Testing Times

The urgent need to decentralise COVID-19 diagnostic testing in the United Kingdom

By Matthew Lesh

EXECUTIVE SUMMARY

- COVID-19 is the biggest public health emergency in modern history. There have already been over 875,000 confirmed cases and 43,500 deaths worldwide. These numbers are expected to grow exponentially in the coming weeks, potentially resulting in millions of cases and hundreds of thousands of deaths.

- The United Kingdom is experiencing a substantial growth in cases and deaths. Over 2,350 people confirmed to have died after contracting the virus. This number is doubling approximately every 3 days, putting the UK on a similar trajectory to the worst affected regions in the world.

- Testing is a key tool to combat infectious diseases. It allows doctors to identify the needs of patients, public health authorities to trace and isolate cases to minimise spread, and epidemiologists to track the spread of an outbreak. It is also essential for healthcare workers to return to the frontline.

- The UK has fallen to the bottom quarter of OECD countries for COVID-19 diagnostic testing, on a per capita basis. South Korea has tested four times as many people as the UK, Germany almost three times and the United States now almost twice as many, per capita.

- The early decision to centralise testing to a single Public Health England (PHE) laboratory has hampered the ability to increase testing in the UK. Testing has now been expanded to 12 labs operated by PHE as well as a limited number of NHS laboratories.

- The most successful countries in testing COVID-19 – such as Germany, South Korea, and more recently, the United States of America – have decentralised testing and embraced a mixture of public, non-government and private laboratories.

- Since March 16, the United Kingdom has just over doubled daily testing capacity. In the same time, the United States has increased daily testing by a factor of 21.

- The private sector has shown an extensive willingness to support the Government's efforts to tackle COVID-19, including the rapid design and manufacture of ventilators and agreeing to transfer beds and staff in independent hospitals to the NHS.

- If the UK Government wants to meet its testing targets and save lives, it must:
    - fast-track approval for private sector laboratories to conduct COVID-19 testing;

- substantially expand usage of NHS and university laboratories to conduct COVID-19 testing;
- undertake rapid approval of private sector developed tests, including mutual recognition of tests approved by other regulatory bodies such as the FDA;
- reduce testing red tape, including any requirements that initial positive tests must be retested centrally by PHE; and
- explicitly call on companies to help make testing kits and develop lab capacity for COVID-19 testing, modelled on the successful call for businesses to make ventilators.

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COVID-19 is widely thought to have begun in late 2019 in the Chinese city of Wuhan, the capital Hubei Province. The initial signs were a high number of pneumonia patients displaying symptoms reminiscent of SARS, that was later identified to be caused by a novel coronavirus to be named SARS-CoV-2. Cases were identified shortly thereafter outside of China, including in Thailand (January 13) and Japan (January 16). On January 23, the Chinese Government placed Wuhan in complete lockdown. However, this was only after local authorities sought to silence doctors and officials attempting to raise awareness of new cases, and downplay the potential for human-to-human transmission, which allowed for spread across China and the rest of the world.[1] On March 11, the World Health Organisation declared SARS-CoV-2, which also became known as COVID-19, a global pandemic.[2] What began in China had now spread to practically every corner of the globe. The number of confirmed cases and deaths, particularly in Europe and the United States, is now following an exponential growth trajectory.[3]

On March 16, the head of the World Health Organisation Tedros Adhanom Ghebreyesus explained that "the most effective way to prevent infections and save lives is breaking the chains of transmission. And to do that, you must test and isolate":

> "You cannot fight a fire blindfolded. And we cannot stop this pandemic if we don't know who is infected.
>
> We have a simple message for all countries: test, test, test.
>
> Test every suspected case. If they test positive, isolate them and find out who they have been in close contact with up to 2 days before they developed symptoms, and test those people too."[4]

Testing provides a range of short and medium to long-term benefits in tackling COVID-19:[5]

• Testing helps patients receive appropriate care.

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1 The Wall Street Journal, "How It All Started: China's Early Coronavirus Missteps" https://www.wsj.com/articles/how-it-all-started-chinas-early-coronavirus-missteps-11583508932.

2 World Health Organization, "WHO Director-General's opening remarks at the media briefing on COVID-19 - 11 March 2020," https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020.

3 John Hopkins University & Medicine, "Coronavirus COVID-19 Global Cases by the Center for Systems Science and Engineering (CSSE) at Johns Hopkins" https://coronavirus.jhu.edu/map.html.

4 World Health Organization, "WHO Director-General's opening remarks at the media briefing on COVID-19 - 11 March 2020" https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020

5 For discussion on the importance of diagnostic testing in epidemic and pandemic, see https://gh.bmj.com/content/4/Suppl_2/e001179; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4823022/; World Health Organization, "Report of the WHO-China Joint Mission on Coronavirus Disease 2019 (COVID-19)" (February 2020), https://www.who.int/docs/default-source/coronaviruse/who-china-joint-mission-on-covid-19-final-report.pdf.

- Testing provides a strong impetus for asymptomatic and mild to moderate patients to isolate to avoid onwards transmission.
- Testing allows healthcare workers to withdraw from active care if found to be positive, or otherwise to be redeployed to the front line if found negative, particularly those with an unrelated cold and flu symptoms.
- Testing allows for the tracking of the pandemic, providing insight on emerging clusters and how to best allocate healthcare resources.
- Testing also allows low-risk patients who are displaying cold or flu symptoms but do not have COVID-19 to stop isolating.[6]
- Testing allows authorities to move from community-wide interventions, such as social distancing, to case-based interventions focused on targeting and isolating individual people who are infected – therefore allowing life to get back to normal.[7]

The typical test for COVID-19 is a polymerase chain reaction (PCR) test. It involves taking a swab from an individual's nose and throat, which is then compared to the genetic footprint of the COVID-19 virus. The first tests were developed within weeks of the COVID-19 outbreak. Ideally testing would be available for hospitalised patients, healthcare workers, close contacts of confirmed patients and individuals with symptoms. In the case of COVID-19, this is a rapidly expanding group of people and therefore requires the development of substantial rapid testing capacity.

