Testing for COVID-19

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What is the Importance of Testing?

- Testing allows confirmed cases to be isolated quickly and known contacts to be identified early, accounting for spread of the illness.
- If we limit testing to those who are very ill, we miss those spreading the disease asymptomatically or with minor symptoms.
- Effectiveness of testing is evident in countries that are experiencing low daily new cases:
  - Test as many people as possible even with minor suggestive symptoms
  - Trace their contacts to identify people who have been exposed to the virus
  - Isolate and test anyone who has been exposed to prevent further spread

Types of Testing

- There are two major groups of tests that are used for COVID-19:
    1. Diagnostic tests
    2. Serological tests

- **A *diagnostic test*** used in the United States identifies people who are currently spreading the virus. The test **identifies people with current infections**.
- A serological test detects antibodies that people produce after they've become infected. Because antibodies can take weeks to appear in someone's blood stream after they've been infected or vaccinated, these tests **do not** indicate whether someone is currently infected. **Rather, they tell you whether someone has been infected in the past.**

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Diagnostic tests

A *diagnostic test* identifies people who currently have the infection and are at risk of spreading it to other people.

- There are two types of diagnostic tests used in the US, and they can utilize a broad array of samples to determine if you are actively infected:
  - PCR, or polymerase chain reaction, tests. **These are the gold standard to see if you are actively infected.**
  - Antigen tests. These are much quicker than PCR tests and much cheaper, while still having a high specificity (low rate of false negatives) when administered 3-5 days after exposure as recommended.

Diagnostic tests: PCR

- PCR, or polymerase chain reaction, tests for COVID-19 require either a nasal/throat **swab** or a **spit** sample.
- Using these samples, PCR tests try to detect RNA from the virus in a person. When viral RNA is detected, it indicates that there is live virus presently infecting your cells and replicating.
- A person can test positive with PCR tests before they have symptoms.
    - This is crucial for reducing the spread of the disease. If someone can be identified as currently infected prior to experiencing symptoms, or if they never experience symptoms, then the number of people they could infect is greatly reduced.

Diagnostic tests: PCR

- **Molecular PCR tests typically take at least a day, on average 24-72 hours, to complete** as they require intensive laboratory processes in order to detect the viral RNA in your nasal/throat swab, spit, or sputum samples.
- While these are the most accurate of the tests, the methods that they require make them **more expensive to complete compared to antigen tests**.
- However, **these tests are very sensitive to the virus and have extremely low rates of false negatives.**

Diagnostic tests: Antigen tests

- Antigen tests for COVID-19 also using nasal/throat swabs and spit samples. Rather than testing for the presence of viral RNA from the virus that causes COVID-19, it **tests for the presence of antigens that your immune system uses to recognize the infection (like proteins that are part of the virus)**. These tests can be completed within hours of having a sample taken so the are known to be **rapid tests**.
- Antigen tests have been widely used to identify diseases like the seasonal flu and are starting to be used more frequently for COVID-19 testing as well.
- **The benefit of these compared to PCR tests is that they are relatively inexpensive and can provide results in minutes.**

Diagnostic tests: Antigen tests

- How accurate are they?
  - **Antigen tests are very specific for coronavirus virus; however, they are not as sensitive as molecular PCR tests.*****
  - False positive test results are rare; however, some tests from private companies can be less accurate and have false negatives up to 50% of the time.
- The benefit of the better-quality rapid antigen tests (having a 10% false negative rate) is that they are cheap enough for people to be tested repeatedly.
  - **It is unlikely that two false negatives will be experienced if performed a few days apart**

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Why are there False Negative Diagnostic Tests?
PCR (the swab or spit/saline gargle) and Antigen (the rapid) tests

- A *diagnostic test* is **only valid for a single point in time**.
- A "false negative" is when someone who has the disease receives a negative test result.
- There are a number of reasons why a *diagnostic test* may result in a false negative:
  - **The most common reason is that** it might be too early in the illness, when the amount of virus in the airway or body is still small.
    - If you have been exposed to someone with a confirmed infection, it is recommended you wait 3-5 days before getting tested.
  - It could be a problem with how the swab was done.
  - There could be issues with the handling or transport of the swab.
  - There could be laboratory error.

