TONY BLAIR INSTITUTE FOR GLOBAL CHANGE

From Science Fiction to Science and Fact: A Realistic Route to Mass Testing

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Contents

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MASS TESTING
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Foreword by Tony Blair

Although the government has increased significantly the amount of testing and although, per capita, the UK does a relatively high number of tests as a country, we do not have the testing capacity we require. As a consequence, we now face difficult choices as the virus starts to rise again, which it was always likely to do. There is still – but only just – enough time to alter strategy, and it is essential that the government at least debate such a change in strategy urgently. Mass testing is the vital component.

At present, as people have returned to more normal activity, the case numbers have risen and the demand for tests has risen. So, for example, as schools have gone back, if a pupil shows any potential symptoms, the pupil and possibly the entire class plus their families are then in quarantine. They all want tests but often can't access them or are asked to travel unacceptable distances to get them. We have rightly prioritised care homes, but with the limits on capacity, they now take up a large percentage of available testing capability.

The government has a clear choice: It either uses all the available capacity including some of the rapid antigen tests being used routinely by many parts of business already in order that we ramp up that capability, or we face a situation where as case numbers rise we simply can't keep up.

This can happen sooner rather than later. We don't have to wait for technology that doesn't exist yet or put up with maxed-out capacity in our test and trace system. What this paper from my Institute shows is that a debate needs to be had on the objective of testing and how this impacts the accuracy requirements for the new tests we can bring online. At its simplest, we argue that tests should be validated based on their ability to identify if someone is infectious rather than if someone simply has the virus. This new development is critical to bringing onboard a series of new, rapid antigen tests that are available now. We accept these are less accurate than the lab-based tests that are being used across the country but they are good enough for mass testing. Don't let the best be the enemy of the good.

When this crucial distinction between the role of tests is made, it unlocks a tranche of new, rapid tests that can be brought online now. These would boost existing capacity and could be rolled out across care homes, universities, schools, airports and large employers. Testing the entire country every day is a vast distance away, but a phased approach, starting with this regular testing across key sectors, is within our grasp. We must act decisively, and we must act now.

Many have and will continue to raise concerns about false positives and false negatives. The truth is, any current asymptomatic carrier is effectively a false negative. And as the virus spreads and we all become subjected to greater restrictions, we risk all of us living the life of a false positive. However, this paper does propose a novel idea for the specific issue of false positives – those who test positive but don't have the virus – by calling for a follow-up test: Anyone who tests positive with a new, rapid test would qualify for a lab-based test. If their positive result is confirmed, they would isolate, commit themselves to track

and trace, and receive economic support during this period. Test negative and they don't need to quarantine. Over time, regular testing would see quarantine reduced from a blanket and destructive 14 days to the time between a positive result and a subsequent negative result.

Covid-19 is going to be around for some time. The game-changers remain out of sight, and we must choose between greater restrictions or a serious, strategic investment in our testing regime.

It's a stark choice but it is a clear one. It requires action to be taken now.

Tony Blair
Executive Chairman

Introduction

Both the prime minister and health secretary have been clear in committing to a strategy of mass testing. This so-called moonshot should be welcomed in ambition, but even the most ardent supporter of the government will have lost faith in its ability to deliver it. The idea has, in the government's hands, become confusing. To have an at-home daily test is not feasible yet because the technology hasn't advanced that far. We should incentivise its acceleration, but the moonshot is presently beyond reach.

This does not mean that mass testing can't be phased in starting now. Clearsighted leadership and the utilisation of innovative rapid tests will allow us to build a mass-testing regime.

We must also immediately address the short-term issues that are plaguing our current testing regime. Demand has far outstripped supply and undermined public confidence in testing. To fix it requires political will and decisions to be made now. All is not lost, but we are at a pivotal moment for the future of testing in this country.

In this paper, we set out a series of short-term measures to boost testing capacity and a set of medium-term actions to be pursued in parallel. Together, these will restore the public's confidence in testing and present a realistic route to mass testing, which remains the only way back to some level of normality.

Towards Mass Testing

Boris Johnson stated on Wednesday 9 September that: "A world we want to move to as fast as possible is a world where everyone can take enabling tests at the beginning of the day, an antigen test to identify whether or not we have the virus."

Since the government announced "Operation Moonshot" several questions have been raised about the feasibility of such an approach. This report seeks to address those, in particular:

1. **How do we scale lab-based capacity?**
2. **What rapid, on-the-spot tests can we use?**
3. **What test should be used when?**
4. **How do we roll out mass testing?**
5. **What happens when someone tests negative or positive?**
6. **How do we deal with false negatives and false positives?**

We believe lab-based testing can be quickly scaled by around a further 300,000 tests per day and that there are viable rapid tests available now, as well as a large number of potentially viable tests in development that could be brought on stream with government support.

While these rapid tests are potentially less accurate than PCR lab testing, this does not mean they are less suitable for the type of testing we recommend they are deployed for. Here, the objective of the test is very important. In mass testing, the objective of a test is to quickly identify and isolate *infectious* carriers of the virus rather than to identify the presence of the virus. This is a question of viral load: The higher the viral load, the more likely a person is to be infectious. This is important when it comes to validating tests. Many rapid tests are less sensitive than PCR tests and may not confirm the presence of low viral loads, but they can identify higher viral loads and are therefore perfectly suited to understanding if a person is infectious.

The test itself is only one aspect of a mass-testing regime. Where someone is identified as being infectious, they must self-isolate. This requires tests results to be delivered quickly – ideally within hours – and to be clearly communicated, including a dedicated results helpline. One of the major barriers to self-isolating is loss of earnings, and the government should mitigate this by providing financial support to those who test positive. Testing must also offer a way out of quarantine. When someone tests negative after isolating following, say, a child in their class testing positive or having been identified through contact tracing, they would no longer need to self-isolate.

By fully drawing on all potential lab capacity for swab tests, bringing on stream viable rapid tests and fully supporting the development of potential rapid tests, we believe the government could put in place a mass-testing regime starting now. In the US the Food & Drug Administration (FDA) has granted Emergency Use Authorisations to firms with capacity to produce tens of millions of rapid antigen tests per month.

We propose that mass testing be phased by sectors and priority areas; this would ramp up over time and, when the technology is available at the scale required, it would eventually result in the population-wide testing the prime minister has called for.

It is our route to putting in place a viable mass-testing regime.

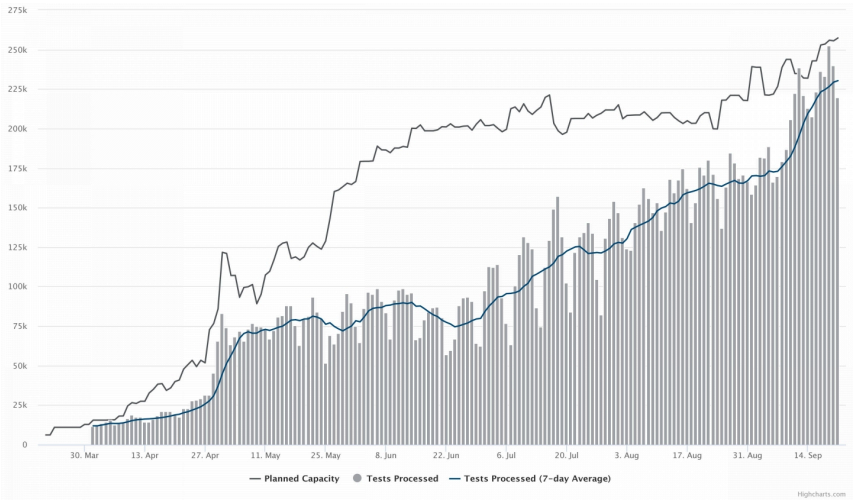
The State of Play on Testing

On 19 August, Matt Hancock said: "This is a really important drive we have across government, to bring in mass testing, population-wide testing … We will ramp it up, certainly over the remainder of this year."

The most recent data by the government indicates that on 15 September, 221,192 tests were completed, and that 3,991 people were confirmed positive through testing on Wednesday 16 September.

