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A report by

OCO GLOBAL

CHALLENGE. CREATE. **COLLABORATE.**

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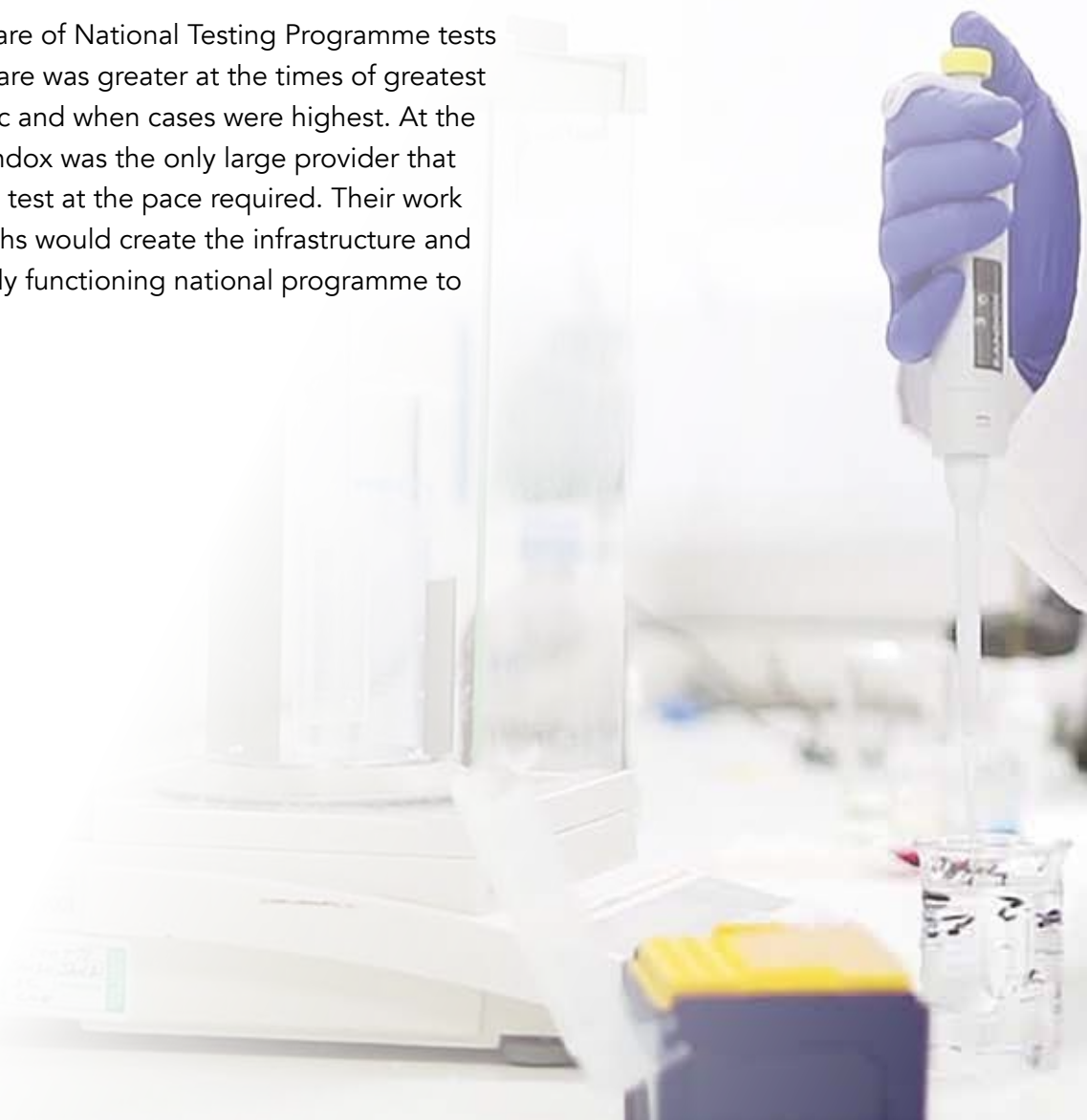
Executive Summary

Five days after the World Health Organisation declared COVID-19 a pandemic in March 2020, its Director General, Tedros Adhanom Ghebreyesus, implored the world to “Test, test, test.” Warning that social distancing and handwashing would not be sufficient to control the pandemic, he likened trying to stop the spread of the disease without testing with trying to fight a fire blindfolded.

Randox were amongst the first companies in the UK to step forward to make their testing capabilities available, and they played a pivotal role in the UK’s response to the pandemic. **Between 30 March 2020 and 20 June 2022, the company processed over 17 million PCR tests as part of the National Testing Programme** and a further 7.7 million PCR tests and around 1.9m Lateral Flow Tests to support corporate clients and international travellers.

Based on our model we estimate that **Randox’s contribution to the UK Government’s National Testing Programme averted 3,136 deaths, 14,100 extra hospitalisations, and boosted the UK’s GDP by £6.48bn.**

Although Randox’s total share of National Testing Programme tests was a little over 12%, its share was greater at the times of greatest need: early in the pandemic and when cases were highest. At the start of the programme Randox was the only large provider that could provide an approved test at the pace required. Their work in these difficult early months would create the infrastructure and learnings that allowed a fully functioning national programme to develop over time.





RANDOX

This was supported by evidence from Shona Dunn, Second Permanent Secretary at the Department of Health and Social Care, who told the Public Accounts Committee that:

“Randox was already an important part of the infrastructure and had the ability to scale and provide an even more important part of an infrastructure that we were still growing.”¹

As more laboratories came on board Randox’s contracted capacity reduced, but at times of emergency they would step up once again. **When Delta and Omicron variants were at their peak it would be Randox who scaled up to meet the challenge.**

For example, with the onset of Omicron, and at the Government’s request, Randox rapidly increased their contracted capacity from 15,000 to 105,000 tests per day from 21 December. However, by the end of December Randox were receiving and handling 30% above this increased contracted capacity, processing 138,000 samples on 30 December and 130,000 on 31 December, providing vital support across the national network.

In addition, the private testing programme for corporate partners and international travellers facilitated the continuation of key services and international trade. **Randox’s private testing is estimated to have facilitated over 4.4m international passenger journeys, with an economic benefit of just over £4.3bn, including £1.82bn for the UK economy.**

Why Randox was successful?

Four themes run through the Randox story and help explain how the company made such a positive contribution to COVID-19 testing and the broader economy.

These include:

- A history of investment in assets and new business models that positioned Randox as the ideal candidate to support a national PCR testing programme.
- A business culture that makes quick decisions and is willing to take calculated risks.
- A willingness to innovate that drove process improvement and efficiencies across both public and private testing.
- A ‘can do’ attitude among staff at all levels of the business.

At the start of the pandemic Randox was the UK’s largest diagnostics company and had a unique set of assets that would allow it to scale up to the challenge presented by COVID-19. It had already established expertise in the area of testing coronaviruses and had experience with end-to-end remote PCR testing through its Randox Health brand. It also had the space to grow having previously invested £160m to purchase and repurpose a Ministry of Defence complex into Randox Science Park. **Over the course of pandemic, Randox would build, equip and staff over 80,000ft² of PCR laboratories at the Randox Science Park, equivalent to a football pitch worth of laboratory space.**

¹Public Accounts Committee (18 May 2022) Formal meeting (oral evidence session): Government’s contracts with Randox Laboratories Ltd





Randox is a privately-owned company that can make decisions quickly, and this proved invaluable in the frenetic early stages of the pandemic when companies and governments across the world were scrambling for supplies and consumables. But this willingness to invest also came with a significant risk: through the majority of the National Testing Programme Randox were only paid for tests completed, and there were no guarantees that the number of tests indicatively contracted for would be received. This placed considerable risk with Randox who were having to purchase vast quantities of consumables, despite the uncertainty around how long the pandemic would last or how government testing policy might change.