PCR tests are not perfect. There is the potential for false-negatives: patients who have the virus but are found in the test to not be positive. This can be because the patient is in such an early stage of a disease that the viral load is too low to be detected, a lack of respiratory symptoms so there is too little of the virus to detect, a problem with sample collection or handling, or even that the virus has mutated. It is therefore necessary to test people multiple times as well as update tests as a virus mutates over time.

This paper will focus on tests that seek to assess the current viral load of patients. The other major test is an antibody test, which seeks to assess past infection, is outside of the scope of this paper. Antibody tests are currently in development, testing and production. They will form an important part in tracking the extent of the COVID-19 spread and enabling life to get back to normal. The UK Government has announced the purchase of millions of these tests and is currently assessing them for use, initially for NHS patients and subsequently for epidemiological purposes. This should be a top priority.

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6 When the Government begins to loosen social distancing rules it is likely those with mild to moderate symptoms will have to continue isolating for 7-14 days, causing substantial absence from work and school. It will be necessary to have plentiful tests to show whether people have a normal cold/flu or COVID-19 to determine the extent of isolation that is necessary.

7 American Enterprise Institute "National coronavirus response: A road map to reopening" (March 2020), https://www.who.int/docs/default-source/coronaviruse/who-china-joint-mission-on-covid-19-final-report.pdf.

There have been widespread concerns about the extent of diagnostic testing for COVID-19 in the United Kingdom. A *Change.org* petition calling for the testing of frontline NHS staff has received 1.3 million signatures.[8] This has been echoed by politicians from across parties who have called for a rapid and substantial increase in testing capacity. Former Health Secretary and current chair of the Health select committee has explained that Jeremy Hunt:

> "If you look at what's happening in Korea, Taiwan, Hong Kong, Singapore, they've actually managed to keep their offices, shops and restaurants open.
>
> "But they do that by having a mass programme of testing, which means that anyone who has suspected Covid-19 symptoms is immediately tested, everyone they've met in the recent past is also tested, and that means you can stay on top of the virus and keep the economy functioning.
>
> "So when we get through this phase and then we think about what is going to happen in the six months to a year that we have to wait for a vaccine to come, if we want to avoid these kind of lockdowns that we're seeing all over Europe then mass testing is the way to do it."

Labour Shadow Health Secretary Jonathan Ashworth has demanded answers on the lack of scaling up of testing:

> "Experts continue to call for the UK to significantly ramp up testing. When Germany is testing around 500,000 people a week, many are asking why we are still not even hitting the 10,000 a day promised on March 11th. We called for enforced social distancing, but it is a blunt tool without a national strategy to test and contact trace."[9]

Former Labour Prime Minister Tony Blair has also explained the need to test "virtually everybody" to combat the virus.[10]

Many of the countries that have been successful in fighting the spread of COVID-19 have decentralised testing, including enlisting the support of private labs to expand capacity. To date, the UK Government has not taken this approach, instead relying exclusively on Public Health England (PHE) and subsequently National Health Service (NHS) labs. This paper outlines the current state of testing in the United

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8 change.org, "Test frontline NHS staff for COVID-19 as a priority," https://www.change.org/p/the-nhs-test-frontline-nhs-staff-for-covid-as-a-priority.

9 Labour, "Labour demands answers on why coronavirus testing is still not being scaled up at sufficient levels," https://labour.org.uk/press/labour-demands-answers-on-why-coronavirus-testing-is-still-not-being-scaled-up-at-sufficient-levels/

10 Sky News, "Coronavirus: Tony Blair says 'virtually everybody' in UK may have to be tested," https://news.sky.com/story/coronavirus-tony-blair-says-virtually-everybody-in-uk-may-have-to-be-tested-11965283.

Kingdom and how other countries have increased testing capacity using the private sector. It concludes that if the UK Government wants to wage a successful 'war' on COVID-19, it will be necessary to enlist all fighters. This means using as much NHS capacity as possible as well as expanding testing to private sector laboratories and a wide array of tests.

THE UK'S LIMITED TESTING CAPACITY

The UK began testing for COVID-19 in January, initially using just one lab: PHE's reference laboratory located at Colindale, London. The UK chose a single state-run lab, initially capable of doing 100 or fewer tests a day. This is in stark contrast to the likes of South Korea and Germany, and later, the United States, who have activated a large network of public and private laboratories.[11] PHE also chose to develop and encourage the use of its own diagnostic tools, rather than seeking the development of a range of private sector tools and providing fast-track approval.

It was not until 10 February that PHE began to expand capacity to all twelve of its labs across England, Wales, Scotland and Northern Ireland — initially only using the diagnostic test developed by PHE. This expanded capacity to 1,000 per a day.[12] Subsequently, NHS labs have been included in testing. The initial strategy was for PHE to contact-and-trace all infections to prevent widespread community transmission. Since March 14, however, individuals staying at home "are not prioritised for testing".[13] The lack of testing and tracing capacity, along with the broader spread, triggered the need for extensive social distancing.

On March 11, the Government stated it would increase testing to 10,000 a day.[14] On March 18, the Government committed to reaching 25,000 tests within 4 weeks — and in the same release the Government stated it 'hoped' to reach 10,000 'by next week'.[15]. However, this goal had not been reached – with just 9,114 tests on Friday, March 27 and 8,278 tests on Saturday, March 28. On March 19, Prime Minister Boris Johnson stated that the Government would "hopefully very soon [increase testing] up to 250,000 per day".[16] On Friday, March 27 the Government again announced the intention to "significantly scale up testing." *The Guardian* has reported that Public Health England has the capacity to undertake 10,949 daily

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11   "How the UK got coronavirus testing wrong" Financial Times, March 27, 2020, https://www.ft.com/content/fa747fbd-c19e-4bac-9c37-d46afc9393fb.