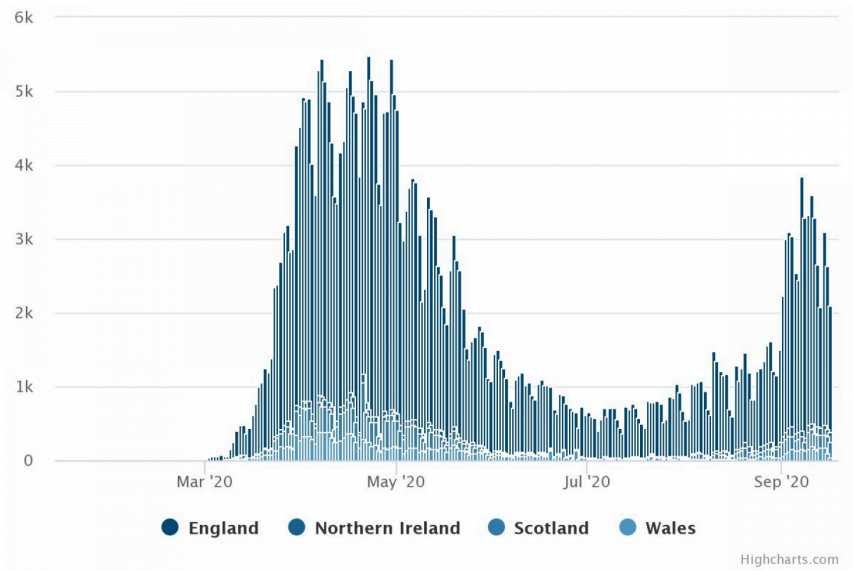
This huge differential could be eased by broader use of rapid testing, leaving core lab tests for priority cases.

Figure 1 – Testing and capacity for UK pillars 1 and 2 (PCR swab testing)



Source: https://coronavirus.data.gov.uk/testing

Figure 2 – Cases by specimen date, by nation



Source: https://coronavirus.data.gov.uk/testing

Operation Moonshot

To implement a strategy of mass testing, the government has put in place Operation Moonshot. The plan was revealed recently by the BMJ. [1]

It sets out how the government will move from the current testing capacity of around 300,000 tests per day to 10 million per day in early 2021. This would involve a £100 billion expansion of funding for testing.

The plan involves a three-stage rollout.

The UK will move from 200,000 to 800,000 tests per day by the end of the year.

From December it is proposed testing capacity then be increased to 2 to 4 million tests per day, with mass testing for whole local areas or cities with high prevalence of the virus, key workers such as teachers, and those needing to access high-risk environments like hospitals and care homes.

A separate document prepared for government by the Boston Consulting Group set out how the UK can expand capacity to 10 million tests per day by early next year. [2]

The Way Forward

Since the emergence of these documents about Operation Moonshot, a number of concerns have been raised about how feasible it is. In addition to this, a recent crisis with huge pressure on the existing testing capacity has added further doubts about how the government can dramatically increase this capability.

The key questions, which we centre the report around, are:

1. How to scale lab testing to meet the recent surge in demand
2. What rapid tests we should bring online now
3. How we roll out mass testing
4. The actions that should be taken by individuals depending on their test results

Without clearly addressing these points, the government will not be able to fully emerge from the current testing crisis or put in place the mass-testing regime it seeks.

This document sets out a path forward for the government on each of these areas.

How Do We Scale Lab-Based Capacity?

Short-term: A Shot in the Arm to Meet the Surge in Testing Demand

From conversations with well-placed sources we believe lab testing can be expanded, potentially by around 300,000 tests per day within the next few weeks. This would take lab-testing capacity to almost 700,000 tests per day.

To increase testing by this amount, decisions would need to be taken quickly by government. We understand the government has continued to miss critical opportunities to take up offers to expand lab capacity, for instance orders of essential supplies needed to test, such as pipettes.

Many of these decisions and opportunities are not visible in the public domain but are known to those involved in the testing programme.

There is a finite amount of materials and machines currently available to purchase, and when the UK misses opportunities to obtain these essential supplies, our ability to ramp up testing capacity is hindered for the short- to medium-term.

Decisions, including purchasing decisions, such as these are vital, both to expand testing capacity in terms of the available machines but also to ensure we have the test kits available to make use of that capacity.

We recommend the government addresses the immediate testing crisis by:

1. Adopting greater levels of automation and uniformity across the Lighthouse Lab network [3]

The large central Lighthouse Labs set-up by government to boost testing capacity have served an important purpose but recent reports show there are significant efficiency gains to be made. [4] These include adopting a uniform tube for the collection and processing of samples and applying greater automation wherever possible. It's critical that time-consuming manual processes are automated where possible.

2. Using the "little ships" network of labs.

There is a robust network of independent labs across the UK which can process small to medium volumes of tests. Combined, these labs would add substantial test volumes to existing Lighthouse Lab capacity. Described as the "little ships" of the testing response by Sir Paul Nurse, many of these laboratories have already organised and co-ordinated themselves through the Covid Testing Network. [5] The government should take advantage of this and work with a central point of contact to onboard as many of these

laboratories as possible in the next week – this is a realistic timeframe as these labs are already certified. This approach has been shown to work from the start in Germany.

In bringing this extra capacity on stream, we need to be careful to ensure the right central oversight, particularly in terms of collecting results. This could be done, for instance, through cloud infrastructure to capture test outcomes. While the logistics of drawing on "little ships" may be more complex than the Lighthouse Labs, we believe they do offer important extra capacity.

3. Securing emergency testing capacity by using overseas suppliers.

We must retain public confidence in the UK testing system if mass testing is ever to become a reality, and this means getting qualifying patients a test now. Ultimately, citizens won't care where their test comes from, so long as it is effective and the results are delivered quickly. Given the current 4:1 ratio in demand versus supply, extra capacity should be procured from abroad. A solution exists whereby UK offices of US-based diagnostics companies can collect samples, transport them to a Washington, DC–based laboratory and receive results relatively quickly. We have spoken to one large testing provider who can deliver an extra 70,000 tests a day *now*, with results returned in less than 30 hours, at a cost of $100 to $150 (about double the total cost of a UK-based test accounting for overheads). This should be a last resort for government, and clear performance metrics – particularly in turnaround time of results and a cost of test *per person* rather than per test – should be built in to any contract. This approach obviously has issues in terms of efficiency, but given the situation we find ourselves in, this extra capacity should be seriously considered.

4. Introducing pooling to increase current PCR testing capacity by four times.

Pooling samples involves mixing several samples together in a "batch", or pooled sample, then testing this new, pooled sample. If a pooled test result is negative, then all specimens can be presumed negative with a single test. If the test result is positive or indeterminate, then all the specimens in the pool need to be retested individually. The advantages of this two-stage specimen pooling strategy include preserving testing reagents and resources, reducing the amount of time and labour required to test large numbers of specimens, and lowering the overall cost of testing.

The most common pooling strategy involves two rounds of testing, where each sample of a positive pool is retested individually. This method is most efficient if prevalence is ≤1 per cent according to researchers and was used effectively in Wuhan with up to five samples per pool. [6]

More countries are beginning to use pooling. In the US, the Centres for Disease Control and Prevention and the FDA have provided guidelines for use of specimen pooling strategy to expand testing capacity. [7] In July 2020, Hong Kong conducted tests on every single worker in every single restaurant in the country. In total, the project involves testing 200,000 workers across 16,000 restaurants, with four saliva samples being combined for PCR testing.

We recommend that samples from areas of low Covid-19 prevalence are pooled and tested as single samples, providing an immediate boost to Lighthouse Lab capacity.

5. Utilising end-point PCR testing.

A further opportunity to scale lab testing is through end-point PCR testing. These machines do not provide quantitative information but give a plus/minus result on whether someone has the virus. They are highly accurate and have been used by the agriculture sector to do as many 150,000 seed PCR tests per day.

Medium-term: Saliva and Testing Trucks

The University of Illinois has introduced twice-weekly testing for all students and staff across its three campuses. In a project codenamed "Shield Campus", the testing programme has seen more than 300,000 tests conducted in the four weeks to 11 September. This is roughly 2 per cent of all tests in the US.