It was this successful risk management that enabled Randox to be one of the best performing laboratories across the National Testing Programme.

Randox was founded on an ethos of innovation and throughout its history has continually invested in R&D, at up to 25% of turnover and well above the 15% average within the industry.² Never was an innovative nature more important than during this pandemic, and the story of Randox revealed in this report is one of overcoming challenges through creativity, collaboration, and intellect.

²European Federation of Pharmaceutical Industries and Associations
<https://www.efpia.eu/publications/data-center/innovation/rd-spending-as-a-percentage-of-net-sales/> (accessed 11/08/2022)

Examples showing the impact of this innovation include:

- The in-house IT team launched the first version of the COVID-19 kit registration portal within 48 hours.
- The Laboratory Information Management System (LIMS) was reconfigured in only two weeks, developing a full end-to-end process that never failed despite the huge increase in tests.
- An automated report delivery service was developed to email customers within five minutes of their result being authorised. In one 24-hour period this system communicated 114,000 results, and in total would communicate more than 25 million results.
- Robotic solutions were developed to automate many of the more labour-intensive processes. In one example, automated box cutters were developed to handle tens of thousands of boxes containing sample tubes daily.
- A script was designed for a robotic sample handling unit to screen for positive samples and automatically transfer them to a 'positive only' sample plate for more detailed variant analysis. This removed the risk of human error and accelerated the identification of new variants.
- Gantry robots were programmed to pick up each sample and scan a barcode that logged the sample on LIMS and determined the sample's age. The samples were then deposited in corresponding racks based on the time left before the sample would pass its expiry date (voided). This helped Randox achieve a better void rate than the average for the National Testing Program laboratories.³

A culture of innovation and willingness to invest drove process improvement at Randox, which in turn improved testing efficiency. For example, **the average Randox in-laboratory turnaround time would reduce from 22.3 hours in July 2020, whilst capacity was being built in the face of rising demand and key equipment shortage, to 8.5 hours by June 2022.**

³National Audit Office (2022) Investigation into the government's contracts with Randox Laboratories Ltd

These improvements would be passed on to the UK Treasury as Randox was able to drive down the cost of testing from an initial fee of £49.60 to £18.00. **Over the course of pandemic, the average cost to UK Treasury of a PCR test from Randox was £26.07.**

Private individuals also benefitted from Randox process improvement as the company was at the forefront of driving down the price of private testing. By October 2021 the cost of a PCR test (click and collect) would be £34.99. This represents a **70% decrease in costs from December 2020.**

Beyond cost, there are a number of operational successes that highlight how efficient the Randox testing process became.

These include:

- Increasing capacity from **300 tests per day** on 30 March 2020 to **120,000 a day** by the end of January 2021.
- By September 2020 Randox had the largest testing capacity within the national testing network.
- In January 2021 they were the first laboratory to report over 100,000 PCR results in one day.

Achieving this level of success was not without its challenges. **There were very limited guarantees within national testing contracts and, in the provision of private testing, Randox was never given advance notice of government policy changes.**

This included multiple policy and operational changes that resulted in immediate and dramatic changes in demand for Randox tests, causing administrative and logistical challenges for Randox - in addition to managing a public struggling to understand the very same policy requirements.

There was also the sheer scale of the pandemic that saw staffing numbers double and the company shifting to working 24 hours a day. **Interviews with staff as part of this project pointed to a 'can-do' attitude across the business as essential for overcoming challenges.** Regular communication and cross-team working became the norm and staff at all levels right up to Senior Management were regularly assisting with opening boxes or a shift on customer services.

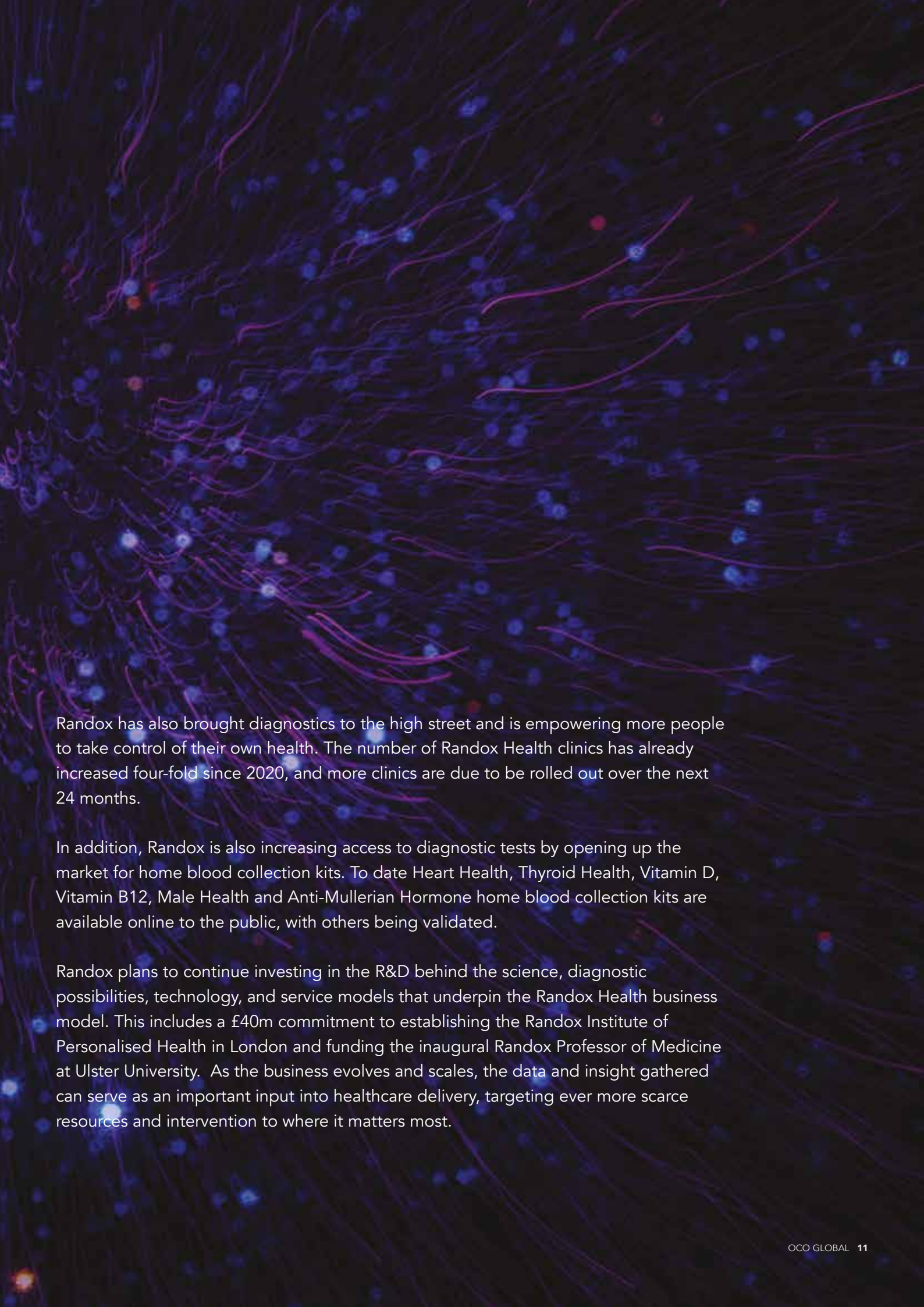
THE LEGACY OF THE COVID-19 TESTING

The importance of diagnostics to future healthcare had already been identified prior to the pandemic. The NHS England strategy of March 2020 stated that demand for diagnostics had increased by 26% in the last five years and an average yearly increase of 8% was predicted.⁴ As the health service becomes increasingly strained there is a growing need for partnership across scientific sectors in industry, academia, health, and charity. Randox is willing and able to play a key role in this future where it can apply its experience and innovations to challenges facing health providers globally.

