

Briefing on COVID-19 Antibody Testing in Virginia

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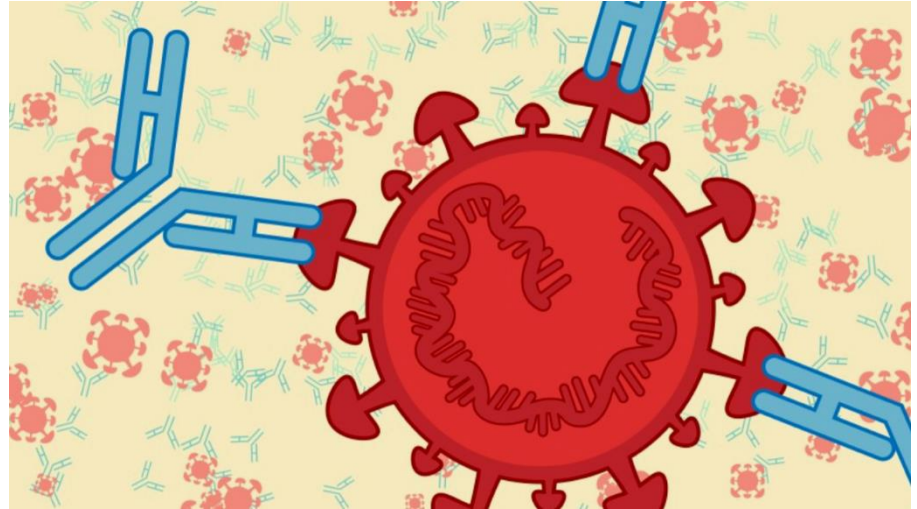
June 3, 2020

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**



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**



93 to 94 people who tested negative did not have COVID-19 in the past ("true negative")

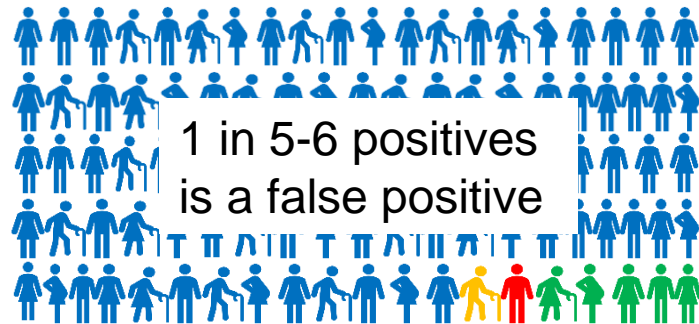
1 person who tested positive did not have COVID-19 in the past ("false positive")





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")

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")

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.

Virginia 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.

CDC Interim Guidelines for COVID-19 Antibody Testing (5/23/2020)

<https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antibody-tests-guidelines.html>

Questions?

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