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Pressing Go on Mass Testing

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Overview

Four months into the UK's response to the Covid-19 pandemic, it is increasingly clear that testing, on mass scale, is the only solution to end damaging nationwide lockdowns and give people the confidence to return to work and go about their daily lives.

The government has made progress on ramping up the country's testing capability, with capacity to conduct 300,000 tests per day. This is to be commended.

Far more is required, however. In the absence of a game-changing solution such as a vaccine or compelling therapeutic drug, mass testing remains the most viable way to live alongside the virus.

To deliver this mass-testing strategy, a step change is required from the government.

Rather than focus solely on symptomatic cases, we believe the government must move quickly to a strategy of putting in place a mass-testing regime, which involves testing a larger proportion of the population to get ahead of, and contain, the spread of the virus. This means significantly scaling up existing infrastructure.

While the country has considerable testing capability for PCR swab tests, and growing capability for lab-based antibody testing, we do not have the rapid point-of-use testing we so urgently need. This is true both for antigen tests, which indicate if someone currently has the virus, and for rapid antibody tests, which indicate whether a person has had the virus.

This ambition is deliverable, quickly. Over the course of five reports on testing, we have spoken with many UK testing suppliers. They each have capacity to deliver a substantial uplift to the UK's testing capability – particularly for rapid point-of-care tests.

Companies such as Biopanda and Mologic have developed viable antibody tests and are making significant progress towards delivering rapid antigen tests. With the right support, their efforts could be catalysed (a section of this report gives an update on these opportunities). These companies have reached out to the government and asked to be included in the UK's supply of testing but, to date, they have not had a response. Now is the time for that to change.

Through bringing onstream all possible rapid tests – both antigen and antibody – and putting in place the right infrastructure to make full use of them, the government can finally press go on mass testing.

A Strategic Shift – From Symptom-Based Testing to Mass Testing

Given what we've learned about the virus, particularly the number of cases post-lockdown from non-symptomatic spreaders, we recommend a wholesale shift in the government's testing strategy from testing those who have symptoms to the regular, ongoing testing of all.

This is a marked but necessary shift. It will be one of the biggest peacetime operations in the UK's history. It will mean building a British diagnostics industry that brings together small, nimble innovators and established testing providers, onboarding new tests and scaling existing ones at record speed. This requires resources and leadership, but it is far from impossible.

In the meantime, we recommend a gradual shift that focuses testing on a number of groups key to getting the UK back on its feet. These include teachers, care-home staff, transport workers and those in the hospitality industry. Testing these groups is possible using existing lab-based capacity.

Our recommendations have merit for the short-, medium- and long-term. Starting at the end, a mass-testing system is an important long-term investment, there to protect us against future pandemics. In the medium-term, our recommendations allow the UK to live alongside the virus and, critically, contain any outbreaks or second waves. In the short-term, our approach to testing would begin to restore confidence and get key infrastructure moving. Below are the key things government must do now.

Pressing Go – What the Government Must Do Now

1. Move to a strategy of mass testing, broadening to cover as many people as possible, as often as possible, not just those with symptoms.
2. Make full use of existing testing capacity to cover key groups, including teachers.
3. Continue to increase the number of people eligible for a test so that the testing regime has more chance of catching non-symptomatic virus carriers.
4. Appoint a Minister for Testing to oversee the move to a mass-testing strategy, supported by the right team of external experts.
5. Set up a government rapid-testing unit that provides support, funding and expedited sign-off to the UK's innovative testing providers to bring onboard the widest possible range of rapid antigen and antibody tests.
6. Introduce pooling in labs to increase testing capacity.
7. Utilise the occupational health sector to administer testing in work settings.
8. Enhance shielding measures for elderly and vulnerable people, including the provision of N95 masks and continuing to mandate mask-wearing in all public spaces, to complement a mass-testing regime.

Part I: Building a Mass-Testing Regime

What Is the Current Approach to Testing?

The government's testing strategy is to test, trace and isolate those with symptoms and certain workers without symptoms. This approach was set out in early March. In the context of that time and with a full lockdown in place, this was the right testing strategy. However, as we've learned more about the virus – particularly how and among whom it is transmitted – it's clear that a testing strategy relying on individuals with symptoms to volunteer (aside from a few notable exceptions) must evolve to account for non-symptomatic carriers. Rather than relying on people to self-identify for tests, a mass-testing regime requires a shift to people being regularly identified to be tested. While the government may be carrying out *more* testing as capacity grows, it is not carrying out *mass* testing – defined as regular, ongoing testing of all citizens to confidently demonstrate their Covid-19 status.

In Prime Minister Boris Johnson's speech on 17th July¹, in which he set out how the UK plans to navigate the winter months and its containment measures, he reiterated the focus on "test, track and trace". This was complemented by a welcome call to increase lab-based testing to 500,000 a day, but it's important to emphasise that this enhanced testing capacity would not be used for what we describe as a mass-testing strategy. This was reaffirmed in the accompanying guidance to the speech which stated that additional testing would be used "wherever an outbreak occurs".² This is an important use, but we recommend going further than this "surge testing" to make asymptomatic testing a regular fixture of the country's testing strategy, combining bolstered lab-based testing capacity with new innovations. Together, they hold the key for returning to near-full social and economic participation.

Who Can Currently Get Tested?

In the UK, anyone with Covid-19 symptoms can now request a test.

If you don't have symptoms, you can also get a test if you are going into hospital for planned surgery, or, as is the case in Leicester, if you have been in close contact with someone with symptoms.³

Where Can You Get Tested?

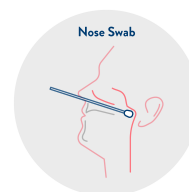
There are a number of options on where to do a test. It can be done via a drive-through testing site, a mobile testing unit or a home testing kit.

Testing is also conducted at NHS facilities for staff and patients.

What Can You Be Tested for?

Anyone with symptoms of Covid-19 can do a swab test, in person or at home, to test whether they have the virus.

As well as PCR tests, there are also antibody tests, which check whether the person has had the virus, with conferred presumed short-term immunity.



The UK now has capacity to conduct 80,000 antibody tests per day. These antibody tests are, however, reserved for health-care staff.

Neither the swab testing nor antibody testing is rapid and point-of-use. Both still require a lab infrastructure to process the tests.

Results

Data through to the beginning of July indicate that 90 per cent of in-person tests carried out by drive-through and mobile testing sites were processed and turned around within 24 hours.