Three examples of innovations from COVID-19 testing that can make a difference in the future include:

- The Randox Cube - a deployable fully robotic testing laboratory that utilises the knowledge gained through full-scale PCR testing laboratory development. It contains a compact testing line with a series of robots and liquid handling systems to handle and process samples and take them through the extraction, amplification and detection stages of the PCR test. The reduced space and staff required for **the Cube provides enormous potential for future scenarios where rapid deployment of multiple smaller scale applications might be required.**
- The Randox Discovery - a fully automated PCR analyser that enhances the efficiency of a full range of PCR tests. **The analyser consolidates the normal workload of multiple laboratories into one compact benchtop analyser,** processes 48 patient samples every hour, and can be adapted for multiple areas of testing.
- The Vivalytic point-of-care analyser - an easy-to-use piece of equipment that **can be rolled out in primary care, pharmacies, care homes and other sites - further reducing demand on primary care and healthcare resources.** Randox provide the biological components needed inside the Vivalytic test cartridges that can deliver results in just 39 minutes.

⁴NHS England (2020) Science in Healthcare : Delivering the NHS Long Term Plan, The Chief Scientific Officer's strategy



Radox has also brought diagnostics to the high street and is empowering more people to take control of their own health. The number of Radox Health clinics has already increased four-fold since 2020, and more clinics are due to be rolled out over the next 24 months.

In addition, Radox is also increasing access to diagnostic tests by opening up the market for home blood collection kits. To date Heart Health, Thyroid Health, Vitamin D, Vitamin B12, Male Health and Anti-Mullerian Hormone home blood collection kits are available online to the public, with others being validated.

Radox plans to continue investing in the R&D behind the science, diagnostic possibilities, technology, and service models that underpin the Radox Health business model. This includes a £40m commitment to establishing the Radox Institute of Personalised Health in London and funding the inaugural Radox Professor of Medicine at Ulster University. As the business evolves and scales, the data and insight gathered can serve as an important input into healthcare delivery, targeting ever more scarce resources and intervention to where it matters most.

INTRODUCTION

In this section, we have provided an overview of the context for this project, the approach we have used to deliver this report and an outline of how the report has been structured.

1.1 BACKGROUND AND CONTEXT

When the World Health Organisation declared COVID-19 a Public Health Emergency of International Concern (PHEIC) on 30 January 2020, the recorded death toll stood at 171. Less than three years later, the official number of lives lost to the pandemic is over 6.5 million⁵, with estimates suggesting the true death toll is significantly higher, with perhaps as few as 1 in 10 deaths in some parts of the world recorded.⁶

In the UK at the time of writing, there have been over 23 million confirmed cases⁷; 843,000 hospitalisations with COVID; an estimated 1.8 million cases of 'Long COVID'⁸ and 188,000 recorded deaths as a direct result of the disease⁹.

The repercussions of COVID-19 have extended well beyond the direct health impacts. The financial NHS bill for handling the pandemic stands at around £92bn¹⁰ but the wider costs to the public purse, including all public services and the cost of supporting businesses and individuals whose incomes were affected, range from £310 billion to £410 billion.¹¹ As a result, the UK borrowed a record £299 billion in 2020 and £187 billion in 2021.¹²

The impact to economic output was arguably greater still. There was a drop in national output of 11% in 2020¹³, the greatest fall on record since the severe frost of 1709. Longer term financial impacts include structural damage to the economy and supply chain disruption that has been a contributory factor in the current cost of living crisis.

The social impacts have also been profound. The pandemic saw a 75% reduction in social contact¹⁴; 270 million in-person school days missed¹⁵ and, perhaps unsurprisingly, 10% reported serious mental health symptoms.¹⁶

And yet it could have been worse. But for the efforts of NHS staff and other public servants and those working in life sciences and elsewhere in the private sector, the impacts could have been significantly more severe.

It is important to remember that the first vaccines were not administered until December 2020 and it was June 2021 before more than half of the adult population in the UK had received the requisite two doses.

⁵<https://www.worldometers.info/coronavirus/>

⁶<https://www.who.int/data/stories/the-true-death-toll-of-COVID-19-estimating-global-excess-mortality>

⁷As of 2 September 2022 <https://www.worldometers.info/coronavirus/>

⁸Where severe symptoms persist for more than 8 weeks <https://www.statista.com/topics/8340/long-covid-in-the-uk/>

⁹<https://www.worldometers.info/coronavirus/>

¹⁰<https://www.gov.uk/government/news/7-billion-for-nhs-and-social-care-for-COVID-19-response-and-recovery>

¹¹<https://commonslibrary.parliament.uk/research-briefings/cbp-9309/#:~:text=The%20Covid%2D19%20pandemic%20has,per%20person%20in%20the%20UK.>

¹²[https://www.ons.gov.uk/economy/governmentpublicsectorandtaxes/publicspending/bulletins/ukgovernmentdebtanddeficitforeurostatmaast/deceember2021#:~:text=UK%20general%20government%20deficit%20\(or,of%20the%20G7%20member%20states.](https://www.ons.gov.uk/economy/governmentpublicsectorandtaxes/publicspending/bulletins/ukgovernmentdebtanddeficitforeurostatmaast/deceember2021#:~:text=UK%20general%20government%20deficit%20(or,of%20the%20G7%20member%20states.)

¹³<https://www.ons.gov.uk/economy/grossdomesticproductgdp>

¹⁴<https://www.lshtm.ac.uk/research/centres/centre-mathematical-modelling-infectious-diseases>

¹⁵<https://schoolsweek.co.uk/270-million-in-person-school-days-missed-due-to-covid-last-year/>

¹⁶<https://www.bmj.com/content/376/bmj.o326>

Before this, the government primarily relied on two levers to control transmission of the virus: testing and social distancing measures.¹⁷ Reducing transmission required reducing contact between the infectious and others; to the extent that testing allowed us to correctly identify the former group, it allowed our collective social distancing to be more targeted. Without testing, transmission would have been higher, or blanket social distancing measures would have had to be stronger.¹⁸

