Department
of Health &
Social Care

Coronavirus (COVID-19)
Scaling up our testing programmes

Department of Health and Social Care

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Ministerial Foreword

One of the worst things about coronavirus is the uncertainty, not knowing who has the infection or when it's safe to return to normal life. Good quality testing can help provide us with certainty. It's a big part of how we're going to defeat this disease.

Public Health England have done world-beating work on testing, designing the first COVID-19 diagnostic test and rolling it out faster than any other novel test in recent history. We are ahead of most European countries for testing at this point, and we have undertaken the third highest number of tests in Europe, behind Italy and Germany. But our testing efforts face big challenges that we now need to overcome. This plan sets out how.

Here are the challenges. First, we are starting from a lower base. Unlike some countries, we didn't go into this crisis with a major diagnostics industry to call on. There is also huge international demand for crucial testing materials like swabs and chemical reagents.

Given that finite capacity we've had to prioritise. I completely understand that NHS staff want to get tested so they can return to the frontline as fast as possible. But early on I took the decision that seriously ill patients had to come first. For them, a test can mean the difference between life and death. My overriding goal is to protect life and I stand by that decision.

We also have to ensure that any new test products are up to the job. Our experts are clear that no test is better than a bad test, and several of the tests we've checked have been too inaccurate to be of any use in this crisis. I will not send NHS staff back onto the wards with the false comfort of a false negative result.

Our ultimate goal is that anyone who needs a test should have one. We will get there through a phased approach, starting with patients who need the test, expanding to NHS workers and their families as we are now doing, then other key workers as we ramp up further, and then expanding to the wider community over time. Our testing strategy has five pillars, which this document sets out in full.

The first pillar is boosting swab testing – testing to find out if you have the virus – in PHE labs and NHS hospitals. We have already reached our ambition of 10,000 tests per day, on time, by the end of March as we committed. We are now committed to reaching 25,000 tests per day by the end of April at the latest.

The second pillar is the creation of brand-new swab testing capacity delivered by commercial partners. Again, this is swab testing to tell if people have the virus. The biggest part of this pillar is the partnership with universities, research institutes and companies such as Amazon and Boots, to build a network of new labs and testing sites across the UK. This new service has just launched and is ramping up rapidly. We are also working with other testing companies to expand Pillar 2 so that over time we have many different commercial companies delivering mass swab testing.

The third pillar is antibody tests: tests are designed to detect if people have had the virus and are now immune. These could potentially be done at home with a finger prick and deliver results in as little as twenty minutes. We are currently working with nine companies who are offering these tests and are evaluating their effectiveness. Antibody tests offer the hope that people who think they have had the disease will know they are immune and get back to life as normal. But crucially, they have to be proven to work.

The fourth pillar is surveillance. We are conducting some of the biggest surveys in the world to find out what proportion of the population have already had the virus. This is done using an ultra-high accuracy antibody test operated by Public Health England at their Porton Down science campus. We will use these tests to help strengthen our scientific understanding and inform us all on the big choices we have to make about social distancing measures and how we exit from this crisis.

The fifth pillar is the most ambitious. We are going to build from scratch the large diagnostics industry that this country currently lacks. Just as our top end manufacturers have joined the national effort to build ventilators, so our pharmaceutical companies will do the same for testing. UK pharmaceutical giants, like AstraZeneca and GSK, which don't have a tradition of diagnostics, are now working with our world leading but smaller diagnostics companies, to build a British diagnostics industry at scale. This new national effort for testing will ensure we can get tests for everyone who needs them.

Taken together, I'm setting the challenge across all five pillars, of 100,000 tests per day, by the end of April. To drive this forward, I'm delighted that Professor John Newton from Public Health England will be taking on a new role to lead this national effort for testing.

These five pillars represent a comprehensive plan to put in place the testing that is mission critical as we fight this battle against COVID-19.

