TONY BLAIR INSTITUTE FOR GLOBAL CHANGE

The Path to Mass Testing

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This paper brings up to date the latest position on Covid-19 testing in the UK.

It sets out the different ways to test and the availability of the different types of tests.

The paper includes a model for mass testing that can evolve as testing capacity increases but importantly offers an operation that can be rolled out now. The authors believe mass testing, combined with other measures discussed in the Institute's latest paper on exit strategies will enable us to exit the lockdown while keeping the level of infections under control.

A Message to Government

This paper is intended to follow our previous contributions to the testing and exit strategy debate in the UK.

Everyone we have interacted with, including those in government and Public Health England, have shown great willingness to improve the UK's testing infrastructure.

They are all working extremely hard throughout a crisis unprecedented in scale and in scope. This paper is intended to stretch thinking and serve as a critical friend.

In particular, it points to a number of key points that government can address and take on board, all of which should be overseen by a new Minister for Testing[1]. Reporting directly into the prime minister in a structure that sits outside of Public Health England (PHE) and convening the best of health, industry, technology and science, this minister would absorb the following into her/his brief:

1. **Scale antigen testing using** *every* **means possible.** This includes taking up every offer of lab space[2], replacing proprietary reagents with white-label reagents where necessary and harnessing an ecosystem of antigen testing suppliers – including rapid antigen tests.

3. **Recognise the importance of an antibody test.** Administered often and at the right point in the disease cycle, this will be accurate and is a good tool in any event for understanding the spread of a disease. These tests can be used at home and millions can be frequently produced and distributed.

4. **Don't let perfection be the enemy of good enough.** Modelling by Nobel prize-winning economist Paul Romer, detailed in this paper, shows that mass testing, based on tests less accurate than 98 per cent, can still be effective in a strategy of mass testing to end lockdown.

5. **Partner British companies in the antibody and rapid antigen space with production lines.** There are many promising tests out there which will only improve in accuracy – indeed, many already meet the criteria of a lower-accuracy test that, according to the excellent work of Romer[3], would still be of benefit. It's important that production is considered now, as tests will need to be produced and distributed at scale.

7. **Ambitiously recognise mass testing at scale involves a large proportion of population.** The UK has struggled to ramp up its testing capacity but this should not drive its objectives: We need testing in the hundreds of

thousands and, eventually, the millions. This is realistic, especially when the specification of tests are lowered and accounted for – as demonstrated by Romer's modelling.

8. **Administer both antibody and antigen tests.** Separately, both tests have value. Together, they are invaluable. Mass testing should incorporate both, ideally at the same time for each patient. It's important to note that the lack of availability for one type of test shouldn't prevent the administering of another.

9. **Contact trace online and offline.** Digital contact-tracing efforts are going to be essential, and with the platform Apple and Google recently provided, the NHS app must be privacy-preserving. However, digital efforts are complementary and not a substitute for human expertise, and resources are therefore necessary to make these a key component to loosening restrictions.

10. **Begin preparations for community testing now.** The ability to test at scale is not just about the availability of tests. To put the infrastructure in place for mass testing, mobilisation needs to begin now.

11. **Draw up immunity-certificate framework.** Antibody tests can demonstrate immunity and the government should ready a framework to introduce immunity certificates. These may be time-limited and, for ethical considerations, may not be used to prioritise re-entry into the job market. However, they would be very important to easing the burden on testing capacity and, as part of a globally coordinated effort, may be part of the solution to lifting international travel restrictions.

12. **Develop a clear exit strategy with mass testing at its heart.** This should combine phased mass testing with other initiatives that will: 1. reduce reinfection rate, 2. ensure there's always enough NHS capacity, and 3. manage burden on testing capacity. These initiatives include contact tracing, phased release of young people from lockdown and other measures referenced in our section on the "STIR" mass-testing strategy later in the paper.

1 https://institute.global/tony-blair/covid-19-testing-uk-unpicking-lockdown>

2 Ref to Sir Paul Nurse and Radio 4 Today's interview with Genomix

3 https://paulromer.net/covid-sim-part3/

What We Now Know About Covid-19

This section focuses on what we currently know about how infectious Covid-19 is, the fatality rate and the effect of Covid-19 and the lockdown on the delivery of other non-Covid health care. Building this understanding is vital in both identifying the right exit strategy from lockdown and establishing the right mass-testing regime.

Infectivity

A good starting point for understanding the infectiousness of Covid-19 is to look at the basic reproduction number or R0. This is an estimate of the average number of people an infected person will spread the virus to without intervention in a population where no one has immunity. Over time, as more people become infected and interventions occur to reduce the spread, the effective reproduction number, Rt, represents the actual infection rates. The purpose of suppression activities is to lower Rt to less than 1, which will cause the number of new cases to fall.

The R0 for Covid-19 has been estimated to be between 2 and 3.[4] However, the large number of asymptomatic undetected cases makes this estimate quite uncertain, and one recent paper estimated the R0 to be 5.7.[5] The R0 estimate matters, because it makes it possible to estimate what proportion of the population needs to be immune to achieve herd immunity. For example, if the R0 is 2.5, then herd immunity is achieved at 60 per cent, but if the R0 is 5, then herd immunity requires 80 per cent.[6]

All this underlies the need for comprehensive testing. This would allow a better understanding of how infectious the disease is, and how close we are to herd immunity.

Lethality

The lethality rate of Covid-19 is ideally recorded through the infection fatality rate – the proportion of deaths among infected individuals.

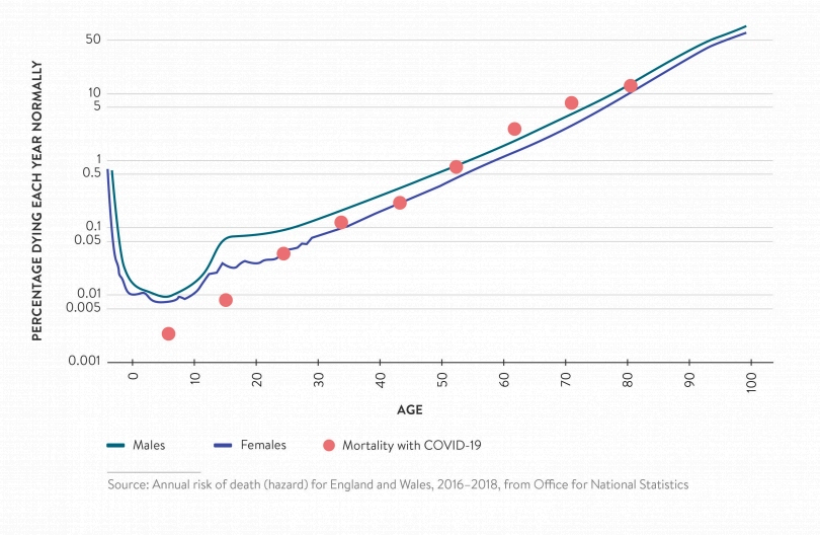
4 https://www.imperial.ac.uk/mrc-global-infectious-disease-analysis/covid-19/report-3-transmissibility-of-covid-19/

A simple estimate based on current numbers of confirmed cases and deaths would suggest a fatality rate of 6.5 per cent, however, this is not likely to be the infection fatality rate for three reasons. First, the number of confirmed cases is likely to be much smaller than the true number of cases, since those who become ill but are asymptomatic or have mild symptoms are often never tested. Second, deaths that occur outside of hospitals may be missed. And third, there is a lag of a few weeks between infection and death, so deaths from the newest cases have not yet been incorporated into the figures.

While the first of these factors would imply a lower death rate, and the latter two factors a higher one, the general consensus is that the number of missed cases is the biggest factor here, so the 6.5 per cent estimate is too high. Current estimates place the infection fatality rate at between 0.1 and 3 percent.[7]

It is useful to put the mortality estimates in context. We know that the infection mortality rate increases with age. Professor David Spiegelhalter found that by looking at infection mortality estimates from Imperial College[8], the risk of dying after being infected with Covid-19 is approximately the same as the risk of death from all causes (see the graph below).

Infection mortality rate of Covid-19 and annual mortality



Source: Winton Centre https://medium.com/wintoncentre/how-much-normal-risk-does-covid-represent-4539118e1196

5 https://wwwnc.cdc.gov/eid/article/26/7/20-0282_article

6 In general, the percentage of the population that needs to be immune to achieve herd immunity is 1-1/r_0

One way to interpret this graph is that a random person infected with Covid-19 undergoes the same risk of death in the next few weeks as they would have done in the whole year if they had not been infected.

This chart does not, however, reveal the effect of underlying health conditions on mortality risk. It is well understood that individuals with serious underlying health conditions (e.g. diabetes, cancer) are at much greater risk of death from Covid-19. While there are many cases of young healthy adults becoming very sick,[9] the most cost-effective mechanism to reduce deaths will be to reduce exposure by the elderly and the unwell to the virus.

Effects on the Delivery of Other Health Care

The spread of coronavirus has created obvious strain on health-care resources, which will likely contribute to excess deaths. In the week to 3 April, there were more than 16,000 deaths in England and Wales, while in a typical year there would only be around 10,000.[10] Around 2,500 of the 6,000 excess deaths were not due to Covid-19, suggesting the pandemic may already be indirectly causing deaths.

The government has focused on increasing the supply of labour and resources (e.g. bringing medical staff out of retirement and setting up emergency Covid-19 hospitals) and decreasing demand for non-urgent care (e.g. by cancelling elective procedures). The NHS has been helped by an almost 50 per cent reduction in A&E admissions, which is likely due to a mixture of individuals deliberately avoiding hospitals, and a possible reduction in accidents.[11]

Despite the increase in labour supply and possible reduction in accidents, the scale of the pandemic will inevitably mean that health-care resources are stretched more thinly between individuals. As a starting point, the NHS has very limited slack to accommodate these changes: The UK has historically low numbers of ICU beds compared to similar countries, and fewer doctors per person (2.8 per 1,000) than the average EU15 country (3.9 per thousand).[12]

While data on the current crisis is limited and descriptive, prior research suggests that reduction in health-care capacity leads to increases in deaths.

7 https://www.newscientist.com/article/2239497-why-we-still-dont-know-what-the-death-rate-is-for-covid-19/

8 https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(20)30243-7/fulltext

A 2012 research paper found that reduction in nursing staff due to a strike led to in-hospital mortality increasing by almost 20 per cent.[13] Beyond the effects of cancelled procedures and lower-quality care, many individuals are likely to be avoiding the hospital altogether, possibly even in emergencies, further contributing to excess deaths.

Parents may also be less likely to vaccinate their children, which would create large risks from other infectious diseases such as measles. Measles is incredibly infectious; it has an R0 of 12-18, meaning that herd immunity requires a vaccination rate of 90-95 per cent.[14] Even small reductions in vaccination rates therefore can make the disease viable again.

The pandemic has also highlighted the serious risk of infection and death faced by medical staff who cannot self-isolate. This may reduce the attractiveness of working in medicine, which could lead to staff shortages or a need to increase compensation.

9 https://www.vox.com/science-and-health/2020/4/8/21207269/covid-19-coronavirus-risk-factors

10 https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/deaths/bulletins/deathsregisteredweeklyinenglandandwalesprovisional/weekending3april2020

11 https://www.ifs.org.uk/publications/14798

12 https://www.ifs.org.uk/publications/14798

13 https://pubs.aeaweb.org/doi/pdfplus/10.1257/pol.4.1.127

14 https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(17)30307-9/fulltext

A Tale of Two Tests

Discussion on testing has permeated the public consciousness. This is good news. As we have argued since March, testing is key to exiting lockdown and mitigating the health and economic harms of Covid-19. The widespread discussion of testing has given rise to confusion around terminology and what testing is available, in what format and the roles different tests would play in any mass-testing regime.