12 Gov.uk, "New surveillance system for early detection of COVID-19," https://www.gov.uk/government/news/new-surveillance-system-for-early-detection-of-covid-19.

13   Gov.uk, "COVID-19: investigation and initial clinical management of possible cases" https://www.gov.uk/government/publications/wuhan-novel-coronavirus-initial-investigation-of-possible-cases/investigation-and-initial-clinical-management-of-possible-cases-of-wuhan-novel-coronavirus-wn-cov-infection#interim-definition-possible-cases; Gov.uk, "Coronavirus testing" https://www.gov.uk/government/news/coronavirus-testing.

14   BBC News, "Coronavirus : NHS to ramp up testing capacity," https://www.bbc.co.uk/news/health-51814874.

15   Gov.uk, "Testing for coronavirus (COVID-19) will increase to 25,000 a day," https://www.gov.uk/government/news/testing-for-coronavirus-covid-19-will-increase-to-25-000-a-day.

16   Financial Times, "Boris Johnson under pressure to accelerate coronavirus testing," https://www.ft.com/content/fce110fc-6eaf-11ea-89df-41bea055720b.

tests – however it is unclear why this has not been reached. PHE told the paper that there have been difficulties "getting all the equipment they need to conduct these tests at a time when everybody in the world wants them".[17]

FIGURE 1: NUMBER OF DAILY UK COVID-19 TESTS, UK, FEBRUARY 1 -MARCH 31
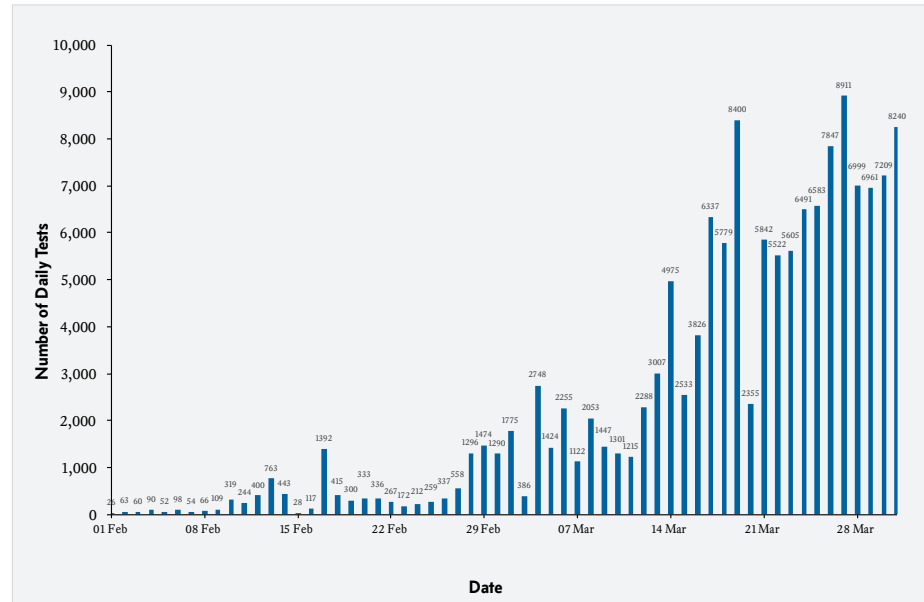
Source: Department for Health and Social Care

The latest advice from Public Health England states that testing is (1) prioritised for in-patients requiring critical care for pneumonia, acute respiratory distress syndrome (ARDS) or influenza like illness (ILI); (2) patients admitted to hospital for pneumonia, ARDS or ILI; and (3) clusters of disease in residential care facilities and prisons.[18] According to a guideline published on March 16, just NHS four labs were approved to undertake COVID-19 testing.[19] A more recent report by *The Sunday Times* states this has been expanded to 40 labs within the NHS in addition to the 12 PHE labs.[20] There is similar guidance in place for NHS Scotland.[21]

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17 The Guardian, "UK ministers accused of overstating scale of coronavirus testing," https://www.theguardian.com/world/2020/mar/30/uk-ministers-accused-of-overstating-scale-of-coronavirus-testing.

18 Gov.uk, "Priorities for SARS-CoV-2 (COVID-19) testing," https://www.gov.uk/government/publications/wuhan-novel-coronavirus-initial-investigation-of-possible-cases/priority-for-sars-cov-2-covid-19-testing.

19 NHS "COVID-19 virus testing in NHS laboratories" (March 2020), https://www.england.nhs.uk/coronavirus/wp-content/uploads/sites/52/2020/03/guidance-and-sop-covid-19-virus-testing-in-nhs-laboratories-v1.pdf.

20 NHS "COVID-19 virus testing in NHS laboratories" (March 2020), https://www.england.nhs.uk/coronavirus/wp-content/uploads/sites/52/2020/03/guidance-and-sop-covid-19-virus-testing-in-nhs-laboratories-v1.pdf; Gov.uk, "COVID-19: how to arrange laboratory testing," https://www.gov.uk/government/publications/wuhan-novel-coronavirus-guidance-for-clinical-diagnostic-laboratories/wuhan-novel-coronavirus-who-to-call-to-request-laboratory-testing#capability; "Test, test, test — how UK is failing in fight against coronavirus" The Times, March 29, 2020, https://www.thetimes.co.uk/article/test-test-test-how-uk-is-failing-in-fight-against-coronavirus-92fdpg70w.

21 NHS "COVID-19 virus testing in NHS laboratories" (March 2020), https://www.england.nhs.uk/coronavirus/wp-content/uploads/sites/52/2020/03/guidance-and-sop-covid-19-virus-testing-in-nhs-laboratories-v1.pdf.