There will be problems, like those that we have already overcome. There will be bumps in the road and criticisms made – some justified. But we have some of the best minds and science in the world at our disposal, and having recovered from the illness myself I am more determined than ever to take the fight to this disease.

[Signature]

Secretary of State for Health and Social Care

Testing matters

1.1 Testing is a key pillar of our plan to protect the NHS and save lives. We are focused on two types of tests: 'swab tests' for people with symptoms to see if they have coronavirus; and 'antibody tests', which test for the presence of antibodies that provide immunity from coronavirus.

1.2 The Government is committed to mass testing: our overall ambition is to provide enough swab tests for everyone that needs one. In the 'contain' stage, our focus was on testing to support contact tracing and investigating outbreaks. At present, whilst the country is being asked to practice social distancing, this means:

(a) providing tests for people with a medical need; and

(b) providing tests for NHS, social care and then wider critical workers and their families who are in self or household isolation, to support them to return to work if they are well enough to do so.

1.3 We are working with partners to expand swab testing to critical NHS staff and their families (details below under Pillar 2), so they can stay in work if they test negative and keep themselves and others safe if they test positive. Once widespread testing is available, we will test critical key workers regularly, to keep them safe and ensure they do not spread the virus. Over time, we hope to make testing available to all NHS staff, other critical key workers, and ultimately to the whole population as needed. Should antibody tests prove to be effective, our strategy will then evolve to also help identify those who have had the disease.

1.4 The Government is setting the challenge to itself and to the whole system - industry, academia, the NHS - to reach 100,000 tests Name Redacted across the UK by the end of this month. This is a huge ambition. Currently, we are delivering around 10,000 swab tests per day - but it is the right ambition to set at this time. If we can go further, then we will. We will work collaboratively but with each nation allocating targets and tests to meet their specific needs

1.5 This is an evolving document that will develop as we learn more about the virus, and progress the work under the five pillars.

Challenges

1.6 **Getting the right supply of people, lab space, equipment and chemicals:** specialist labs are needed to analyse each sample with the right diagnostic machines and skilled professionals. We are also obtaining large numbers of chemicals needed in the testing process. But there is a global shortage in some types of swabs and reagents needed for the two key steps of the testing process, known as the RNA extraction and the PCR test. We are taking every step to address these shortages: working alongside industry to increase our global share of 'closed platform' kits (integrated kits in which all elements need to come from the same supplier) from existing large suppliers - and to scale up our volume from new suppliers; rapidly identifying and expanding capacity of open platforms in the NHS (open platforms can take testing components from a wider range of suppliers, increasing the suppliers available); and creating other local sources of supply of components, including through local manufacture or the use of appropriate alternatives (e.g. making use of dry swabs as well as wet swabs).

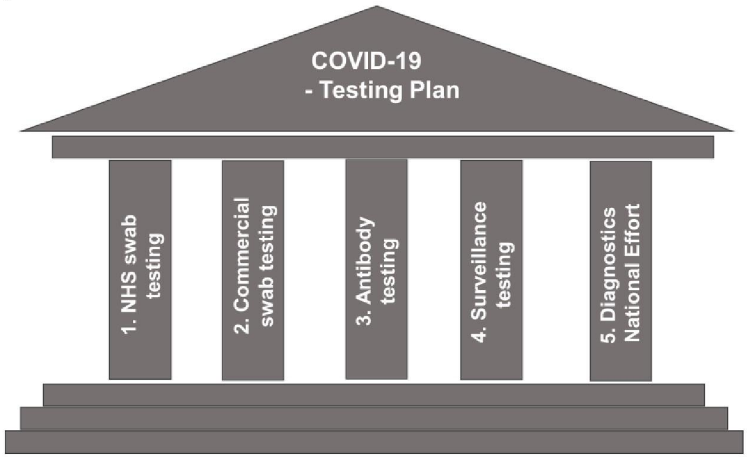
1.7 **Logistics:** with a highly contagious disease and tests that need to be done correctly to get a result, we have had to think through carefully: how people with symptoms access testing facilities; how swabs are stored and transported to laboratories where they can be tested; and how results can be fed back to those tested. We need to harness traditional logistical capabilities, including assistance from the military, alongside new digital solutions to make this happen, whilst providing people being tested with clear information about what is happening throughout the process. And are needing to put all this in place in weeks, rather than over years.

