[5] Serology and virus testing: the basics, and the latest results

Conceptually, there are three main approaches a region could take after the first COVID-19 wave subsides (and in each case, restrictions on international travel may be required to prevent importation of new cases):

- **Keep flattening the curve and gradually let people go back to work as infection levels drop.** The problem with this approach: it only takes a small number of infectious people wandering around to ignite a second infection wave without a healthcare system that can track down and isolate new clusters\(^1\). It is still unclear if seasonal changes (sunlight/heat/humidity) will materially change the virus dynamics, and even if they did, a new wave could appear in the fall.

- **Relax lockdowns, and use a swat-team approach to identify any new clusters.** Immediately isolate and quarantine new clusters as well as their contacts via contact tracing\(^2\). Life gets back to normal faster, but this approach works best when combined with an **extremely well organized healthcare system**, a compliant population that obeys social distancing rules, a legal system that allows the government to use a wide variety of tracking approaches (credit card receipts, cell phones, close circuit television, GPS, etc) to monitor the population and enforce rules; and **when the run rate of new daily infections is low enough to handle the influx of new cases**. I consider this scenario to be the most likely in many countries.

- **Through serological testing, identify people who have been exposed to the disease, possess the antibodies to prevent them from infecting others or getting sick again, and let them get back to work.** Biggest challenge: requires higher immunity levels for maximum impact.

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\(^1\) Best illustrated via a [visualization](http://www.youtube.com/watch?v=3Blue1Brown) from Grant Sanderson at 3 Blue 1 Brown

\(^2\) This approach can be thought of as a real-life version of “**Code 2319**” in the movie *Monsters Inc*, when a swat team descends on anyone infected by a human article of clothing, and then quarantines and decontaminates them.
Serology testing for COVID-19 antibodies

Antibody testing could determine who has been exposed to the virus so they could go back to work once they recover. Once people have had COVID-19, they usually develop antibodies that virologists believe will prevent them from getting sick again. While other human coronaviruses that cause seasonal colds do not typically result in long-lasting immunity, SARS and MERS antibodies persisted for at least 2-3 years.

How might an antibody-based “return to work” process occur? First, a period of days is needed for people to recover from the virus. As shown on the left, by day 10, viral culture studies from Germany show that most people are no longer infectious. The viral decline is the result of the body’s immune response, part of which involves the appearance of virus antibodies in many patients which can be measured as well. A March study from Shenzhen provides one assessment. Using serology tests, they measured the presence of general virus antibodies (Ab), early stage immune response antibodies (Immunoglobulin M) and antibodies for long-lived immunity (Immunoglobulin G). Some patients’ antibodies appeared during the first week; more showed up in the second week; and after 15 days, 80%-100% of patient samples contained one or more classes of antibodies. Overall, they found strong empirical support for routine application of serological testing in the diagnosis and management of COVID-19 patients.

Sources

“Antibody responses to SARS-CoV-2 in patients of novel coronavirus disease 2019”, Zhao et al, Institute of Hepatology, National Clinical Research Center for Infectious Disease, Shenzhen Third People’s Hospital, Shenzhen

“Neutralizing antibody responses to SARS-CoV-2 in a COVID-19 recovered patient cohort and their implications”, Fan Wu et al, Shanghai Public Health Clinical Center, Fudan University, March 30, 2020
On the prior page, we show viral culture results as an “infected/infectiousness” measure since PCR tests often involve substantial numbers of false negatives. Based on information gathered from 7 different studies with a total of 1,330 samples, PCR tests may only identify 30% of infected people on Day 4. "Sensitivity" (the probability of infection actually being detected in an infected person) peaks at 80% on Day 8 and falls back to 30% by Day 21 as they clear the virus. In other words, even at peak effectiveness, the PCR test only found 80% of infected people⁴ (see chart below).

This error level is probably the reason for news stories of people being “reinfected”. As per my contacts, a handful of people testing positive again a few weeks after disease onset most likely represents either a prolonged tail to the infection with false negative testing somewhere along the way, or prolonged shedding of virus with false negative testing as well. So far there are less than 100 reports of reinfection, which should be expected based on test sensitivity errors alone.

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³ “Variation in False Negative Rate of RT-PCR Based SARS-CoV-2 Tests by Time Since Exposure”, Lauren Kucirka et al, Johns Hopkins School of Medicine, April 2020.
One issue that policymakers will have to consider: COVID-19 virus antibodies may not be as prevalent in all recovered patients. A recent paper from Fudan University reported that as many as one third of recovered patients in a 175-person cohort did not possess high levels of COVID-19 antibodies normally associated with disease recovery. They concluded that the low-antibody patients might have recovered since their T-cells, cytokines or other parts of their immune systems defeated the virus instead. Whether low-antibody patients are still susceptible to the disease remains to be determined.