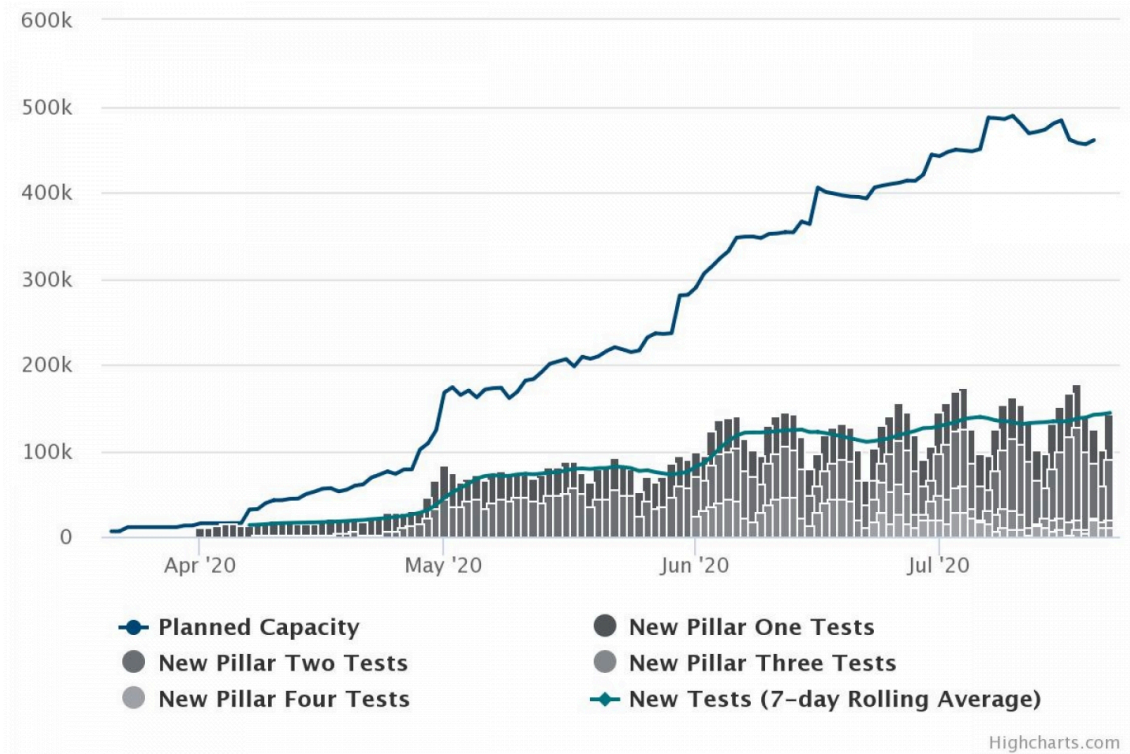
Testing Capacity

The UK now has a combined testing capacity – covering both PCR swab testing and antibody testing – of more than 300,000 tests per day. The most recent seven-day average on the number of tests conducted per day is 143,628.

On 20 July, the UK conducted the following proportion of tests:

- Pillar 1 (NHS and, in England, PHE): 39,747 tests
- Pillar 2 (Commercial partners): 62,825 tests
- Pillar 3 (Antibody): 1,720 tests
- Pillar 4 (Surveillance): 20,758 tests

Figure 1 – Covid-19 testing and test capacity in the UK



Source: <https://coronavirus-staging.data.gov.uk/testing>

As this data shows, the UK has made significant progress in developing its swab PCR testing capacity. Where it is lagging behind is in delivering increased capacity of rapid point-of-use antigen and antibody tests, which are the critical building blocks of a mass-testing strategy.

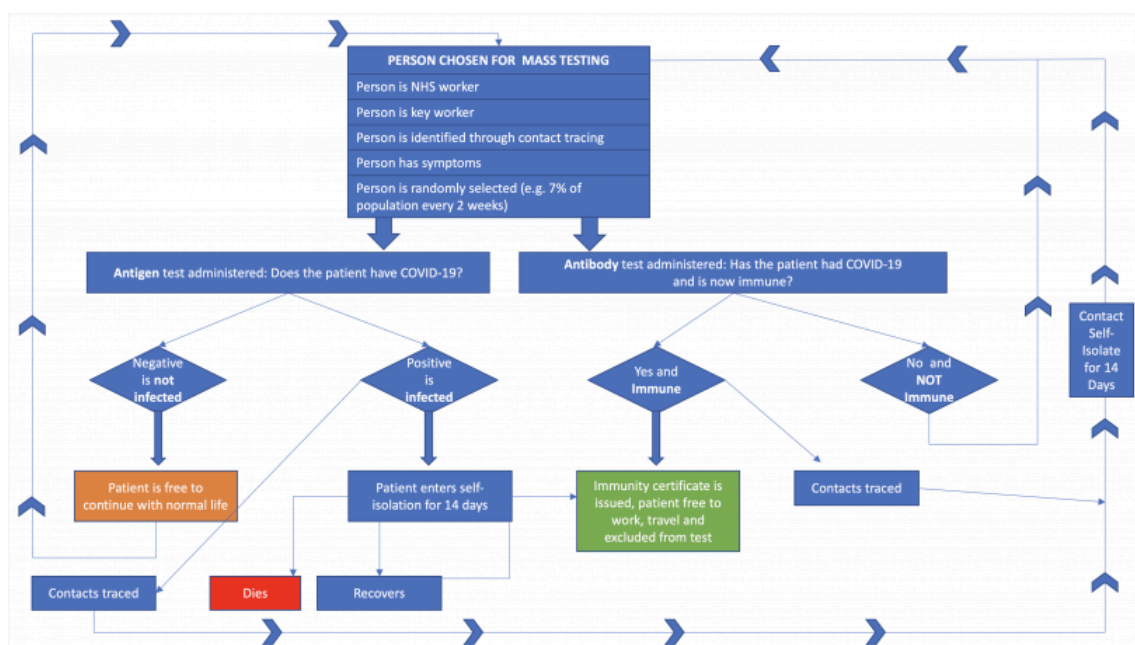
What Does a Mass-Testing Regime Look Like?

We define a mass-testing regime as one that includes regular, ongoing Covid-19 testing of all citizens. The purpose of such a regime is to identify asymptomatic cases and break the chains of infection.

This testing would be conducted in a variety of settings: at home, at work, at transport hubs and at a diverse range of other testing sites. The testing regime would make use of rapid point-of-use tests – both antigen and antibody.

