Briefing on COVID-19 Antibody Testing in Virginia

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Briefing Outline

• Antibody testing for COVID-19
  • Background
  • Limitations
  • Roles for antibody testing for COVID-19
• Antibody tests results received by VDH
• Virginia Coronavirus Serology Project
• Other VDH antibody testing projects
• What to do if you have a positive COVID-19 antibody test result
Antibodies in brief

• Our immune system makes antibodies in response to an infection (virus or bacteria).
• These Y-shaped proteins bind onto viruses.
• If they bind tightly enough at the right spot, antibodies block the virus from infecting our cells.
• Viruses coated in antibodies are also more likely to be engulfed and destroyed by our immune cells.

Source: *San Diego Union-Tribune* (illustration by Michelle Guerrero)

During a COVID-19 infection, antibodies may be present earlier but are not detected reliably until 2-3 weeks after onset of the infection.
COVID-19 and the role of serology (antibody) testing

Limitations with antibody testing and COVID-19

• Antibodies are indirect evidence of a past infection.
  • Need a viral (PCR) test to diagnose an active infection.

• We don’t know:
  • If detected antibodies are evidence of protection (immunity) from re-infection?
  • How long protection lasts?
  • If you get re-infected, will the illness be milder?
  • If you get re-infected, will you be contagious?
Tests are not perfect - we have to think about which test to use

- Assume 5% of the population had a COVID-19 infection
- Test has 90% sensitivity and 95% specificity

1 in 2 positives is a false positive

89 to 90 people who tested negative did not have COVID-19 in the past (“true negative”)
5 person who tested positive did not have COVID-19 in the past (“false positive”)
5 people who tested positive did have COVID-19 in the past (“true positive”)
<1 person who tested negative did have COVID-19 in the past (“false negative”)

- Assume 5% of the population had a COVID-19 infection
- Test has 90% sensitivity and 99% specificity

1 in 5-6 positives is a false positive

93 to 94 people who tested negative did not have COVID-19 in the past (“true negative”)
1 person who tested positive did not have COVID-19 in the past (“false positive”)
5 people who tested positive did have COVID-19 in the past (“true positive”)
<1 person who tested negative did have COVID-19 in the past (“false negative”)

Infographic concept courtesy of John Brush, MD, Professor of Medicine, Eastern Virginia Medical School & Sentara Health
Tests are not perfect - we have to think about who we test

- Assume 5% of the population had a COVID-19 infection
- Test has 90% sensitivity and 99% specificity

93 to 94 people who tested negative did not have COVID-19 in the past (“true negative”)
1 person who tested positive did not have COVID-19 in the past (“false positive”)
5 people who tested positive did have COVID-19 in the past (“true positive”)
<1 person who tested negative did have COVID-19 in the past (“false negative”)

- Assume 1% of the population had a COVID-19 infection
- Test has 90% sensitivity and 99% specificity

98 people who tested negative did not have COVID-19 in the past (“true negative”)
1 person who tested positive did not have COVID-19 in the past (“false positive”)
1 people who tested positive did have COVID-19 in the past (“true positive”)
0 person who tested negative did have COVID-19 in the past (“false negative”)

1 in 5-6 positives is a false positive
1 in 2 positives is a false positive
Uses of COVID-19 antibody testing

• Clinician-initiated for individual patient diagnosis
  • With PCR testing in workup of suspect COVID-19 patient, especially if presenting late in illness
  • As part of diagnostic workup for a new health condition or change in existing condition to assess if past COVID-19 infection could be a contributing factor

• Identification of plasma donors for the collection of therapeutic antibodies
Uses of COVID-19 antibody testing

• Case investigation & definition by public health
  • Using a positive COVID-19 antibody test to classify a “probable case”

• Outbreaks
  • Using PCR tests and antibody tests in a outbreak investigation (e.g., LTCF/ALF or workplace)

• Seroprevalence assessments
  • Testing a sample of the population to find what percent of the populations has antibodies indicating past infection (with or without symptoms)
COVID-19 seroprevalence in Virginia

• We really do not know.

• 50,329 antibody test results (FDA-authorized only) reported to VDH to date
  • 5.5% of all tests were positive for antibody
  • Of Virginia’s confirmed cases, 2.1% (898 of 43,277) also have a positive antibody result
  • Of the probable cases, 30.3% (653 of 2,151) have a positive antibody result

• Of the “not cases” with antibody test results, 2.5% were positive.
  • Some percentage of those will be false positives
Virginia Coronavirus Serology Project

• **Purpose** - Estimate the proportion of the adult population with antibodies to SARS-CoV-2 as an indicator of previous symptomatic and asymptomatic COVID-19 infections in Virginia overall and within each of the state’s five health planning regions.

• **Plan**
  - Enroll 5,000 adults statewide: ~1000 in each health planning region.
  - Sample size is sufficient to estimate the prevalence of SARS-CoV-2 antibodies for each region with a precision of +/- 1%, based on an assumption of 2% prevalence of infection.
Virginian Coronavirus Serology Project

- **Eligible participants** - adults seeking care or services at the health systems’ existing locations (e.g., outpatient clinical and lab collection sites)
- **Enrollment quotas** - seek representation of each region’s population by age and race/ethnicity
- **Locations** - chosen to provide some diversity by geography and by population served regionally
- **Elements** - consent, short questionnaire, blood sample collection
- **Testing** - single lab running Abbott Architect SARS-CoV-2 IgG assay (FDA-issued EUA: 100% sensitivity, 99.6% specificity)
- **Timeline** - Enrollment early June - mid July; report (preliminary) NLT July 31
Virginia Coronavirus Serology Project

• UVA
  • Project management
    • Eric Houpt, MD (professor in infectious diseases) is project leader
  • Laboratory testing
  • Enrollment for Northwest region

• Other enrollment locations
  • Inova - Northern
  • Sentara Healthcare - Eastern
  • VCU - Central
  • Carilion Clinic - Southwest
Virginia Coronavirus Serology Project

• **Strengths**
  • Representative by age groups and race/ethnicity
  • Participants already out of their home and through health screening at health care sites
  • Uses site’s existing clinical studies staff and existing blood draw services
  • Higher participation of persons with chronic health conditions

• **Weaknesses**
  • Unlikely to enroll sufficient participants from all health districts for reliable estimates
  • Will underrepresent uninsured and underserved populations
  • No children and youth
Other serology projects

• VDH is analyzing and deciding how to best present the reported antibody test results on the COVID-19 Dashboard.

• VDH is working to add capacity in order to do more antibody testing.
  - Community seroprevalence investigations
  - Tool in outbreak investigation or management
  - Children and youth serology project (regional)
  - Division of Consolidated Laboratory Services antibody testing capabilities
What to do with a positive antibody test

- Continue to follow all general recommendations to prevent COVID-19 infection (distancing, mask, etc.) in the community and in specific environments (workplace, congregate living, etc.).
- No change in actions if symptoms compatible with COVID-19 develop (leave workplace, self-isolate, PCR testing).
- No change in clinical practice or use of personal protective equipment (PPE) by health care workers & first responders.
- Do not use to make decisions about grouping persons residing in or being admitted to congregate settings, such as LTCF/ALF, school, dormitory, or correctional facility.
- Do not use to make decisions about returning persons to the workplace.

Questions?

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