Further, the unprecedented innovation in the biotechnology sector at home and abroad – a very welcome development – has see new developments, particularly in the field of rapid testing. It's important to note that both the antigen and antibody tests have the potential to be delivered at speed, but currently this only really applies to the antibody test.

To avoid confusion, this paper will use the following terms:

	Antigen Test	**Antibody Test**
Scientific description	Reverse Transcription Quantitative Polymerase Chain Reaction (RT-qPCR)	Serological immunoassays that detect viral-specific antibodies (IgM and IgG) or antigens
Utility in exit strategy	Tests if a patient has the virus and is contagious; used to determine who self-isolates and for contact tracing	Tests if a patient has had the virus and is therefore considered immune; used to issue immunity certificates and for contact tracing
Operation	A sample is collected – usually with a deep nasal swab – and analysed in a laboratory	A blood or saliva sample is applied to a strip that identifies presence of antibodies
Accuracy	70%+ sensitivity and specificity rates	80%+ sensitivity and specificity rates
Rapid testing?	In development Some rapid-testing devices have been given emergency FDA approval	Yes
Current UK capacity	25k + per day	None are currently approved by PHE

	Antigen Test	Antibody Test
Potential UK capacity	100k+ per day	Millions per day
Other names	PCR test Molecular test	Serology test Immunity test

The State of Testing

As of 9am on 20 April, the UK had conducted 501,379 tests for Covid-19, with 19,316 tests carried out on 19 April.

Of the 386,044 people tested, 124,743 were positive.[15]

Government Strategy

The government's strategy on testing is set out in a paper published by the Department of Health on 4 April.[16]

This strategy aims for the UK to be conducting 100,000 Covid-19 tests per day.

To achieve this, the government has set out five pillars of work:

1. Boosting PCR swab testing. This testing would be conducted by PHE and NHS labs for patients and frontline NHS workers. The government target for this pillar is to reach 25,000 tests per day by mid- to late-April.
2. Creation of new swab testing capacity delivered by commercial partners. This pillar sees partnership with universities, research labs and private companies as a route to building a network of new labs and testing sites.
3. The government is working with several companies to bring online antibody tests.
4. The government is conducting a large-scale survey to work out what proportion of the population has had the virus. They are doing this using antibody tests operated by PHE at the Porton Down science campus.
5. Building a large Germany-style diagnostic industry in the UK.

As we have set out previously, we fully support the government's strategy, particularly as a stepping stone to moving to mass testing.

Concerns have been raised, however, in recent weeks on both the capacity of scaling the PCR tests to the level required and whether antibody testing can be brought online in time.

15 https://www.gov.uk/guidance/coronavirus-covid-19-information-for-the-public

16 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/878121/coronavirus-covid-19-testing-strategy.pdf

The Antibody Test, Explained

As we have set out previously, the antibody test is used to establish whether someone has had and is therefore immune (at least in the short term – see below) to the virus.

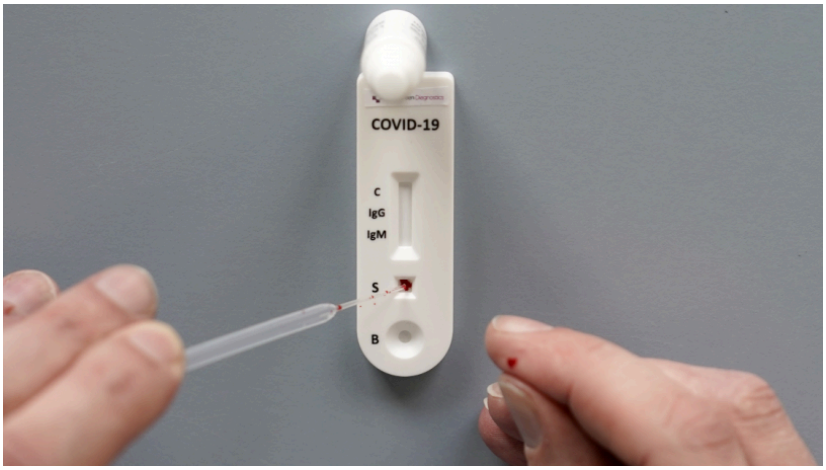
How Do Antibody Tests Work?

A typical antibody test would involve taking a small sample of a patient's blood – for instance via a pin prick. The test looks for two types of antibody: IgG and IgM.

- IgM (Immunoglobin M) are the first antibodies to be produced by the immune system. They have a half-life of around five days. IgM antibodies usually appear within five to seven days of infection and peak at around 21 days. Detection of these antibodies suggests the person has existent or a recent infection.
- IgG (Immunoglobin G) antibodies are more numerous and can be detected around 10 to 14 days after infection. The presence of these antibodies indicates a person has recovered from the virus and is now immune.

The results using this test (example in image below) would indicate:

- A positive for IgM would show someone has the virus or has recently had the virus.
- IgM and IgG positives would indicate someone is within the first month of infection and immune.
- Just IgG would indicate someone is immune and the infection occurred some weeks ago.

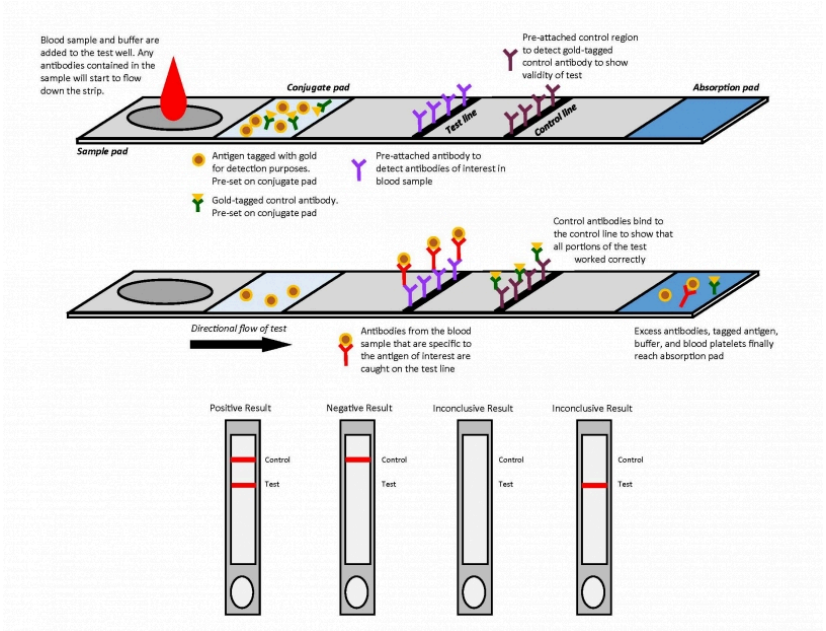


Types of Test

Rapid diagnostic test (RDT):

This is a simple positive/negative lateral flow assay test, like a pregnancy test kit, that can be done at home or at point of care. Typically, these tests have used a finger prick to produce a small blood sample but could also utilise saliva samples or nasal swabs.

These tests would take between 10 and 30 minutes.

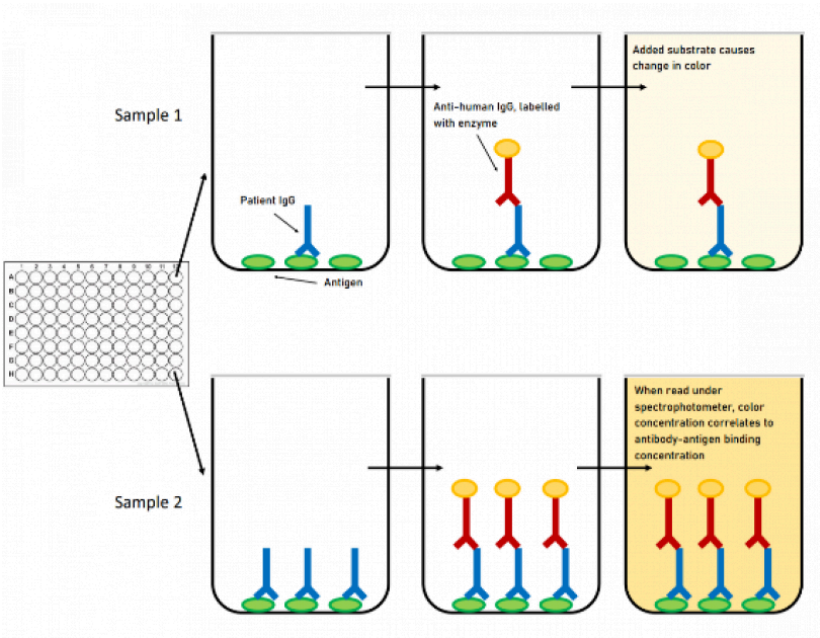


Source: Center for Health Security
http://www.centerforhealthsecurity.org/resources/COVID-19/serology/RDT-figure.pdf

Enzyme-linked immunosorbent assay (ELISA):

This is generally a lab-based test. It tests whole blood, plasma or serum samples. This method uses a plate that is coated with viral protein. Patient samples are then incubated with the protein and if the patients has antibodies to that protein, they bind together. The bound complex can be detected using another wash of antibodies that produces a colour readout.

Time to results is around one to five hours.



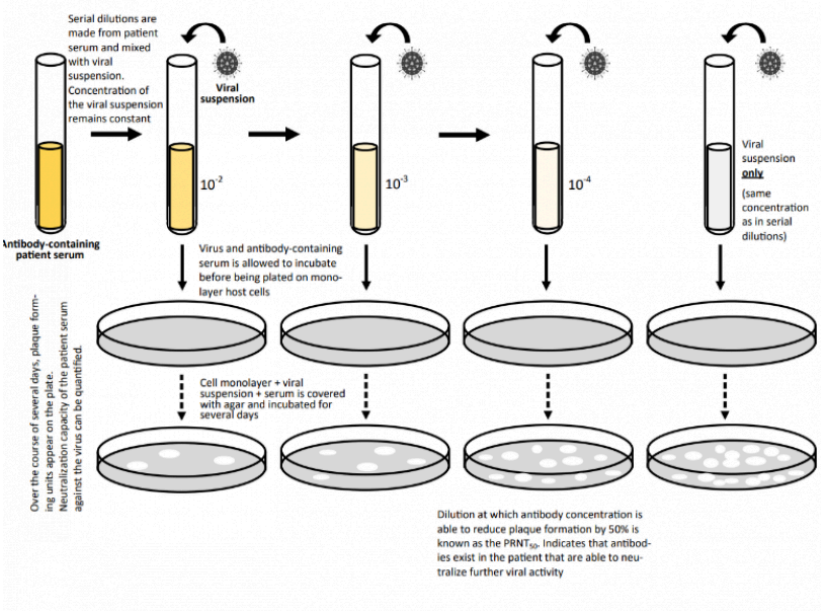
Source: Center for Health Security
http://www.centerforhealthsecurity.org/resources/COVID-19/serology/RDT-figure.pdf

Neutralisation assay:

The neutralisation assay test uses patient antibodies to prevent the viral infection of cells and is conducted within a lab setting. The test utilises whole blood, serum or plasma from a patient. It shows if a person has active antibodies that are effective against the virus. The test relies on cell culture to allow Covid-19 growth. When the virus and cells are grown in decreasing

concentrations of patient antibodies, it can show how many antibodies are in the patient serum that are capable of blocking virus replication.

The time to a result is between three and five days.



Source: Center for Health Security
http://www.centerforhealthsecurity.org/resources/COVID-19/serology/RDT-figure.pdf

Recovery = Immunity?

Insight into potential long-term immunity comes from studies of the nearest relative coronaviruses, SARS and MERS. Considering the data from these two different viruses was cited as unlocking the "best guess" on Covid-19 immunity by Danny Altmann, Professor of Immunology at Imperial College London in a recent British Society for Immunology Webinar[17].

Altmann shared a long-term longitudinal study[18] of those infected by MERS in South Korea which shows a significant degree of immunity post-infection, lasting for up to a year albeit with some waning. They were tested with a plaque reduction neutralisation test (PRNT), considered to be the "gold standard" for detecting and measuring antibodies.