The programme uses RT-PCR saliva-based tests which are conducted in a lab. The turnaround time from sample to result is usually between six to eight hours and a rapid action team interacts with individuals once a confirmed positive result is obtained. The university's data show how critical this is as delays in contact tracing have obvious consequences for its hyper-mobile and social student population. Campus positivity is currently below 0.31 per cent and outbreaks – associated with unofficial parties – have already been identified and squashed. All students and staff are regularly tested, with frequency for each group determined by modelling that determines risk. Some students are tested three times a week while faculty and staff are tested once weekly given their respective measured risk.

We believe the UK has a lot to learn from the University of Illinois.

Learning From the University of Illinois: Introducing Mobile Testing Trucks to the UK

Given the success of the university's testing programme, there has been demand from other institutions and sectors looking to bring in mass testing. This has led to the creation of mobile labs which are repurposed, 50-foot trailers capable of conducting 10,000 tests per day. The trucks carry equipment that allows RT-PCR testing and robotic handling of samples to take place, as well as technology for the uploading and communication of results. The trucks could also easily deploy LamPORE testing equipment. These mobile testing trucks allow flexibility in testing locations and would reduce the UK's reliance on the Lighthouse Labs, which are the large centralised testing facilities. Given the tests use a saliva-based sample, the sample collection sites can be placed anywhere because they transport well. This would open up regular testing to many parts of the UK.

The lessons from the University of Illinois are clear. The equipment is readily available, and the UK is in a privileged position with its car manufacturing industry to build these mobile testing trucks now. They would complement existing lab capacity and bring in additional advantages: While further work is needed to normalise them as a platform, saliva-based tests should be much easier to collect and transport and have high degrees of accuracy. Automation means they do not require specialists to run them and the operation could be overseen by the army.

We recommend that the government partners with British-based car assembly plants and brings a significant number of mobile trucks online in the next month. With each truck adding capacity of 10,000 tests per day, they should be deployed to high-risk areas, universities, schools and care homes in the first instance. Over time, a network of mobile testing labs could potentially service the entire country.

Bringing Saliva-Based Tests to the UK

We recommend that the government work with a saliva-based-testing provider and contract for substantial test volumes, providing a dedicated team to help on sourcing and regulatory approval.

Saliva-based testing is key component of any testing regime and is missing in the UK. The tests are suited to vulnerable adults – such as those in care homes – and children who may not be comfortable with a deep nasal swab. If the government effectively engages with these providers now, it is within the realms of possibility that a UK lab could be set up within six weeks and deliver somewhere between 50,000 to 100,000 tests a day.

> ### Case Study: Curative
>
> Curative is at the forefront of coronavirus detection and offers a saliva-based Covid-19 test. The authors of this paper first interacted with the company when it effectively started up in early March and was looking to support the UK government in building its testing capacity. Having delivered 4 million tests in the USA since then, and with a capacity of more than 1 million tests per week, it is now one of the largest testing providers in the US, with its third lab in Austin, Texas, now online. Curative still doesn't provide tests in the UK, but a willingness remains.
>
> Curative supplies tests to more than 15 US states including California, Delaware, Florida, Louisiana, Alaska, Georgia, Illinois and Texas, as well as to the United States Air Force. It is accustomed to mass testing – including the Texan prison system and the Florida care homes testing programme, where more than 200,000 staff at 3,804 care homes across the state are tested on a rolling two-week basis.

What Rapid, On-the-Spot Tests Can We Use?

There are a large number of rapid antigen and antibody tests available. According to the website FindDX, which the European Centre for Disease Prevention and Control refers to, there are 223 tests of this kind that have been commercialised so far.

We are also aware of a wide number of tests in development which, with government support, could be brought on stream quickly.

Rapid Antigen Tests

According to FindDX, 28 rapid antigen tests have been commercialised (four are currently designated as research-use only). [8]

Abbott recently received FDA Emergency Use Authorisation for a new rapid antigen test called BinaxNOW. The test delivers a result within 15 minutes and requires no instrumentation. The manufacturers say it has a sensitivity of 97.1 per cent and specificity of 98.5 per cent. Abbott says it will ship tens of millions of tests in September, ramping up to 50 million per month at the beginning of October. [9]

BD (Becton, Dickinson and Company), a medical technology company, recently announced that the FDA had granted an Emergency Use Authorisation (EUA) for its rapid point-of-care antigen SARS-CoV-2 diagnostic test. The test delivers a result in 15 minutes and is easy to use and portable. Clinical studies performed at more than 20 sites across the US demonstrated that the test is capable of achieving 84 per cent sensitivity and 100 per cent specificity. [10]

Quidel, the maker of another rapid antigen test approved in the US, says its test has demonstrated a clinical sensitivity of 80 per cent and specificity of 100 per cent when compared with an EUA molecular device. [11] The test delivers a result in 15 to 30 minutes and uses a nasopharyngeal swab. [12]

In late August the FDA provided a further EUA to LumiraDx Ltd for its rapid antigen test. The test combines a single-use immunoassay device with an instrument that provides a result within 12 minutes. The firm say it is low cost and highly scalable. The company says the test has a sensitivity of 98 per cent and a specificity of 97 per cent. [13]

A list setting out the potential capacity of a selection of rapid antigen tests is attached in Annex B.

Rapid Antibody Tests

FindDX then lists 195 commercialised rapid antibody tests. [14] The government has queried the accuracy of these tests. From our conversations with experts and testing suppliers, we believe a range of these tests, including a number made within the UK, are accurate enough for population-level testing. A range of those under development in the UK are included below in the section "Emerging Tests".

LAMP Testing

Progress has also been made on developing LAMP (loop-mediated isothermal amplification) tests. These tests work by turning plate readers – the instruments that form the backbone of every molecular biology lab in the UK – into diagnostic tools.

In May, the government announced a trial in Hampshire using a point-of-care reader by OptiGene. Despite it being reported as a rapid antigen test, the recent trial is actually for a LAMP test. [15] The test has also been misreported as giving a 20-minute result. A high viral load could return a positive result within 20 minutes, but the entire process requires a full LAMP reaction – which takes about an hour – to confirm negatives. The trial has been considered successful in clinical settings and it is now being used in some A&E departments, GP testing hubs and care homes.

The UK government has also announced it will be deploying Oxford Nanopore's LamPORE assay, which uses LAMP to amplify viral nucleic acids. The test uses a palm-sized device to identify Covid-19 sequences by running amplified DNA through a protein nanopore. The government has placed an initial order of 450,000 tests. Each GridION machine is capable of processing up to 20,000 samples a day.

UAE-based Group 42 (G42), an AI and cloud-computing company, announced in June that it was working on a "population-scale technology" using an end-to-end solution to rapidly and accurately detect Covid-19. G42 has been working in partnership with Oxford Nanopore to develop an "ultra-high parallel processing capacity … this innovation uses the LamPORE assay, which is based on the LAMP technique and Oxford Nanopore's rapid sequencing platform, in combination with the high-throughput automation, sample processing and reporting workflows developed by G42." [16]

Hibergene Diagnostics recently announced that its new fast molecular Covid-19 test had received CE marking from the EU. This followed a clinical evaluation at a private hospital in Dublin. The project received a grant of €930,000 from Horizon 2020, the EU programme for research and innovation. The test uses a simple sample preparation protocol and has performed well with high to moderate viral

loads. The portable LAMP PCR test can deliver positive results within 30 minutes on average, and negative results within 60 minutes.

Testing based on LAMP – while not uncomplicated to scale – and other molecular platforms have the capacity to also unlock hundreds of thousands of tests per day. The key to unlocking this capacity is expediting regulatory approval for a wider range of testing technologies, particularly those that draw on different reagent and equipment supply chains.

