem Inflammatory Syndrome (MIS-C) can occur during or after COVID-19 infection in children

VDH Testing Guidance

Consider testing the following persons for medical reasons if there are sufficient supplies:

- Pregnant women in labor/Neonates born to women with confirmed or suspected COVID-19
- People undergoing aerosol-generating procedures
- People undergoing major time-sensitive surgery
- Immunocompromised people admitted to the hospital

Consider testing the following persons for containment purposes if there are sufficient supplies:

- Close contacts of case patients*
- People who work or live in a long-term care facility (LTCF)
- People who work or live in a congregate setting, other than an LTCF, that is having an outbreak

*Close contact is defined as
- Living with or providing care for a person with COVID-19 OR
- Being within 6ft of a person with COVID-19 for at least 15min OR
- Having exposure to respiratory secretions (e.g. being coughed or sneezed on, sharing utensils, kissing) from a person who has COVID-19

Infographic Available Here

## VDH Guidance on Prioritization of COVID-19 Testing

<table>
<thead>
<tr>
<th>Prioritization Level</th>
<th>Private/Commercial Lab Testing</th>
<th>Public Health Lab Testing</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>High Priority</strong></td>
<td>• Hospitalized patients*</td>
<td>• Contact and outbreak investigations</td>
</tr>
<tr>
<td></td>
<td>• Healthcare workers and first responders with COVID-19 symptoms*</td>
<td>• Residents and workers with COVID-19 symptoms*</td>
</tr>
<tr>
<td></td>
<td>• Un- or underinsured persons with COVID-19 symptoms*</td>
<td>• In, or newly arriving to, congregate settings (e.g., long-term care facilities, prisons, jails, or behavioral health facilities)</td>
</tr>
<tr>
<td></td>
<td>• Residents and workers with COVID-19 symptoms* In, or newly arriving to, congregate settings (e.g., long-term care facilities, prisons, jails, or behavioral health facilities)</td>
<td>• Un- or underinsured persons with COVID-19 symptoms**</td>
</tr>
<tr>
<td><strong>Priority</strong></td>
<td>• Persons with COVID-19 symptoms*</td>
<td>• Public health monitoring, including point prevalence surveys</td>
</tr>
<tr>
<td></td>
<td>• Persons without symptoms</td>
<td>• Sentinel surveillance and seroprevalence studies</td>
</tr>
<tr>
<td></td>
<td>• Close contacts of cases**</td>
<td>• Community testing clinics</td>
</tr>
<tr>
<td></td>
<td>• Prioritized by clinicians based on their best clinical judgment (e.g., for medical procedures)</td>
<td></td>
</tr>
</tbody>
</table>

*Indicates priority for immediate attention, **Indicates priority if resources are available.*

Table 1: VDH Recommendations for prioritizing SARS-CoV-2 testing
### COVID-19 Testing in Virginia

Testing Encounters Total: 1,157,924

Current 7-day Positivity Rate Total: 7.5%

#### Testing Encounters by Health District, PCR Only

<table>
<thead>
<tr>
<th>Health District</th>
<th>Encounters</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fairfax</td>
<td>119,257</td>
</tr>
<tr>
<td>Prince William</td>
<td>66,937</td>
</tr>
<tr>
<td>Loudoun</td>
<td>44,784</td>
</tr>
<tr>
<td>Virginia Beach</td>
<td>52,276</td>
</tr>
<tr>
<td>Chesterfield</td>
<td>48,470</td>
</tr>
<tr>
<td>Henrico</td>
<td>52,306</td>
</tr>
<tr>
<td>Rappahannock</td>
<td>33,778</td>
</tr>
<tr>
<td>Arlington</td>
<td>26,971</td>
</tr>
<tr>
<td>Norfolk</td>
<td>31,650</td>
</tr>
<tr>
<td>Lord Fairfax</td>
<td>29,390</td>
</tr>
<tr>
<td>Richmond</td>
<td>30,441</td>
</tr>
<tr>
<td>Peninsula</td>
<td>35,766</td>
</tr>
<tr>
<td>Alexandria</td>
<td>20,505</td>
</tr>
<tr>
<td>Thomas Jefferson</td>
<td>31,588</td>
</tr>
<tr>
<td>Roanoke</td>
<td>32,111</td>
</tr>
<tr>
<td>Chesapeake</td>
<td>79,591</td>
</tr>
<tr>
<td>Central Shenandoah</td>
<td>28,110</td>
</tr>
<tr>
<td>Rappahannock Rapids</td>
<td>19,177</td>
</tr>
</tbody>
</table>

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

[Graph showing testing encounters and positivity rate over time]
COVID-19 Tests (PCR, Antigen, and Serology) and Their Interpretation
General Considerations for COVID Testing

- Depending on study, about 25-40% of COVID-19 patients are asymptomatic.