Interestingly, the study also showed a small number of people with relatively undetectable amounts of antibodies. In this instance, T-cells also provided a reliable guide to immunity and those with lower antibodies in the study had comparable T-cell counts compared to those with high antibody counts.

Elsewhere, a UCL research team looked at the historical patterns of three common coronaviruses[19]. Their results provide some evidence of immunity against reinfection by the same virus, as they did not identify any people who were reinjected by the same virus. Based on their simulations, if people had no immunity after being infected, the probability of zero reinfections by the same virus in their study sample was only 3.48 per cent, which they say suggests some immunity is likely.

'Reinfection' in South Korea

South Korea's Centre for Disease Control and Prevention recently reported that 91 patients who had been infected with Covid-19 and then later tested negative had now tested positive again[20]. If these were genuine reinfections, they would cast doubt on the strength of the immunity the patients had developed. It's possible that testing flaws may be to blame for this, and many scientists[21] believe it likely that these patients had a false negative test. Given that Covid-19 closely resembles the coronaviruses that cause SARS and, to a lesser extent, MERS, and the fact there are no reports of reinfections with the SARS virus, we are confident for the purposes of this paper that immunity will be conferred.

It can be reasonably inferred that exposure to and recovery from Covid-19 will provide some level of immunity. For the purposes of this paper, we have assumed that such immunity exists and it can be identified through the presence of antibodies.

There are questions around how long such immunity lasts and whether it is conferred in every case of Covid-19. For the purposes of this paper, we have made a confident assumption that there will be a level of immunity. Once more is understood about the virus, changes can be made to a mass-testing and tracing model, for example:

- An expiry date on immunity certificates that matches the length of an immunity period following the contraction of Covid-19
- Consecutive antibody tests before an immunity certificate is issued
- Exploring development and use of T-cell tests
- Ongoing but less-frequent antigen testing to ensure that reinfection has not occurred
- Continuation of self-isolation if a person exhibits the symptoms of Covid-19

We watch with interest the work of the British Society for Immunology, whose expert group are currently collating what is known about the immunology of Covid-19 and developing immunology research priorities in response to the coronavirus outbreak[22]. The group will publish their outputs within approximately three weeks (May 2020), with the intention of urgently mobilising and coordinating the UK's immunology research response to coronavirus (Covid-19).

17 BSI webinar: Emerging lessons about immunity to COVID-19, 8th April, https://www.immunology.org/coronavirus/connect-coronavirus-webinars/bsi-webinar-emerging-lessons-about-immunity-covid-19

18 PG Choe et al., 2017, EID23, 1079

19 Aldridge RW, Lewer D, Beale S et al. Seasonality and immunity to laboratory-confirmed seasonal coronaviruses (HCoV-NL63, HCoV-OC43, and HCoV-229E): results from the Flu Watch cohort study [version 1; peer review: awaiting peer review]. Wellcome Open Res 2020, 5:52 (https://doi.org/10.12688/wellcomeopenres.15812.1)

20 https://uk.reuters.com/article/us-health-coronavirus-southkorea/south-korea-reports-recovered-coronavirus-patients-testing-positive-again-idUKKCN21S15X

21 https://www.nytimes.com/2020/02/29/health/coronavirus-reinfection.html?searchResultPosition=3

22 https://www.immunology.org/coronavirus/immunology-and-covid-19

Antibody Testing in the UK – The Unpassable Test?

On 24 March the government indicated it had purchased 3.5 million antibody tests, saying they would be available "very soon".

On 30 March there were indications it had made an agreement in principle to purchase 17.5 million antibody tests.

On 4 April Professor John Newton, National Testing Co-ordinator, said none of the tests they had looked at had proved viable, but that he was hopeful one would become available in months.

Last week the Medicines and Healthcare products Regulatory Agency (MHRA) published the specifications it is looking for from the antibody tests.

We understand the UK government is now sceptical of being able to secure a viable lateral flow antibody test to use for mass testing.

Instead they are actively investigating the potential of ramping up the ELISA testing PHE is doing via the Porton Down laboratory.

Specifications

The MHRA specifications for a point-of-care antibody test require 98 per cent sensitivity and specificity:

Specification criteria for serology/antibody point of care test (POCT)[23]

These are initial specifications based on our best information, but the science is rapidly evolving. These specifications are subject to review and may need to be updated at short notice.

Key Features	Desired	Acceptable
Clinical sensitivity (false negatives	Greater than 98% (within 95%	Greater than 98% (within 95%

Specification criteria for serology/antibody point of care test (POCT)

–telling someone they haven't had the infection when they have)	confidence intervals)	confidence intervals)
Clinical specificity(false positives -telling someone they have had the infection when they haven't)	Greater than 98% (within 95% confidence intervals) for IgG between 14 and 20 days from appearance of first symptoms	Greater than 98% (within 95% confidence intervals) for IgGbetween 14 and 20 days from appearance of first symptoms

For antibody self-tests, MHRA requires sensitivity of 95 per cent and specificity of 98 per cent:

Specification criteria for serology/antibody self-tests[24]

These are initial specifications based on our best information, but the science is rapidly evolving. These specifications are subject to review and may need to be updated at short notice.

Key Features	**Desired**	**Acceptable**
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23 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/878659/Specifications_for_COVID-19_tests_and_testing_kits.pdf

24 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/878659/Specifications_for_COVID-19_tests_and_testing_kits.pdf

Do Antibody Tests Work?

Discussions on the accuracy of antibody tests broadly fall into two categories:

- The specificity and sensitivity of the tests
- When they are used

Accuracy of the Test Itself

- Sensitivity refers to how well the test works in identifying the IgM and IgG antibodies associated with the coronavirus. The higher the sensitivity score, the more likely the test is to detect these antibodies (and therefore avoid producing false negatives).
- Specificity is the measure of how focused the particular test is on identifying the specific antibodies it is designed to detect (for coronavirus) and not other similar ones. A higher specificity score means the test is more accurate at specifically identifying Covid-19 antibodies.

There are legitimate steps that need to be taken to ensure a test meets the right sensitivity and specificity to be viable.

Timing of Testing

A further issue in terms of accuracy is the timing of when the test is used. Antibody tests are more effective, and accurate, when used post-infection. Where they are used around 14 days after infection – when IgG antibodies are detectable – they are most effective. So while the test must be effective in and of itself, it is also vital it is used at the right time.

Antibody Testing: What's on the Market?

Appendix A includes a list compiled by Johns Hopkins of serology tests that have been approved for diagnostic use in other countries, as well as others under development.

Alongside this list we have also been in discussion with a range of companies that believe they are close to having a validated test (in the US), or have viable tests that have not yet been approved by PHE in the UK.

Examples of UK companies who claim to have viable tests are included below:

- **Biopanda**: A Northern Irish biotech company that produces a rapid antibody test. The firm is selling its testing privately within the UK and has also previously despatched orders "throughout Europe and across the world."
- **SureScreen**: Private company based in Derby that says it has developed a rapid test that can reach results with 98 per cent accuracy. It is based on using a finger-prick blood sample and can produce a result in 10 minutes. SureScreen says its tests are being used by private buyers in the UK, Ireland, Germany, Kuwait, Netherlands, Oman, Spain, Switzerland, Turkey and the UAE.

In the US the Food & Drug Administration (FDA) has given Emergency Use Authorisations (UEAs) to three tests:

FDA EUAs granted for Covid-19 antibody tests

Date EUA issued	Company	Test	Antibodies detected
14 April	Chembio Diagnostic System	DPP Covid-19 IgM/ IgG System	IgM and IgG
14 April	Ortho Clinical Diagnostics	Vitros Anti-Sars-CoV-2 Total Reagent Pack	Total antibody (incl IgM and IgG)
1 April	Cellex	qSars-CoV-2 IgG/IgM Rapid Test	IgM and IgG

Source: FDA

This week Abbott launched a new test, without an EUA, which specifically looks for IgG antibodies, rather than both IgG and IgM. The company claims its test, when it is used at least two weeks after someone shows symptoms, has a sensitivity rating of 100 per cent and a specificity of 99.5 per cent.[25]

25 https://www.evaluate.com/vantage/articles/news/corporate-strategy/new-covid-19-test-and-decent-first-quarter-buoy-abbott

Antibody + Antigen = Gold Standard

The Two Tests Together = a 98.6% Detection Rate

The best test for an early infection is combining the antibody test and the PCR swab taken from the patient. Then we have a 98.6 per cent detection rate[26] within the first five-and-a-half days of infection. According to a study, the combined use of antigen and antibody testing improved identification of positivity through various phases of illness.

While antibody tests alone may not be enough to diagnose Covid-19, they can be a valuable diagnostic tool when combined with antigen tests. Owing to their scalability, antibody tests can tell us huge amounts about the spread and behaviour of Covid-19 and help us understand the immunity response to the virus.

Reminder: What Does The Antibody Test Reveal and When?

A suitable antibody test for Covid-19 would reveal the presence (or not) of two antibodies:

- **Immunoglobulin G (IgG):** This is the most common antibody. It's in blood and other body fluids and protects against bacterial and viral infections. IgG takes approximately 14 days to appear but then remains, providing immunity.
- **Immunoglobulin M (IgM):** Found mainly in blood and lymph fluid, this is the first antibody the body makes when it fights a new infection. It usually appears seven days post-infection and peaks at 21 days.

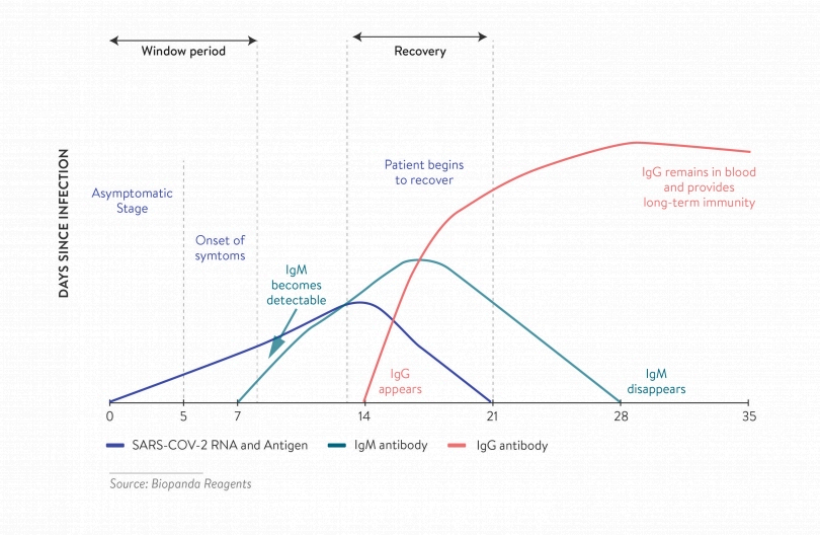
The following table shows the clinical significance of combining results from antigen tests (RT-qPCR) with the results from antibody tests. In this paper, we make the recommendation for mass testing to utilise both.

Test results			Clinical Significance
RT-qPCR	IgM	IgG	
+	–	–	Patient may be in the window period of infection.
+	+	–	Patient may be in the early stage of infection.
+	+	+	Patients is in the active phase of infection.
+	–	+	Patient may be in the late or recurrent stage of infection.
–	+	–	Patient may be in the early stage of infection. RT-qPCR result may be false-negative.
–	–	+	Patient may have had a past infection, and has recovered.
–	+	+	Patient may be in the recovery stage of an infection, or the RT-qPCR result may be false-negative.

Source: Diazyme http://www.diazyme.com/covid-19-antibody-tests

This table is based on the current knowledge about the rise and fall of Covid-19 antigens, IgM antibody and IgG antibody and the correlation of these level variations with the initial time of infection, onset of symptoms and recovery phase[272829]. As shown in the graph below, serological tests are recommended to be used on patients at least three days after onset of symptoms or seven to 10 days after infection with the virus.

