COVID - Testing

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What is an antibody?

- It is a protein produced by the immune system in response to invading organisms such as bacteria and viruses.

- Antibodies have the ability to specifically recognize foreign invaders in the body, coat them by binding to them and then allow the immune cells of the body to clear them from the blood or mucous membranes, or sites like the lung.

- Each antibody can bind to only one specific enemy substance. Some destroy it directly; others make it easier for white blood cells to destroy the pathogen.

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Antibodies

About six to 10 days after viral exposure, the body begins to develop antibodies that bind and react specifically to the proteins found on SARS-CoV-2. The first antibody produced is called immunoglobulin m (IgM), which is short-lived and only stays in the bloodstream for a few weeks. The immune system continues to refine the antibodies and just a few days later will start producing immunoglobulins G (IgG) and A (IgA), which are much more specific. IgG stays in the blood and can confer immunity for months, years, or a lifetime, depending on the disease it's protecting against.

At this time, the presence of COVID IgG immunity remains unknown and is currently continuing to undergo research to measure levels of immunity as well as resultant levels of immunity to re-infection.

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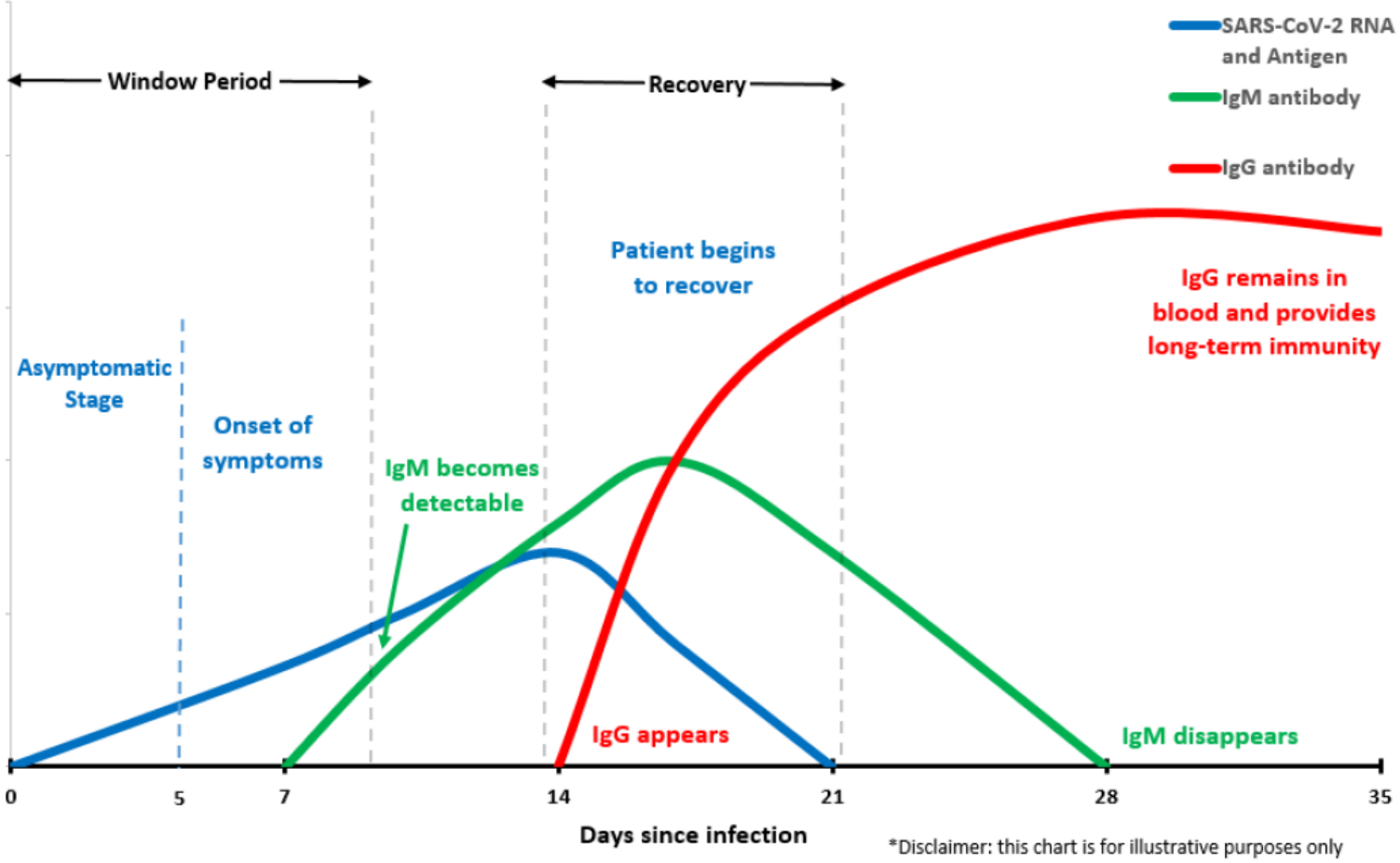