- Clinical correlation is always important (especially if test results are negative but patient is symptomatic, i.e. concern for false negative).

- For people previously diagnosed with symptomatic COVID-19, retesting is not recommended for asymptomatic patients within 3 months after the date of symptom onset except in special circumstances with the input of an infectious disease specialist (see www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html).
COVID-19: Molecular (PCR) Testing

Reverse Transcription Polymerase Chain Reaction (RT-PCR):

• Preferred VDH test for diagnosing acute COVID-19
• Detects presence of SARS-CoV-2 RNA
• PCR-based testing commonly done on a nasopharyngeal swab, but can be done on other upper or lower respiratory tract specimens
• Recommend using a PCR-based test that has received an Emergency Use Authorization (EUA) from FDA (see www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas#imft1)
• As of July 26, four point-of-care “rapid” tests that have FDA EUA
• PCR-based tests generally have high specificity which means false positive test results are very uncommon (corrected text)
• PCR test performance depends on adequacy of test specimen. If doing NP swab, want to obtain nasal or nasopharyngeal secretions
Specimen collection videos

- **NP swab collection:**

- **Deep nasal swab collection:**
  https://youtu.be/lz5RBtFfImI - from VCU and VHHA, 7/9/2020, duration = 3:33

- Both videos well worth viewing
COVID-19: PCR Interpretation & Action

Positive RT-PCR Test

• Patient is presumed to be infected with SARS-CoV-2 and contagious
• Isolate patient until he/she meets criteria to discontinue isolation

Negative RT-PCR Test

• No active infection - advise standard infection control measures (social distancing, cloth mask, hand hygiene, environmental cleaning)
• If patient is a known close contact of a COVID-19 case, continue self-quarantine for 14 days (following last exposure to positive case)
• If patient has clinical symptoms consistent with COVID-19, isolate, notify VDH, and consider retest despite initial negative test
COVID-19: Viral Antigen Diagnostic Tests

- Detects the presence of SARS-CoV-2 protein (nucleocapsid) antigens
- As of July 26, two tests have FDA EUA
- Testing can be done at commercial labs, and both tests available as CLIA-waived point-of-care (POC) assays
- Viral antigen can be detected in acute phase of infection
- Viral antigen tests are less sensitive than PCR tests—this may generate false negative results
COVID-19: Viral Antigen Test Interpretation and Action

Positive Antigen Test
- Nucleocapsid antigen present
- Clinical correlation with patient history and other diagnostic info needed to determine infection status.

Negative Antigen Test
- Nucleocapsid antigen NOT detected
- Negative result should be treated as presumptive and confirmed with PCR test.
- Take patient’s clinical history, presentation, diagnostic testing into account
Lab Testing and Capacity (as of 7/22)

Percent of total tests conducted by performing facility, 7/15-7/21:

**Commercial**
Average turnaround time: **4.8 days**
Total Tests: 121,458
7-Day Average Positivity Rate: 9%

**Hospital**
Average turnaround time: **1.0 days**
Total Tests: 41,518
7-Day Average Positivity Rate: 10%

**Public**
Average turnaround time: **4.8 days**
Total Tests: 11,459
7-Day Average Positivity Rate: 4%

**DCLS**
Average turnaround time: **3.0 days**
Total Tests: 6,245
7-Day Average Positivity Rate: 6%

Efforts to address delays in testing turnaround times:
- Exploring refinements in testing criteria
- Bringing on new labs
- Consideration of emerging testing modalities, being discussed in Testing Advisory Council (e.g., antigen, pooling)

Data sources: Internal VDH
Key Resources

Thank you

Questions and Discussion
Additional Resources
Specialized Testing Recommendations for Nursing Homes

• During Phase I or during an Outbreak Investigation:
  • **Test all staff AND all residents weekly** (except those previously testing positive within the past 8 weeks). Testing should continue weekly until there are no new cases among staff or nursing home (NH)-onset cases in residents for the previous 14 days

• Once the facility is no longer testing staff and residents weekly:
  • **Immediately test any resident or staff with symptoms.**
    • A new case identified as originating within the nursing home will restart weekly testing
    • A case identified as not originating within the nursing home will prompt weekly testing of close contacts or unit/ward

Evidence Contributing to Recent Changes in CDC Guidance:

- The likelihood of recovering replication-competent virus also declines after onset of symptoms. For patients with mild to moderate COVID-19, replication-competent virus has not been recovered after 10 days following symptom onset (CDC, unpublished data, 2020; Wölfel et al., 2020; Arons et al., 2020; Bullard et al., 2020; Lu et al., 2020; personal communication with Young et al., 2020; Korea CDC, 2020).