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Serological tests: Antibody tests

- A *blood-based* serological test detects antibodies that people produce after they've become infected. Antibodies detect the immune system's response to a past infection, **not the current presence of the virus**. While this type of test is not helpful in determining who is *currently infected,* it does have other important uses.
  - This test has epidemiological uses, supporting retrospective case counts, as well as diagnostic uses.
  - This test is also used to determine whether someone has immunity, or protection, against a second infection.

Why are serological tests so important?
The Blood Sample

- Gold standard, but labor intensive, take longer to receive results, and expensive
- Assesses IgM levels which indicate ongoing, or recent, infection.
- Excellent tests for determining true immunity by antibody titers.
  - "Titers," or levels of antibodies, provide a quantification of antibody presence (high or low)

- **Identifies people who were not known to be infected**:
  - Identifies current, silent (asymptomatic) infections, as well as those who have recovered.
  - Supports contact tracing.

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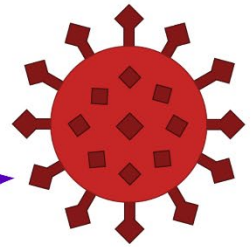
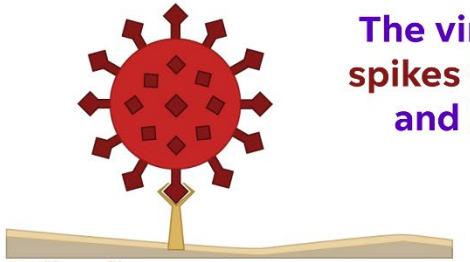
Antigens are structural parts of a virus.

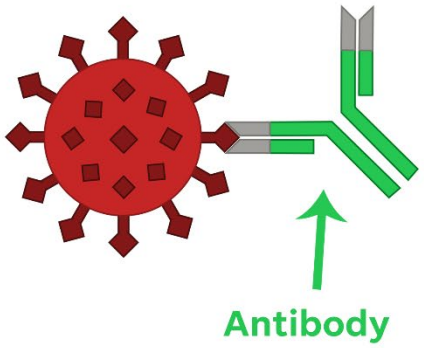
In the novel coronavirus, a series of spikes on the outside help the virus spread





The virus uses these spikes to bind to cells and infect them.

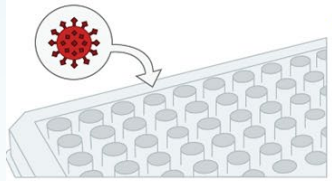
These spikes can be neutralized, or blocked by antibodies.



Antibodies are proteins produced by the immune system to fight infection.

Developing a <u>blood based</u> serological test

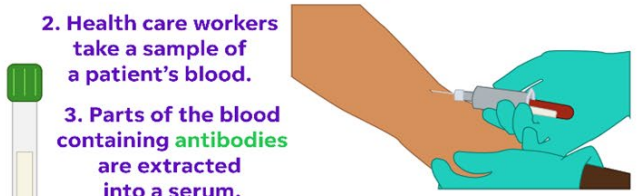
How COVID-19 antibody testing works:



1. Researchers take lab-grown COVID-19 antigens and put them into special plates that immobilize them.

Antigens are structural parts of viruses.

2. Health care workers take a sample of a patient's blood.

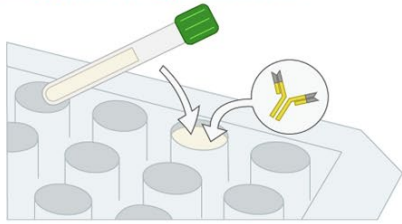


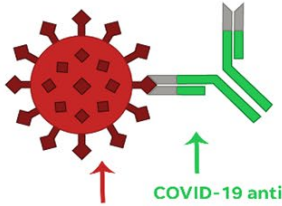
3. Parts of the blood containing antibodies are extracted into a serum.

Antibodies are produced by the immune system to fight infection.

4. The serum and a detector antibody are added into the special plate mixture.

Detector antibodies alert researchers to the presence of virus antibodies.