CRISPR Testing

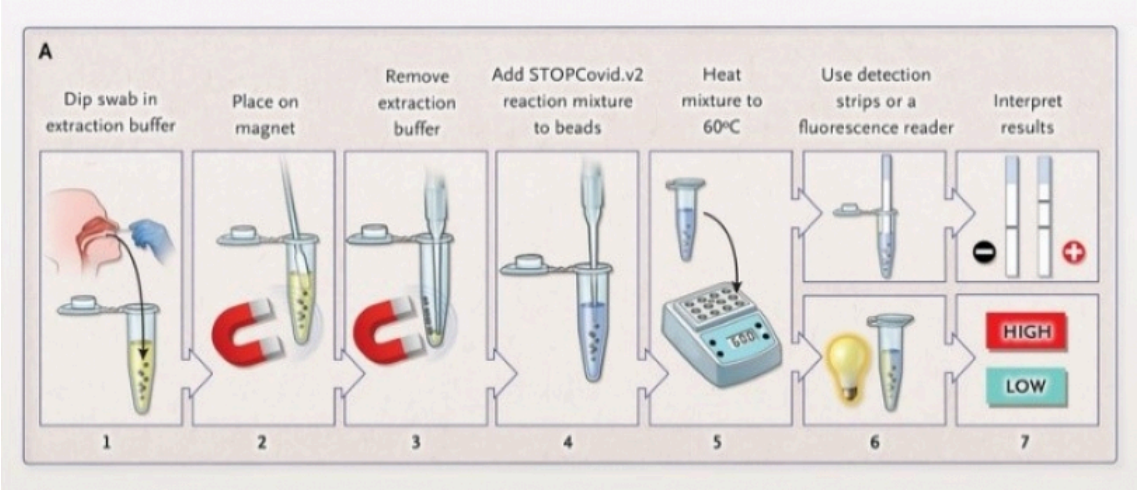
Clustered Regularly Interspaced Palindromic Repeats (CRISPR) is an established biotechnological tool for gene editing. It works by being programmed to detect specific sequences of DNA within a gene of interest and subsequently 'snipping' it. No genes need to be edited but the first part of the process – the identification of the sequence – lends itself to identifying Covid-19. By being programmed to detect specific sequences of DNA that uniquely exist in the SARS-CoV-2 virus, the tool can diagnose Covid-19 – and quickly. There are already promising kits on the market that can return results in less than 20 minutes and which can be scaled rapidly. These use labs but the technology lends itself to rapid, on-the-spot devices.

TataMD SARS-CoV-2 CRISPR Test v1.0

Tata Medical & Diagnostics (TataMD) has developed a lab-based CRISPR test that uses an oral or nasal swab. It was approved on 19 September for use in India [17]. The test has 96 per cent sensitivity and 98 per cent specificity, has a processing time 30 to 90 minutes faster than typical RT-PCR reactions and does not involve expensive qRT-PCR equipment. The result readout is on a lateral flow strip, which also aids ease of use and quick turnaround. A second saliva-based version of this test is also being developed in partnership with the University of Illinois and will be usable at the point of care and easier to scale.

Our Tata CRISPR test – and India's first CRISPR Covid-19 test – has been approved today for use in India.

SHERLOCK One-Pot Testing [18]



The sensitivity of this test is similar to RT-PCR. STOP (SHERLOCK testing in one pot) is a streamlined assay that combines simplified extraction of viral RNA with isothermal amplification and CRISPR-mediated detection. This test can be performed at a single temperature in less than an hour and with minimal equipment. It has been granted emergency approval by the FDA.

In blinded testing at an external laboratory at the University of Washington, the test was applied to 202 Covid-positive and 200 Covid-negative samples obtained from patients. This testing showed a sensitivity of 93.1 per cent and a specificity of 98.5 per cent. All of the false negative samples were on viral loads unlikely to be deemed infectious, while positive samples were detected in just 15 to 45 minutes.

How Much Do These Tests Cost?

It is not possible to accurately state the cost of tests as economies of scale will drive prices down significantly. Compared to the gold-standard RT-PCR test, innovative rapid tests will remove expensive laboratories and transportation of samples. It's estimated that the current lab-based tests range in price from £25 to £40 per test. Where they are bought on scale, for instance by Lighthouse Labs, they can be cheaper, around £10 per test.

A number of manufacturers have pitched their rapid tests substantially lower (Abbott's ID Now costs $5 for a test once the machine has been purchased, and a recent rapid saliva-based test created by Yale costs $10 per test. [19])

Ultimately, through a concerted effort and by cultivating an ecosystem of testing suppliers, we're confident the government could procure rapid lateral flow tests for as low as £10 a test in the medium-term and £1 in the long-term. Crucially, the cost to the taxpayer will be far outweighed by the benefits of reopening the economy.

How Are Businesses Using Testing at the Moment?

Editor's Note: To understand how businesses are currently using testing, we spoke with Dr Mark Simpson FFOM, chief medical officer at Health Management Limited. Health Management has contributed to a previous paper we wrote on testing and, as a specialist in this area, has contributed the following section.

The uptake of testing by businesses remains inconsistent and has also been affected by the wider recent challenges facing the NHS Test and Trace programme due to laboratory capacity.

Tests in use by employers are:

- PCR swab tests. These can be taken by a clinician/technician, or done as home kits, before being sent for laboratory analysis.
- Antibody/serological tests. Currently the only commercially available approved antibody tests require a venous blood sample.
- We are also seeing uptake for single-use cassette antibody tests, with a variety of providers now promoting these commercially.

Lab-based PCR swabs are dependent on laboratory processing and results, and in the week commencing 14 September turnaround times were severely impacted by the national capacity issues. The issues with Test and Trace have also pushed up demand from employers in recent weeks.

It is important that occupational-health providers avoid providing unreliable or inaccurate tests. All tests offered must be either CE marked or approved by the Medicines and Healthcare products Regulatory Agency (MHRA). All tests must take place with full medical support, with a physician advising the individual around any positive results. Testing is conducted by a major accredited laboratory, and all positive tests are fed back into Track and Trace.

One major difference between employer-led testing and standard NHS testing is that the consent is in place for the results to be shared with the employer as well as the employee. This allows employers to take proactive steps both to maintain business activities and to prevent further transmission.

Generally, employers are using tests to support business continuity and planning, and to maintain specific business activities in five ways:

- **To avoid shutting down facilities and production lines.** Particularly in the manufacturing sector, food, consumer goods, clothing and industrial manufacturers have used PCR tests for workforces when one person has had symptoms but might not have been able to access a government test. This is beneficial for business continuity and maintaining operations. A number of large manufacturers have also bought tests for use in factories in the event that their local area goes into lockdown. Here, a one-off test is administered to a defined population.

- **To support with planning activities or events with higher risk of transmission.** The aim here is to enable critical business activities to continue through targeted repeat PCR swab testing, particularly where social distancing cannot be guaranteed by the intrinsic nature of operations. For example, broadcasters are using weekly PCR testing for production crew and technicians who are mobile across on-site shooting sets, and thus coming into close proximity with many people. Major fashion brands were also using PCR tests before and during London Fashion Week to mitigate risk of transmission and ensure key commercial activities can continue. These are provided as regular testing for a defined population.
- **To facilitate travel for internationally mobile populations.** Testing is provided to employees on international deployments who need to provide proof of negative testing 48 or 72 hours ahead of departure. For example, we are supporting a major contractor who has staff travelling regularly to South Korea, where they must show two negative tests 48 hours apart ahead of travel. These are provided as one-off tests for specific individuals.
- **Antibody testing to support PCR testing.** Where employers are running larger scale antigen testing (eg, to avoid shutting down operations), some are also offering antibody testing so that they can avoid regular PCR testing for a three-month period.
- **Antibody testing provided as an employee benefit.** Some employers, particularly in financial and legal services, are providing voluntary antibody tests to individuals to enable them to find out whether they have had coronavirus earlier in the year.

In recent months there has been increased interest in antigen testing. However, to date, we haven't seen any evidence of mass antigen testing by employers to manage core business activities. This is primarily because only lab-based swab tests are currently available. The key game-changer in the way employers will use testing will be the commercial availability of simple self-sampling (nasal or oral swabs) and rapid turnaround of results using alternative test modalities to PCR.

Widespread availability of instant-result antibody tests (eg, the AbC lateral flow test) may also enable employers to monitor whole-workforce immunity status over time.