1.8 **Accuracy and reliability of tests**: as with everything we are doing to tackle coronavirus, we need to be led by the science. No test is better than a bad test. We need to ensure that all the tests we use are validated, reliable and give us an accurate result. We also need to understand the quality of new tests such as the antibody test before we start using them. We are working with a number of companies to evaluate tests and this validation is ongoing - but the science is new and uncertain. This shows the importance of having a rigorous process in place and checking every step for accuracy and reliability.

1.9 Testing rates differ across countries, depending on what stage the infection is at; how it is spreading; and existing testing capacity. The UK is carrying out the same or more swab tests per positive case as many of our European neighbours at this stage of the virus. However, other countries such as South Korea and Germany, have higher testing rates and we can learn from how they have achieved these goals. Germany has been able to take advantage of the existing technology and infrastructure in its large diagnostics industry, with over 100 cutting edge testing labs. The UK is a world leader in life sciences, and we can harness this capacity to help us scale up rapidly. We have seen many examples of innovative UK companies offering their support to tackle this crisis, both to move into diagnostics and to scale up testing capacity.

Scaling up our testing programmes

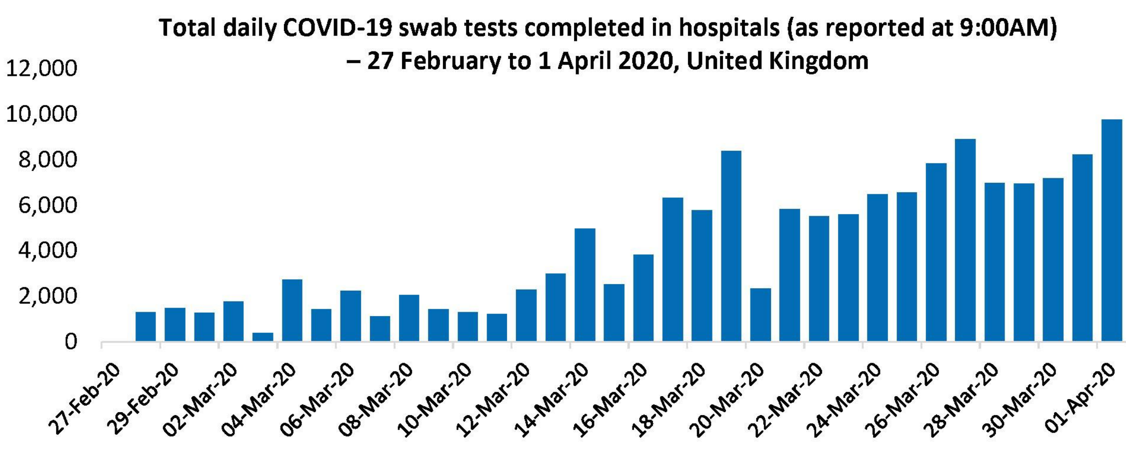
1.10 The Government is working with the best minds in science, industry and logistics across the country and the world to scale up our testing capacity. Our strategy has five pillars:



Pillar 1) Scaling up NHS swab testing for those with a medical need and, where possible, the most critical workers

1.11 This type of testing allows the NHS to identify and effectively care for those who are most seriously ill – saving lives by helping clinicians decide the most effective treatment options. These swab tests are largely delivered through Public Health England and, now, NHS laboratories across the country. The number of these tests done has doubled from 5,000 a day to 10,000 a day over the last fortnight. This puts us ahead of most other European countries at this stage of an outbreak.