Variation of the levels of antigen and IgM and IgG antibodies after infection



Source: Biopanda Reagents https://www.biopanda.co.uk/php/products/rapid/infectious_diseases/covid19.php

Han Yan, a regulatory officer at antibody-test producer Biopanda, told Channel 4 that, "there is a window period where a person can be infected, and even show symptoms, but during which the antibody test will not come back positive. However, during this time, a PCR test should detect the presence of the virus.

"With all this in mind, we would never recommend our antibody test as a way of replacing RT-PCR for early-mid stage diagnosis of Covid-19 because of the risk of false negatives ...

26 https://www.jwatch.org/na51255/2020/03/31/serologic-tests-sars-cov-2-first-steps-long-road

"So if the antibody test is being used to diagnose current infection, it must be used with RT-PCR."[30]

The key conclusion is that the results of antigen and antibody tests do not necessarily need to agree. A disagreement between the two tests provides useful data and can often be traced to the after-infection time points at which the tests were performed. Overall, while antigen testing may be appropriate for the detection of the Covid-19 virus during the acute phase, antibody testing is appropriate during the chronic phase. Since the exact time of infection is often unknown, combining both tests improves the accuracy of the Covid-19 diagnosis.

Evidence we cite above from a study conducted in China, published in the *New England Journal of Medicine*, shows combining PCR and antibody testing dramatically improves the chances of achieving an accurate result.

The study looked at blood samples from 173 patients (in Shenzhen) and found that antibody tests began to give more reliable results than PCR testing after the first five-and-a-half days of the illness. By combining antibody testing with PCR testing, doctors were able to detect 98.6 per cent of coronavirus cases, as compared with 51.9 per cent by using PCR testing alone.

The study found that, "Serologic tests can improve early diagnosis of Covid-19. Because of the high false-negative rates with PCR, serologic tests will be a useful supplement to RNA detection.[31]

Based on what we know of the virus, there are limitations to the antibody test that mainly relate to the slow pace of the human antibody response to Covid-19. Several studies are ongoing but current science is not conclusive and it would appear antibodies may not be detectable before three days after onset of symptoms – or at least seven to 10 days after infection.

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27 Lauer, S. et al., 2020. The Incubation Period of Coronavirus Disease 2019 (COVID-19) From Publicly Reported Confirmed Cases: Estimation and Application. Annals of Internal Medicine.

28 National Health Commission of the People's Republic of China, New Coronavirus Pneumonia Diagnosis and Treatment Program (Trial Version 7).

29 5. To KK, Tsang OT, Leung WS, Tam AR, Wu TC, Lung DC et al. (2020). Temporal profiles of viral load in posterior oropharyngeal saliva samples and serum antibody responses during infection by SARS-CoV-2: an observational cohort study. Lancet Infect Dis. 2020 Mar 23. pii: S1473-3099(20)30196-1.

30 https://www.channel4.com/news/factcheck/factcheck-qa-the-new-coronavirus-blood-tests

31 https://www.jwatch.org/na51255/2020/03/31/serologic-tests-sars-cov-2-first-steps-long-road

The STIR Testing Circuit: Screen. Trace. Isolate/Immunity. Repeat.

We agree with Professor Neil Ferguson of Imperial College in calling for the government to have a "single-minded emphasis" on developing mass testing and tracing and tracking new cases.[32]

To achieve this, we propose a four-step model to mass testing – the STIR testing circuit – that can be scaled up as both testing capacity increases and more people become immune to the virus.

S Screen all people and administer both antibody and antigen tests. Prioritise key workers and those identified through contact tracing based on availability of tests.

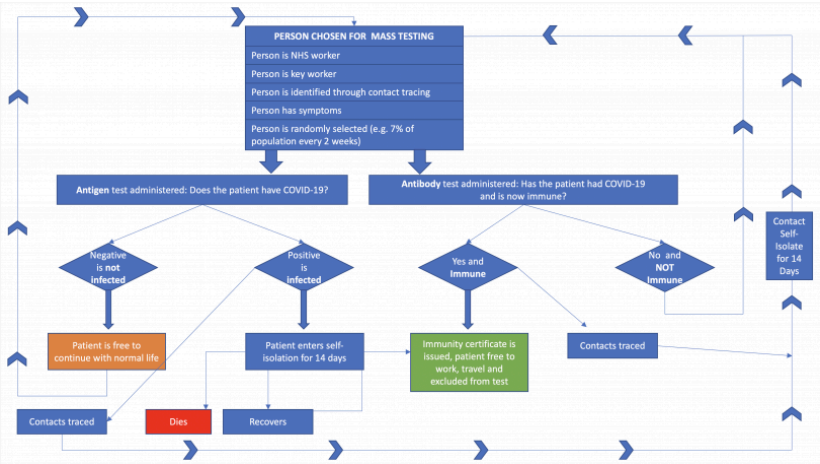
T Trace anyone who has come into contact with a person positive Covid-19. This will use a combination of tracing technology and offline community tracing.

I Isolate anyone who tests positive and initiate contact tracing (antigen).

Immunity certificates issued to anyone who has sufficient antibodies (antibody).

R Repeat the process on a daily basis for key workers and biweekly for others.

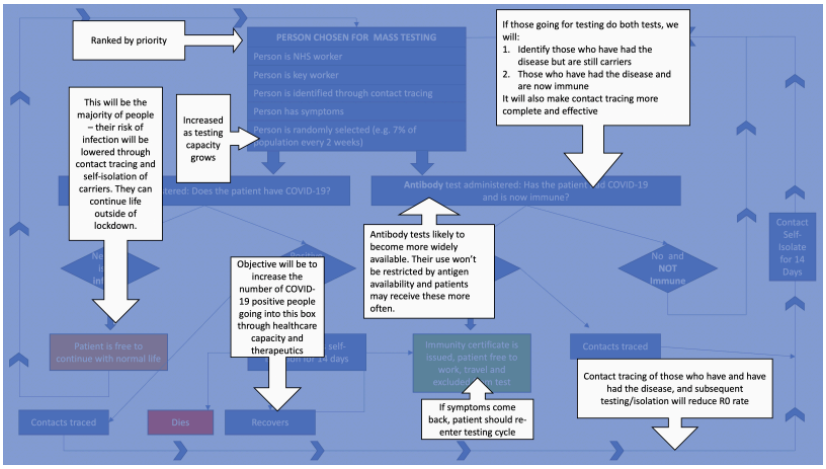
The Mass Testing Operation: How It Would Work



Source: TBI **Download a large version**

- The government's objective should be to get as many patients as possible through testing on a regular basis and into the orange category (active socially and economically, not affected).
- If a policy of herd immunity is pursued, the government may switch priority to focus on getting as many people as possible into the green category in the above chart (active socially and economically, immune).
- The number of people who die from this disease will be mitigated by:
  1. Shielding of vulnerable groups
  2. Reduction in transmission (enhanced by contact-tracing, isolation and other measures including masks)
  3. Therapeutics, which may reduce the need for shielding once widely available
- Administering both tests will become increasingly feasible, especially when rapid antigen tests become available. That's why we recommend other measures, such as shielding, to reduce testing demand
- Further, we wouldn't limit antibody testing because of the availability of antigen testing – so people may receive the former while production of the latter is being scaled.

The Mass Testing Operation: In Depth on the Phases



Source: TBI

The "Joint European Roadmap towards lifting Covid-19 containment measures" makes clear how important this testing strategy is to easing restrictions.

32 https://www.standard.co.uk/news/uk/coronavirus-lockdown-extended-neil-ferguson-action-needed-a4415971.html

As the document sets out, a key criterion for lifting the lockdown is: "Appropriate monitoring capacity, including large-scale testing capacity to detect and monitor the spread of the virus combined with contact tracing and possibilities to isolate people in case of reappearance and further spread of infections. Antibody detection capacities, when confirmed specifically for Covid-19, will provide complementary data on the share of the population that has successfully overcome the disease and eventually measure the acquired immunity."[33]

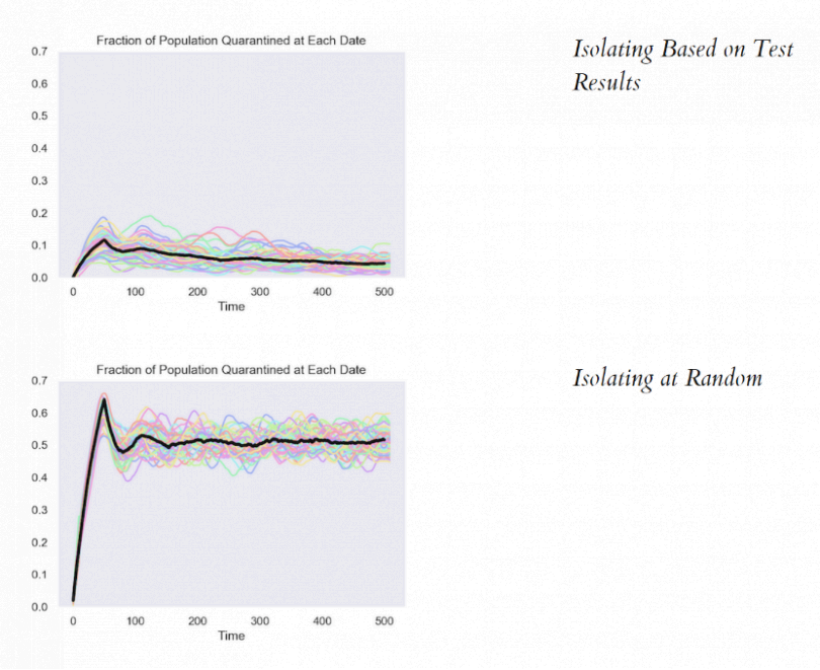
33 https://ec.europa.eu/info/sites/info/files/communication_-_a_european_roadmap_to_lifting_coronavirus_containment_measures_0.pdf

Don't Make the Test the Enemy of the Good

Economist Paul Romer's modelling shows the importance of testing as part of a wider approach to handling the virus. (The coloured lines in the graphs below show the results from 50 runs of the model. The black line is the average at each date of these 50 runs.)

The Benefit of Testing to Suppress

Romer's modelling shows that if testing is used to determine who needs to isolate, then the number of people needing to be confined is dramatically smaller.

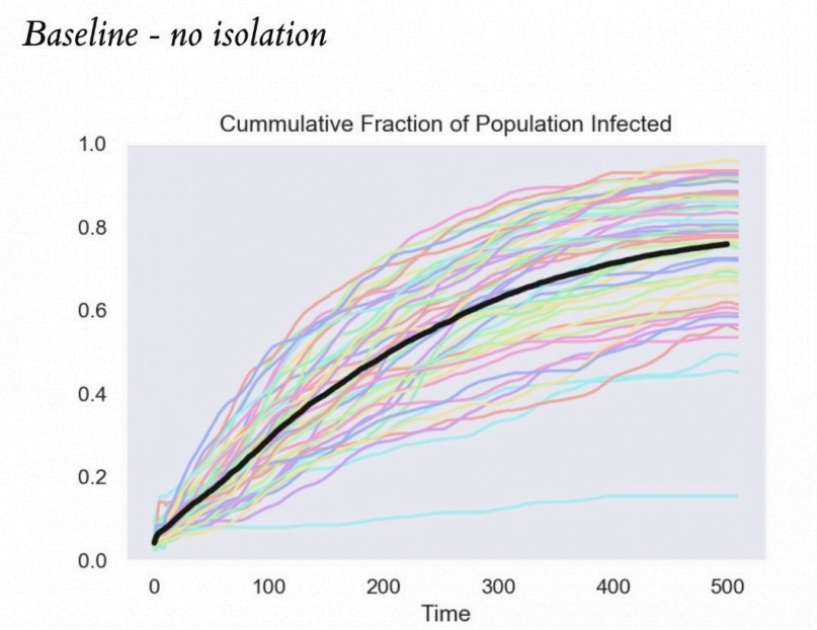


Source: Paul Romer https://paulromer.net/covid-sim-part2/

Accuracy

The modelling shows that these benefits are possible even with an imperfect test.