We have previously set out a model for how this would be done.

Figure 2 – Our proposed STIR model for mass testing



As we argued in our previous paper, "[Changing the Game on Testing](#)", we believe these rapid tests should then be combined with gold standard lab-based tests. By combining on-the-spot tests with lab-based tests, in addition to regularly testing individuals, we are able to more effectively manage risk.

Antigen Testing: Reducing false positives and catching asymptomatic false negatives

Anyone presenting with suspected Covid-19 symptoms is currently offered a PCR swab test and in the case of on-the-spot antigen testing, we recommend a positive result for Covid-19 be followed up with a lab-based PCR test for confirmation. This would maximise the chances of correctly identifying a positive case.

The gap in this approach for mass testing is asymptomatic individuals who test negative as part of the regime but do in fact have the virus, i.e. 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 and by regularly testing those without symptoms, we maximise the chances of isolating transmitters early in their infection.

Antibody Testing: Reducing false positives

We apply the same recommendations to on-the-spot antibody testing. Any positive case would be confirmed using the highly accurate lab-based ELISA test.

The gap here arises where someone could 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.

There is a lower risk of false results with combined rapid and lab-based testing than arises in the current government strategy.

What Infrastructure Does This Mass-Testing Strategy Require?

Delivering this regime of mass testing requires the right infrastructure, and in many key areas, the UK is still behind the curve.

Strategy

A mass-testing regime is not about volume, but strategy. In ramping up to mass testing, the government needs to determine how often and when people will be tested. There are two main approaches that it could take:

1. **Test by interaction:** This is testing at point of contact, be that a workplace, mass gathering or transport hub to ensure the safety of locations.
2. **Test by person:** This requires regular, routine testing of the population to identify and quickly isolate carriers of the virus, thus minimising spread.

Either of these approaches could be applied at a national level or in a more localised way to identify and contain local outbreaks. We need a hybrid model that includes testing both by interaction and by person to ensure the regular testing of the population required to map the prevalence of the virus and create the confidence needed for specific interactions.

Organisation

Mass testing on the scale we believe is needed can only be realised by bringing together the full capacity of lab-based tests and all potentially viable rapid antibody and antigen tests – including those we set out later in this paper.

Achieving this will require a step change within government, including, in particular:

- Operational support for innovative testing providers, including funding, advanced orders, access to patient samples and support with validation.
- Supporting and expediting the validation of innovative tests, for instance via a US-style Emergency Use Authorisation.

We believe this new approach will require the government to work in a more agile and open way than it has to date. For this reason, we believe the whole operation of delivering mass testing should be overseen by a **Minister for Testing**, reporting directly to the Prime Minister. This has been set out in [previous papers](#).

Pooling

Inspired by the Covid-19 Testing Network⁴, this approach involves collecting samples from patients, pooling a tenth of each sample in the lab, and then testing this compilation sample. If the results come back negative, we can conclude there were ten negative samples; if the sample comes back positive, then the ten original samples are retested to determine which is positive. It works particularly effectively in mass testing where the number of positives is likely to be low (currently this is one in 1,700) and most tests are confirming a patient's negative status.

By pooling samples we can increase, overnight, testing by three- to fivefold. Over time, with automation and more effective sample collection (onsite and using saliva), this method could increase current lab-based capacity by ten times.

Physical Infrastructure

We still don't have the physical infrastructure that enables mass testing. Increased testing capacity coincided with reducing transmission rates. It's not clear that our existing infrastructure can cope with the possibility of increased transmission rates later in the year, let alone the asymptomatic testing which is required as part of a mass-testing regime. As set out above, government needs to make use of the technology available to increase its capacity. It also needs to enhance the infrastructure that enables access to testing:

- **Home testing:** Theoretically there is unlimited capacity for these tests, but the logistics of getting tests to people's homes means they are currently running at a much higher unit cost. Scaling this method will become far more viable once rapid antigen tests come online, which are cheaper to use and require less transportation.
- **Mobile testing centres:** To generate the coverage required for mass testing, far more community-based testing centres are required. Working in partnership with local agencies these could be easily established using existing infrastructure such as polling stations.
- **Point of interaction testing:** Once rapid tests are online this requires working with organisations such as transport companies and venues for high-volume events (sports, music, theatre, conference) to distribute tests. The use of testing as part of the Premier League is an example of this being effective.
- **Flexible infrastructure:** We have seen targeted increases in testing capacity in response to local outbreaks, for example in Leicester and Blackburn. However, this capacity has been predominantly used to test those who have symptoms. Case studies from places such as Gütersloh and Hong Kong show how governments have responded to outbreaks with broader testing of the local population to get ahead of the spread of the virus. Government needs to have the flexibility to ramp up greater testing capacity in a locality at pace.

Case Study: The Role of Occupational Health-Care Providers

The occupational health sector holds close relationships with many employers and is leveraging its expertise to support employers to adapt their operating models in response to Covid-19. In the absence of mass testing, many employers are seeking support with their own testing regimes.

Health Management, one of the UK's leading occupational health providers, is supporting several clients across different sectors with large-scale employee testing, including:

- **Banking:** All staff of a major City bank have been offered one-off ELISA antibody testing, which Health Management are undertaking.
- **Broadcasting:** As TV production schedules have restarted, the company is undertaking PCR testing on a weekly basis to crew and cast members as they move around the country to different filming sites.
- **Manufacturing:** A Health Management client has switched production to manufacture PPE garments for the NHS. They provide with cause PCR testing to any contacts of a suspected individual to prevent the production line from closure.

However, the data protocols mean much of this work currently takes place in isolation from the wider government track and trace effort. Antibody test results, for example, are reported to the employee/employer, but there is no link in to national and local government. All PCR test results are reported to Public Health England (PHE) via Health Management's laboratory to be included in national reporting. Positive results are followed up by the test and trace programme.

Occupational health providers are an example of the possible infrastructure government could draw on to pursue an employer-led testing strategy. The sector covers around half of the UK workforce, with 92 per cent of large employers having existing relations with providers.

Tests

Over the course of the five papers we have now written on testing we have spoken to a wide range of people directly involved in the testing space. Many rapid test suppliers have expressed their frustration at both the lack of speed and support by the government.

To put in place the mass-testing regime we envisage the government will need to move quickly to diversify from centralised lab-based testing, which draws on a small number of large suppliers, to working with the broadest possible range of suppliers, building an ecosystem of both large and small, domestic and international, suppliers.