- Recovery of replication-competent virus between 10 and 20 days after symptom onset has been documented in some persons with severe COVID-19 that, in some cases, was complicated by immunocompromised state (van Kampen et al., 2020). However, in this series of patients, it was estimated that 88% and 95% of their specimens no longer yielded replication-competent virus after 10 and 15 days, respectively, following symptom onset.

- A large contact tracing study demonstrated that high-risk household and hospital contacts did not develop infection if their exposure to a case patient started 6 days or more after the case patient’s illness onset (Cheng et al., 2020).

- Although replication-competent virus was not isolated 3 weeks after symptom onset, recovered patients can continue to have SARS-CoV-2 RNA detected in their upper respiratory specimens for up to 12 weeks (Korea CDC, 2020; Li et al., 2020; Xiao et al., 2020). Investigation of 285 “persistently positive” persons, which included 126 persons who had developed recurrent symptoms, found no secondary infections among 790 contacts attributable to contact with these case patients. Efforts to isolate replication-competent virus from 108 of these case patients were unsuccessful (Korea CDC, 2020).

- Specimens from patients who recovered from an initial COVID-19 illness and subsequently developed new symptoms and retested positive by RT-PCR did not have replication-competent virus detected (Korea CDC, 2020; Lu et al., 2020). The risk of reinfection may be lower in the first 3 months after initial infection, based on limited evidence from another betacoronavirus (HCoV-OC43), the genus to which SARS-CoV-2 belongs (Kiyuka et al, 2018).

- Currently, 6 months after the emergence of SARS-CoV-2, there have been no confirmed cases of SARS-CoV-2 reinfection. However, the number of areas where sustained infection pressure has been maintained, and therefore reinfections would be most likely observed, remains limited.

Definitions of Severe Illness or Severely Immunocompromised (CDC):

- Some conditions, such as being on chemotherapy for cancer, untreated HIV infection with CD4 T lymphocyte count < 200, combined primary immunodeficiency disorder, and receipt of prednisone >20mg/day for more than 14 days, may cause a higher degree of immunocompromise and inform decisions regarding the duration of Transmission-Based Precautions.

- Other factors, such as advanced age, diabetes mellitus, or end-stage renal disease, may pose a much lower degree of immunocompromise and not clearly affect decisions about duration of Transmission-Based Precautions.

- Ultimately, the degree of immunocompromise for the patient is determined by the treating provider, and preventive actions are tailored to each individual and situation.

Estimated Variation Over Time in Diagnostic Tests for Detection of SARS-CoV-2 Infection Relative to Symptom Onset

Estimated time intervals and rates of viral detection are based on data from several published reports. Because of variability in values among studies, estimated time intervals should be considered approximations and the probability of detection of SARS-CoV-2 infection is presented qualitatively. SARS-CoV-2 indicates severe acute respiratory syndrome coronavirus 2; PCR, polymerase chain reaction.


Detection only occurs if patients are followed up proactively from the time of exposure.

More likely to register a negative than a positive result by PCR of a nasopharyngeal swab.
COVID-19: Serology tests

- Not recommended for the diagnosis of COVID-19
- Tests can be useful for serosurveys to determine true COVID-19 infection rates and learn more about the body’s immune response to COVID-19
- Antibodies start developing within 1-3 weeks after infection
- **Positive result** = person has likely been infected with COVID-19 in past
  - If clinically indicated, perform PCR or viral antigen testing
  - Positive test result does NOT necessarily mean person is immune to COVID-19, issue needs more study
  - People and HCWs should continue to practice standard infection control measures. For HCWs, continue to wear PPE despite positive antibody test
- **Negative result** = person unlikely to have been infected with COVID-19
  - If clinically indicated, perform PCR or viral antigen testing
  - Other reasons for a negative antibody test = antibodies had not developed at the time of specimen collection, are too low to detect, or sufficient immune response may not have occurred in immunosuppressed patients
  - Do not use antibody test to determine if someone can return to work
  - Do not use tests as a means to cohort groups of people (e.g., in jails, dormitories, etc.)
## Guidance on Interpreting COVID-19 Test Results