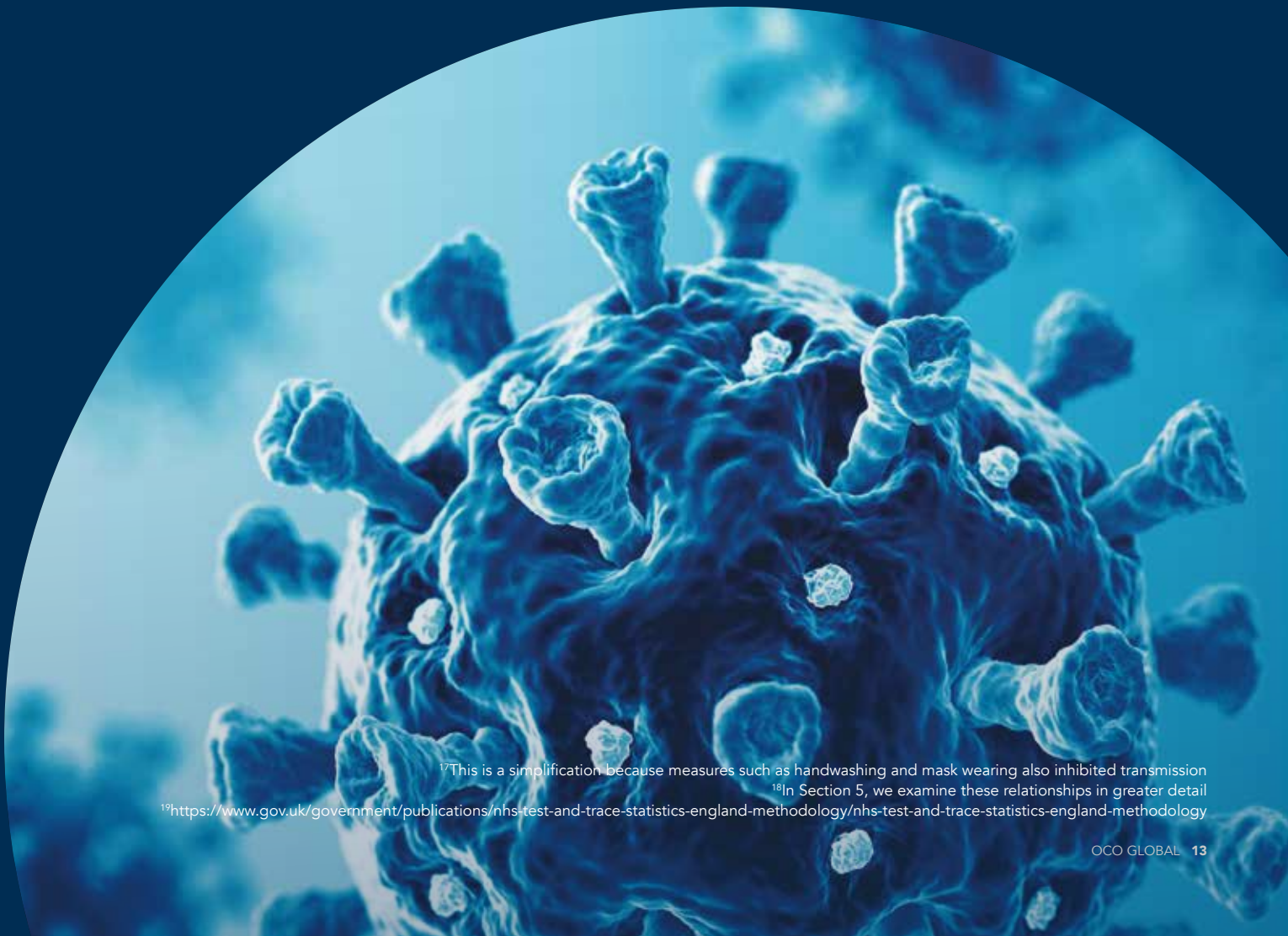
The UK government organised a National Testing Programme for COVID-19 under four pillars.¹⁹ Pillar 2 provided for virus testing, initially for vital national services and then for the general population and was delivered by a mixture of public and private laboratories. Randox processed 17,150,737 samples under Pillar 2 of the National Testing Programme – some 12.2% of the total - recording 1,027,931 positive test results.

In the early days of the pandemic, one of the sectors most severely affected was international travel. After several months when most flights were grounded, cross-border journeys began to resume later in 2020. However, many governments, including the UK's, attempted to reduce the likelihood of importing cases – and later, new variants – of the virus by implementing requirements for pre- and post-travel testing. These tests were supplied by the private sector. Randox conducted over 7.5 million private PCR tests and 1.8 million lateral flow.

¹⁷This is a simplification because measures such as handwashing and mask wearing also inhibited transmission

¹⁸In Section 5, we examine these relationships in greater detail

¹⁹<https://www.gov.uk/government/publications/nhs-test-and-trace-statistics-england-methodology/nhs-test-and-trace-statistics-england-methodology>



1.2 PROJECT OVERVIEW AND APPROACH

With generalised free testing under Pillar 2 of the National Testing Programme ending on 31 March 2022, and with most countries having lifted their testing requirements for international travel, there is an opportunity now to reflect on the impact of the testing performed by Randox.

Randox has engaged OCO Global to research and report on Randox's contribution to COVID-19 testing in the UK and to estimate the health, social and economic impacts of that testing. To fulfil that brief, we have endeavoured to tell the story of Randox's testing programme, articulate and evaluate its impacts and reflect on its legacy.

Throughout this assignment we worked closely with the Randox management team, meeting regularly to obtain information and share findings. This document represents the final output of the research and analysis.

The second chapter begins with Randox's background as a diagnostics company and its significance in the build up to the pandemic. Chapter 3 moves on to how Randox developed and rapidly scaled its COVID-19 PCR testing capability to meet the needs of the National Testing Programme and deliver on its contract with the NHS. Chapter 4 deals with the rollout of private testing for travel, corporates and sports teams. Chapter 5 articulates and evaluates the impact of Randox's testing on health, social and economic outcomes, before Chapter 6 reflects on the legacy of the pandemic for Randox and diagnostic testing.



THE BUILD UP TO NATIONAL TESTING

In this section, we consider why Randox became a diagnostics company uniquely qualified to deliver a National Testing Programme. This involved a combination of experience, expertise and the infrastructure to expand at short notice.

2.1 A SHORT HISTORY OF RANDOX

Established in 1982, Randox has grown to become the largest diagnostics company in the UK, and one of Northern Ireland's biggest employers and privately-owned companies. It was set up to address a gap in diagnostic capability within the UK that was identified by its founder, Dr Peter Fitzgerald. It was also assessed that, noting the limited numbers of tests being conducted, that diagnostic technologies were not being optimised within the health service.

The mission of Randox was to improve healthcare by using innovative diagnostic technologies to enable early, accurate and timely diagnosis and treatment, improving health outcomes and overall system efficiency.

Over the next four decades the company would develop comprehensive R&D, manufacturing and laboratory capabilities. In recent years Randox have manufactured over four billion tests per

year, with operations across 145 countries. This global distribution and supply chain experience would prove invaluable during the COVID-19 pandemic.

The main clinical products offering includes a wide variety of diagnostic reagents, clinical chemistry immunoassay and molecular analyser systems, and associated internal quality control, calibrators, and external quality assurance. The company is also an accredited manufacturer of medical devices and runs laboratories with quality assured processes. Randox's patented Biochip Array Technology allows multiple tests (multiplex) to be performed simultaneously from a small volume of patient sample, enabling evidence based decision making by clinicians and improved patient outcomes.

The company was founded on an ethos of innovation and health improvement, and this has informed investment ever

since. Around a quarter of staff are research scientists or engineers, and up to 25% of Randox's turnover annually is spent on R&D; a figure that is well above the average of 15% for pharmaceuticals and biotechnology companies.²⁰

This investment has allowed Randox to become leaders in diagnostic innovation, often pioneering new processes and delivering new products to the international market. For example, in 2017 its Evidence Evolution was unveiled as the world's first fully automated random-access biochip testing platform, capable of delivering 2,640 results in one hour, with the first delivered in just 37 minutes.

The company also has a history of involvement in the UK's innovation ecosystem, having been awarded six innovation grants between 2017 and 2022 from the national funding body UK Research and Innovation.