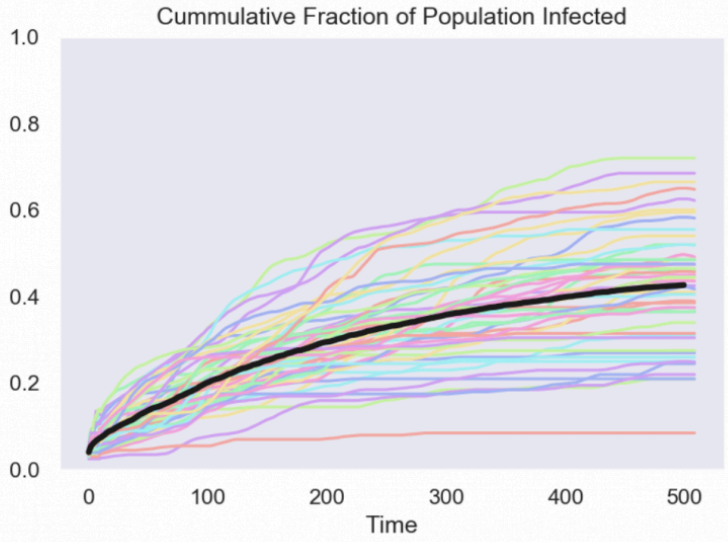
"How much difference does it make if the test used to send people into quarantine is bad? Not as much as you might think," Romer has said.[34]



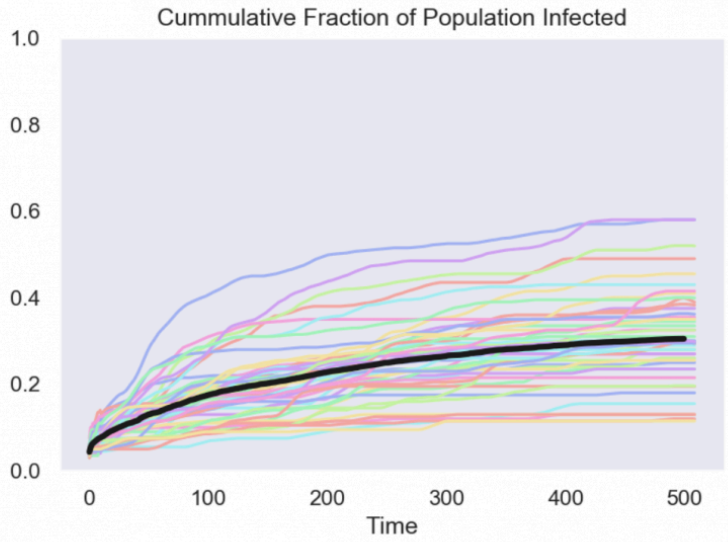
Source: Paul Romer. The coloured lines in the graphs show the results from 50 runs of the model. The black line is the average at each date of these 50 runs.

34 https://paulromer.net/covid-sim-part3/

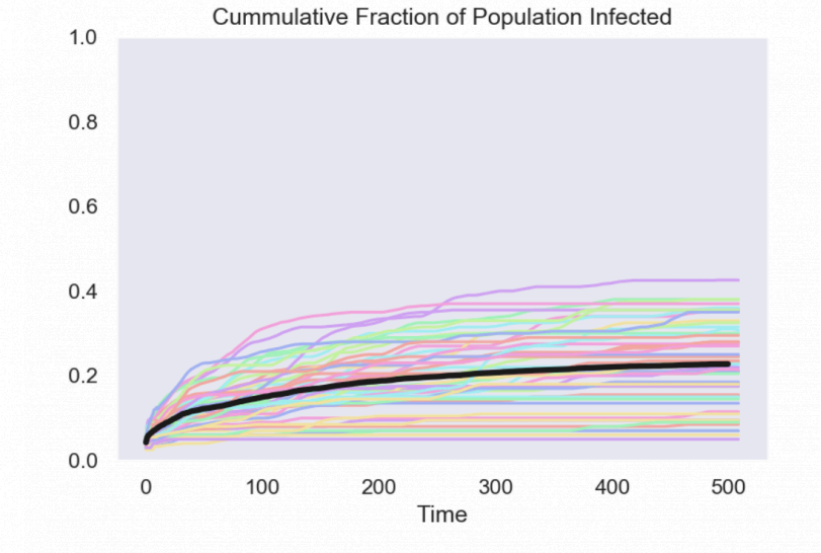
Isolate using test with 80% false negatives



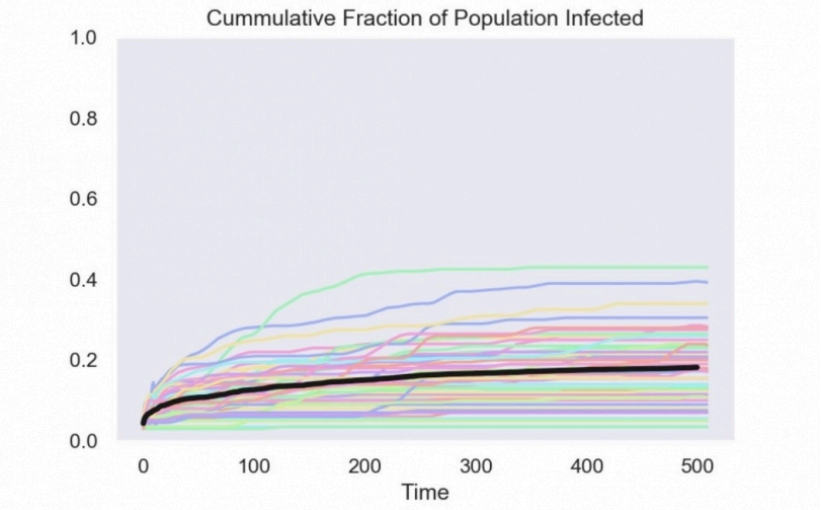
Isolate using test with 60% false negatives



Isolate using test with 40% false negatives



Isolate using test with 20% false negatives



As Romer concludes, "The simulated data here contrast policies that isolate people who test positive using four different assumptions about the quality of the test. Even a very bad test cuts the fraction of the population who are ultimately infected almost in half. And when I say bad, I mean bad – an 80% false negative rate, which means that 4 out of 5 of people who are truly infectious will get a negative test result – i.e. a result saying that they are not infectious."

Therefore, we believe that the pursuit of a "perfect" test is misguided for the purposes of informing strategy for exit from a lockdown. This should be distinguished from the use of such tests for clinical purposes, where the need for accuracy is much higher. The modelling above

demonstrates that there is a clear net gain from using a test that successfully isolates even 60%+ of those with Covid-19 in society, and we are confident that tests with higher accuracies are currently on the market. The impact of lower accuracy is further mitigated by other measures including shielding, PPE (including masks) and staged exit from lockdown of key groups.

Trace: Online and Offline

As we have set out in a previous paper on contact tracing[35], tracing is going to be a key component of response and integral to any exit strategy, with measures adopted in this area needing to be both online and offline. However, there are a number of policy considerations that need to be worked through, in particular on digital tracing efforts, encompassing privacy, take-up and efficacy, even to the question of what defines close contact, both in terms of distance and duration.

Largely being explored for the first time, around the world a number of digital contact-tracing efforts are already underway. These use different approaches and different degrees of intrusiveness:

- South Korea, for example, uses GPS and location tracking, having made significant legal changes around powers for data collection in a health crisis, following their experience with MERS.
- Singapore's open-source app, TraceTogether, uses Bluetooth technology, but has set out clear guardrails around privacy and time-limited collection of anonymised data.
- The European Union has also developed a toolkit for member states in developing apps, with guidelines specifying that they need to be voluntary, approved by the national health authority, privacy-preserving ("personal data is securely encrypted"), and dismantled as soon as no longer needed.

Researchers and technology companies are also assisting with efforts, with groups such as Covid-Watch, MIT's Private Kit: Safe Paths and DP3T working on privacy preserving approaches, as well as shared protocols. And Apple and Google recently announced a collaboration on interoperable, privacy-protecting APIs to enable the development of tracing apps. As well as requiring these to be used only on an opt-in basis, they will also limit certification to national health authorities in an attempt to limit the risk of disruptive or malicious "false flag" activities.

In the UK, the government has announced that it is developing an app, which is likely to be embedded within a strategy to loosen restrictions, although the details of this are yet to be released. Given the broader developments in this area, there are a number of areas and trade-offs the government will need to consider:

- **Privacy**: Apple and Google have now provided the framework for which apps should be developed, but there are still some privacy questions about how positive identifiers are collected, and risks around tracking,

including correlation attacks and deanonymisation, as well as broader cyber-security concerns. The government will need to be clear about what the architecture, access to data and purpose is, as well as how it is collected, how it is stored and retention.

- **Efficacy**: The speed and timing at which this is deployed is key and must be in unison with other elements of the strategy and when the R0 number is low. There are some definitional issues that will also need to be worked through, as well as mechanisms to deal with false positives. One put forward by Covid Watch's Tina White is confirmation from health-care providers provided via a separate app, but which also underlines the need for testing on scale.
- **Take-up**: One of the issues with Singapore's efforts has been a low level of take-up. Modelling from Oxford University suggests 56 per cent of the total population needs "to use the app to completely suppress the epidemic, if combined with 'shielding' of over 70s."[36] The government are working with the Behavioural Insights Team on this issue, but public acceptance and take-up will be dependent on them being perceived to be effective and trustworthy and that they will be limited in duration. That Apple and Google have pushed it down to a platform layer helps. Government will build the app on top, pushing out targeted marketing and clearly explaining utility. Communications will therefore be key and working in unison with the health service and communities will be essential, with the app provided by the NHS, not Gov.uk. One other constraint, however, which also raises equity concerns, will be those without access to devices.

Online and Offline

What is clear however, is that digital methods should also be seen as complementary to other methods, not a substitute. Both online and offline should work together as part of a broader toolkit. This is something a senior official in the Singaporean Government, Jason Roy, has recently emphasised, saying that digital contact tracing should work alongside manual, with a "human-in-the-loop system" being "necessary to allow judgment to be applied, given the high likelihood of pre-symptomatic transmission of the SARS-CoV-2 virus."[37]

This is particularly important to deal with issues around false positives and negatives. Manual tracing is labour intensive, but it is clear that human skills

35 https://institute.global/policy/contact-tracing-and-fight-against-covid-19-how-digital-tools-can-help

and expertise are a necessary part of the equation. In Wuhan, efforts allegedly included 1,800 teams of epidemiologists, each with a minimum of five people. As the UK launches its app, it is therefore crucial that digital efforts support human ones.

36 https://045.medsci.ox.ac.uk/for-media

37 https://blog.gds-gov.tech/automated-contact-tracing-is-not-a-coronavirus-panacea-57fb3ce61d98

Community Testing: A Workable Plan for Roll-Out

The building blocks for a mass-testing regime are swabbing sites; the workforce to conduct swabs; tests and equipment; and coordination. The biggest constraint to scale lies in the availability of tests and protective equipment, on which there is substantial focus. The government should set out a strategy for mass testing so that plans can be activated immediately to mobilise the other components.