The UK's COVID-19 testing has been dangerously slow, excessively bureaucratic and hostile to outsiders and innovation. There appears to be an innate distrust of outsiders. PHE has actively discouraged use of private sector testing.[22] Even within the system, the process for testing and validation is very centralised. According to Public Health England advice last updated on March 28, all tests are initially considered 'presumptive positives' and must be referred to the reference laboratory at PHE Colindale for confirmatory testing.[23] A more recent online news report indicates that this may no longer be the case, however the process remains opaque.[24] (For comparison, as discussed below, the United States' Centre for Disease Control (CDC) suspended a similar centralised reconfirmation process on March 14.) PHE has also been slow to approve additional tests, and has as-yet not approved private sector testing. A senior academic who has worked across UK laboratories raised concerns about bureaucratic fiefdoms undermining the expansion of testing. "If I'm running a lab where every sample of a really interesting new disease has to come to me for testing, then I am in control of the data," the academic said.[25] It has also been reported that the UK intentionally did not pursue a strategy of widespread testing, instead preferring a mitigation strategy in which the outbreak would not be suppressed initially.[26] This has left the UK without necessary testing capacity, only made more problematic by shortages in raw materials.[27]

PHE have defended their rollout of testing, stating that it has been the "fastest deployment of a novel test to PHE and NHS labs in recent history, including in the swine flu pandemic in 2009" and "rollout of additional capacity requires properly trained staff, equipment and a supply of consumables as well as a thorough validation process for the lab to ensure the results are correct."[28]

THE POTENTIAL FOR PRIVATE SECTOR TESTING

The private sector has been extensively involved in responding to the challenges posed by COVID-19. This ranges from supermarkets increasing supply chain capacity to offers by hundreds of companies to build ventilators.[29] In healthcare,

22 Gov.uk, "COVID-19: rapid tests for use in community pharmacies or at home," https://www.gov.uk/government/publications/covid-19-rapid-tests-for-use-in-community-pharmacies-or-at-home/covid-19-rapid-tests-for-use-in-community-pharmacies-or-at-home.

23 Gov.uk, "COVID-19: laboratory investigations and sample requirements for diagnosis," https://www.gov.uk/government/publications/wuhan-novel-coronavirus-guidance-for-clinical-diagnostic-laboratories/laboratory-investigations-and-sample-requirements-for-diagnosing-and-monitoring-wn-cov-infection

24 Buzzfeed News, "Even The US Is Doing More Coronavirus Tests Than The UK. Here Are The Reasons Why," https://www.buzzfeed.com/alexwickham/uk-coronavirus-testing-explainer

25 "How the UK got coronavirus testing wrong" Financial Times, March 27, 2020, https://www.ft.com/content/fa747fbd-c19e-4bac-9c37-d46afc9393fb.

26 Buzzfeed News, "Even The US Is Doing More Coronavirus Tests Than The UK. Here Are The Reasons Why," https://www.buzzfeed.com/alexwickham/uk-coronavirus-testing-explainer

27 Chris Smyth, Oliver Wright, Oliver Moody, "Global shortage of coronavirus testing kits threatens expansion plan," https://www.thetimes.co.uk/article/global-shortage-of-coronavirus-testing-kits-threatens-expansion-plan-chglmtm93

28 ibid.

29 "Manufacturers told to start making thousands of ventilators" The Telegraph, March 26, 2020,

independent providers have committed to do all they can to support the NHS. On March 21, the independent hospital sector struck a major deal to expand the capacity of the NHS.[30] The independent sector will provide 8,000 staff, 1,200 ventilators, 10,000 nurses, over 700 doctors and 8,000 other clinical staff. Recent reports indicate that the Government has also asked private firms to develop the necessary kit for testing.[31]

The involvement of the private sector could be expanded by fast-tracking approval for non-government laboratories to begin testing for COVID-19. It would also be necessary to fast track the approval of additional tests. The official guidance on testing states that all "the participating microbiology/virology labs will be UKAS 15189 accredited and have an accredited quality management system".[32] There are over 600 accredited medical laboratories in the United Kingdom, of those 474 are NHS, 120 are private, and 12 are PHE and Public Health Wales.[33] Additionally, there are dozens of research labs owned by pharmaceutical, biotechnology and diagnostic manufacturing companies that may be able to be repurposed for testing COVID-19 patients. It will be necessary to develop quality assurance processes to ensure that testing undertaken by independent operators meet validation and acceptance criteria. This could be done, for example, by sampling a small number of tests through a retest at the PHE laboratories. If there are persistent inconsistencies, it could trigger further retesting and investigation. It is clear from international experience – where most are using private labs to expand testing capacity for COVID-19 – that validation is not an insurmountable challenge.

It would also require a culture change within PHE, including an embracing of the private sector. There have also been reports that PHE actively turned away offers by private firms with testing kits because of an aversion to the private sector.[34] The Telegraph has also reported that offers from Oxford University and the Francis Crick Institute have been rebuffed.[35] This must change. It is also notable that COVID-19 testing is already being undertaken by Health Services Laboratories, which is a partnership between an independent provider, The Doctors Laboratory, and Royal Free London NHS Foundation Trust and University College London

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https://www.telegraph.co.uk/business/2020/03/26/manufacturers-told-start-making-thousands-ventilators/..

30 NHS, "NHS strikes major deal to expand hospital capacity to battle coronavirus" https://www.england.nhs.uk/2020/03/nhs-strikes-major-deal-to-expand-hospital-capacity-to-battle-coronavirus/.

31 "Coronavirus testing effort hampered by kits contaminated with Covid-19" The Telegraph, March 30, 2020, https://www.telegraph.co.uk/news/2020/03/30/uks-attempt-ramp-coronavirus-testing-hindered-key-components/.

32 NHS "Guidance and Standard Operating Procedure COVID-19 Virus Testing in NHS Laboratories" https://www.rcpath.org/uploads/assets/90111431-8aca-4614-b06633d07e2a3dd9/Guidance-and-SOP-COVID-19-Testing-NHS-Laboratories.pdf.