COVID-19 immune response

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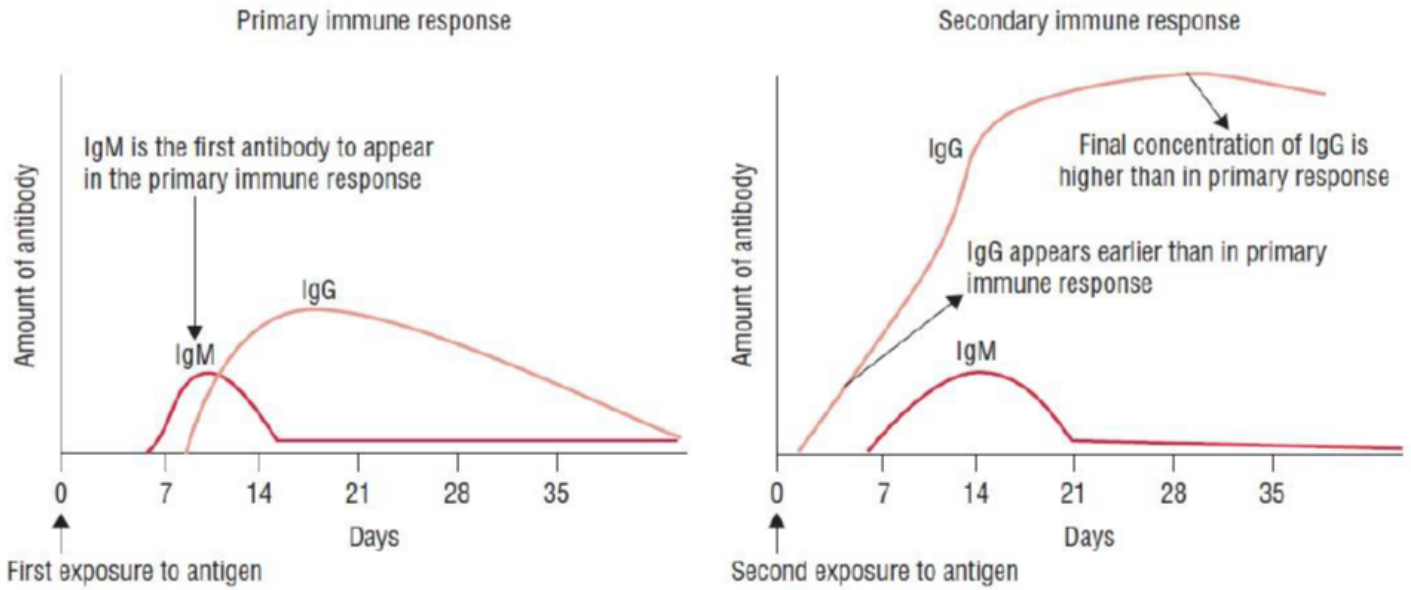

Primary immune response

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COVID-19 Testing options

- The commonly available tests for Covid-19 can be divided into:
  - Polymerase chain reaction (PCR) SWAB test
  - Serologic (blood) antibody tests i.e. Rapid COVID test.

- These tests measure different hallmarks of the SARS-CoV-2 virus.

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RT-PCR Molecular Nasopharyngeal SWAB Test

- Reverse Transcription Polymerase Chain Reaction (RT-PCR)
- RT-PCR tests are used to detect the presence of **viral RNA** (specific viral genetic material) in the secretions of the respiratory tract (nose, throat, sputum). Viral RNA may be present in respiratory tract before the common symptoms of cough, sore throat, and fever develop. The viral load (the amount of virus in secretions) is higher early in the illness and more easily passed on to others. This test is very helpful in detecting an infection early when the symptoms may be minimal.
- This test indicates an active infection. Once identified the person can be isolated (seclusion precautions until after symptoms have resolved) and contact tracing can begin to identify others that may have been exposed to the ill person. Contact tracing will help identify others who may be infected and should go into quarantine (seclusion and monitoring for the development of symptoms). The goal of the current major diagnostic test strategy with PCR testing is to identify the infected, with or without symptoms, so that you can break that transmission chain.
- The RT-PCR test cannot detect if a person had an infection with the virus in the past but if there is an active infection at the present. A swab taken from the back of the nose (nasal) or throat (pharynx) are the most common sites to get samples to test for the virus.