- **Swabbing sites:** Establishing a network of swabbing sites is necessary to test the numbers of people required, while not putting health settings at risk. A mix of models for these sites are required to respond to different geographies and the needs of the population. Versions of all of these models are in operation or development in the UK but require immediate plans for scale. A number of drive-through sites are operating effectively for NHS staff and provide a comparatively high-volume method and should be a core part of the network of testing sites. For vulnerable people, motorbike couriers are in operation and are able to take swabs direct from people's houses. In more rural areas, or low car-density locations, mobile-testing units may provide an appropriate option.
- **Workforce:** Frontline health staff are focused on the care of patients; therefore, a temporary workforce needs to be identified and trained to conduct tests. The PCR test requires a practitioner to take a throat and nasal swab. The quality of these swabs will vary between practitioners. Locally based systems have already been activated using staff newly trained in the collection of these swabs. It will be important to monitor quality, but there is no evidence to date that this is not a viable route to scale.
- **Coordination:** NHS Acute Trusts are currently coordinating the testing regime; this is entirely appropriate as testing priorities are focused around health needs. However, as emphasis shifts from testing for health purposes to testing a broader population, a new governance arrangement should be put in place. The aim should be to bring in other agencies who are better placed to coordinate a testing regime for a broader population, and provide the significant resource that will be required for contact tracing. This will enable acute trusts to focus on patient care.

Recommendations

- To deliver mass testing in the community, planning to scale operations

must commence immediately.

- Central government should set out a framework for mass testing, indicating who should be prioritised and how regularly they should be tested. This should then be operationalised locally.
- Responsibility for mobilising and administering the testing regime should broaden beyond NHS Acute Trusts.

Scaling Testing

Antigen Testing

Reaching the capacity to test hundreds of thousands – if not millions – of people on a regular basis is necessarily ambitious. The government has made very positive steps to reach such scale, including the organisation and appropriation of university labs to increase testing capacity.

Scale will be achieved through a combination of measures that include the following:

1. Managing the demand on antigen testing. This will be aided by shielding measures and immunity certificates, phasing the entry of citizens into the "STIR testing circuit". See above.
2. Increasing lab capacity and efficacy.
3. Improving the collection, quality and delivery of samples.
4. Integrate collection and delivery of results through software solution.

How do we ramp up antigen testing?

Scale lab-side capacity	**Scale sample collection**	**Boost testing capacity**
Objective: Increase lab capacity and efficacy	**Objective: Improve the collection, quality and delivery of samples**	**Objective: Focus industrial, political and scientific resource on testing**
Oversee procurements, supply chains, etc.	Expand drive-through testing capacity	Appoint senior Minister for Testing reporting into prime minister

Scale lab-side capacity	Scale sample collection	Boost testing capacity
Objective: Increase lab capacity and efficacy	**Objective: Improve the collection, quality and delivery of samples**	**Objective: Focus industrial, political and scientific resource on testing**
Drive inter-compatibility of supply-chain materials, e.g. reagents	Expand community testing capability, e.g. through polling-station infrastructure	Drive development and fast-tracking of rapid antigen testing
Integrate all existing lab capacity, including private providers	Diversify sample collection, including introducing new modes of collection	

Antibody Testing

Antibody tests are, feasibly, much easier to produce on mass scale. The roadblocks to achieving a mass rollout of these tests lie, at present, largely around the issue of test validation.

To scale up this capacity we therefore suggest the following:

- PHE to set out the exact process for the validation process.
- PHE to make available patient samples to ensure the private sector has full capacity to develop and validate their own tests. In particular PHE should ensure it makes available seroconversion panels (blood samples of patients positively confirmed as having the virus and then having recovered). These samples should be used to validate tests, ensuring they are carried out on blood containing IgM and/or IgG antibodies.
- Government and PHE to publish robust modelling showing the levels of accuracy of home antibody tests that would enable a mass testing regime to be effective. We believe a lower threshold than 98 per cent will be workable for home testing.
- Government and PHE to procure antibody testing kits from the widest possible network of suppliers – both small and large producers, as well as from domestic and international companies.

The Role of Therapeutics

There are currently no approved therapeutic drugs to treat Covid-19 in the UK. The need for effective treatment for patients suffering from Covid-19 is high, given the fact that one in seven patients hospitalised with the virus die and about 50 per cent of ICU patients eventually die. The UK controls the supply of drugs that appear to be relevant for managing Covid-19, many of which are also used to manage other diseases; they are being prescribed for trials and are discouraged for use outside such research.

The UK government, through its NIHR and UK Research and Innovation, has provided £20 million in funding "for research projects that will contribute to our understanding, diagnosis, prevention or management of coronavirus."[38] The call for proposals covers two categories, one of which is vaccines and therapeutics. The fund closed on 13 February with results expected within 18 months. Given the overwhelming burden on hospitals in the UK (and elsewhere), development of treatments for Covid-19 is critical.

Regulatory authorities have fast-tracked the process for bringing drugs to market because of the scale of the pandemic. In conjunction with a nationwide testing program, therapeutics offer the hope of easing the burden on the country's hospital system, hastening recovery from the virus, and allowing people to resume their lives, including returning to work.

Ongoing global research to develop treatments for the virus falls into three categories:

1. Drugs already approved and publicly available for treatment of other diseases that are being tested for treatment for Covid-19.
2. Unapproved drugs that have shown promise in animal studies with severe acute respiratory syndrome (SARS) and Middle East respiratory syndrome (MERS).
3. New research (pre-clinical trial) to develop new drugs and approaches. These will take the longest to develop.

The last category includes the use of antibodies, which are harvested from the blood plasma of people who have the virus. The challenge is that the process is slow as it requires donations of blood plasma, which must then be turned into a usable form that can be used as a therapy. Several SARS antibodies may hold some promise in treating coronavirus.

38 National Institute for Health Research website, "NIHR and UKRI launch £20 million funding call for novel coronavirus research," 4 February 2020, available at

In the case of the UK, research funds are focused on supporting projects that show the potential for rapid development: "[r]e-purposing of existing therapeutics, e.g. proteases, helicases or entry inhibitors; development of mAbs or other biologics." [39]

The European Medicines Agency listed the following treatments that are currently undergoing clinical trials to assess safety and efficacy:

- remdesivir (investigational)
- lopinavir/ritonavir (currently authorised as an anti-HIV medicine)
- chloroquine and hydroxychloroquine (currently authorised at national level as treatments against malaria and certain autoimmune diseases such as rheumatoid arthritis)
- systemic interferons and in particular interferon beta (currently authorised to treat diseases such as multiple sclerosis)
- monoclonal antibodies with activity against components of the immune system[40]

A full list of therapeutics under evaluation in the UK through its special fund follows at the end of this paper as Appendix B. Most trials are of existing, approved drugs.

Hydroxychloroquine

Evidence suggests that usage of hydroxychloroquine is in widespread use beyond the United States. Sermo, a health-care data company, surveyed 5,000 physicians in 30 countries and found that 44 per cent prescribed the drug for Covid-19 patients; 38 per cent stated that it was making a positive difference.

Hospitals in the US are using hydroxychloroquine in combination with azithromycin, to treat coronavirus patients. Despite its efficacy in some cases, a small study (81 hospitalised patients) of the anti-malarial drug in Brazil was recently stopped because patients given the higher dosage (600 mg of chloroquine for 10 days) experienced heart arrhythmias; 11 patients eventually died. Results for the smaller dosage (450 milligrams of chloroquine twice a day for five days) could not be determined due to the small number of patients in the study.

As we have argued in previous papers on testing, we believe there is a vital role for therapeutics in navigating an end to lockdown and supporting a programme of mass testing.

https://www.nihr.ac.uk/news/nihr-and-ukri-launch-20-million-funding-call-for-novel-coronavirus-research/23942

39 Ibid.

By alleviating the symptoms of the virus, slowing its development, and giving the body time to recover, therapeutics offer a path to reduce demands on frontline health care and allow for medical interventions in the community.

40 https://www.ema.europa.eu/en/documents/press-release/update-treatments-vaccines-against-covid-19-under-development_en.pdf

Conclusion: Mass Test to End Lockdown

As this paper has shown, the only viable basis upon which to build an exit strategy from lockdown is mass testing.

Such an approach would see the UK government scale up antigen testing (both PCR and rapid tests) and roll out antibody testing.

While this remains the government's stated objective, it will need the right structure and strategy.

Critically this must be driven by the appointment of a senior minister with sole responsibility for testing, reporting to the prime minister.

Mass testing would build on both the existing superlabs being created, the full capacity of smaller labs across the country, and scaled-up community testing (e.g. expanding drive-through testing and adding more community testing points like polling stations).

While questions have been raised about the accuracy of antibody testing, we understand that regular testing, using both PCR and antibody testing, is highly accurate – 98.6 per cent accuracy – and that antibody testing will become vital (through detection of IgG antibodies in particular) in identifying those now immune and who can therefore leave the mass-testing procedure.

The economic damage of lockdown (estimated at £2.4 billion per day) is not sustainable. But, equally, we cannot simply lift lockdown and risk a significant spike in cases of the virus.

A paper published last week by the *Lancet* argued that, "Close monitoring of the instantaneous effective reproduction number and real-time tuning of policy interventions to ensure a manageable second wave remains the over-riding public health priority … Early detection of cases is essential … [Significant levels] of testing should be maintained, if not increased, to monitor the real-time point prevalence of Covid-19, so that any possible reintroduction of infected cases could be swiftly identified and isolated, and their contacts traced and quarantined."[41]

We fully support these conclusions and hope this paper, read alongside our colleagues' paper on ways to end the lockdown, can act as a catalyst for ensuring the UK puts in place the right exit strategy, with the right architecture and capacity on mass testing.

41 https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)30746-7/fulltext

Appendix A: Availability of Antibody Testing

Information is taken from Johns Hopkins School for Public Health:

Country of development	US/China
Type of serological test	RDT
Authors/ company	Cellex Inc.
Description	RDT, lateral flow assay, which detects IgM and IgG to the nucelocapside protein of SARS-CoV-2. The sensitivity is 93.8% and specificity is 95.6%, when tested at 2 Chinese hospitals in a total of 128 Covid-19-positive patients, and 250 Covid-19-negative patients (as detected by RT-qPCR).
Phase of development	Approved by FDA for EUA on diagnostics, has CE approval
Proposed release	available for purchase by research labs/healthcare providers (product number 5513)
Date	1 April 2020

Country of development	US/China
Type of serological test	RDT, solid phase immunochromatographic assay
Authors/ company	Aytu Biosciences/Orient Gene Biotech
Description	The (Covid-19) IgG/IgM Rapid Test will assay patient antibodies to SARS-CoV-2 from blood or plasma samples. The sensitivity is 87.9% and specificity is 100%

	for IgG, and for IgM it is 97.2% and 100%, respectively.
Phase of development	CE approved, used in China in clinical settings, awaiting FDA approval
Proposed release	Shipments should be ready by early April
Date	10 March 10 2020

Country of development	US/China
Type of serological test	Proprietary
Authors/ company	ScanWell Health/INNOVITA
Description	This kit is for detection of IgG and IgM for SARS-CoV-2 in the blood, taking only 15 minutes, and is an at-home test. The test has 87.3% sensitivity and 100% specificity.
Phase of development	Cleared by China's National Medical Products Administration (NMPA), and pending approval by US FDA
Proposed release	6-8 weeks (1 May to 15 May), depending on FDA approval
Date	20 March 2020

Country of development	Singapore
Type of serological	Not explicitly stated, though their “gold standard” is a neutralisation assay

test	
Authors/ company	Singapore/ Wang Lab
Description	The Wang lab developed two tests. One, which has about 90% sensitivity, is rapid and uses recombinant viral proteins to detect reactive antibodies. The second is their "gold standard" and utilises a viral neutralization assay but takes 3-5 days.
Phase of development	Deployed in Singapore
Proposed release	Not stated
Date	1 March 2020

Country of development	China
Type of serological test	Lateral flow assay (RDT)
Authors/ company	Guangzhou Wondfo Biotech Co Ltd
Description	Wondfo SARS-CoV-2 Antibody Test, which is a lateral flow assay that assays patient IgG and IgM. The article did not specify target antigens, sensitivity or specificity
Phase of development	CE/IVD, approved by NMPA in China for point of care testing
Proposed release	CE/IVD in the EU
Date	22 February 2020