²⁰European Federation of Pharmaceutical Industries and Associations <https://www.efpia.eu/publications/data-center/innovation/rd-spending-as-a-percentage-of-net-sales/> (accessed 11/08/2022)

2.2 THREE KEY MILESTONES

2.2.1 Establishing Radox Health (2012)

In 2012 Radox created their Radox Health brand to take diagnostic innovation directly to consumers. Radox Health offers a range of comprehensive health checks across general health, sexual health and respiratory health, through either walk-in clinics or, for some tests, online (involving secure registration and postal delivery). Through Radox Health, the company had already developed an end-to-end service capability for remote PCR testing. Although relatively small-scale, it provided experience in creating PCR collection kits designed for public use, understanding outbound and inbound logistics, and developing in-house IT systems for remote registration and electronic distribution of results.

2.2.2 Creating the Radox Science Park (2013-2015)

In 2013 Radox bought Massereene Barracks from the Ministry of Defence. The complex stretched to almost 17 hectares and incorporated more than 400,000 ft² of accommodation space, including a 200,000 ft² light industrial hangar space. Two years later, in what the Financial Times referred to as 'a rare piece of economic good news for the province'²¹ the company announced a £161m investment in the now renamed Radox Science Park.



Figure 2(1):
The Central Hangar
Radox Science Park

This represented one of the largest private-sector capital investment and job-creation announcements in Northern Ireland in recent years, with the redevelopment of the site into a manufacturing, research and development campus creating 540 jobs.

Even with this investment, only around 30% of the total building space had been converted to manufacturing by 2019 meaning there remained plenty of room for immediate expansion during the pandemic, a luxury few diagnostic laboratories could ever consider.

²¹Financial Times Northern Ireland former barracks to be redeveloped into science park (14/01/2015)

2.2.3 Developing experience with coronaviruses (2017)

Prior to the emergence of COVID-19, Randox had already been establishing significant expertise in the area of testing for coronaviruses, having previously developed tests for four coronavirus variants — 229E/NL63 and OC43/HKU1. Their 2017 Respiratory Pathogens Array, which included these coronavirus tests, was the most comprehensive multiplex test for infections of both the upper and lower respiratory tracts, simultaneously detecting 22 viral and bacterial pathogens from a single sputum, lavage or nasopharyngeal sample.

‘Always on the lookout for a new virus’

As one molecular scientist at Randox stated, the company was ‘always on the lookout for a new virus’²² and it was this forward-thinking culture, mixed with previous experience that would help Randox become one of the first companies in the world to produce a COVID-19 assay, only two weeks after their scientists had started to work on a solution.

As the world headed towards a global pandemic, Randox was uniquely prepared to assist, thanks to a culture of innovation, experience in end-to-end consumer PCR testing, expertise with coronaviruses and novel assays for laboratory and Point-of-Care analysers, and the physical space to rapidly expand in response to a national emergency.

2.3 Developing a test for Covid

The start of December 2019 is now recognised as the first known case of COVID-19: a man in his seventies falling ill in Wuhan, China. By the end of the month, dozens of people would be admitted to hospitals with high fever and pneumonia. At the same time health officials in China said they were monitoring the cases to prevent the outbreak from developing into something more severe.

By 31 December rumours of an outbreak similar to SARS had spread outside China, but the World Health Organization (WHO) had not received official notification of any outbreak. It would be two more days before China delivered a limited response describing 44 cases of viral pneumonia of unknown cause. By 11 January 2020, China had announced its first death, and it wasn’t long before cases were being confirmed in other countries. Then, on 30 January the WHO declared a ‘public health emergency of international concern’, before finally naming the mystery illness as “coronavirus disease 2019” or COVID-19 for short on February 11.

Scientists at Randox were watching these developments carefully. As it became clear that the virus was not as well contained as the Chinese authorities had initially claimed, the need for a new assay for testing became clear.

²²Interview conducted by OCO at Randox Science Park (22/07/2022)

One molecular R&D scientist at Randox recalled a phone conversation with the company's Chief Scientist at 10.30pm on Saturday 25 January as the starting gun for developing a test.²³ Within just two weeks the team of scientists at Randox had created their test – ready before the virus had a name.

To conclude the validation of the assay, Randox would need to test it against positive samples. The company's Managing Director contacted the Secretary of State for the Department of Health and Social Care (DHSC), Matt Hancock, by email on 27 January. The email confirmed that Randox currently had tests for coronaviruses but not yet for the new strain. However, they could have tests for the new strain within 2-3 weeks but would need 10 positive sputum samples to confirm the accuracy of the test.²⁴

This email was passed on to the Department of Health and Social Care by the Secretary of State who asked someone to look into it. The Department also sought formal advice from UK's Chief Medical Officer in an email sent 28 January.²⁵

Creating a diagnostic tool is only the first step in testing; scaling and delivering it quickly is what can really save lives. Therefore, what followed next were several frustrating weeks for Randox as they tried to engage with the department but made little progress. At this stage, the then MP for North Shropshire and a paid consultant for Randox, contacted the Secretary of State for Health.²⁶ In a series of WhatsApp messages between the two, he sought answers for Randox on why Public Health England had not responded to Randox's request and forwarded a concern about a general lack of urgency in the department.²⁷

The later publication of these communications shows that the intervention helped speed up the process for all companies involved in testing. This is evidenced by the Secretary of State's response in which he told his department he was concerned that other companies might also be receiving limited engagement similar to Randox:

*"Please can I have chapter and verse on our engagement with UK life sciences for COVID purposes. If we are treating other companies like this we are failing."*²⁸

When Randox eventually received approval for the COVID-19 assay from Public Health England on 24 March 2020 it proved what their scientists had long known, namely that they had the expertise to develop a test for COVID. The first positive samples for testing were then received on 29 March.

²³Interview conducted by OCO at Randox Science Park (22/07/2022)

²⁴Email dated 27 January 2020 in parliamentary motion on Randox contracts passed on 17 November 2021

²⁵Email dated 28 January 2020 in parliamentary motion on Randox contracts passed on 17 November 2021

²⁶In these communications Mr Patterson declared he was a consultant to Randox.

²⁷WhatsApp message 25 February 2020 in parliamentary motion on Randox contracts passed on 17 November 2021

²⁸Direct communications from Minister on Randox engagement with PHE (SMS) in parliamentary motion on Randox contracts passed on 17 November 2021

2.4 THE ROAD TO A NATIONAL TESTING PROGRAMME

On 11 March the WHO declared a global pandemic, and a few days later (16 March) the Director General of the WHO Tedros Adhanom Ghebreyesus delivered his now famous press conference where he stated:

"You cannot fight a fire blindfolded... test, test, test"

*"But 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."*²⁹

On the same day, Randox was invited to a stakeholder meeting at 10 Downing Street to discuss testing capabilities needed in the developing crisis. The meeting was chaired by the Prime Minister and Secretary of State for Health and Social Care, with a number of senior officials including the Chief Medical Officer, Chief Scientific Officer and senior representation from MHRA, Public Health England and the Office for Life Sciences. Private sector other attendees at the 17 March meeting included Wellcome Trust, Alliance Boots, Roche, Thermofisher, Thriva, 23 and me, Medsci, Altona Diagnostics, Qiagen, Luminec Corp, Amazon, Serco, Brunel University, Babylon Health and TDL Pathology Diagnostics.

During the meeting, the government outlined plans to step up its testing programme. At this time, testing was mainly being undertaken by academic and local NHS organisations; at that point NHS capacity was stated to be 2,400 COVID-19 tests per day. The national requirement was for the NHS to expand to 25,000 tests per day for their internal use, a target which was stated to be demanding, with an additional government objective to provide an additional 100,000 tests per day by the end of April 2020 for key services and general population testing.