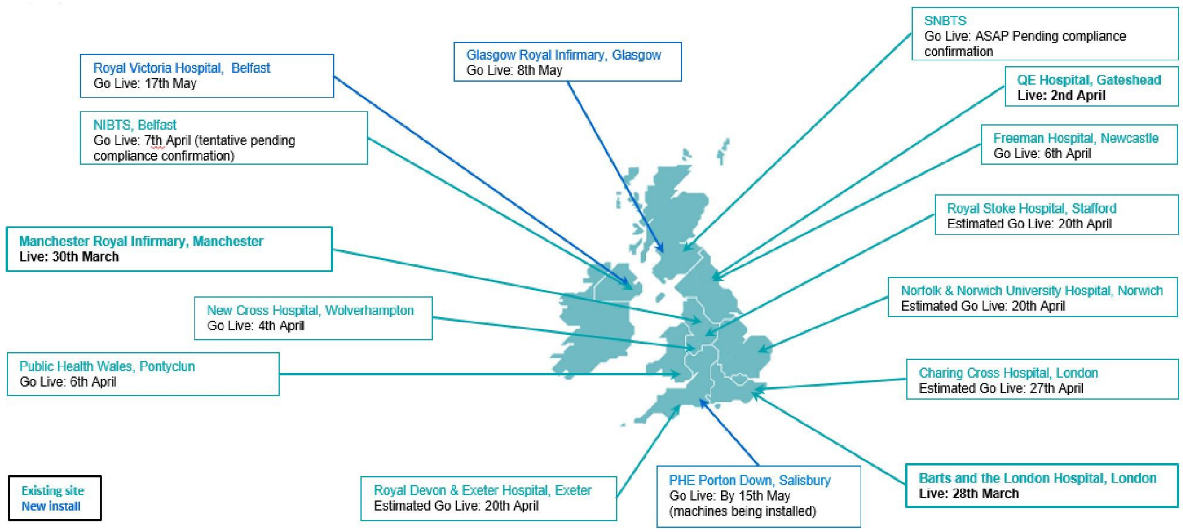
Chart 1: Total daily COVID-19 swab tests (27 February to 1 April 2020, UK)



Source: Public Health England, NHS England / Improvement (2020)

1.12 But we need to go further, as fast as possible. PHE and NHS England and Improvement are committed to increasing their capacity to 25,000 swab tests per day by the end of April, including through a partnership with Roche Pharmaceuticals, which will see new testing facilities opened throughout the UK.

Figure 2 - Public Health England /Roche Partnership: COVID-19 High-throughput, Real-Time PCR automated testing sites - Update as of 2 April 2020



Source: Public Health England (2020)

1.13 In line with our strategy, the majority of this testing has been for those with a medical need - for example, identifying coronavirus sufferers amongst the most unwell people in hospital to allow clinicians to separate them from other vulnerable patients; or investigating specific outbreaks.

1.14 Within these numbers, some critical NHS workers have already been tested for COVID-19, where there has been spare capacity. As capacity increases, it is now possible to also ramp-up the volume of critical staff testing. Yesterday, as NHS Trusts had created further additional capacity, NHS England instructed that any spare capacity can be focused on testing critical frontline workers (or their symptomatic family member), allowing them to return to work.

Pillar 2) Mass-swab testing for critical key workers in the NHS, social care and other sectors

1.15 As of this morning over 2,800 NHS workers have been tested across five new testing sites. Over the coming weeks and months, we want to increase the scale of testing at much greater rates – to reach thousands more health and care staff – and to also cover critical workers in other sectors, e.g. prisons, police, and some local authority services. This will allow us to release more staff who are well enough to work but currently self or household isolating back to the frontline, boosting capacity at a time when public services are under pressure.