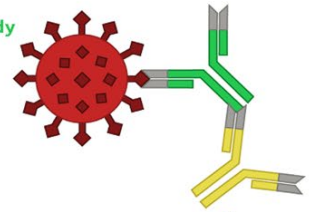




5. If COVID-19 antibodies are present, they will stick to COVID-19 antigens and block them.

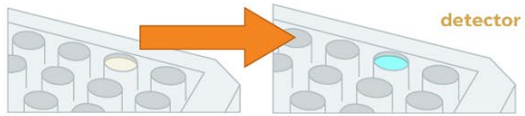
COVID-19 antibody

COVID-19 antigen



6. The detector antibodies will stick to the COVID-19 antibodies to cause a reaction.

detector antibody



7. The reaction causes the liquid in the plate to turn blue. If the liquid turns blue, it means the patient has had or currently has COVID-19.

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How often should you get retested?

- A crucial part of re-entering society and interacting more with others outside of your own home is **retesting**, because each test only provides information about a snapshot in time.

- Currently, it is recommended that you get a PCR (**the swab or spit**) or antigen (**the rapid**) test if you **have been exposed** to someone with a known infection and/or are **experiencing symptoms** consistent with COVID-19.
  - PCR (**the swab or spit**) tests are fully covered via your insurance provider, or through Medicaid funds the government has allocated to cover the cost of testing for those who are uninsured.

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How often should you get retested?

- How often you get **retested** for COVID-19 will **vary depending on your occupation, volunteer activities, and the availability of tests among other reasons**.
    - Those in occupations with a *high risk of infection* (like first responders and healthcare workers) would be required to be **retested** more frequently using PCR (**the swab or spit**) tests **because of their routine and prolonged exposure with people who have COVID-19.**
    - Individuals who work in office settings or occupations with the ability to remain physically distant, follow mask wearing recommendations, and institute adequate disinfecting protocols **would only need to be retested** with a PCR (**the swab or spit**) test **if they have been exposed or are showing symptoms.**

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How often should I be retested with serology (the blood sample) tests?

- Because serology (**the blood sample**) tests determine whether you have EVER had the infection and not whether you have an active infection, how often you get **retested** with serology (**the blood sample**) tests **will be less frequent.**
  - Serology (the blood sample) tests detect antibodies to the infection which do not form unless you've had the infection or have been vaccinated against it.
  - As outbreaks progress, and a greater proportion of the population has been infected, **retesting** with these tests will become more important.
- **Currently, however, retesting with serology (the blood sample) tests should be relatively infrequent compared to PCR (the swab or spit) tests.**

Pooled PCR testing (the swab)

- States have reopened and individuals have relaxed their mitigation efforts due to fatigue from the past year. Because of this, there is a great need for testing. One method to address this is via **pooled PCR (the swab or spit) testing.**
  - **Pooled PCR (the swab or spit) tests combine parts of individual samples from groups of individuals and test them as one sample** using sensitive molecular biological detection methods.
  - If the sample comes back positive, then each person's original sample that was included in the pooled sample is tested individually to determine who among the group has an active infection.
  - If the sample comes back negative, then each individual sample does not need to be tested.
  - This saves money, time, and significant numbers of test kits and increases the test capacity of the existing laboratory infrastructure.

Retesting using Pooled PCR (the swab) tests

- Pooled PCR (**the swab or spit**) tests can be used in instances where large groups of individuals need to get routinely tested to prevent outbreaks from occurring such as in long-term care homes, educational institutions, healthcare facilities, etc.
- Because this method saves money, time, and significant numbers of test kits, it would **increase the test capacity** of the existing laboratory infrastructure **and enable larger groups of people to be tested more frequently**, as opposed to testing every person individually when one in the group begins to show symptoms.

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Pooled testing also contributes to a sense of community

- When a group that interacts routinely is tested together, they get a sense of shared risk as well as shared responsibility to each other.
- This in **turn supports a shift from individual behavior change to group norms that support the health of the unit** – say people who work together in close quarters.
  - This might translate, for example, to mask wearing, or physical distancing
- **This also facilitates contact tracing:** if one person tests positive in the site, then others know all need to isolate as well as get a PCR test to see if they may have in turn transmitted the virus to family members or other groups, they interact with routinely

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