Examples of those we believe the government should now be actively engaging with are included below.

Data

The availability of data to the right people at the right time is crucial to the effectiveness of any testing regime. The results of a single test might be useful to an individual, but the purpose of a mass-testing regime is to map and contain the spread of the virus. The supporting data infrastructure is therefore critical to aggregating and analysing those results.

Despite the current testing regime being highly centralised, the interpretation and sharing of that data has been problematic and, in the case of Leicester, possibly detrimental to preventing the spread of the virus. In implementing a mass-testing regime, the volume of tests carried out and the introduction of point-of-use tests will add complexity to the ability to monitor and communicate the prevalence of the virus. This includes the implementation of testing by private organisations, as described in the case study above. Implementing a mass-testing regime requires a thorough look at the data collection and sharing architecture to support it.

Applications of Mass Testing

Case Study: Learning From the English Premier League

The English Premier League (EPL) is a prime example of how mass testing can be deployed to remove the threat of transmissions from a specified group. Their approach, scaled, could hold the key to the UK learning to live with Covid-19 and removing the threat posed by non-symptomatic spreaders, who have been identified as a major source of outbreaks and transmissions post-lockdown.

By acknowledging the role of asymptomatic spreaders early on – a demographic that footballers, given their age, are likely to belong to – the EPL demonstrated excellent foresight in adopting a mass-testing strategy. This involved systemic, twice-weekly testing of every player and staff member across all 20 clubs, along with officials and others involved in the sport. It is estimated that this equates to 40,000 tests in total since the season's restart.

The Premier League worked directly with Project Screen by Circle, a consortium of industry experts led by Prenetics, together with the University of Birmingham, The Doctors Laboratory and support from delivery company Stuart. They set up sample collection stands at clubs' training grounds and offering home testing to those with symptoms and officials. Following a test, results were uploaded within hours to a digital health passport which – assuming a negative result – provide the holder with access to stadiums on matchdays and other safe zones. Any person testing positive self-isolated for two weeks.

Of the approximately 40,000 tests completed, there was a positive rate of less than 0.12 per cent ⁵ prevalence in England but reflects cases over a period rather than at any given moment. Either way, it demonstrates a remarkable containment of cases from the EPL. This number could have been significantly higher if asymptomatic carriers had not been identified and been exposed to the many interactions of a Premier League footballer, on and off the pitch.

We recommend that this approach of testing a specified group is adopted in other settings, including but not limited to sports. Given the economic benefits of reopening and epidemiological benefits of mass testing, along with the opportunity to learn even more about Covid-19, the cost of tests could be guaranteed by the government but with an expectation that those responsible for these settings would pay for testing. These include:

- Other professional sports
- Social-care providers
- University halls of residence
- Large employers
- Restaurants, cafes and bars (staff – see Hong Kong study below)

- Festivals

Case Study: Testing to Restore Confidence in Hong Kong's Restaurants

Mass testing all in a specific group regardless of symptoms is proving effective in Hong Kong. Since reopening, the country has faced a crisis of confidence among consumers who fear contracting the virus if they were to return to enclosed spaces such as restaurants. Recognising this barrier to the sector fully reviving post-lockdown, the Hong Kong authorities commissioned Prenetics⁶ – testing suppliers to the EPL – to conduct tests on every single worker in every single restaurant.

The testing administrators were given a list of every restaurant in the country, with a bar code for each. Saliva collection tests were then delivered to each restaurant, where workers were required to complete a quick pre-registration before being educated on sample collection. Using saliva tests made this much easier.

Once a restaurant's workers had all been tested, the restaurant then qualified for a government-issued sticker that could appear in the window informing potential customers that everyone on the premise had been tested and was Covid-free. This serves as a huge confidence boost to patrons.

In total, the project involves testing 200,000 workers across 16,000 restaurants. At the time of writing, the work is ongoing but it is all due to take place within a two-week period and there are plans afoot for testing to become a routine procedure.

Travel: Testing to Reduce Quarantine to Five Days

At the height of the summer travel season, we've seen the fragility of the travel corridor system and the impact this can have on the travel industry. At the time of writing, the FCO advises against all foreign travel other than to areas designated as travel corridors⁷; these are the exception not the rule. If a citizen returns to the UK from somewhere not designated as a travel corridor, they must quarantine for two weeks.⁸

When Spain's status as a travel corridor was removed overnight, it caused confusion amongst Britons in the country and those planning to travel there.⁹ The cost of quarantine on their return would be significant – both in terms of lost productivity and lost wages for the individual themselves, with many now opting not to travel at all.

Testing presents a more appealing alternative which could see the post-travel quarantine period reduced to just five days.

This requires a risk calculus. No test is completely accurate, but studies suggest that testing eight days after infection will be 80 per cent accurate, whereas testing three days from infection (i.e. in the pre-symptomatic stage for most people) will see accuracy reduced to 68 per cent.¹⁰ To account for this and allowing for an acceptable level of risk, we recommend the quarantine period is reduced to five days on condition of citizens having a negative test at the end of this period. This would account for those who contract the virus towards the end of their holiday and affords holidaymakers foresight, allowing them to time their return to the UK five days before returning to work. The incentive to shorten the quarantine period serves as a behavioural tool, encouraging take-up of testing among returning travellers. As an insurance, any traveller who develops symptoms and anyone testing positive should quarantine for the entire 14 days, accounting for the incubation period of the virus.¹¹

Reciprocal agreements to cover testing on departure could be introduced, funded by countries who have an interest in British tourists visiting their countries and whose testing capability is of a high standard. Data on the quality of international testing is readily available to the government, as this is already being regularly assessed by the Joint Biosecurity Centre, in close consultation with Public Health England and the Chief Medical Officer, as part of their criteria for determining which countries should have travel-corridor status.¹² This new approach to travel testing and quarantine would go hand in hand with drawing out greater clarity around the process of how countries are identified for the travel corridors.

We have seen Germany move towards this approach, with all states agreeing that return travellers should be voluntarily tested at ports. Bavaria remains an outlier, calling for these tests to be made mandatory.¹³

Potential Use in Other Settings

Universities

University is as much about learning from others and meeting new people as it is about learning a subject. Built into a student's calculus about what they wanted from their study (and the amount of fees they were willing to pay) would have been an expectation that they would meet new people. Most importantly, networking and interactions with others has inherent value and improves social mobility outcomes. This is severely at risk for a new generation of students, including those who had planned to study on campus.