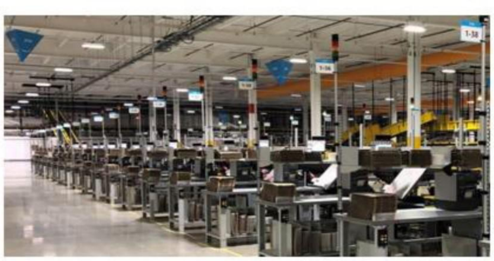
1.16 To deliver this mass expansion in testing, in mid-March we began a partnership with universities, research institutes and companies such as Amazon and Boots to create a mass testing infrastructure in the UK through the creation of a network of new labs and testing sites across the UK.

1.17 New testing laboratories are being set up in Milton Keynes, Manchester and Scotland using Thermofisher test machines donated by universities across the country. We are working with Boots and other partners to establish over 50 regional test centres around the country, starting in some of the main hotspots of the virus, such as London and the Midlands. And we are urgently working on standing-up a home-testing service for key workers, supported by Amazon's logistics network and other commercial partners.

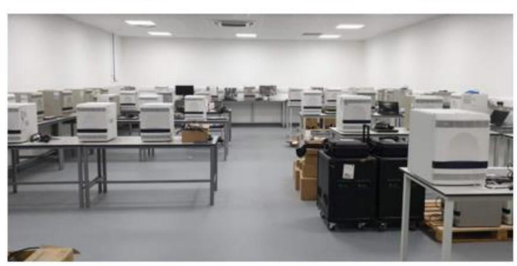
New test centre in Nottingham live

Staff training in Nottingham

Dedicated Amazon fulfilment centre



New lab operational in Milton Keynes



1.18 As part of this national effort, we have also partnered with Randox in Northern Ireland, to establish a major laboratory in the Province to strengthen the UK-wide testing capacity for health and care staff and other key workers. Randox have also led in the development and production of sample self-collection kits, distributed through Amazon, to enable testing of key workers throughout the UK whilst they remain at home.

1.19 We are already working in many partnerships to maximise testing capacity and are keen to explore all options including:

(a) Offering our support to innovators that are producing promising new types of tests, such as DNANudge that has been used at Imperial and Samba at Addenbrookes, which provide fast turnaround point of care testing.

(b) Working with universities and with Universities UK. For example, through the creation of a new online portal, supported by Reed employment. This was launched today, and allows university staff with laboratory skills to volunteer to assist with the testing programme. Some specialist labs in universities are already supporting the validation of new consumables and tests and providing lab technicians, equipment and consumables (for example reagents) to the programme. We will be working with Universities UK and others to provide further guidance on how our university sector can help the mass testing effort.

(c) Working with colleagues at the Department for Environment, Food and Rural Affairs (DEFRA), who are already supporting the COVID-19 testing programme and have provided specialist laboratory equipment (PCR and robots) and expert personnel to support Public Health England and government labs. In addition, DEFRA and other scientists plus Public Health England and Department of Health and Social Care colleagues are committed to working together to agree how best to use the remaining capacity of three major animal testing labs to further support the testing effort (the Animal and Plant Health Agency, Fera Science, Pirbright).

Pillar 3) Mass-antibody testing to help know if people have immunity to coronavirus

1.20 We will secure and if appropriate distribute millions of antibody tests, which could tell people whether they have had the virus and are now immune. Such tests are done by taking a blood sample and looking for the presence of the right COVID-19 antibodies. Once proven in a laboratory setting, in time, this testing could potentially be done at home with a finger prick and deliver rapid results - maybe in as little as twenty minutes. Hence, we would hope to use a combination of laboratory-based serology testing, and home-based testing.

1.21 These antibody tests are brand new and are still being developed. No government in the world has yet rolled out a full COVID-19 antibody testing programme. Therefore, we are currently engaged with a growing number of companies and urgently testing the quality, accuracy and effectiveness of potential tests with scientific experts and regulators. We have bought our current stock on the basis of minimum initial volumes to enable clinical testing. If the outcome of this is that the antibody tests do not work, no further tests will be purchased and where possible orders cancelled.