Process:

Occupational-health providers have technology systems in place which support health surveillance activity and these have been repurposed to provide employer oversight of Covid-19 testing results (antigen and antibody). Typically, employers will provide employee data; home kits and/or on-site testers are sent out; the tests are sent to the laboratories, and results are returned. With the individual's consent, results are shared with the employer as well as the individual, allowing informed operational deployment decisions. The government has been made aware that this technology, systems and clinical workforce is available to support employers at greater scale.

What Tests Should Be Used for What Purpose?

As we move towards mass testing, the right tests must be deployed for the right purpose. A test's functionality is a key factor when deciding how to deploy it.

- **Lab-based tests**
  Slower but more accurate
  Used for those who are interacting with the public, such as NHS and key workers, and in situations where risk is high and there's likely to be more positive cases, such as outbreak areas and care homes.
- **Rapid tests**
  Faster but less accurate
  Used to test large groups on a regular basis, such as at universities.

As set out above, saliva-based mobile testing trucks should be deployed to outbreak areas and priority sectors including care homes, universities and schools. They bridge the gap between the two groups of tests above, as they use lab-based tests but can turn around results relatively quickly as samples are collected local to the lab.

The Accuracy of Rapid Tests

Aside from availability, a key question on how mass testing can be rolled out centres on the accuracy of rapid tests. There are three main criticisms levelled in this regard:

1. Detecting viral load: Rapid tests don't always register very light viral loads.
2. Early testing – at a pre-symptomatic stage – could miss the presence of the virus.
3. Positive predictive rates: In a situation where an entire population is being tested but prevalence of the virus is low, there will be more false positives than real ones.

As we set out below, these issues are mitigated by being clear on the role of rapid tests to detect infectiousness (and not simply viral load), by using follow-up tests, and by conducting regular testing. This is all possible and affordable if the government changes its approach to rapid tests.

Taking Risks

The government has failed to make a consistent calculus of risk in its Covid-19 response. In some areas, like Eat Out To Help Out, the government is willing to run risks, but in others, like testing, it is not. This has left countless potential tests and testing suppliers on the shelves, despite the fact these tests can play a role now.

A Note on Sensitivity and Specificity

- **Sensitivity** refers to how good a test is at detecting the thing it is meant to detect. The higher the sensitivity, the more likely a test will identify Covid-19 and give fewer false negatives.
- **Specificity** measures how good a test is at identifying the correct virus, without being triggered by other similar ones. Low specificity means tests could mistake another virus for Covid-19 and give a false positive. The higher the specificity, the more likely it will only identify Covid-19 and give fewer false positives.

In the case of rapid antigen tests, which will likely form the backbone of the mass-testing regime, they are generally highly specific, but less sensitive than lab-based tests. For the purposes of population-wide mass testing however, this is not a problem. Lower sensitivity means they will still be detecting those with high viral loads and who are infectious.

Mass testing requires tests to detect those who are infectious NOT those who have the virus.

Mass testing requires tests that identify if someone is infectious – not merely if the virus is present. These may seem like one and the same, but the difference is very important. Understanding this distinction will have profound implications on the speed at which the UK can establish the mass-testing regime it urgently needs.

A developing literature is emerging on the infectiousness of Covid-19, particularly looking at how this relates to viral load (the total amount of the virus a person has inside them). While there are, as yet, no definitive answers on this, there are clear trends emerging around the likely levels of viral load that will mean someone is infectious or not. [20]

Rapid, on-the-spot tests to confirm if a person is infectious are cheaper and easier to administer than those that detect the presence of the virus. They have lower accuracy requirements and their bar for approval – set against the "gold standard" tests to determine if a person has any trace whatsoever of the virus – should therefore be much lower. Put simply, we require a rapid test capable of detecting a higher amount of the virus. This is much more feasible than a rapid test which detects lower viral loads.

While RT-PCR tests can detect viral loads that are so low the person isn't infectious, rapid tests provide a cruder "yes" or "no" on whether someone has a high viral load and is therefore infectious. The government should draw this distinction between the purposes of tests and fast-track the approval of tests that determine if an individual can infect another.

By testing people regularly, we would also avoid the problem of identifying a person with a low viral load but being unsure as to whether their infection is on the way up or on the way down; patients would be able to ascertain their lack of infectiousness (or low/zero viral load) with their next tests.

Given rapid antigen tests are cheaper and easier to use, we would recommend phasing in the use of regular, on-the-spot rapid tests to a defined group. Used in this way we believe the issue of accuracy is resolved.

This was a point made clearly by Sir John Bell on the BBC on 15 September. He explained that for different purposes different tests are viable. In this regard, quicker tests with faster processing times are best for use in schools, at work or for those attending football matches. While these tests may be less sensitive, they will catch people with a high viral load and are therefore infectious. [21]

Regular testing with quick turnaround of results is key:

Critically, where these rapid tests are used frequently, with fast reporting of results, the impact of sensitivity is only marginal.

The paper "Test Sensitivity Is Secondary to Frequency and Turnaround Time for COVID-19 Surveillance" [22], written by Harvard, the University of Colorado and the Howard Hughes Medical Institute, looked at the importance of testing being done quickly, with results turned around at speed. It sets out the following on this point:

"Because SARS-CoV-2 can spread from individuals with pre-symptomatic, symptomatic, and asymptomatic infections, the re-opening of societies and the control of virus spread will be facilitated by robust surveillance, for which virus testing will often be central. After infection, individuals undergo a period of incubation during which viral titers are usually too low to detect, followed by an exponential viral growth, leading to a peak viral load and infectiousness, and ending with declining viral levels and clearance. Given the pattern of viral load kinetics, we model surveillance effectiveness considering test sensitivities, frequency, and sample-to-answer reporting time. These results demonstrate that effective surveillance depends largely on frequency of testing and the speed of reporting, and is only marginally improved by high test sensitivity. We therefore conclude that surveillance should prioritize accessibility, frequency, and sample-to-answer time; analytical limits of detection should be secondary**."** [23]

We recommend that the government onboards rapid tests with lower sensitivity than RT-PCR tests and works with industry and science to define an accuracy standard that, on the balance of risk, will identify those who are carrying an infectious level of viral load. This should be built into a US-style Emergency Use Authorisation that enables rapid tests to be more readily brought online. This requires a new framework for validation.

A Framework for Validating Rapid Tests

Given what we have set out regarding the UK's precise testing need, we can evaluate what tests are most appropriate for what purpose.

For specific purposes, like testing in care settings, we will continue to need gold-standard lab-based tests, but we should adapt to use saliva samples and begin to introduce mobile labs.

For wider purposes, such as population-level testing, such a high level of accuracy is not needed. This has been set out above. Less sensitive tests are capable of detecting higher viral loads, where the person is infectious. This is the critical role required of them for large-scale testing.

In light of these facts, we call on the government to put in place a fully transparent validation process for rapid tests intended for mass testing. This should include the benchmark these tests need to meet to be effective at detecting infectious cases, as opposed to anyone with the virus. A variety of studies, included in this paper, have set out the best evidence on the viral-load threshold for being infectious. We note that this is not exact, and data will be emerging for many years, but to get moving we believe this body of evidence is sufficient.

This information should be made clear to companies and the public, with collective buy-in. On the basis of this information, as many rapid tests as possible should be brought on stream using an expedited process – similar to the FDA's Emergency Use Authorisation – to get them into use.

By operating in such a way, the government can escape the trap it has been stuck in so far by setting requirements for rapid tests needed for clinical purposes and making the best the enemy of good enough.

Through these changes we believe a large number of viable tests can be brought on stream for population-level testing.

How Do We Deliver Mass Testing?

While we fully support the government's plan to put in place a strategy of mass testing, we believe they have miscommunicated their plan.

Rather than focus too much on the end goal of testing X million people per day, we believe it needs to set out a staged, structured and achievable path to increasing testing capacity from the current level and to bringing on stream more tests.

We set out such a plan below.

A Phased Approach

Rather than go straight for the moon, a phased approach to mass testing should be clearly set out. This would restore confidence in the concept and better make sense of available testing capacity. Over time, we'd see a transition from limited, regular testing amongst key sectors using primarily lab-based testing, to mass population testing that uses new innovative rapid tests. This end state – the moonshot – should not be dismissed as impossible, but it does require steps to be taken now.