Our recommendation of a mass-testing model is easily applied to universities and this group presents an ideal pilot. Focusing on halls of residence, students could be tested weekly from September onwards. Given their ages – again, like those involved in EPL – students are more likely than other groups to be asymptomatic carriers of Covid-19. Moreover, this group is digitally native and would be comfortable using a health passport, akin to that used by players and staff in football. Universities could contribute to the cost of testing – alongside private providers of halls of residence – and a system could be established that meant students could return safely and securely in September, while addressing the legitimate concern from local communities that this mobile group contributes to outbreaks in the areas they're moving to.

To do this wholesale among students living in university-maintained and private halls of residence would require 510,000 ¹⁴ tests. The government's current testing capacity of 1.4 million should prioritise mass testing of key groups, see above, and the test, track and isolate system, but with leadership, alongside the adoption of innovative tests and lab-efficiency measures, such as pooled testing, this additional capacity is well within reach. This is especially so given the co-location of labs and university campuses.

Adopting this approach would give students the confidence to fully participate in university life while also signalling to other sectors the possibilities of mass testing.

Care Homes

In the midst of lockdown, a number of community transmissions could be traced back to care homes and the key workers within these environments. ¹⁵ Many were asymptomatic and therefore weren't eligible for testing. Post-lockdown, care-home outbreaks have been significantly reduced thanks to enhanced shielding measures and effective isolation from the outside world. Understandably – and for the mental wellbeing of carers and staff – this is changing at pace and care homes will need to return to some level of normality.

Moving forward, care-home residents, staff and selected visitors could be tested regularly. This is particularly important for workers, who often belong to a demographic that over-indexes on new cases post-lockdown – according to recent data from Pillar 2 of the government's testing regime, women aged 50 to 59 account for 12 per cent of all positive cases outside of hospitals ¹⁶. Adopting a mass-testing approach would allow staff and visitors to enter or leave the care-home environment with relative assuredness around their infection status. Regular testing would reduce the exposure of anyone unfortunate enough to catch Covid-19 and would make tracing the source of infections much easier.

Schools

As we have set out in our previous paper "Back in September: A Test for Our Schools", mass testing would play an important role in restoring confidence for parents, teachers and pupils to fully return to school in September while also controlling potential future outbreaks. Both issues warrant such an intervention, as the fear is real ¹⁷ and, since limited reopening began, schools have been contributing to post-lockdown outbreaks. ¹⁸

By testing the entire pupil population of 2,000 schools over a three-week period, we can build a sufficient dataset to confidently designate "super-spreader setting" status by type and location of school. For example, rural primary schools may be risk-free while inner-city secondary schools could be revealed as hotspots for virus transmission. Those confirmed as super-spreader settings would qualify for ongoing, twice-weekly testing for all persons within the setting to contain outbreaks and provide reassurance. Disproval of a school's status as a super-spreader setting would – by its very nature – serve as a

confidence boost for a return to school. Regular monitoring would offer ongoing reassurance should the situation change.

Employers

Employers could introduce regular, ongoing testing for their employees, either through a local consortium or, if they are of sufficient size with adequate resources, on-site. This approach mirrors that of the Premier League and others, and would also serve as a useful tributary to the NHS Test and Trace system, introducing testing for a broad group of people. We have seen this adopted among large, global employers. One company, Tech Mahindra ¹⁹, a large India-based technology company with 125,236 employees, has introduced an individual risk score that uses AI to pull on different data sources and combines them with test results, allowing employees to know their Covid-19 risk and make informed decisions.

Conclusions & Recommendations

While the UK has made progress in ramping up its PCR swab testing capacity, it is in danger of lagging behind the curve on rapid point-of-use testing.

These rapid tests should form the backbone of the right mass-testing strategy. This strategy would move beyond testing solely those with symptoms to covering as many people as possible, as regularly as possible.

Testing in this way would be administered through rapid tests, in various settings, for instance at the workplace, and the results would be double-checked with the gold standard lab-based tests.

Delivering this change in strategy requires a step change in how the government approaches this issue. Organisationally it will require a Minister for Testing, reporting directly to the Prime Minister and with the right support team. It will mean engaging with the widest possible pool of suppliers in a much more open and dynamic way.

As Part II of this document will clearly set out, there are many UK companies with significant capacity and capability to deliver this strategy of mass testing. To date, they have tried to engage with government with limited success. A range of government support, from access to patient samples to funding opportunities, could quickly change this situation and build an ecosystem of testing suppliers, contributing testing capacity and developing new rapid tests. This ecosystem would serve as the foundation for a mass-testing strategy. The willingness is there, but it requires coordination, leadership and vision. It's why a Minister for Testing, reporting directly to the PM, is needed if we are to put in place the testing regime the UK needs.

In the absence of a game-changing solution to Covid-19, we are going to have to learn to live alongside the virus for the foreseeable future. This can only be done on the basis of a credible mass-testing regime. It is time for the UK government to press go on making this happen.

Recommendations

1. **An organisational step change from the government on testing.** This will require the appointment of a Minister for Testing, with the right support team to engage in a faster and more agile approach to the range of available testing suppliers.
2. **A shift to testing everyone, regardless of symptoms.** The country needs the widest possible testing strategy. This means moving beyond testing just those with symptoms to testing as many people as possible, as often as possible.
3. **Putting the appropriate data architecture in place.** Increasing the volume of tests and adding point-of-use tests to the regime will increase complexity to the data-collection and data-sharing processes. Successful implementation of a mass-testing regime requires a thorough look at the data protocols in place.

4. **Building an extensive ecosystem of testing suppliers.** This paper identifies a range of UK companies with viable tests who could make a valuable contribution to the country's testing regime.
5. **Deepening and broadening engagement with a wide range of stakeholders.** As this document highlights, there is a wide range of stakeholders who can help the UK implement the mass-testing regime it needs. This requires the government to work in a more cooperative way, building the widest possible range of relationships with those who can contribute.
6. **Bringing onstream the widest possible range of tests.** To deliver the mass-testing strategy we believe is necessary, the UK cannot rely on a small number of tests by large suppliers. The widest possible range of viable tests from around the world should be brought onstream and used as part of the testing programme.
7. **Ensuring the UK has capacity for a two-step testing process.** By validating rapid point-of-use tests with "gold standard" lab-based tests, potential issues around false results can be mitigated.
8. **Applying testing regimes to a number of different settings.** Inspired by the success of the Premier League and examples from abroad, regular testing of all in a specific setting could be applied to those in care homes, businesses, universities and other locations.
9. **Replace the 14-day quarantine period with a shorter five-day quarantine period, subject to a negative Covid-19 test.** Given what we understand about the accuracy of tests and the incubation period of the virus, a shorter quarantine period using testing presents a net benefit. This should be constantly revised as we learn more about the virus and subject to its prevalence.
10. **Moving towards a health passport for all citizens.** Connected to their testing data, this health passport would allow individuals to know their Covid-19 status at any given time and confidently participate in social and economic activities.