Country of development	China
Type of serological test	RDT (colloidal gold lateral flow assay)
Authors/ company	Guangdong Hecin-Scientific
Description	Tests for IgM against SARS-CoV-2.
Phase of development	Cleared by China's National Medical Products Administration (NMPA)
Proposed release	Approved for use in China
Date	22 February 2020

Country of development	China
Type of serological test	RDT
Authors/ company	Dynamiker
Description	The test, DNK-1419-1, assays for patient IgG and IgM with 92% accuracy.
Phase of development	The NMPA has approved it in the 7th edition of Diagnostic and treatment protocol of Covid-19
Proposed release	Used in China, no other approvals to
Date	Not given

Country of development	The Republic of Korea
Type of serological test	RDT
Authors/ company	SD Biosensor
Description	US supplier Henry Schein will distribute the test for IVD use only Phase of development Approved for diagnostic us outside the US, Research use only in US
Proposed release	2-3 weeks
Date	26 March 2020

Country of development	US
Type of serological test	ELISA
Authors/ company	MayoClinic/University of Minnesota
Description	MayoClinic is developing an ELISA to test for antibodies to SARS-CoV-2. The types of antibodies are not stated, nor is sensitivity or specificity. Phase of development Clinical
Proposed release	6 April 2020
Date	1 April 2020

Country of development	US

Type of serological test	RDT
Authors/ company	Advaite
Description	RapCov Rapid Covid-19 Test is an in vitro diagnostic test for IgM and IgG antibodies. In a study with 18 healthy and 18 Covid-19 positive patients, the sensitivity was 89% and specificity was 100%. It should be noted that "specificity" was only performed on healthy patient samples, not patient samples from related viruses. Further testing is necessary to validate the test. It is currently being used to study community prevalence in Chester County, PA.51 Phase of development Research use only (IVD), not approved for diagnostic use. This company was not found on any FDA categorisation of tests
Proposed release	April 2020
Date	6 April 6 2020

Country of development	US
Type of serological test	RDT
Authors/ company	Premier Biotech
Description	The Premier Biotech Covid-19 rapid test assays for patient IgG and IgM. Sensitivity and specificity were not reported. It is currently being provided to urgent care centres in Charlotte, NC for testing. It has not been approved by the FDA for EUA. Phase of development Research use only (IVD), not approved for diagnostic use. This company was not found on any FDA categorisation of tests
Proposed release	April 2020

Date	9 April 2020

Tests that have been approved for research or surveillance purposes only

Country of development	US
Type of serological test	ELISA
Authors/ company	Epitope Diagnostics, Ltd
Description	KT-1032 tests for IgG to SARS-CoV-2, while KT-1033 tests for IgM to SARS-CoV-2. The kits do not state the antigens of interest.
Phase of development	Approved by FDA, for clinical use only and for research use. Not for at home testing. The test itself has not been evaluated by the FDA
Proposed release	Ongoing
Date	3 March 2020

Country of development	US
Type of serological test	RDT

Authors/ company	CTK Biotech
Description	The test, Covid-19 IgG/IgM Rapid Test, tests for patient IgG and IgM in a lateral flow assay.
Phase of development	Not approved for use in the US, but available for purchase by research labs/healthcare providers
Proposed release	Available for purchase by research labs/healthcare providers and export out of the US
Date	12 March 12 2020

Country of development	US
Type of serological test	RDT (colloidal gold lateral flow assay)
Authors/ company	BioMedomics
Description	This assay detects patient antibodies, IgG and IgM, on a lateral flow assay. It uses a recombinant viral antigen, though it does not state the specific antigen. The test is a three-line read-out, one line for a control, one line to detect IgM, and one to detect IgG. Three lines indicates the patient has both IgG and IgM.
Phase of development	CE/IVD, approved by FDA but only for research use
Proposed release	CE/IVD, available for purchase by research labs/health-care providers in the US, but only for research use
Date	16 March 2020

Country of development	US

Type of serological test	RDT
Authors/ company	Ray Biotech
Description	This test, the Coronavirus (Covid-19) IgM/IgG Rapid Test Kit, detects patient IgM and IgG to SARS-CoV-2 in patient blood samples. It detects antibodies against the viral N protein.
Phase of development	CE/IVD, approved for research use only in the US. Approved for research use under FDA EUA.
Proposed release	available for purchase by research labs/health-care providers, CE/IVD approved
Date	19 March 19 2020

Country of development	US
Type of serological test	ELISA
Authors/ company	Creative Diagnostics
Description	Kit DEIASL019 detects patient IgG for SARS-CoV-2, and uses the whole virus lysate as the antibody binding target. The reported sensitivity and specificity are 100% (from 16 and 30 samples, respectively). The DEIA2020 kit only tests for patient IgG that reacts to N protein.
Phase of development	Not approved for diagnostic use; for research use only
Proposed release	Available for purchase by research labs/health-care providers, but not for diagnostic use
Date	20 March 2020

Country of development	US
Type of serological test	ELISA
Authors/ company	Eagle Biosciences
Description	This company has two kits, one (KTR-1032) that targets patient IgG, and one (KTR-1033) that targets IgM. The target antigen is an "HRP-labeled-Covid-19 antigen." They did not list sensitivity or specificity.
Phase of development	Research use only, CE/IVD outside the US
Proposed release	Available for purchase by research labs/health-care providers, but not for diagnostic use
Date	Not given

Country of development	China/US
Type of serological test	RDT
Authors/ company	Sure Biotech
Description	The Coronavirus Rapid Test assays for IgG and IgM antibody in blood or plasma samples, with 92-96% accuracy.
Phase of development	CE approved
Proposed release	Available for purchase by research labs/health-care providers, CE approved
Date	February 2020

Country of development	China/US
Type of serological test	RDT, immunofluorescence, colloidal gold
Authors/ company	BioEasy/Shenzhen BioEasy Biotechnology Co.
Description	There are three tests: 1) the 2019 nCoV Ag test, which assays sputum or nasal swabs for SARS-CoV-2 antigens and gives a fluorometric read out, 2) the 2019-nCoV Ag GICA test, which uses colloidal gold, and 3) the 2019 nCoV IgG/IgM GICA rapid test which assays for patient antibodies to the virus from blood samples
Phase of development	CE/IVD approved
Proposed release	Available for purchase by research labs/health-care providers, CE/IVD approved
Date	Not given

Country of development	The Republic of Korea
Type of serological test	RDT (colloidal gold lateral flow assay)
Authors/ company	Sugentech
Description	This test is a colloidal gold lateral flow assay that can be read in 10 minutes, and measures presence of patient IgG and IgM.
Phase of development	CE/IVD approved
Proposed	Available for purchase by research labs/health-care

release	providers, CE/IVD approved
Date	Not given

Country of development	The Republic of Korea
Type of serological test	RDT
Authors/ company	SD Biosensor
Description	This company currently offers 3 tests. 1) The Standard Q Covid-19 IgM/IgG Duo which tests for both IgG and IgM patient antibodies to SARS-CoV-2. Sensitivity was 82% and specificity was 97% (based on data from 30 healthy donors and 33 Covid-19 positive individuals. 2) Standard Q Covid-19 Ag, which detects virus antigen from nasopharyngeal swabs, and 3) Standard F Covid-19 Ag FIA, which detects viral N protein present in nasopharyngeal swabs in a fluorescence-based assay.
Phase of development	Korea EUA approved
Proposed release	Available for purchase by research labs/health-care providers, but not for diagnostic use
Date	Not given

Country of development	Singapore
Type of serological test	RDT, prescreen step
Authors/ company	Sensing self

Description	This is a pre-screening, at home test (though not authorised for at-home use yet). It tests for IgG and IgM antibodies, and is reported to be 92% accurate.
Phase of development	CE certified awaiting FDA EUA.
Proposed release	available for purchase by research labs/health-care providers, CE/IVD approved
Date	Not given

Country of development	Germany
Type of serological test	ELISAs
Authors/ company	Euroimmun AG
Description	This company has two tests, including EI 2606-9601 A, which tests for patient IgA, and EI 2606-9601 G, which tests for patient IgG. The target antigens were not stated, nor were specificity or sensitivity of tests.
Phase of development	Research use only, CE/IVD in EU
Proposed release	CE/IVD in the EU
Date	12 March 2020

Country of development	Germany
Type of serological test	RDT, lateral flow assay

Authors/ company	PharmACT
Description	This RDT tests for IgM and IgG of patients, with 92-98% sensitivity in later stages of the infection (day 11-24) with 100% sensitivity.
Phase of development	Research use only
Proposed release	Appears available for purchase by research labs/health-care providers, but no clear approvals
Date	Not given

Country of development	China
Type of serological test	RDT (colloidal gold lateral flow assay)
Authors/ company	Liming Bio
Description	Covid-19 IgG/IgM Combo Rapid Test Device is an RDT that tests for patient IgG and IgM antibodies. The sensitivity and specificity for total antibodies were 93.1 and 100%, respectively. For IgG, sensitivity is 82% and specificity is 100%. For IgM, the sensitivity is 62% and specificity is 100%.
Phase of development	CE/IVD
Proposed release	CE/IVD
Date	February 2020

Country of	China

development	
Type of serological test	Not listed
Authors/ company	Snibe Co
Description	The company provides two tests the 2019-nCoV IgG , and 2019-nCoV IgM tests. The test is a chemiluminescent immunoassay (CLIA). It has been clinically tested in China, though the exact specificity and sensitivity was not stated.
Phase of development	CE/IVD approved
Proposed release	available for purchase by research labs/healthcare providers, CE/IVD approved
Date	Feb. 19, 2020

Country of development	China
Type of serological test	ELISA
Authors/ company	Beijing Wantai
Description	They offer, 1. Wantai SARS-CoV-2 Ab Rapid Test Kit, 2. Wantai SARS-CoV-2 IgM ELISA kit, and 3. Wantai SARS-CoV-2 Ab ELISA kit. The kits do not state which antigens are used as targets. 93.1% sensitivity and 100% specificity.
Phase of development	Approved for Research use only, unclear if available in the US
Proposed release	Released in China

Date	Feb. 25, 2020

Country of development	China
Type of serological test	ELISA
Authors/ company	Shenzhen Yhlo Biotech Company
Description	This company provides 2 tests, the iFlash-SARS-CoV-2-IgG and the iFlash-SARS-CoV-2-IgM, which test for patient antibodies to the virus. The target antigen is not specified. The sensitivity of the IgG assay is over 90%, and specificity is over 95%. For the IgM test, the sensitivity and specificity are both over 95%, based on assaying over 1200 Chinese patient samples.
Phase of development	CE/IVD approved
Proposed release	Available for purchase by research labs/healthcare providers, CE/IVD approved
Date	27 February 2020

Country of development	China
Type of serological test	RDT (colloidal gold lateral flow assay)
Authors/ company	Sanuo Biotech
Description	The SARS-Cov-2 Antibody Test strip tests for patient IgG and IgM. The press release did not disclose sensitivity or specificity of the test.