We have set out a phased approach to mass testing (see Figure 3, below).

Figure 3 – A phased approach to mass testing

Phase	Timing	Objective	Who	How
Current	**September**	1) Restore capacity and confidence in existing testing system by increasing number of tests available and speeding up time from booking test to receiving results	• Anyone with symptoms • Key workers	Lab-based test
Phase One	**October**	1) Identify and isolate asymptomatic carriers in key sectors 2) Increase public understanding of and confidence in mass testing through piloting regular testing	• Key workers • Care homes • Universities	• Lab-based tests • Mobile labs

Phase	Timing	Objective	Who	How
			• Schools	
Phase Two	**November-December**	1) Identify and isolate asymptomatic carriers in key sectors 2) Restore confidence in economically hit sectors	• Key workers • Care homes • Universities • Travel • Employers	*In order of quantity:* • Lab-based tests • Rapid tests • Mobile labs
Phase Three	**January-February**	1) Introduce random testing of population ahead of move towards mass testing 2) Introduce health passport to open up hospitality and large gatherings	• Random samples • Health passport volunteers	*In order of quantity:* • Rapid tests • Lab-based tests • Mobile labs
Phase Four	**March onwards**	1) Launch population-wide regular testing linked into health passport	Every citizen over age of 10	*In order of quantity:* • Rapid tests • Lab-based tests • Mobile labs

This phased approach allows us to do more than just talk about mass testing – it allows us to operate in a sensible, practical way. No more false promises, just smart plans.

A key element in rolling out this approach is ensuring those who test positive are able to take appropriate action as a result. Most vital in this regard is putting in place economic support for those needing to isolate for 14 days.

What Happens When Someone Tests Negative or Positive?

What Happens When Someone Tests Positive?

In mass testing, two main types of test would be used – lab-based tests and rapid tests.

Where someone tests positive with a lab-based test, given they are the gold-standard test, that person would be required to isolate for 14 days.

If a rapid test is used, the person would be able to request a secondary lab test to verify. In some cases, for instance where people are working from home alone, a backup test may not be needed, but for those regularly interacting with others, a validating, lab-based PCR test would be offered.

By using these follow-up tests, we would mitigate the challenges of a low positive predictive rate. This is a real possibility when the virus prevalence is low (it's currently estimated at 0.11 per cent [24]) meaning that even a highly specific test, administered across a large sample of the population, would throw up more false positives than real ones. As we're using rapid tests in the first instance, there would be sufficient lab capacity to administer these follow-up RT-PCR tests.

During isolation the individual would continue testing every three days with rapid, point-of-care tests; when their result becomes negative, they would be able to leave isolation.

Economic Support for Those Who Need to Isolate

Ramping up testing, doing it at speed and turning around results quickly are all vital. Alone, though, they will not be enough. The final piece of the puzzle is fully enabling people to act on the test results.

The most important element of bringing this about is giving the right type of economic support for those who need to isolate. Failing to do so and to the levels required could render testing ineffective as those who are financially disadvantaged ignore quarantine restrictions and return to work. There is already precedent for this in the UK with an official study recognising that only "...around 20% of those reporting symptoms of Covid-19 report fully self-isolating by staying at home." [25]

There are a number of international examples to draw best practice from. In South Korea, compensation is given to those needing to self-isolate for 14 days or more, where they are not given paid leave by their

employer; the amount is calculated by the size of their family and the length of isolation. Other countries provide support directly to individuals isolating or through their employers.

New changes brought in by government will require people by law, from 28 September, to self-isolate where necessary. Those on low incomes who cannot work from home will be supported by one-off payments of £500. [26] We welcome this change from the previous £13 per day support.

Former Prime Minister Gordon Brown recently put forward the suggestion of offering workers forced to stay at home a wage subsidy. We support initiatives on these lines to look at how best we support those unable to work because of Covid-19.

Case Study: South Korea's "Test, Trace, Isolate, and Treat" Strategy

At the beginning of the pandemic, South Korea initially faced the largest outbreak of Covid-19 cases outside of Wuhan, China. Yet even in the absence of a full lockdown, South Korea managed to get their outbreaks under control and have maintained low rates of infection across the country. [27]

The government's ability to control the spread of the virus is largely attributed to the country's expansive "test, trace, isolate and treat" strategy. A rapid test-and-trace programme was put into place, isolation was strictly enforced, and those isolating were provided with compensation to cover the basic costs of living. [28]

In February, the government announced that it would provide 1.23 million won (equivalent to around £800 as of 7 February) per month to four-person families that have a member in quarantine. For single people forced to qualify, the government provides around £300 pounds per month. [29] The amount given is adjusted based on family size and the duration of required isolation.

These measures are part of the government's effort to compensate people who cooperate with isolation guidelines in order to reduce the spread of the virus, as well as to cover basic living expenses for those who are isolating and cannot work. The financial compensation is available to those who were in hospital or self-isolation if they are not receiving paid leave from their employers. [30]

Case Study: Singapore

At the onset of the pandemic, Singapore announced strict penalties for those breaking quarantine rules as well as S$100 (£57) per day of isolation for those who are required to isolate. Individuals who are self-employed apply directly whereas the quarantine allowance is given to Singapore-based employers if the individual is a salaried employee as the quarantine period does not come from their annual leave. [31]

While foreigners are eligible to apply for the South Korean allowance, the S$100 per day from the government in Singapore is only available to citizens and permanent residents, not travellers or tourists.

In response to rising Covid-19 cases among migrant workers in dormitory blocks around Singapore, the government announced a mandatory 14-day isolation period for around 20,000 migrants in early April. The workers were paid their salaries, employers were able to claim around S$100 per day to cover those wages, and meals were provided along with masks and hand-sanitiser. [32]

Case Study: Australia

Western Australia offers the Pandemic Leave Disaster Payment, a lump sum of AUS$1,500 for each 14-day quarantine period. Individuals are eligible if they are unable to earn an income because they were directed to self-isolate by WA Health or are caring for someone who has Covid-19. [33]

Case Study: New Zealand

New Zealand also offers support for those who cannot go into work and are unable to work from home. In this scheme, employers apply for support to pay employees and the self-employed or contractors apply directly. Workers eligible to receive these payments include those who are high-risk individuals, those who came in contact with a confirmed Covid-19 case, those who have tested positive for Covid-19 and need to isolate or be cleared, or those who have household members who are high-risk individuals. Most businesses are eligible to participate in the Covid-19 Leave Support Scheme. [34]

Supporting Those Who Cannot Isolate Where They Live

One further element that should be considered is how we support those who need to isolate and cannot do so safely where they live. We know that the rate of secondary transmission among households with someone infected with Covid-19 is around 30 per cent, so supporting people to safely isolate is therefore critical. It may be a way to utilise under-used hospitality spaces. [35]

Centralised Isolation Centres

In some Asian countries, centralised, out-of-home isolation centres appeared to be helpful in reducing the transmission of the virus. In Hong Kong, authorities contacted those believed to have been exposed to Covid-19 and then sent them to government-run facilities to quarantine for two weeks. In South Korea, people with moderate symptoms were told to isolate at government isolation centres. [36] At the

beginning of the pandemic, Singapore used large spaces originally designed for exhibitions and events to house and treat those recovering from Covid-19 or those with mild symptoms. [37]

A report published by Harvard University's Edmond J. Safra Centre for Ethics estimated that 14 per cent of infected or exposed people in the US would need a place to voluntarily isolate as they cannot do so safely at home. The report concludes that "There is substantial evidence that providing a voluntary option to safely isolate will help to dramatically reduce spread of infection to one's family and therefore the spread of infection overall." [38] [39]

For those who do not have spare bedrooms, an extra bathroom, or live in densely populated buildings in a city, isolating at home may not be the safest or most efficient method of suppressing the spread of the virus. A survey of New York City hospitals conducted in May found that 66 per cent of those who were hospitalised had been staying at home, only 17 per cent of whom were employed. This may indicate that isolating at home is not the best option under certain circumstances. [40] [41]

How Do We Deal With False Negatives and False Positives?