Part II: Missed Opportunities

As well as the ambition set out in Part I, delivering a mass-testing regime will require the government to draw on the available capability in the market. Over the course of producing five papers on testing, we have been in touch with many UK suppliers. This section documents the rapid tests that are available for use, and the capability that exists within the market to significantly increase the capacity of UK testing.

What Rapid Tests Are Out There Now?

Rapid Antigen Tests

According to the website FindDX, which the European Centre for Disease Prevention and Control refers to, 17 rapid antigen tests have been commercialised ²⁰ (15 have been CE marked, while two are designated as research-use only).

In the US, BD (Becton, Dickinson and Company), a medical technology company, recently announced that the Food and Drug Administration (FDA) had granted them and Emergency Use Authorisation (EUA) for a 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. ²¹

Quidel, the maker of the 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. ²² The test delivers a result in 15 to 30 minutes and uses a nasopharyngeal swab. ²³

Rapid Antibody Tests

FindDX then lists 187 commercialised rapid antibody tests. ²⁴ The query the government has raised on these tests is around their accuracy. 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.

LAMP Testing

Progress has been in recent weeks on developing LAMP (loop-mediated isothermal amplification) tests.

These tests work by turning plate readers, the backbone of instruments in 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 misreporting of it being a rapid antigen test, the recent trial is for a LAMP test. ²⁵ The test has 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 reportedly been considered successful in clinical settings and the test is now being used in some A&E departments, GP testing hubs and care homes.

UAE-based Group 42, 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.”

Testing based on loop-mediated isothermal amplification – 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.

Case Study: Detect by Homodeus

Detect by Homodeus is an accurate, rapid, affordable home test for the novel coronavirus and is currently under development. A true home test, its methodology does not require samples to be sent to a lab for verification. Detect is built for scalability, and Homodeus is working to ensure Covid-19 is the last pandemic in which people do not have easy means to get tested.

Homodeus is a life-sciences company based in Guilford, Connecticut, and led by Chairman Dr Jonathan Rothberg. Dr Rothberg won the 2013 National Medal of Technology and Innovation from President Barack Obama for pioneering inventions and commercialisation of next-generation DNA sequencing technologies, and leads the 4Catalyzer incubator – seven companies that combine proprietary hardware innovation with artificial intelligence and cloud computing to make medicine and diagnostics more accessible globally. ²⁶

As reported by Homodeus, Detect is moving an entire laboratory into an at-home, do-it-yourself nucleic acid home test with test results in less than an hour. This contrasts with lab-, clinic- and hospital-based tests, which require a trained technician and a significant upfront cost per device, and can take several hours.

As a nucleic acid (molecular) test, Detect identifies the genetic material of the virus as soon as it is present, even in asymptomatic people. The company’s approach also differentiates from the common Covid-19 antigen and antibody tests, which cannot rule out active infection and are effective only at a much later point in the infection lifecycle (two to four days, and seven to ten days later, respectively, than molecular tests).

Working closely with the US FDA and pending FDA Emergency Use Authorisations, Homodeus aims to first distribute COVID Detect for point-of-care facilities and, shortly after, in a home setting.

Supporting the Testing Pipeline

Alongside the above tests are a number of other viable tests that are awaiting verification for use. These include rapid point-of-care antibody and antigen tests and novel innovations combining both antigen and antibody tests. Some innovators have focused on creating completely new tests, whereas others have developed new analysing or automation approaches that repurpose or maximise existing technologies. Either way, it's clear that there is collective will and brainpower out there to create a testing infrastructure that can underpin a mass-testing regime. It requires a commitment to innovation and leadership from the government.

In developing this paper, we have spoken with several innovators – many British-based – who have been kind enough to share their technology and to offer their insight into how the government could better support them to bring online their technologies. Many of them are already supplying the private sector or other countries to great effect.

All of this is done with the aim of boosting the UK's testing capacity and reducing the speed at which results are turned around – from days to minutes. Specific technologies that can achieve this are set out in the section titled “Available Opportunities on Testing”.

The collective insight of these testing providers tells us that government must do the following:

- **Provide clarity on mass-testing strategy – particularly on the role of rapid antigen and antibody tests.**

The companies believe there has been mixed messaging, for instance, around the use case for antibody testing. Here, the government has purchased 10 million lab-provided antibody test kits but currently do not allow pharmacies to use test kits that have been through the same approval process. Companies want to see the data on behavioural impact of an antibody test result that the government has generated already, again with a view to using this to inform their product development.

- **Set up a re-engagement meeting and ongoing interaction with small innovators to establish an ecosystem of testing suppliers.**

One of the clear themes that came out of the conversations with the suppliers was the difficulty they have had engaging with the government and maintaining a dynamic and open dialogue. Rectifying this through meetings and regular interaction will be vital to tapping the potential these companies have.

- **Offer a clear, transparent and open regulatory approval process.**

Many of the providers have engaged with the evaluation process and, many weeks later, not heard back. They say the process feels opaque and unclear, with a lack of communication.

This process should also be opened up to rapid lateral flow diagnostics, which will be important in providing rapid on-the-spot tests for public use.

- **Ensure a level-playing field.**

For several providers it appeared that the speed at which things had to be done had led to “who you know” being the ruling factor on getting tests validated. The government should ensure through communication and the pre-mentioned open regulatory approval processes that this is not the perception and provide a point of contact to address any issues smaller providers might have.

- **Introduce a streamlined approval process, including a viable emergency regulatory approval process for innovative devices.**

One of the firms we spoke with emphasised the importance of the Medicines and Healthcare products Regulatory Agency (MHRA) allowing a return to the normal process of regulatory approval for Covid-19 self-tests, which in normal times is a different process from professional use.

One element of this is ensuring the UK has a workable EUA process to bring onstream much needed tests that are good enough for public use. The current system does not appear to have kept pace with the demands of the pandemic.