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COVID Antibody "RAPID" test

- The COVID antibody test checks to see if there are the antibodies to the COVID-19 virus in the blood. The body makes antibodies to help fight an infection. Antibodies are easily measured a week or two after an infection. The antibodies help to clear the virus from the body and prevent a new infection with the same virus.
- The test tells us who's been infected and who should be immune to the virus because they have already had an infection, even if the symptoms were very mild. It is not currently being used for detection of an active infection because it takes some time for the body to make the antibodies. Antibody tests can detect exposure to the virus even after the patient has recovered.
- There are two antibody types measured with the rapid test. The detection of immunoglobulin M (IgM) antibodies indicate a recent exposure to COVID-19, while the presence of immunoglobulin G (IgG) antibodies indicates the person had the virus and may now be building immunity and may be protected from the virus.

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WHO
COVID Antibody immunity position

- WHO has published guidance on adjusting public health and social measures for the next phase of the COVID-19 response.1 Some governments have suggested that the detection of antibodies to the SARS-CoV-2, the virus that causes COVID-19, could serve as the basis for an "immunity passport" or "risk-free certificate" that would enable individuals to travel or to return to work assuming that they are protected against re-infection. There is currently no evidence that people who have recovered from COVID-19 and have antibodies are protected from a second infection.
- At this point in the pandemic, there is not enough evidence about the effectiveness of antibody-mediated immunity to guarantee the accuracy of an "immunity passport" or "risk-free certificate." People who assume that they are immune to a second infection because they have received a positive test result may ignore public health advice. The use of such certificates may therefore increase the risks of continued transmission. As new evidence becomes available, WHO will update this scientific brief. (April 24, 2020)

https://www.who.int/news-room/commentaries/detail/immunity-passports-in-the-context-of-covid-19

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PCR Test Considerations:

- RT-PCR tests only detect the virus while the person is currently infected.
- If the sample is not taken properly, it may yield false negative results. Therefore, if your swab test comes back negative, you cannot rule out the chance of having COVID-19.
- RT-PCR tests can take up to several days to process
- RT-PCR relies on capturing and detecting the virus and so it is possible to miss patients who have cleared virus and recovered from disease.
- The distribution of virus across the respiratory tract varies between patients, so even if a person is infected, the virus may only be detectable in sputum or nasopharyngeal swab but not necessarily at both locations at the same time.
- The CDC recommends use of nasopharyngeal (NP) swabs for molecular testing because in most patients, the nasopharynx, or the space above the soft palate at the back of the nose, appears to have the highest concentration of virus.
- NP swab samples are technically challenging to obtain, and a suboptimal collection may reduce test sensitivity and increase the likelihood of obtaining a false-negative result in a patient with the virus.
- The timing of sample collection is also important because the amount of virus present in the nasopharynx varies over the course of infection. Ideally, samples should be collected near the time of symptom onset to achieve the highest test sensitivity. Patients who are infected but not yet symptomatic may have false-negative test results, as may those whose symptoms are waning.

Rapid COVID Antibody Test Considerations:

- SARS-CoV-2 hasn't been around long enough for investigators to know whether detectable antibodies may decline or even disappear over time. We do know that immunity to other coronaviruses responsible for colds can wane after ONE year, whereas immunity to the more closely related SARS-CoV-1 lasts closer to three years.
- It is not yet known that just because someone has developed antibodies, that they are fully protected from reinfection, or how long any immunity lasts.
- In the early days of an infection when the body's immune response is still building, antibodies may not be detected, which is why serological antibody tests should not be used as the sole basis to diagnose or exclude active infection with the SARS-CoV-2 virus.
- According to data compiled by *EvaluateMedTech*, 29 commercial assays designed to detect antibodies to the novel coronavirus are on sale in the US, only three of which have been granted the FDA's backing in the form of an emergency use authorisation. But none of these tests, even those with EUAs, have had their accuracy evaluated by the FDA or any other regulatory body.

Differences	Swab test (PCR)	Blood test (antibody)
Biggest difference	Can detect early and onset infection with most accuracy	Quicker to get results, not as sensitive as PCR test for early infection
How does it work?	Directly detects the presence of the virus' genetic material (RNA)	Indirectly detects the virus by measuring our body immune response (IgM, IgG) to the virus
Sample needed	Nasopharyngeal (nose/throat) swab, could be uncomfortable	2-3 drops of blood using finger prick
Time to get result	Typically a few days or week (if sent to a lab), or less than an hour (rapid test)	In an hour or less (rapid test)
When should you get it?	You can get this test if you have symptoms of COVID-19	You can get this test if you had COVID-19 and recovered