There are also concerns that different serology manufacturers’ kits may differ on “specificity” (false antibody positive) and “sensitivity” (false anti-body negative), in which case antibody presence could be misestimated4. A recent study from UCSF and UC Berkeley analyzed 12 different serology tests, and provides some insight into these questions. The authors found “good to excellent sensitivity for all evaluated tests in hospitalized patients three or more weeks into their disease course”, and that their data “demonstrate specificity > 95% for the majority of tests evaluated, and > 99% for three of them”5.

The bigger issue when thinking about serology testing as a “back to work” mechanism: you need higher levels of infection first. To mitigate the burden on healthcare systems, many countries have used lockdown and other measures to “flatten the infection curve”. While this mitigates the healthcare burden, it also delays the onset higher immunity levels.

What are the latest serology test results in actual populations?

In recent weeks, research institutions and hospital systems have released results of random serological tests for COVID-19 antibodies. As shown below, these results indicate much higher levels of COVID-19 exposure than are implied by reported case to population ratios, which are often at least one order of magnitude smaller. In simpler terms, serology results show that there’s a large number of unreported infections due to people who couldn’t get a test, only had mild symptoms, were asymptomatic, etc. And since antibodies show up with a lag, a more accurate tally of current and prior infections may be even higher than serology results currently indicate. Note that many of these studies report very wide confidence bands around their results; mean levels shown below could be substantially different from actual infection levels in broader populations. Some of the study sizes are also very small. Anyway, warts and all, here are some serology test results.

<table>
<thead>
<tr>
<th>Country</th>
<th>Time from outbreak to day of serology test</th>
<th>Reported case to population ratio</th>
<th>Est. population with antibodies</th>
<th>Reported case fatality rate</th>
<th>Case fatality rate based on serology estimate</th>
<th>Study size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scotland</td>
<td>21</td>
<td>0.1%</td>
<td>1.2%</td>
<td>0.4%</td>
<td>0.04%</td>
<td>1,000</td>
</tr>
<tr>
<td>Denmark</td>
<td>35</td>
<td>0.1%</td>
<td>2.7%</td>
<td>2.2%</td>
<td>0.1%</td>
<td>1,000</td>
</tr>
<tr>
<td>Netherlands</td>
<td>49</td>
<td>1.6%</td>
<td>3.0%</td>
<td>1.5%</td>
<td>0.8%</td>
<td>7,000</td>
</tr>
<tr>
<td>NY State</td>
<td>52</td>
<td>1.4%</td>
<td>13.9%</td>
<td>7.4%</td>
<td>0.7%</td>
<td>3,000</td>
</tr>
<tr>
<td>Geneva, Swi</td>
<td>52</td>
<td>0.5%</td>
<td>5.5%</td>
<td>8.8%</td>
<td>0.8%</td>
<td>760</td>
</tr>
<tr>
<td>Santa Clara</td>
<td>64</td>
<td>0.1%</td>
<td>3.3%</td>
<td>3.4%</td>
<td>0.1%</td>
<td>3,330</td>
</tr>
<tr>
<td>Gangelt, Ger</td>
<td>73</td>
<td>2.4%</td>
<td>14.0%</td>
<td>2.3%</td>
<td>0.4%</td>
<td>500</td>
</tr>
<tr>
<td>Chelsea, MA</td>
<td>74</td>
<td>1.8%</td>
<td>32.0%</td>
<td>5.5%</td>
<td>0.3%</td>
<td>200</td>
</tr>
<tr>
<td>Los Angeles</td>
<td>76</td>
<td>0.1%</td>
<td>4.2%</td>
<td>2.9%</td>
<td>0.1%</td>
<td>863</td>
</tr>
</tbody>
</table>

Source: JPMAM, JHU. 2020. See page 7 for serology data sources.

4 On serology tests: please do not send me emails stating that you believe that false positives outnumber actual positives unless (a) you have made an estimate of disease prevalence and can explain how that affects your results; (b) you estimate the number of actual (correct) negatives relative to false positives and are prepared to discuss the public policy implications of this comparison; and (c) you cite false positive and false negative accuracy of PCR virus testing kits, since that’s the most likely alternative/complement to serology-based reopening strategies.

Now let’s get to the next question: how do immunity levels evolve over time?