- **Provide access to funding and patient samples for the ecosystem of testing suppliers.**

This would need to cover, for example, access to patient swabs to help with antigen and RNA test development. For T-cell tests the companies would need fresh blood samples.

This could be done by helping develop partnerships between these firms with a research institution that is attached to a hospital.

- **Ensure clarity and coordination with laboratories.**

For companies working on software that collects results from different providers – an essential component of a mass-testing strategy and a health passport – there were calls for setup and account management per lab site to allow for more effective “plugging in” of patient-facing software. Trained personnel would be required. Providers also recommended that government be more open to working with private smaller laboratories.

- **Make advanced orders of the requisite number of tests to support development.**

One of the firms we spoke with indicated that they have capital in place to deliver ramped up capacity but need advance demand requirements in the form of purchase orders.

- **Support the pre-purchase of reagents and other materials needed to bring these tests onstream and ramp up capacity.**

Assistance of this kind would enable the companies to progress with development in a coordinated manner with policy.

- **Galvanise the ecosystem of innovators around the future innovations that will be needed to tackle the pandemic.**

This requires the government to foster collaboration between partners and to introduce “moonshots” – high-risk, high-reward innovations that don’t yet exist but which would change the game on testing. Examples include a rapid antigen test that could be scaled into the tens of millions. This should inform a future product pipeline, where the government focuses and incentivises the collective brainpower of different diagnostic providers – and gives innovators access to data. The successful ventilator challenge was cited as an example.

Available Opportunities on Testing Overview



As part of our ongoing work on the topic of testing, we have spoken to a range of testing suppliers.

This section contains information from seven companies we have engaged with recently:

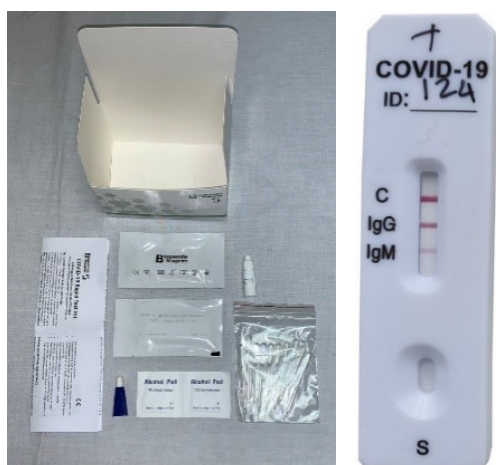
- Biopanda Reagents
- Mologic
- BioSURE
- Diagnostics.ai
- Omega Diagnostics
- QuantuMDx
- Project Screen by Circle: A consortium of industry experts led by Prenetics, together with the University of Birmingham, The Doctors Laboratory and support from Stuart [27](#)

In the following case studies, we show what these companies currently offer, what they are working on and what they could bring onstream with the right support from government.

Biopanda Reagents

What's available now?

Biopanda has developed a Covid-19 rapid antibody test that deliver results within minutes. Similar to pregnancy tests in appearance and application, it is primarily intended to test for past infection, which could be a useful surveillance tool deployed at a regional or population level. The tests can also be used to diagnose current infection when paired with antigen or RNA testing.



Biopanda has been supplying tens to hundreds of thousands of tests to Bahrain, Slovakia, the Czech Republic and Spain. Its tests have been registered with the Saudi FDA, and they are also pending registration in South Africa, Mexico and Nigeria. In the UK, Biopanda is still waiting for a standardised validation panel from Public Health England (PHE). Biopanda has submitted information to the New Test Approvals Group (NTAG) but has not heard anything back.

What's in the pipeline?

- **A rapid antigen test**

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.

- **An RNA test based on loop-mediated isothermal amplification (LAMP)**

This test is similar to PCR but does not require the use of expensive thermocyclers and is suitable for use in a point-of-care setting.

- **Covid-19 antibody ELISA test**

This is a lab-based version of Biopanda's existing rapid antibody test. This test specifically detects antibodies against the receptor binding domain (RBD) of the coronavirus. These antibodies are believed to have neutralising properties and so may confer immunity. Some vaccine candidates will operate by

inducing an immune response to the RBD and, therefore, this ELISA will be useful to researchers as a way of measuring the immune response generated by a vaccine.

- **Covid-19 Interferon Gamma Release Assay**

This lab-test is designed to test for cell-mediated or T-cell immunity, which is an increasingly important element in the immunity debate.

What could be contributed to UK's testing capacity now?

Today, Biopanda have the capacity to manufacture up to 50,000 rapid antibody tests per day, which could be supplied to the UK. This is an additional 350,000 tests per week.

Mologic

What's available now?

Mologic currently has four serology tests available.

- **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 PHE, but there have been positive conversations with PHE Colindale.

- **Professional RDT for IgG, IgM and IgA**

These diagnostic devices would identify a full range of antibodies. Forms have been submitted to 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+ capacity units here and in Africa.

- **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.

- **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's 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.

What could be contributed to the UK's testing capacity now?

- ELISA Test for IgG: 500,000 tests a week
- Professional RDT for IgG, IgM and IgA: 385,000 devices per week
- IgG Self-Test: 385,000 devices per week
- Laminated Test: Millions per annum

BioSURE

What's available now?

The BioSURE Covid-19 Antibody Self-Test, which is similar to a home pregnancy test. It can be performed by individuals on their own without the need for a health-care professional to be present, and they can read and interpret their own result all within just over 10 minutes. The test result is simple and binary – positive or negative. The intended use in the UK is to inform people that they have had the virus.

This product has been fully validated and is ready to go into full scale manufacture. The device is entirely based on the BioSURE HIV Self-Test, which has been CE marked (through BSI) and placed on the European market since April 2015. Almost 400,000 of these tests have been distributed in the UK since launch. The sole difference between the HIV test and the Covid-19 test is what is measured. The Covid-19 test measures a range of IgG class antibodies to SARS-CoV-2. Each test kit is supplied with all necessary components to run one test. The test kit can be supplied with two tests.



The BioSURE HIV Self-Test has already received a positive review ²⁸ from NTAG, and the company has been told that it is on the Department for Health and Social Care evaluation list, although the reference sample panel for evaluation (scheduled for the end of June 2020) is not yet available so this process cannot begin. The BioSURE HIV Self-Test has not yet been evaluated by PHE.

BioSURE has submitted a performance evaluation to address the MHRA suggested usability performance data deficiencies, with a decision expected in the coming weeks.