<table>
<thead>
<tr>
<th>RESULT</th>
<th>INTERPRETATION</th>
<th>RECOMMENDED ACTION</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>VIRAL TESTING:</strong> (testing for current infection)</td>
<td>Positive: Most likely you do currently have an active COVID-19 infection and can give the virus to others.</td>
<td>Stay home* and follow CDC guidance on steps to take if you are sick. *If you are a healthcare or critical infrastructure worker, notify your work of your test result.</td>
</tr>
<tr>
<td></td>
<td>Negative: Most likely you do NOT currently have an active COVID-19 infection.</td>
<td>If you have symptoms, you should keep monitoring symptoms and seek medical advice about staying home and if you need to get tested again. If you don’t have symptoms, you should get tested again only if your medical provider and/or workplace tells you to. Take steps to protect yourself and others.</td>
</tr>
<tr>
<td><strong>ANTIBODY TESTING:</strong> (testing for past infection with the virus)</td>
<td>Positive: You likely have had a COVID-19 infection.</td>
<td>You may be protected from re-infection (have immunity), but this cannot be said with certainty. Scientists are conducting studies now to provide more information. Take steps to protect yourself and others.</td>
</tr>
<tr>
<td></td>
<td>Negative: You likely never had (or have not yet developed antibodies to) COVID-19 infection.</td>
<td>You could still get COVID-19. Take steps to protect yourself and others.</td>
</tr>
<tr>
<td><strong>BOTH:</strong> (antibody and viral testing)</td>
<td>Viral Positive, Antibody Positive: Most likely you do currently have an active COVID-19 infection and can give the virus to others.</td>
<td>Stay home* and follow CDC guidance on steps to take if you are sick. *If you are a healthcare or critical infrastructure worker, notify your work of your test result.</td>
</tr>
<tr>
<td></td>
<td>Viral Positive, Antibody Negative: Most likely you do currently have an active COVID-19 infection and can give the virus to others.</td>
<td>Stay home* and follow CDC guidance on steps to take if you are sick. *If you are a healthcare or critical infrastructure worker, notify your work of your test result.</td>
</tr>
<tr>
<td></td>
<td>Viral Negative, Antibody Positive: You likely have had and recovered from a COVID-19 infection.</td>
<td>You may be protected from re-infection (have immunity), but this cannot be said with certainty. Scientists are conducting studies now to provide more information. You should get tested again only if your medical provider and/or workplace tells you to. Take steps to protect yourself and others.</td>
</tr>
<tr>
<td></td>
<td>Viral Negative, Antibody Negative: You likely have never had a COVID-19 infection.</td>
<td>You could still get COVID-19. You should get tested again only if your medical provider and/or workplace tells you to. Take steps to protect yourself and others.</td>
</tr>
</tbody>
</table>

*This text is ever perfect. All tests occasionally result in false positive results (the test result should be negative because you DO NOT have COVID-19 but come back positive) or false negative results (the test result should be positive because you DO have COVID-19, but come back negative). Sometimes the results are not definitive (the result is unclear, and you don’t know if it is positive or negative). For this and other reasons, results should always be discussed by a healthcare professional. *Viral tests are typically performed on respiratory specimens such as nasal swabs or throat swabs. They test for the presence of the virus, usually by testing for the virus’s RNA or sometimes by testing for the virus’s proteins ("antigen testing"). Antigen testing may be less sensitive than tests for the virus’s RNA, so your antigen test is negative, please ask your healthcare provider if additional testing is needed and how long you should stay home. *Antibody testing, also called "serologic testing" or "serology", is typically performed on a blood sample. Ideally, the results show whether you have ever been infected with the virus in the past or may be currently infected. Antibody tests check for antibodies that appear in the blood after a case of COVID-19 or in other symptoms and may remain as long as a lifetime. Antibody tests may be positive while a person is infected. It is not yet known whether these antibodies protect against reinfection with the COVID-19 virus. For many other clinical values, antibodies are protective for years or longer, but we do not yet have adequate data to know for COVID-19.
Number of Testing Encounters, Number of Positive Testing Encounters, and Percent Positivity by Lab Report Date, PCR Only - Central Region

6.5% Positivity
Number of Testing Encounters, Number of Positive Testing Encounters, and Percent Positivity by Lab Report Date, PCR Only - Eastern Region

12.2% Positivity
Number of Testing Encounters, Number of Positive Testing Encounters, and Percent Positivity by Lab Report Date, PCR Only - Northern Region

6.2% Positivity
5.6% Positivity
Number of Testing Encounters, Number of Positive Testing Encounters, and Percent Positivity by Lab Report Date, PCR Only - Southwest Region

6.1% Positivity