Phase of development	CE/IVD approved
Proposed release	available for purchase by research labs/healthcare providers, CE/IVD approved
Date	12 March 12 2020

Country of development	China
Type of serological test	RDT (colloidal gold lateral flow assay)
Authors/ company	BioTime
Description	The SARS-CoV-2 IgG/IgM kit tests for patient antibodies to the virus from blood or plasma samples. There is no reported sensitivity or specificity.
Phase of development	Only approved for in vitro diagnostic use
Proposed release	Available for purchase by research labs/health-care providers
Date	Not given

Country of development	The Republic of Korea
Type of serological test	RDT
Authors/company	GenBody
Description	GenBody FIA Covid-19 IgM/IgG (COVI025)

Phase of development	Research use only, CE/IVD in EU
Proposed release	CE/IVD in the EU
Date	2 March 2020

Country of development	United Kingdom
Type of serological test	RDT
Authors/ company	Mologic
Description	Seems to be an RDT (probably to IgM and IgG). No description was given, other than 3.5 million tests were ordered.
Phase of development	UK has purchased 3.5 million, they are validating now with Liverpool Trop Med and St. Georges, London
Proposed release	Not given
Date	29 March 2020

Country of development	China
Type of serological test	RDT
Authors/ company	Livzon Diagnostics
Description	RDT, lateral flow assay, which detects IgM and IgG to the nucelocapside protein of SARS-CoV-2. Phase

	of development Research use only, CE/IVD approved
Proposed release	Available for purchase by research labs/health-care providers
Date	Not given

Country of development	US
Type of serological test	Not stated, seems to be ELISA
Authors/ company	Emory University
Description	Emory University has developed a serological test for Covid-19. Details of the test, such as method, target antigen, and antibody type are not listed. The Clinical Immunology section of Emory Medical Laboratories (EML) plans to begin testing 300 people per day, scaling up to 5000 tests per day by June. They state that it will take one vial of blood. Phase of development Research use only, approved under FDA Policy for Diagnostic Tests for Coronavirus Disease-2019 Section IV.A
Proposed release	April 2020
Date	13 April 2020

Country of development	US
Type of serological test	RDT
Authors/ company	Confirm Biosciences

Description	This RDT detects IgM and IgG, though the target antigen is unclear. Sensitivity appears to be 93.8%, and sensitivity is 99.1%, in 704 samples tested. The location of the trial was not disclosed. Phase of development Research use only, not approved by the FDA
Proposed release	Available for purchase by research labs/healthcare providers
Date	15 April 2020

Tests that are still in development

Country of development	US
Type of serological test	CRISPR-based lateral flow assay
Authors/ company	Broughton et al (Mammoth Biosciences)
Description	Using a CRISPR-Cas12 based method, they can specifically detect virus RNA for the E and N genes. This is called the DETECTR assay, and does not assay for patient antibodies, but the presence of viral RNA. The CRISPR-Cas12 RNA targeting is followed by isothermal amplification of the target, resulting in a visual readout with a fluorophore.This was 90% sensitive and 100% specific.
Phase of development	Pre-clinical
Proposed release	In development
Date	10 March 2020

Country of development	US
Type of serological test	Not stated
Authors/ company	CDC
Description	They are now beginning testing in specific populations, 1) people who have not been diagnosed but live in a Covid-19 hotspot, 2) a later national survey, and 3) populations like health-care workers.
Phase of development	Clinical
Proposed release	Not given
Date	4 April 2020

Country of development	US
Type of serological test	ELISA
Authors/ company	Amanat et al.
Description	An ELISA based method using recombinant receptor binding domain (RBD) regions of the spike protein or the full length spike protein. Covid-19 patient sera was most reactive to the full length spike protein, while non-Covid-19 patient sera did not react to either protein above background
Phase of development	Pre-clinical
Proposed release	Not stated

Date	18 March 2020

Country of development	US
Type of serological test	Proprietary
Authors/ company	United Biomedical (UBI)/ c19
Description	This kit is being tested in a small community in Colorado, in partnership with the Public Health Department of San Miguel County, to test all residents for a SARS-Cov-2 antibody. The assay is testing for antibodies to recombinant fragments of the S, N, and M proteins. So far, the test has 100% sensitivity and specificity after day 10 of symptoms, according to their website. This has not been approved by the FDA. They also state that "Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E"
Phase of development	In testing in San Miguel, CO
Proposed release	Ongoing trials in Colorado, no stated release

Date	19 March 2020

Country of development	Netherlands
Type of serological test	ELISA
Authors/	Okba et al

company	
Description	Modifying existing beta version ELISA kits (EUROIMMUN Medizinische Labordiagnostika AG) for IgG or IgA, and an in-house ELISA kit, they coated plates with recombinant S1 domain of the spike protein. The commercially available kits are not yet approved for use. They found that the kits were sensitive and specific for the S1 region of SARS-CoV-2, looking at 45 samples overall.
Phase of development	Pre-clinical
Proposed release	Not stated
Date	20 March 2020

Country of development	China
Type of serological test	RDT
Authors/ company	Jiangsu bioPerfectus technologies
Description	This company has two tests, the PerfectPOC Novel Corona Virus (SARS-CoV-2) IgM/IgG Rapid Test Kit and the PerfectPOC Novel Corona Virus (SARS-CoV-2) Ag Rapid Test Kit. The IgM/IgG test assays for patient antibodies to the virus from a blood sample, while the Ag Rapid test assays for SARS-CoV-2 antigen from nasal swab samples.
Phase of development	Developed, awaiting approval
Proposed release	Appears available for purchase by research labs/ healthcare providers in China, but no clear approvals
Date	3 March 2020

Country of development	China
Type of serological test	RDT
Authors/ company	Wuhan EasyDiagnosis Biomedicine Ltd
Description	The SARS-CoV-2 IgM/IgG Antibody test kit uses blood or plasma samples to detect patient antibodies. There is no listed sensitivity or specificity
Phase of development	No clear approvals
Proposed release	available for purchase by research labs/healthcare providers, but no clear CE or FDA approvals
Date	Not given

Country of development	Belgium
Type of serological test	Dipstick (lateral flow assay)
Authors/ company	Coris Bioconcept
Description	This lateral flow assay detects SARS-CoV-2 antigen in nasal mucus samples. The sensitivity was approximately 60% when tested in two different hospitals.
Phase of development	Clinically testing
Proposed release	Available for purchase by research labs/health-care providers, does not appear to have any approvals
Date	24 March 2020

Country of development	US
Type of serological test	ELISA
Authors/ company	Vitalant/UCSF
Description	It appears that Vitalant (a blood donation company) and UCSF have teamed up to make an in-house antibody test for SARS-CoV-2. It is an ELISA based assay, though they have not disclosed which antibodies are detected. Phase of development In development
Proposed release	Not given
Date	31 March 2020

Country of development	US
Type of serological test	ELISA
Authors/ company	Klein lab, JHSPH
Description	They have adapted an ELISA, based on Amanat et al 2020, that tests for IgG and IgM to the full length Spike protien and to the receptor binding domain (RBD). They are now working to get a mucosal IgA ELISA working. So far, they are using the kit to test samples from Johns Hopkins Hospital. Phase of development Pre-clinical
Proposed release	Not given, but being used for research use
Date	6 April 2020

Country of development	China
Type of serological test	ELISA
Authors/ company	Zhang et al
Description	This group developed an in-house ELISA testing for patient antibodies (IgM and IgG) to the SARSr-CoV Rp3 nucleocapside (N) protein. They found that on day 5, 81% of patients were positive for IgM and 100% were positive for IgG (of 16 Covid-19 positive patients). Phase of development Pre-clinical
Proposed release	Not given
Date	17 February 2020

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42 https://www.centerforhealthsecurity.org/resources/COVID-19/serology/Serology-based-tests-for-COVID-19.html

Appendix B: Therapeutics Currently Being Evaluated for Treatment of Covid-19

Table is taken from the website of the National Institute for Health Research:

Study name and drug(s) to be analysed	Manufacturer/ Funder/ Sponsor	Clinical trial	Approval Date	Study Description
5773 Safety and Antiviral Activity of Remdesivir for severe Covid-19 Remdesivir	Gilead Sciences	Phase 3 randomised study	25 March 2020	"Evaluate the efficacy of 2 remdesivir (RDV) regimens with respect to the normalization of temperature and oxygen saturation through Day 14 in participants with severe coronavirus disease (Covid-19)"
5774 Safety & Antiviral Activity of Remdesivir for moderate Covid-19 Remdesivir	Gilead Sciences	Phase 3 randomised study	25 March 2020	Evaluate the drug's efficacy in time to discharge in patients with moderate Covid-19 patients
A study to evaluate TCZ in patients with severe Covid-19 Pneumonia Tocilizumab (TCZ)	F. Hoffmann-La Roche Ltd	Randomised, double-blind	26 March 2020	Patients with severe Covid-19 pneumonia
Adaptive Covid-19 Treatment Trial (ACTT) Remdesivir	Sponsored by University of Minnesota (US), with funding from	Multicenter, adaptive, randomised blinded, controlled	27 March 2020	For Covid-19 treatment in hospitalised adults

Study name and drug(s) to be analysed	Manufacturer/ Funder/ Sponsor	Clinical trial	Approval Date	Study Description
	National Institutes of Health (NIH), United States	trial controlled trial		
CANCOVID Canakinumab (CANCOVID)	Novartis	Phase 3 multi-centre study	6 April 2020	Covid-19 pneumonia and cytokine release syndrome
Chloroquine prevention of coronavirus disease (Covid-19) in the healthcare setting; a randomised, placebo-controlled prophylaxis study (COPCOV) Chloroquine	N/A (CI is Professor Nicholas Day)	Randomised, placebo-controlled, prophylaxis study	30 March 2020	Prevention and in the treatment of Covid-19 infections
PRINCIPLE Platform Randomised trial of Interventions against Covid-19 In older people Hydroxychloroquine or the antibiotic Azithromycin	UKRI / NIHR funded, U of Oxford sponsored	1st clinical trial	11 March 2020	Reduce the need for people to go to hospital or speed up their recovery for older people (over 50 with comorbidities and over 65 years old
RECOVERY TRIAL Lopinavir-Ritonavir, Interferon β1b, low-dose corticosteroids	Funded by Medical Research Council, sponsored by University of Oxford	Randomised evaluation	11 March 2020	No additional treatment vs Lopinavir-Ritonavir vs Interferon β1b vs low-dose corticosteroids with respect to in-hospital death, discharge, and need for ventilation
REMAP – CAP antivirals, immune	Funded by the European	Randomised, embedded,	27 March	" generate evidence that

Study name and drug(s) to be analysed	Manufacturer/ Funder/ Sponsor	Clinical trial	Approval Date	Study Description
modulation drugs and corticosteroids + more treatments as new evidence emerges	Commission, sponsored by University Medical Centre Utrecht (Netherlands)	multifactorial, adaptive platform trial for community-acquired pneumonia	2020	can be applied during the pandemic to reduce mortality, reduce intensive care use, and reduce morbidity in severely ill patients with Covid-19 infection"
Repair of ARDS by Stromal Cell Administration (REALIST) Mesenchymal Stromal Cells (MSCs)	Funded by Wellcome Trust, sponsored by Belfast Health & Social Care Trust	Phase 1 trial followed by a randomised, double-blind, placebo-controlled phase 2 trial.	02 April 2020	"A trial of Mesenchymal stromal Cells (MSCs) for acute respiratory failure
RUXCOVID Ruxolitinib	Novartis	Phase 3 multi-center study	6 April 2020	Assess the efficacy and safety of ruxolitinib on Cytokine Release Syndrome (CRS) in patients with Covid-19
SARS-CoV-2 Infection inhaled SNG001 (IFN-β1a for nebulisation)	Synairgen Research Limited	randomised double-blind placebo-controlled trial	30 March 2020	Prevent/limit the worsening of lower respiratory tract illness
nCOV: Developing CoV-bnMABs for therapy of highly pathogenic coronaviruses including SARS-CoV-2 developing antibodies	Funded by UKRI/NIHR, sponsor N/A, CI is Professor Xiao-Ning Xu	Pre-clinical	11 March 2020	Develop potential antibody therapy
Repurposing FDA-Approved Drugs for Treatment of 2019-nCoV-	Funded by, UKRI / NIHR, sponsored by Queens	Pre-clinical	11 March 2020	Tests on cells in the laboratory to determine if

Study name and drug(s) to be analysed	Manufacturer/ Funder/ Sponsor	Clinical trial	Approval Date	Study Description
induced Disease "library of approximately 1,000 drugs already approved for use in humans"	University Belfast			any can reduce the toxic effects of novel coronavirus infection

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43 https://www.nihr.ac.uk/covid-studies/

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