33 UKAS, "Browse Accredited Organisations, Medical Laboratories" https://www.ukas.com/list-all-organisations/?org_type=7&parent=Medical%20Laboratories.

34 https://twitter.com/mattwridley/status/1244890123197693953

35 Bill Gardner and Gordon Rayner, "Health officials ignored offers of coronavirus testing help as anger mounts at Government's failure to ramp up capacity" The Telegraph, April 1, 2020, https://www.telegraph.co.uk/news/2020/03/31/public-health-england-ignored-offers-testing-help-amid-mounting/

Hospitals NHS Foundation Trust.[36] This indicates a very real ability for greater decentralisation of testing.

The Sunday Times noted that additional testing of NHS staff would be enabled by adding three additional labs, with equipment loaned from universities, research institutes and companies including Thermo Fisher Scientific and Randox.[37] The report also noted that the problem is not a lack of tests but rather "a lack of both capacity and staff in our laboratories to turn around the results."[38] It is unclear why the Government has chosen to operate these new labs rather than outsource it to existing capacity and staff at non-government labs. The existence of various private sector services offering for-pay testing for COVID-19 indicates that some private lab capacity could be purchased by the NHS to expand capacity.[39]

A major factor cited by the Government in preventing further testing is a lack of 'chemical reagents'.[40] "One of the constraints on our capacity to increase testing overall is supply of the specific reagents, the specific chemicals, that are needed in order to make sure that tests are reliable," Cabinet Secretary Michael Gove said. There have been a range of reports about the lack of availability of test reagents and consumables, which are under intense global demand.[41] The Chemical Industries Association, however, have stated that there is no such shortage.[42] If PHE or NHS are lacking in supplies it may be necessary to call on Britain's pharmaceutical, agricultural, chemical, and petrochemical industries to collaborate to produce much needed reagents en masse.

36 NHS "COVID-19 virus testing in NHS laboratories" (March 2020), https://www.england.nhs.uk/coronavirus/wp-content/uploads/sites/52/2020/03/guidance-and-sop-covid-19-virus-testing-in-nhs-laboratories-v1.pdf.

37 "Test, test, test — how UK is failing in fight against coronavirus" The Times, March 29, 2020, https://www.thetimes.co.uk/article/test-test-test-how-uk-is-failing-in-fight-against-coronavirus-92fdpg70w.

38 "Test, test, test — how UK is failing in fight against coronavirus" The Times, March 29, 2020, https://www.thetimes.co.uk/article/test-test-test-how-uk-is-failing-in-fight-against-coronavirus-92fdpg70w.

39 "Private firms criticised over £295 coronavirus testing kits" The Guardian, March 18, 2020, https://www.theguardian.com/world/2020/mar/18/private-firms-criticised-over-295-coronavirus-testing-kits.

40 https://twitter.com/itvnews/status/1245021086049284096

41 Chris Smyth, Oliver Wright, Oliver Moody, "Global shortage of coronavirus testing kits threatens expansion plan," https://www.thetimes.co.uk/article/global-shortage-of-coronavirus-testing-kits-threatens-expansion-plan-chglmtm93

42 Robert Peston, "Robert Peston: Is Michael Gove right that there is a shortage of coronavirus test kit ingredients?" https://www.itv.com/news/2020-03-31/robert-peston-is-gove-right-that-there-is-a-shortage-of-test-kit-ingredients/

In recent days, a minister claimed that the UK is 'right at the top of the league table' for COVID-19 testing.[43] On March 14, the UK ranked 5th for COVID-19 tests.[44] However, the UK has since fallen behind most comparable countries because of a failure to ramp up testing. **The UK is now ranked 26 of 34 OECD for COVID-19 testing per capita based on available data. This places the UK in the bottom-quarter of countries.** As of March 30, the UK had undertaken 1,998 tests per a million people. This is much lower than the likes of Norway (13617), Australia (9,670), South Korea (7,622), Germany (5,812) or the United States (2,914).[45] This may even be an underestimate as, unlike the UK, some countries data is up to a week out of date.

**FIGURE 2:   COVID-19 TESTING GLOBAL LEAGUE TABLE, PER CAPITA, SELECTED COUNTRIES**
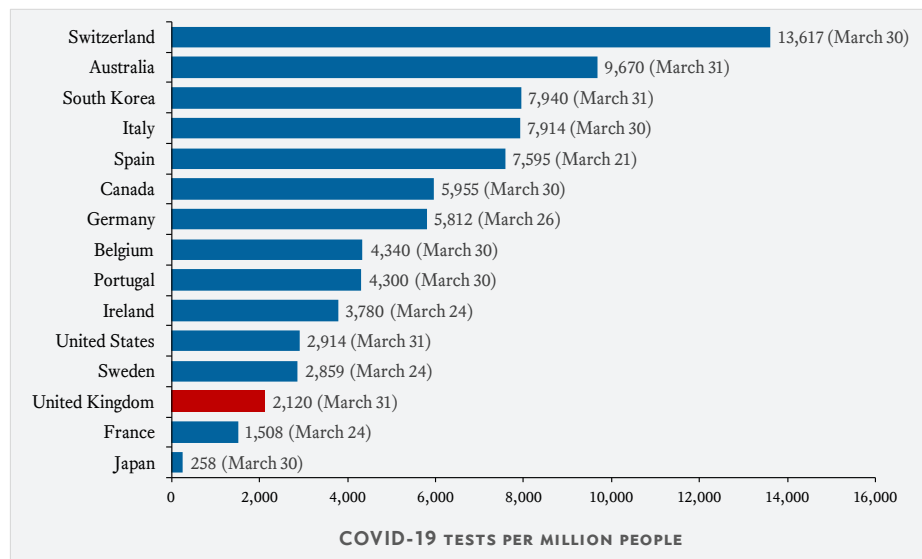
Source: See Appendix 1

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43 "Coronavirus: Questions over testing as minister claims UK is 'right at the top of the league table'" Sky News, March 30, 2020, https://news.sky.com/story/coronavirus-questions-over-testing-as-minister-claims-uk-is-right-at-the-top-of-the-league-table-11965700.