What's in the pipeline?

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

What could be contributed to the UK's testing capacity now?

BioSURE is currently able to manufacture around 100,000 Covid-19 antibody self-tests per week. These would benefit from existing distribution channels online (owned and affiliated) and in UK retail pharmacy to provide an over-the-counter service. These tests could be delivered directly to consumers who could pay for their own testing.

Diagnostics.ai

What's available now?

Diagnostics.ai automates data-analysis and quality assurance for all qPCR tests including Covid-19 tests. The clinically validated solution – pcr.ai – uses patented AI to crucially reduce manual labour and increase output while improving accuracy. It is currently in use at NHS King's College Hospital and has enabled testing to be ramped up without compromising on accuracy and patient safety. Pcr.ai has processed around 50,000 tests for three different Covid-19 test kits.

The pcr.ai cloud-based system is designed to automate the interpretation and quality assurance of Covid-19 tests in a fast and standardised manner. It can work with raw data created on any equipment (i.e. thermocyclers) used for testing, allowing standardised reporting regardless of lab setup.

Pcr.ai enables remote access for experts off-site and real-time diagnostic data to be aggregated across multiple sites for further analysis, and it could be easily integrated into track and trace processes to reduce infection spread. Multi-site data aggregation can be seen in diagnostics.ai's work with the Gates-funded PERCH study in which pcr.ai was used to analyse 300,000+ results from multiple sites internationally as part of the largest ever global health study.

Pcr.ai has been clinically validated as more accurate and faster than existing solutions, with 100 per cent accuracy for 20,000+ results, by the West of Scotland Specialist Virology Centre at NHS Glasgow.

What's in the pipeline?

Gettested.ai is a new system that connects labs and patients online, enabling patients to easily order a lab-test to their home and track the results. Gettested.ai allows swabs to be delivered to patient homes (or care homes, etc), arranges for the swab to be delivered back to the lab and, finally, sends results back to patients in an easy-to-use app.

Additionally, pcr.ai is integrating serology test support (for antibody testing), managing orders into the laboratory and also working on a new version that complies with requisite requirements, including an updated user interface.

What could be contributed to the UK's testing capacity now?

Diagnostics.ai has the ability to ramp up the UK's existing testing capacity while crucially ensuring accuracy and patient safety are maintained. Its automation of complex processes – including data analysis, quality assurance and the ability of patients to track their test results regardless of supplier – will be critical to a mass-testing system. Pcr.ai can process hundreds of thousands of tests a day, it is hosted on Amazon Web Services and is simple to scale up.

Diagnostics.ai can be used for point-of-care testing in homes, care-home testing and border-control testing. The results from all of these systems can be combined to deliver real-time dashboards to a centralised source, to help with track and trace and policy decisions on how to manage local outbreaks.

Omega Diagnostics

What's available now?

Headquartered in Alva, Scotland, with an additional facility in Littleport, Cambridgeshire, Omega Diagnostics has the capability to manufacture both ELISA tests and lateral flow tests.

It currently has a CE-marked antibody ELISA test that was completed through its partnership with Mologic (see above), and the test was CE marked back in April. It has since been robustly validated in studies with more than 1,300 patients by the Liverpool School of Tropical Medicine and St George's University Hospital.

The company is currently validating both a finger stick and dry blood spot sample-collection method, which will allow samples to be taken at home and returned to a lab for testing. It expects this method to be CE marked and available by mid-August.



Omega is also completing the technical transfer of Mologic's lateral flow professional-use antibody test, and this will be CE marked by the end of August. Like the ELISA, this has been robustly validated by both Liverpool and St. George's.

Omega still awaits the outcome of evaluation by PHE, having submitted kits earlier this year.

What's in the pipeline?

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 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.

What could be contributed to the UK's testing capacity now?

ELISA tests: 275,000 tests per week (increasing to 1 million+ by end of year)

Lateral flow production: 100,000 tests per week (increasing to 1 million+ by end of year)

QuantuMDx

What's available now?

QuantuMDx has developed a real-time reverse-transcription polymerase chain reaction (rtRT-PCR) assay to specifically detect the virus. The kit was developed using advanced bioinformatics to maximise performance and combines all required reagents into a single tube for the convenient performance of RT-PCR from extracted nucleic acids.

The test is provided in a vial format for ease of use and extended shelf life. It has been designed to return concise Covid-19 status with no “indeterminate” result. QuantuMDx’s test has been validated against a number of RNA-extraction kits and thermocyclers, is CE marked and has been designed and manufactured in the UK.

The test has undergone independent evaluations in seven locations (five of which were in the NHS), including Hampshire who performed the validation on currently used NHS tests. QuantuMDx was informed that PHE validation had been paused, causing the company to shift its focus to direct interactions with the NHS.

What's in the pipeline?

A rapid, portable molecular point-of-care solution (Q-POC) will 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.

What could be contributed to UK's testing capacity now?

1 million tests are available for immediate dispatch, rising to 2 million in the medium-term

Project Screen by Circle

What's available now?

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. ²⁹

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 ³⁰ to test every single restaurant worker. It is able to work

with specific settings to allow employers to bring employees back to work. The company is currently working with:

- Premier League and other sports
- Numerous airports
- Numerous film productions
- Numerous sports
- Numerous corporates

In essence the availability of these solutions will be consumed by projects in the pipeline as the company continues to build further capacity for larger projects.

What's in the pipeline?

The group has invested in RT-LAMP technology with a new partner, FRANKD technology solutions. This will become a solution offering highly accurate point-of-care analysis with high sensitivity and specificity as a screening tool. The cost of test is lower, throughput is higher, and this is also linked to health-passports solutions and identification.

The product can test up to 90 people at a time in 60 minutes (post-sample collection time). It is currently in position as part of the Heathrow trials, has been deployed in a large Southampton trial ³¹ and is also in a trial at Birmingham airport.

The product is in the process of emergency FDA approvals and is already CE marked. The specificity of the test is 100 per cent and sensitivity is at 97 per cent – comparable and often surpassing lab-based tests. The capacity for RT-LAMP is practically limitless as Project Screen by Circle is investing in the company behind the technology for the benefit of its own supply chain.

What could be contributed to UK's testing capacity now?

The group has capacity for approximately 5,000 RT-PCR tests but can deliver up to an additional 20,000 tests per day using RT-LAMP technology and various deployment models on-site and otherwise.

Footnotes

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