The issue of false negatives and positives is therefore largely solvable by repeat testing. Through such an approach, individuals with significant levels of the virus will invariably test positive. False negatives would also be resolved through regular tests. Where this is then backed up by PCR tests for positive results, an extra layer of certainty is added.

For this reason, we recommend putting in place a system of double-checking rapid tests through the use of gold-standard lab tests.

Antigen Testing

- Anyone presenting with suspected Covid-19 symptoms is currently offered a RT-PCR swab test and, in the case of on-the-spot antigen testing, we recommend a secondary lab-based PCR test be offered to validate the result.
- This would maximise the chances of correctly identifying a positive case.
- The potential gap in this approach to mass testing is asymptomatic individuals who test negative as part of the regime but do in fact have the virus, ie, they have a false negative – so they would not then qualify for an affirmative test.
- Such false-negative cases, however, are not covered under the existing government strategy.
- In any case, however, by regularly testing those without symptoms (for instance, every three days), we would maximise the chances of isolating transmitters early. As studies cited in this report show, through regular, rapid testing, any issues with sensitivity are mitigated.
- The paper "Test Sensitivity Is Secondary to Frequency and Turnaround Time for COVID-19

Surveillance" cited above made this point clearly in stating that the results of their study "…demonstrate that effective surveillance depends largely on frequency of testing and the speed of reporting, and is only marginally improved by high test sensitivity." [42]

Antibody Testing

- We apply the same recommendations to on-the-spot rapid antibody testing. Any positive case would be confirmed using the highly accurate lab-based ELISA test.
- The gap here arises where someone could potentially receive a negative result but actually has antibodies. In such a case no risk arises – the person likely has short- to medium-term immunity but isn't aware of it.

By combining rapid and lab-based testing there is a lower risk than arises in the current government strategy.

A Mass-Testing Master Plan

As we have set out previously, the right strategy for mass testing puts rapid tests at its heart.

While lab tests are a critical part of the testing infrastructure, and provide a gold standard, testing on the scale we envisage must be built around on-the-spot rapid tests.

Without these rapid tests, which can provide a result within around 15 minutes, the UK will not be able to put in place a regime that tests that the number of people required, as often as necessary.

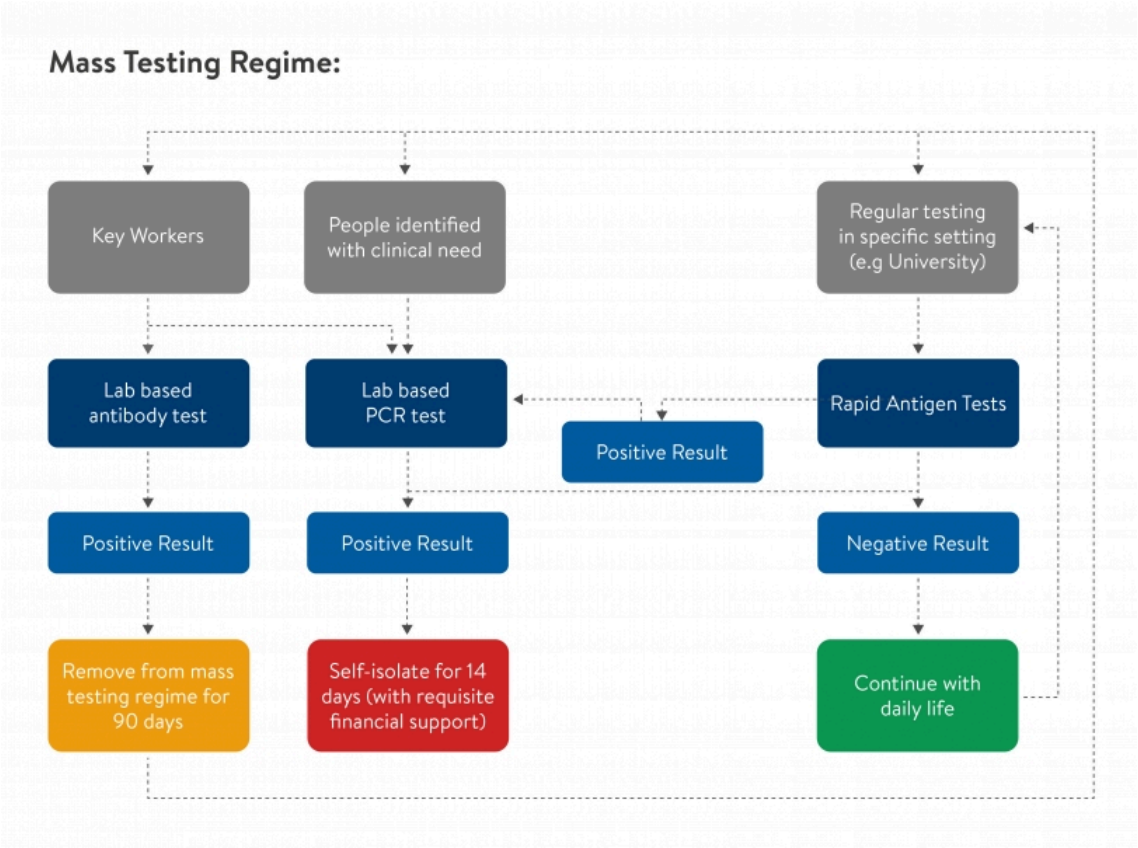
We envisage these tests being deployed in various settings – at homes, schools and workplaces, for instance.

Anyone taking a rapid antigen or antibody test that tests positive would then have the result checked with a lab-based test.

A large number of rapid tests are therefore required. A key question around how feasible mass testing is relates to the availability of these tests.

We have set out a simplified user journey for testing in the UK (see Figure 4, below). This shows how a confirmatory test would be applied and the crossover between different groups.

Figure 4 – Mass testing in the UK



Antibody testing is potentially an important part of the puzzle. Further evidence is needed on the level of immunity conferred by infection, but we believe it does confer a level of protection from reinfection. In addition, we are increasingly seeing evidence of long-term health implications in patients who have had Covid-19. Without a broader understanding of who has had the virus, we will not be able to understand this issue more fully. Large-scale rapid antibody testing will help build up a picture of who has had the virus, providing important information.

Recommendations: The Actions That Must Be Taken

This document sets out a plan for how the government can realise its strategy of mass testing. It demands that government take a series of decisive actions. These include immediate actions to address the crisis in test and trace, and some actions which will not have immediate political payback but will be important in the long-term.

The manner in which the rollout of mass testing is approached is just as critical as the actions we recommend: The government must be prepared to take risks. This means working with new, innovative

suppliers and accepting that in any mass-testing regime there will be issues, but these far outweigh the costs of not implementing it. Above all else, we must not let the best be the enemy of "good enough" any longer.

We set out actions that must be taken below.

Actions to Address Short-Term Challenges in Testing

1. **Boost existing lab space and capacity.**

Urgent decisions are required on expanding existing lab testing capacity. This includes working with the "little ship" network of labs, supported by cloud software, and moving quickly on procurement. We understand decisions are in front of government around accessing extra materials, machines and kit to boost capacity by around 300,000 tests per day. These opportunities cannot be missed. Alongside this, automation should be utilised in all Lighthouse Labs.

2. **Prioritise access to testing.**

The current difficulties the government is facing on lab testing derives from a lack of clear prioritisation around who should be accessing the capacity available. The UK urgently needs a clear, public set of criteria for who should have priority access to testing. This should draw on support from GP surgeries to ensure those who need a test get one. Critically, it must be built around ensuring testing is given to those with clinical need, but also to those with a wider need in terms of being required to attend work in person.

This should mean prioritising key sectors such as:

- Social care
- Emergency services
- Transport workers
- Education, including schools, colleges and universities
- Travel, including at ports of entry

3. **Introduce sample pooling to the UK's Lighthouse Labs.**

Samples taken from areas where there is lower prevalence of Covid-19 should be combined to create pooled samples. If these test negative, then all the original samples should be deemed negative.