Antibody presence of less than 15% might seem small, and *would* be if viruses evolved linearly. But viruses only attack susceptible hosts, and as they progress, susceptible populations shrink. An epidemiologist contact of mine was pleased to see the results so far, and suggested we look at them (imperfect as they are) through the lens of an “SIR” virus model⁶ to see why, using serology results as a proxy for “true” infection. Actual results of course differ from the theoretical model, particularly with large regional differences in spread prevention policies. **Even so, the general principle that susceptible populations at some point enter an accelerated pace of decline appears to be happening; we will know more in a few weeks.** We will update the chart below as new serological observations emerge.

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### How does regional immunity to infectious disease evolve over time? percent of population

Source: JPMAM, JHU. 2020. See page 7 for serology data sources.

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To be clear, there are a lot of uncertainties here: models are highly sensitive to input parameters (particularly the timing of outbreak and serology test results); serology tests for COVID-19 may involve false positives (unclear how large an issue this might be), as well as people who test positive with “insufficient” antibodies; sample populations might not be representative of the whole; and they may not be applicable across countries. **Furthermore, even if larger levels of immunity were reached⁷, the virus would still spread, but at a slower rate involving smaller clusters that are dealt with independently.**

Even with all these caveats, these models are helpful in illustrating the evolution of a virus and its antibody aftermath, and **provide a rationale for serological testing as part of a “back to work” plan in the summer or fall (assuming that a society can organize itself to do it).** The current batch of serology tests are not plentiful or accurate enough now; nor do scientists know the degree of antibodies needed to provide long-lasting immunity. All of these issues will need to improve in the months ahead.

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⁶ “SIR” models are used to track the distribution of a population exposed to a virus over time into three categories: “susceptible”, “infected” and “removed” (recovered or deceased). The susceptible population declines rapidly once the pool of potential hosts migrates into the removed category. However, the susceptible population does not decline to zero since immune individuals act as “fire-breaks” who buffer susceptible individuals from infection.

⁷ I have been very careful not to use the phrase “herd immunity” in this section. At this point, no one knows what that might entail for COVID-19, since herd immunity estimates require a very good understanding of the basic reproductive number (R₀) of the virus. Many publications assume a COVID-19 R₀ of 2.5, in which case herd immunity would require around 60% exposure. But if R₀ were 3.0 or 3.5 instead, exposure might have to reach 75%-80% for herd immunity to be attained.
Serology tests: who’s using them, who’s making them and what the CDC has to say about it

The CDC and private companies are scrambling to produce serology tests; Germany may use them to issue immunity certificates to survivors, and China and Singapore are using them to measure more accurate infection rates. On top of that, the US FDA is allowing doctors to use serology tests to identify recovered patients whose antibodies could treat emergency cases. There are over 50 companies that have informed the FDA of their intention to sell serology test kits in the US. Roche intends to ramp up production to the “high double digit” millions by June, which can be processed using their device with 300 results per hour. However, all kits are self-validated, and the FDA requires that the following disclosures be included:

- The tests have not been reviewed by the FDA
- Negative results do not rule out SARS-CoV-2 infection. Follow-up testing with a molecular diagnostic should be considered to rule out infection
- Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status
- Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains

These are strongly worded caveats, which some countries already appear prepared to disregard, or at least acknowledge as “acceptable” risk as the world focuses on getting back to work.

What about the risk of a second wave?

If lockdowns are relaxed quickly, a second wave is considered likely by many virologists. However, if instead at some point over the summer there are very few or no new cases reported in a given region, does that mean that COVID-19 has been eradicated? Not necessarily:

- It takes time to figure out if a virus is eradicated. The last smallpox case occurred in 1977, and the disease was not deemed to be eradicated until 1979
- COVID-19 (unlike SARS) can be transmitted by pre-symptomatic individuals, so the possibility exists that it could simmer undetected and re-emerge when conditions are more conducive to it spreading. This could produce periodic “flare-ups” of COVID-19 for several months even after the major waves now occurring subside. If that’s the case, COVID-19 could persist in humans until there’s a vaccine
- Even if COVID-19 disappeared from humans, it will not have disappeared from the animals from whom it “jumped” in the first place, so there’s always a possibility it could “jump” again. Not only that, but there’s always the risk of other zoonotic viruses appearing unless the world gets more serious about human-animal interfaces and the tools needed to accelerate vaccine development.
Serology sources

“Preliminary results and conclusions of the COVID-19 case cluster study”, Bonn University Hospital, March 2020

“Blood banks will test whether donors have had coronavirus”, SN.DK, April 4, 2020


“New York antibody study estimates 13.9% of residents have had the coronavirus, Gov. Cuomo says”, CNBC, April 23, 2020.


“Dutch study suggests 3% of population may have coronavirus antibodies”, Reuters, April 16, 2020.

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