As a result, the government had decided to develop Pillar 2 laboratories, outside of the NHS estate (Pillar 1). Given the speed of the developing crisis, the government had decided to use emergency procurement provisions that allowed for a negotiated procedure rather than the typical open tender process. In a later review of the contracting process conducted by the National Audit Office, the Department of Health and Social Services stated that they:

²⁹World Health Organisation WHO Director-General's opening remarks at the media briefing on COVID-19 - 16 March 2020 <https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-COVID-19---16-march-2020> accessed 11/08/2022



“...used this procurement route because a competitive tender was ruled out due to the need to move quickly, and that it could not award the contract from an existing framework as the value of the contract exceeded the framework limit.”³⁰

At a follow-up meeting on 18 March, Randox outlined their end-to-end capabilities including sample collection kit production, IT systems for secure registration and result transmission, and the testing of samples. Negotiations ensued from 19-30 March with Randox proposing an initial capacity of 300 tests per day, rising to a maximum of 2,800 tests per day within three weeks. A total of 100,000 tests per day would be achievable after that, although additional support from government may be required noting the unprecedented demand for PCR materials and the impact of lockdowns and international travel restrictions upon suppliers.

On 30 March 2020, the Department of Health and Social Services awarded a £132.4m contract without competition to Randox for the provision of COVID-19 testing services. This was for 2,669,100 tests and covered a 12-week period due to end in June 2020. The contract was for 300 tests per day in March 2020, rising to 60,000 per day by mid-May.

While there were no specific performance indicators in the contract, the actual payment would be based on the number of tests completed rather than reported capacity. A unit price of £49.60 per test was agreed.

Only four months after the mystery virus had appeared in China, Randox had devised a COVID-19 test and been contracted to manage one of the largest national health campaigns in a generation. Delivery of the contract would demonstrate the value of the company's experience and innovative culture.

2.5 MANAGING RISK IN THE CONTRACT

Randox were amongst the first companies in the UK to step forward to make their testing capabilities available on a large-scale basis. Even before they had received any commitment from government, their understanding of the shape and scale of any testing programme meant various steps needed to be put in place if the testing programme could be significantly scaled up in the timeframe required.

This involved significant upfront investment which committed the company to forward orders on consumables, often involving a significant increase in the scale of order. Plans were also put in place, and investments made, to significantly increase laboratory space, IT systems and infrastructure.

Randox also took on significant risk in negotiating the contracts. Although the contracts were awarded on accelerated timelines and with a lighter procurement process, this in itself created challenges, not least that the requirements were not entirely clear.

³⁰National Audit Office (2022) Investigation into the government's contracts with Randox Laboratories Ltd



Secondly, the procurement process was scant on detail and defaulted to the price per test submission requested. Given the uncharted territory being entered into, and the inherent complexity of the process, this meant risk was borne by Randox as the initial contract had no volume guarantees, and both the original and subsequent contracts were awarded only for short timeframes - typically three months at a time, with no commitment to continued requirements beyond the end date.

The management of risk would become a theme throughout the testing programme as exponential growth in cases and changing government policies would require Randox to make early decisions and investments to stay ahead of the game.

EXECUTING THE TESTING PROGRAMMES

In this section, we explore each national testing contract and show how innovation and process improvement helped Randox become an essential part of the national testing infrastructure – delivering at times of national emergency.

3.1 THE NATIONAL TESTING PROGRAMME OVERVIEW

In April 2020, the Department of Health and Social Care published their plans to scale up the COVID-19 testing programme in the UK. This report outlined the essential role that testing would play in the pandemic:

“It’s a big part of how we’re going to defeat this disease”

“One of the most challenging 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.”³¹

The testing programme would involve five pillars:

- Pillar 1 - boosting swab testing by PHE and NHS laboratories to check for the virus among patients and frontline workers in the NHS.
- Pillar 2 - creation of brand new swab testing capacity delivered by commercial partners to build a network of new laboratories and testing sites across the UK.
- Pillar 3 – antibody testing to detect if people have had the virus and are now immune.
- Pillar 4 – surveillance to understand what proportion of the population have already had the virus.
- Pillar 5 – spearheading a Diagnostics National Effort to build a mass-testing capacity at a completely new scale.

Randox were involved in Pillar 2, building a national testing capacity, which would be essential to meeting the government’s initial stated challenge of 100,000 tests per day within Pillar 2. However, as will be shown later in this report, Randox have also had a significant impact on the ambition of Pillar 5, building the UK’s diagnostic industry for the future.

Figure 3(1) shows testing that occurred under the whole programme. Over this time Randox would process just over 17 million samples and identify over one million positive cases. To support the programme Randox, by January 2021, provided a capacity of 120,000 tests per day. The total Pillar 2 maximum capacity eventually exceeded 1m tests per day, in late January 2022.

³¹Department of Health and Social Care (2020) Coronavirus (COVID-19) Scaling up our testing programmes

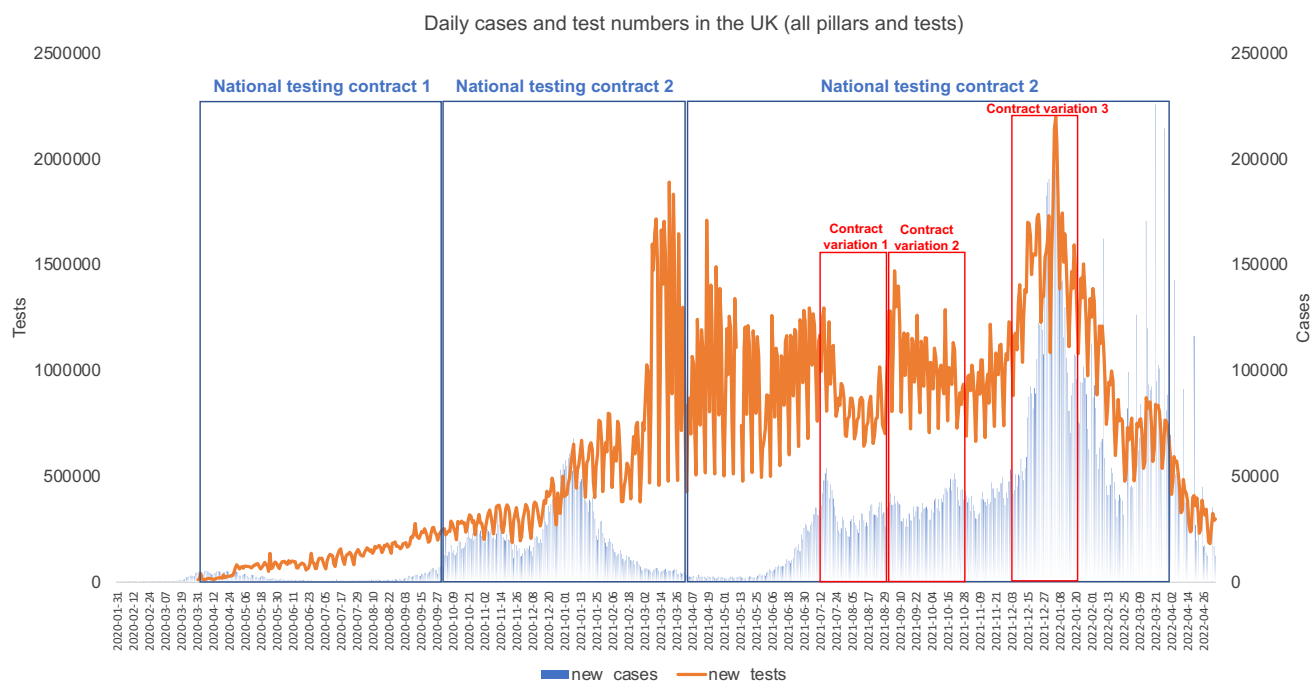


Figure 3(1) Daily COVID-19 cases and testing and the National Testing Programme

Main contracts for testing capacity					Contract variations		
Date	Requirement	Period covered	Procurement route	Contract value	Date	Details	Value
Mar-20	Testing capacity	12 weeks	Direct award	£132.4m	Yes	Yes	Yes
Oct-20	Testing capacity	Up to Mar-21	Contract variation of direct award	£328.3m	Dec-20	Minimum guaranteed payment to ensure testing continued during an increase in volumes resulting from an increase in the spread of the virus	£0: amendment within the existing contract value
Mar-21	Testing capacity	Up to Mar-22	Call off (direct award) from a framework agreement	£60m	Jan-21	Additional commitment because the Department had depleted its minimum commitment of tests	£0: amendment within the existing contract value
					Jul-21	8 week requirement to increase testing capacity	£44.4m
					Aug-21	12 weeks to support surge capacity	£52.5m
					Dec-21	Variation to increase testing capacity in response to Omicron variant	£151.5m