44 THE UK'S INDEPENDENT FACT CHECKING CHARITY, "There's limited data on how many Covid-19 tests are being done globally, but the UK doesn't rank third in the world," https://fullfact.org/health/coronavirus-testing-numbers-UK/.

45 Author calculations based on available data, see Appendix 1

Figure 3: **COVID-19 testing global league table, total tests, selected countries**
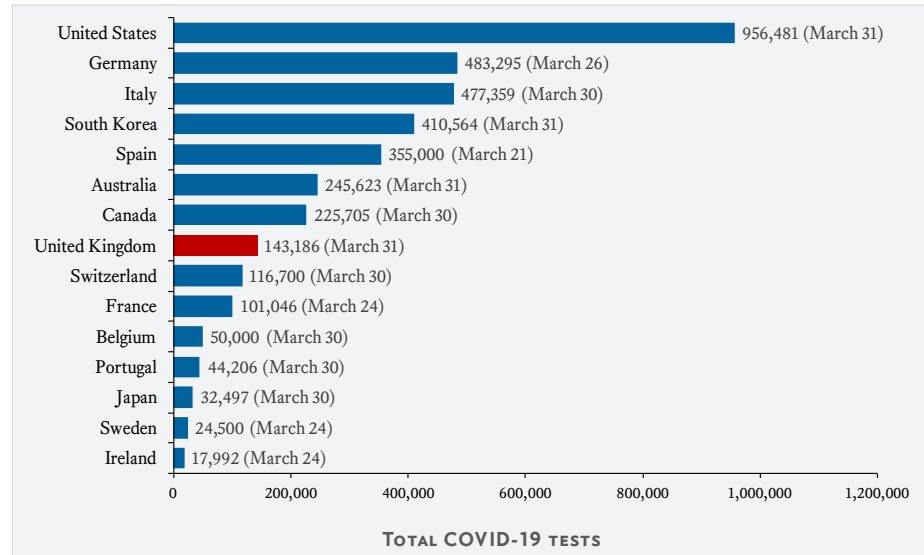
Source: See Appendix 1

The following section explains how South Korea, Germany and the United States have decentralised testing, including using public and private capacity, to increase testing.

South Korea

South Korea involved the private sector in the development and rollout of mass testing capacity from the onset of cases in January. This helped South Korea to track the outbreak, undertake extensive testing and tracing, and prevent a community outbreak while minimising economic disruption.

On the 27th of January, South Korean regulators summoned the top 20 medical companies to a special meeting to give them one key task: develop an effective test to detect the novel coronavirus.[46] At the time, South Korea had just four known cases. Over the coming weeks tests were briskly vetted. Authorities approved, using a fast-track process, a private company's coronavirus test and began shipping kits as early as February 4.[47] (By comparison, the UK was still only using a single PHE laboratory and a single PHE-developed test at this juncture.) Seven weeks after the initial call for companies to begin testing, South Korea had tested 290,000 people.

South Korea subsequently made global headlines for pioneering drive-through screening centres that have been testing thousands of people every single day.[48] Just

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46 Reuters, "Special Report: How Korea trounced U.S. in race to test people for coronavirus," https://uk.reuters.com/article/uk-health-coronavirus-testing-specialrep/special-report-how-korea-trounced-u-s-in-race-to-test-people-for-coronavirus-idUKKBN2153CG.

47 "Novel coronavirus test kits to be available at hospitals this week" YONHAP News Agency, February 4, 2020, https://en.yna.co.kr/view/AEN20200204005251320.

48 "South Korea pioneers coronavirus drive-through testing station" CNN, March 3, 2020, https://edition.cnn.com/2020/03/02/asia/coronavirus-drive-through-south-korea-hnk-intl/index.html.

like a McDonald's, patients pull into a parking lot where health workers dressed in hazmat suits take swaps to test for COVID-19. They have also used technology, including an app called Corona 100m that informs citizens if they have been within 100m of someone who has tested positive.[49] In total, South Korea has opened nearly 600 testing clinics. While case numbers have varied over time, outbreaks of the disease have largely been limited to a small number of clusters, including in the city of Daegu and the Shincheonji Church of Jesus. This strategy of extensive testing, utilising private sector capacity, appears to have prevented widespread community transmission now witnessed in Europe and the United States. In total, South Korea has had just 9,661 confirmed cases and 158 deaths as of March 29 – with fewer than 150 new daily cases since early March.[50]

Germany

Germany, in a similar model to South Korea, ramped up testing capacity from early in the outbreak. This enabled effective 'testing and tracing' that has substantially limited the spread and number of deaths in Germany. As of March 29, Germany had 63,929 confirmed cases but just 560 deaths.[51] This equates to one of the world's lowest fatality rates from coronavirus, at just 0.9%. This compares very favourably to the United States (1.8%), the United Kingdom (6%), France (6%), and Spain (9%).[52] In absolute numbers of deaths, Germany also compares favourably to many surrounding countries such as Italy (11,591), Spain (7,340), France (3,024) and even the United Kingdom (1,408).

Germany began mass testing much earlier than most countries. Between late February and late March, Germany was testing around 120,000 people per a week (just under the total number of tests in the UK to date).[53] By March, 26 a survey by Germany's infectious disease agency, the Robert Koch Institute, found that 483,295 tests had been undertaken.[54] A few days earlier the Association of Accredited Medical Laboratories in Germany (ALM e.V.) reported that capacity had increased to 58,000 tests per day.[55] More recent reporting indicates that Germany is rapidly expanding capacity to 500,000 per week or 72,400 per day.

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49 "South Korea took rapid, intrusive measures against Covid-19 – and they worked" The Guardian, March 20, 2020, https://www.theguardian.com/commentisfree/2020/mar/20/south-korea-rapid-intrusive-measures-covid-19.