1.22 Should these kits work, we will work to deploy them in their millions. In time, and subject to clinical advice, they could be used to inform the use of social distancing measures in the future. However, our experts are clear that an unreliable test is worse than no test. We need to be led by the evidence. Therefore, the Chief Medical Officer discourages in the strongest terms organisations from buying their own unvalidated antibody tests.

Pillar 4) Surveillance testing to learn more about the disease and help develop new tests and treatments

1.23 Robust population surveillance programmes are essential to understand the rate of infection, and how the virus is spreading across the country. They help us to assess the impact of measures taken so far to contain the virus, to inform current and future actions, and to develop new tests and treatments.

1.24 Since the end of February, we have established a national surveillance programme for population blood testing, using an ultra-high accuracy antibody test operated by Public Health England at Porton Down, to find out what proportion of the population have had the virus.

1.25 Public Health England is testing samples of the population and is in the process of analysing the first 400 samples collected. We are expanding this programme so that we have the potential to test up to 3,500 samples per week.

1.26 We will also roll out a national mass population sample over the coming months. UK Biobank will invite their participants (aged 50-75 approximately) and their adult children who do not live with them to participate in a study involving at-home immunity testing every 4-weeks over a 6 to 12-month period. UK Biobank are aiming to enrol 16,000 to 20,000 people who will undergo repeat testing. This will add to the data, as well as telling us about immunity and how long it lasts.

Pillar 5) Spearheading a Diagnostics National Effort to build a mass-testing capacity at a completely new scale

1.27 Britain has an innovative, but relatively small diagnostics industry. We now need to grow it, massively and quickly. We are calling on all British life science companies to turn their resources to creating and rolling out mass testing at scale. In the short-term, this will help meet the supply outlined in the other strands in this plan, and then help us develop a homegrown resilient, diagnostic capability in the UK capable of meeting the testing demands over the coming months and years.

1.28 We are therefore asking industry to work with us on how this can best be achieved. We want proposals for new national industrial capability that meets a set of clear principles.

(a) It must be flexible, able to quickly adapt both the tests themselves and the delivery of those tests as the virus and our response evolves over time. We want to explore increasingly decentralised models of testing, moving away from central labs to testing in local hospitals, at work or in the home.

(b) The solutions must enable testing at huge scale, but with extremely high levels of accuracy and sensitivity. A bad test is worse than no test.

(c) It needs to be resilient - the end to end supply chain for the test should be domestically based as far as practically possible, with a clear and deliverable plan for the capacity and capability to deliver the scale of testing we need.

(d) It must as open source as possible with the ability for components, consumables, chemicals and digital components to be produced by a range of manufacturers - quickly and easily. And it should be clear how new companies can join and contribute to the approach.

1.29 We will be issuing a series of calls over the coming days - these will be asks on specific areas where we need current capability to be ramped up, as well as more detail on our plans for the growth in our national diagnostic industry.

1.30 We are already working with our multinational companies like AstraZeneca, GlaxoSmithKline, key trade bodies like the UK Bio Industry Association, the British In-Vitro Diagnostic Association, and the Association of the British Pharmaceutical Industry, and a range of smaller companies with innovative solutions. Over the coming days, we will ramp up this engagement further, working with many others to develop this national effort.

Next steps

1.31 This is a comprehensive plan to put in place the testing we need to fight this battle against COVID-19:

- First, the NHS will now be using all their spare capacity to test critical staff at the frontline of health and care;
- Second, we will complete the pilot of our new commercial swab testing programme and hope to then offer thousands of swab tests per day;
- Third, we will complete our evaluation of the antibody test kits we are working with and share the results; committing to develop further any promising tests for clinical and then potential home use;
- Fourth, we will ramp up our efforts to survey the population, to learn more about this virus so we can develop tests and treatments and, hopefully, vaccines; and
- Finally, we are going to rapidly build a diagnostics industrial strategy that will develop our manufacturing capabilities in order to secure a stable supply of the tests, equipment and consumables we need for mass-testing at scale.