Date	Requirement	Period covered	Procurement route	Contract value
Feb 21	Automated sample picking	Feb-Mar 21	Contract variation	Weekly payments of £30,000, up to a maximum of £159,000
Apr 21	Automated sample picking	Apr – Mar 22	Contract variation	Weekly payments of £15,000 totalling £0.78 million

Between January 2020 and December 2021, the Department, PHE and UKHSA also awarded 12 contracts or contract variations to Randox and Qnostics Ltd (a strategic partner of Randox) for the provision of COVID-19 testing goods with a combined value of £6.9 million. All goods were delivered and there were no examples of any contractual non-performance or failures to meet contract specifications.

Table 3(1): contracts and variations under the National Testing Programme

3.2 THE FIRST TESTING CONTRACT

3.2.1 The initial contract

The first testing contract from March 2020 was a 12-week contract involving an end-to-end process including the provision of the sample collection kit, registration portal, laboratory testing, and transmission of results to individuals. In total, 2.7m sample collection kits were assembled with over 1.5 million being dispatched to Amazon warehouses who were contracted by the government to deliver kits to individual users or testing sites such as care homes.

This contract carried significant risk for Randox who were being paid for test completed rather than contracted numbers. At this stage of the pandemic there was no guarantee that the 2.7m tests would be undertaken and Randox could be left with surplus stock and consumables that had already been paid for.

To help manage the contract Randox established a liaison team who were available 24 hours a day, seven days a week to work with the Department of Health and Social Care. Throughout the contract period this team remained constant to help develop strong relationships and provide daily reports on key metrics such as throughput, positivity, and void rates.

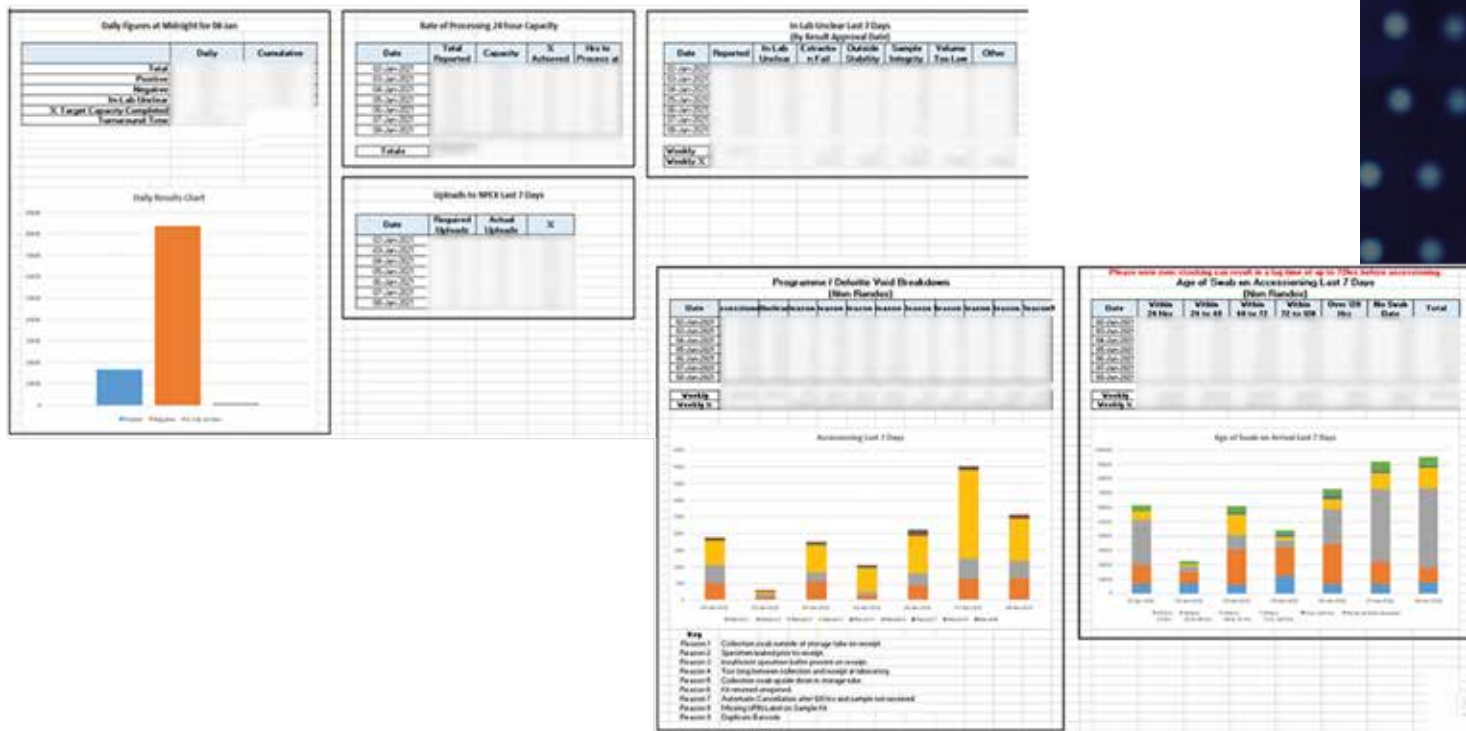
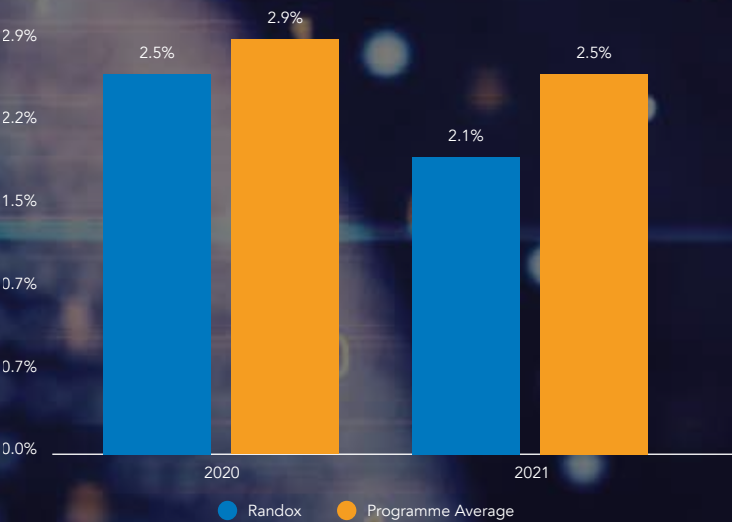


Figure 3(2): Examples of the detailed reports provided to Public Health England each day

The IT portal that had been developed by Randox prior to the contract was an early example of how their experience enabled a quick scaling solution that would not have been available to other providers. The system linked individuals with their test sample through a Unique Reference Number on the sample tube. This allowed testers to reach back to the registration data and determine the age of the sample and prioritise older samples that were more at risk (i.e. at risk of being outside the sample validity timeframe).