50 John Hopkins University & Medicine, "Coronavirus COVID-19 Global Cases by the Center for Systems Science and Engineering (CSSE) at Johns Hopkins" https://coronavirus.jhu.edu/map.html.

51 ibid.

52 Author calculations from https://coronavirus.jhu.edu/map.html, as of March 30.

53 NPR, "Why Germany's Coronavirus Death Rate Is Far Lower Than In Other Countries," https://www.npr.org/2020/03/25/820595489/why-germanys-coronavirus-death-rate-is-far-lower-than-in-other-countries?t=1585591574189&t=1585670864986.

54 Robert Koch Institute "Coronavirus Disease 2019 (COVID-19) Daily Situation Report of the Robert Koch Institute" (March 2020), https://www.rki.de/DE/Content/InfAZ/N/Neuartiges_Coronavirus/Situationsberichte/2020-03-26-en.pdf.

55 Accredited Medical Laboratories in Germany (ALM e.V.), "ALM is committed to the resource-oriented use of the coronavirus SARS-CoV-2 tests - specialist laboratories have carried out over 400,000 tests since the beginning of March" https://www.alm-ev.de/pressemitteilung/alm-fuer-ressourcenorientierten-einsatz-der-coronavirus-sars-cov-2-tests-ueber-400000-tests-seit-anfang-maerz.html

Dr Christian Drosten of Berlin's Charité University Hospital has explained that "The reason why Germany has so little deaths [sic] compared to its number of confirmed cases can be explained by the fact that we have a lot of laboratory diagnoses."[56] This has enabled Germany to identify infected individuals and meticulously trace and test their contacts to break 'infection chains'.[57] Germany has been particularly successful in identifying younger carriers before they can unknowingly spread the virus further.

Germany has undertaken the mammoth task thanks to the decentralisation of testing. Drosten explains that:

> "We have a culture here in Germany that is actually *not* supporting a centralized diagnostic system… so Germany does not have a public health laboratory that would restrict other labs from doing the tests. So we had an open market from the beginning."[58]

This resulted in quicker, earlier and more widespread testing than in most countries.

United States

The United States initially limited testing to a single, federal government developed test. This substantially limited testing capacity. However, from mid-March the US allowed state-bodies and the private sector to undertake independent testing, as well as rapidly approving a multitude of private sector tests. Since these regulatory changes, US capacity has hugely expanded resulting in more tests than any other country in the world. The US is now testing hundreds of thousands of people every single day. The US shows how even after a slow start, it is possible to expand testing capacity by embracing the private sector.

The US testing was initially limited by "technical flaws, regulatory hurdles, business-as-usual bureaucracies," according to a *New York Times* investigation.[59] The initial approach by the Centre for Disease Control (CDC) was to develop a proprietary, in-house test. However, flaws with this test's reagents became apparent in February when it was first shared to state labs. A further investigation by *USA Today* outlines how the CDC sought to monopolise testing, discouraged the private

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56 "Germany 'increases its COVID-19 tests to 500,000 per week'" Euronews, March 27, 2020, https://www.euronews.com/2020/03/27/germany-increases-its-covid-19-tests-to-500-000-per-week.

57 Loveday Morris, Washington Post, "Why Germany's coronavirus death rate is so much lower than other countries' rates," https://www.washingtonpost.com/world/europe/germany-coronavirus-death-rate/2020/03/24/76ce18e4-6d05-11ea-a156-0048b62cdb51_story.html

58 Rob Schmitz, NPR, "Why Germany's Coronavirus Death Rate Is Far Lower Than In Other Countries," http://npr.org/2020/03/25/820595489/why-germanys-coronavirus-death-rate-is-far-lower-than-in-other-countries?t=1585591574189

59 Michael D. Shear, et. al., New York Times, "The Lost Month: How a Failure to Test Blinded the U.S. to Covid-19," http://nytimes.com/2020/03/28/us/testing-coronavirus-pandemic.html

sector developing its own tests and misled state and local authorities about efficacy of its tests.[60]

By mid-February, the US was only testing 100 samples per day. At this point, the United States had not approved the initial German-designed WHO test, instead depending on the CDC-developed test. Furthermore, tests were limited to those who had recently travelled to China or had encountered someone who had the virus. This severely hampered the ability to track the spread of the virus. It became impossible to undertake surveillance testing to see where the virus might be hiding.

Following this early failure, there was a substantial change in approach by the US federal government between late February and mid-March that enabled a substantial expansion of test capacity within weeks. On February 29, the federal government rolled back restrictions by allowing both private and public labs to start developing their own tests. The Food and Drug Administration (FDA) subsequently opened the emergency authorisation process to rapidly approve a wide array of new tests, including a testing kit that takes just 2 minutes.[61] On March 14, the FDA removed requirements that laboratories use the CDC assay and submit their samples for CDC confirmation. On March 16, the FDA expanded the laboratories and manufacturers that can provide testing.[62] The FDA have since taken subsequent steps to expedite the review of diagnostic tests to combat COVID-19.[63]

Following these regulatory changes, the number of tests has skyrocketed. On February 27 there were a total of 200 tests in the United States, including 62 undertaken directly by the CDC and a further 138 by public health labs.[64] This increased to 9,017 by March 14, and 434,613 by March 29, according to the Covid Tracking Project which gathers data from across the public and private sector in all states. While the number of cases in the United States, which surpassed 150,000 on 29 March, may appear high compared to many European countries, this figure is now biased by the extent of testing (and the larger population).