4. **Deploy mobile, saliva-based testing trucks.**

These testing trucks would provide 10,000 additional tests a day and could be deployed to test those working in key sectors, including schools and care homes. The sampling can be done and collected in

large numbers and then processed in mobile labs with rapid result turnaround that would expedite contact tracing. This will add vital additional capacity in terms of accurate lab testing.

5. **Issue a framework for validation and introduce emergency use authorisation for innovative tests.**

Government should take urgent action to put in place a new validation framework for rapid tests that uses an authorisation system akin to the FDA's Emergency Use Authorisation in the US. The existing requirements for tests are too high and are appropriate only for tests being used in clinical settings. Rapid tests with lower sensitivity are able to detect people with higher viral loads. We have a much better understanding of the level of viral load likely to be infectious. This must be reflected in a new framework that is clear and transparent, enabling all possible viable tests to be brought on stream.

6. **Use international testing to give a short-term boost to testing (and only as a last resort).**

If demand remains unmet, the government should use international laboratories, working with the air force to see results turned around within a day. This should only be used if essential and as a stopgap before bringing domestic capacity online.

Actions to Build up Long-Term, Mass-Testing Capacity

1. **Set-up saliva-based testing labs.**

The government should work with a supplier such as Curative, detailed above, to establish a series of laboratories that specialise in saliva-based testing. These will make sample collections easier and better suit vulnerable and younger patients.

2. **Bring on stream all possible viable tests and support those in development.**

With a validation framework in place the government should bring on stream all possible viable rapid tests. It will also enable them to work openly and support those British companies with tests in development. We include full details of these as Annex A.

3. **Implement a phased rollout of mass testing.**

We believe the government should set out quickly how the ambition of mass testing can be realised by rolling it out in a phased way, focusing on key sectors and pilot programmes in hotspot areas. By building up in this way, the government can build confidence and make any course corrections needed to reach the target of testing as many people as possible, as often as possible.

4. **Put in place the right tests for the right purpose.**

To build towards a genuine mass-testing regime, the government needs to set out a clear plan of the kind we include in this document on how it plans to use the various tests. We believe lab-tests should be

deployed for those with a clear clinical need and for key workers, while rapid tests should be used in settings where a rapid turnaround is needed.

Annex A: UK-Based Providers for Mass Testing

Biopanda Reagents

Biopanda has a rapid antigen test in development. There are two versions in progress: one that can be read by eye which creates challenges from a sensitivity perspective, and a second that uses immunofluorescence through a handheld reader.

Mologic

Mologic currently has four serology tests available.

1. **ELISA test for IgG only:** This test is available now, and production could be scaled to 500,000 tests per week. As it stands, there is no sign of the test being validated by Public Health England (PHE), but there have been positive conversations with PHE Colindale.
2. **Professional RDT for IgG, IgM and IgA:** These diagnostic devices would identify a full range of antibodies. Forms have been submitted to the New Test Approvals Group (NTAG) but no reply has been received. The test is being provided on a not-for-profit basis with a number of international partners and there are proposals for 200 million-plus capacity units here and in Africa.
3. **Self-test for IgG only:** This home-testing kit could be used by a layperson to identify if they had IgG antibodies and therefore had some evidence of past infection. To date, the regulatory pathway has been blocked by MHRA.
4. **Laminated test in IgG only or G, M and A:** The laminate tests provide a quick result and show if a patient has had exposure to Covid-19. Plasma from a sample soaks along a laminate of what is essentially paper, encountering a zone that has known coronavirus antigens. If the plasma has antibodies to the coronavirus proteins, those will bind to the test antigens and carry them along up the strip giving a result. These tests are being developed for both professional use and self-testing. They are being distributed internationally.

What's in the pipeline?

In the medium-term, Mologic is developing T-cell and Memory B-cell marker variants of the antibody test to confirm immune memory. These are critical to the debate around immunity.

The pre-mentioned antigen tests are subject to regulatory hold-up but could be online very quickly. The company is also looking to develop peptide antigen driven tests (for lower cross-reactivity), similar to that of the HIV rapid tests.

BioSURE

The company is developing saliva-based antigen self-tests and anticipates that these could be available by Q4 this year.

Omega Diagnostics

Through its partnership with Mologic, the company is developing ELISA and lateral flow antigen tests that will use saliva as the sample type. These tests will offer a quicker time to result and an easier sample-collection method than current testing methods (particularly swab tests). The expectation is that the ELISA antigen test will be available by the end of September and the lateral flow test by the end of October or November.

Omega recently informed us that it is currently working towards manufacturing capacity for rapid tests of 0.5 million per week. The company believes it could double this quite quickly with government support – particularly in terms of financial and logistical support.

QuantuMDx

QuantuMDx is developing a rapid, portable molecular point-of-care solution (Q-POC) that is scheduled to be released in September, alongside a SAR-CoV-2 assay. These two tests will enable on-the-spot testing. The company is also developing a respiratory panel test that will run on the Q-POC system.

Project Screen by Circle

Project Screen by Circle is a consortium of industry experts led by Prenetics, together with the University of Birmingham, The Doctors Laboratory and support from Stuart. [43]

Combined, it offers an out-the-box mass-testing solution aimed at returning employees to work safely and confidently. It was responsible for the highly successful Premier League testing regime, which saw the football season return with no outbreaks among players, staff and others involved in the game, and it has recently been contracted by Hong Kong to test every single restaurant worker. [44]

What do they have available now?
Project Screen's laboratory (Anglia) has currently 3,000 to 5,000 tests available which is being integrated into a Pillar 2 type scheme on the basis that 3,000 will be committed on a regular basis; as such, it is going to invest in greater capacity.

What could they bring on stream?

Project Screen believes it can bring onboard 10 million Lamp POC tests by November 2020 with a government commitment. This includes not only mouth swab but also a new oral "mouth wash" as part of its partnerships. The oral rinse would be a game-changer. It also has a 30-minute fast POC PCR machine that can process four samples per hour, or 40 if sample pooling is used.

What support do they need to get this extra capacity on stream?

- Fast track validation into national framework to widen the cohort to prove utility
- Access to a pool of positive samples that is not stored in Viral Transport Medium
- Recognition of new innovation at senior government level and ability to priority test

Annex B: Potential Antigen Test Capacity

Many of the rapid antigen tests that have been commercialised around the world are increasing their production capacity and producing millions of tests each month. Most notably:

- Roche, the multinational health-care company, announced in the beginning of September that it will produce around 40 million of its SARS-CoV-2 Rapid Tests per month. Its capacity is expected to increase more than twofold by the end of the year in order to help with the testing demand of health-care systems around the world. [45]
- By the end of September, BD, a leading global medical technology company, expects to increase the production of its rapid, point-of-care, SARS-CoV-2 diagnostic tests to 2 million tests per week. [46]
- Quidel is an American manufacturer of diagnostic health-care products that originally had the capacity to produce around 1 million of its rapid antigen tests per week. A recent grant from the National Institutes of Health has enabled Quidel to expand its production by about 140 million tests per year, according to company officials. [47] The grant has allowed the company to support larger distribution centres, and its testing capacity has now reached around 220 million tests per year. [48]
- LumiraDX's SARS-CoV-2 Ag Test is reported to be one of the fastest, most sensitive Covid-19 antigen point-of-care tests that is commercially available. The test uses a nose swab to detect antigens in around 12 minutes and the company is on track to produce 2 million tests in September and up to 10 million tests in December. [49]
- Abbott's BinaxNOW COVID-19 Ag Card is a rapid, portable, and affordable antigen test as it is the size of a credit card and will cost $5. Current estimates have Abbott shipping around 1 million tests per day, but Abbott plans on increasing the number of tests shipped to 10 million per month starting in October. [50]

Footnotes

1. ^ https://www.bmj.com/content/370/bmj.m3520?ijkey=b2cd143268276960b7f3c7362048f4af4f48c3e4&keytype2=tf_ipsecsha
2. ^ https://www.bmj.com/content/370/bmj.m3558
3. ^ https://www.lighthouselabs.org.uk/
4. ^ https://www.thetimes.co.uk/article/chaos-and-inefficiency-in-coronavirus-testing-labs-dbsvt7n25
5. ^ https://www.covid19-testing.org/
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