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60 Brett Murphy and Letitia Stein, USA TODAY, "The coronavirus test that wasn't: How federal health officials misled state scientists and derailed the best chance at containment," https://eu.usatoday.com/story/news/investigations/2020/03/27/coronavirus-test-officials-botched-rollout-derailed-containment/5080781002/
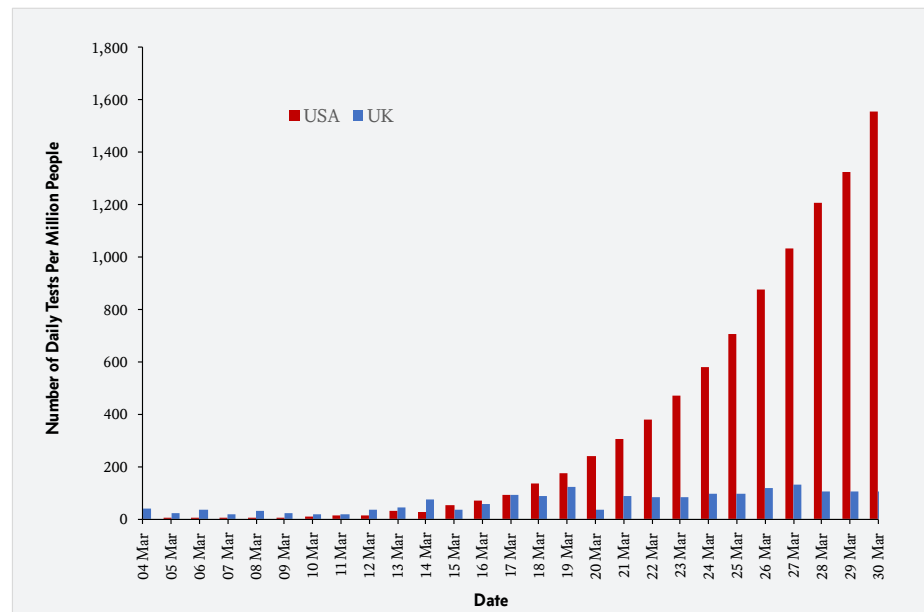
61 Marisa Fernandez, Axios, "FDA authorizes two-minute antibody testing kit to detect coronavirus," https://www.axios.com/fda-coronavirus-two-minute-testing-kit-bodysphere-a665429d-488d-4edf-bd36-9180e2a06e4c.html

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64 CDC, Testing in U.S., https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/testing-in-us.html

Source: Author calculations, Covid Tracking Project, & Department for Health and Social Care

CONCLUSION AND RECOMMENDATIONS

Every single day that the United Kingdom fails to substantially expand testing capacity by using all possible resources more people will suffer the health and economic consequences of COVID-19. A significant reason for the limited numbers of tests is the policy to centralise testing in PHE and a limited number of NHS laboratories. There are hundreds of NHS, university, and private sector laboratories across the UK that are currently not being utilised to undertake testing.

If the UK Governments wants to increase testing capacity and save lives they should:

• fast-track approval for private sector laboratories to conduct COVID-19 testing;
• substantially expand usage of NHS and university laboratories to conduct COVID-19 testing;
• undertake rapid approval of private sector developed tests, including mutual recognition of tests approved by other regulatory bodies such as the FDA;
• reduce testing red tape, including any residual requirements that initial positive tests must be retested centrally by PHE; and
• explicitly call on companies to help make testing kits and develop lab capacity for COVID-19 testing, modelled on the successful call for businesses to make ventilators.

Country	Tests per million population	Total tests	Positive cases	Positive cases %	Date
Iceland[1]	45,789	16,484	1,086	6.6%	29-Mar
Norway[2]	16,237	87,191	4,226	4.8%	30-Mar
Switzerland[3]	13,617	116,700	15,475	13.3%	30-Mar
Slovenia[4]	10,215	21,349	763	3.6%	29-Mar
Australia[5]	9,670	245,623	4,559	1.9%	31-Mar
Estonia[6]	9,324	12,401	745	6.0%	31-Mar
South Korea[7]	7,940	410,564	9,786	2.4%	31-Mar
Italy[8]	7,914	477,359	101,739	21.3%	30-Mar
Latvia[9]	7,712	14,807	398	2.7%	31-Mar
Spain[10]	7,595	355,000	24,926	7.0%	21-Mar
Israel[11]	7,248	66,461	4,372	6.6%	30-Mar
Canada[12]	5,955	225,705	7,298	3.2%	30-Mar
Austria[13]	5,881	52,344	9,634	18.4%	31-Mar
Germany[14]	5,812	483,295	36,508	7.6%	26-Mar
Denmark[15]	4,761	28,230	2,994	10.6%	31-Mar
Czech Republic[16]	4,583	48,811	3,002	6.2%	31-Mar
Belgium[17]	4,340	50,000	11,899	23.8%	30-Mar
Portugal[18]	4,300	44,206	6,408	14.5%	30-Mar
New Zealand[19]	4,185	20,798	647	3.1%	31-Mar
Lithuania[20]	4,043	11280	533	4.7%	31-Mar
Finland[21]	3,797	21,000	1,384	6.6%	30-Mar
Ireland[22]	3,780	17,992	1,329	7.4%	24-Mar
Netherlands[23]	3,102	54,065	9,982	18.5%	29-Mar
United States[24]	2,914	956,481	162,399	17.0%	31-Mar
Sweden[25]	2,859	24,500	2,510	10.2%	24-Mar
United Kingdom[26]	2,120	143,186	25,150	17.6%	31-Mar
Chile[27]	1,683	32,096	2,449	7.6%	30-Mar
France[28]	1,508	101,046	20,068	19.9%	24-Mar
Hungary[29]	1,448	14,146	492	3.5%	31-Mar
Slovakia[30]	1,442	7,857	363	4.6%	30-Mar
Poland[31]	1,339	51,419	2,132	4.1%	31-Mar
Turkey[32]	926	76,981	10,827	14.1%	30-Mar
Japan[33]	258	32,497	1,494	4.6%	30-Mar
Mexico[34]	75	9,480	1094	11.5%	30-Mar

65 Testing data is not avaliable for Greece and Luxembourg, which have not been included in this analysis.

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