Over the next two years this technique would help Randox achieve lower void rates than the national testing average. Void rates were further reduced by innovatively increasing the use of automation. Had the broader Pillar 2 programme reduced void rates to those achieved by Randox, a further 490,000 COVID results could have been provided first time.

Source: National Audit Office (2022) Investigation into the government's contracts with Randox Laboratories Ltd

Figure 3(3): Randox void rates were consistently below the programme average

The diagram below shows the end-to-end process of the initial contract including the IT registration, accessioning, laboratory processing, reporting and waste disposal. It also shows how the real-time PCR process introduced later in the contract helped reduce the number of stages in the process.

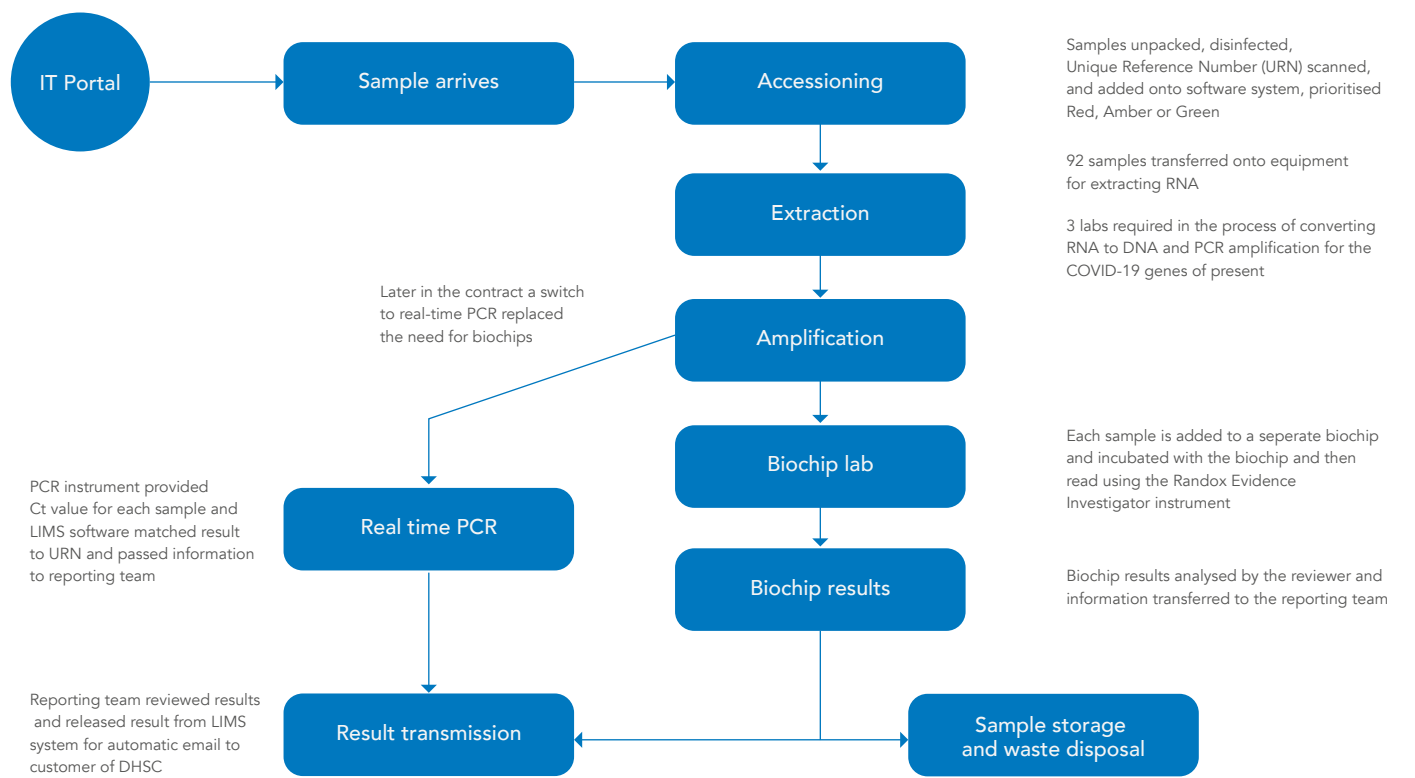


Figure 3(4) The testing process



3.2.2 Scaling up

To give an idea of how far Randox would scale up their capacity, Figure 3(6) below shows how the initial laboratory capability was eventually expanded by four bespoke purpose built lanes of laboratories (lanes A to D in Fig 3(6) below) operating at the Randox Science Park. Over the course of these contracts Randox would build, equip and staff over 80,000ft² of PCR laboratories, equivalent to a football pitch worth of laboratory space.

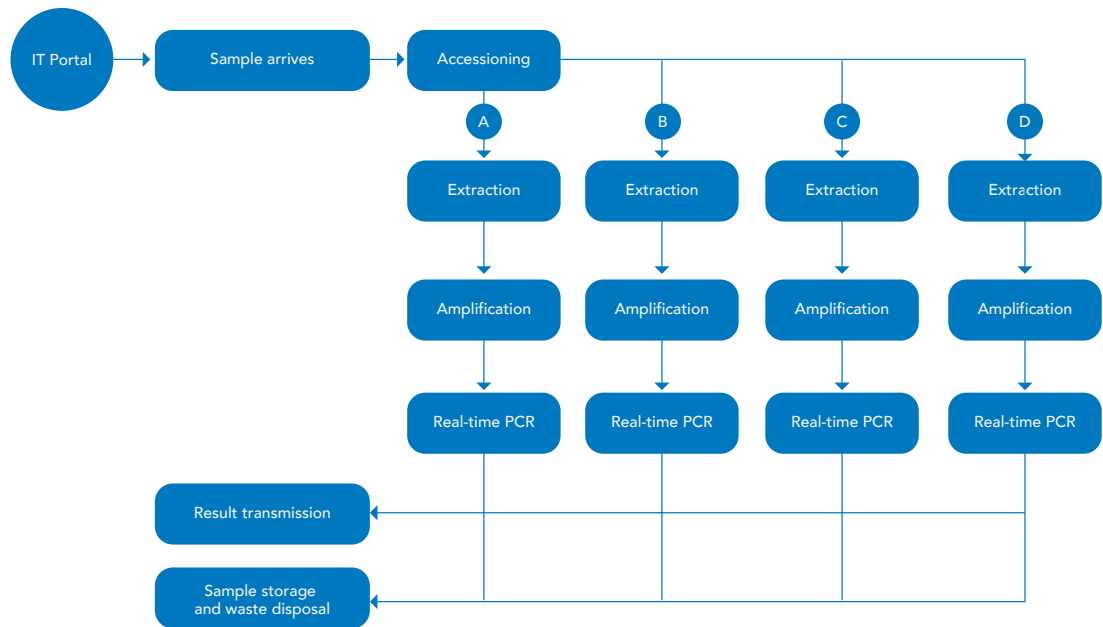


Figure 3(6): How Randox would expand their capacity through an additional four lanes of laboratories at the Randox Science Park

A key challenge at the very beginning of the COVID Testing programme was getting the new laboratories fully operational and securing sufficient reagents and consumables to ensure the testing demands were met. Over the course of two years, Randox would purchase 157 million pipette tips, 17 million reaction tubes, 2.5 million labels and 1.6 million PCR plates.

In a calculated risk for Randox, the procurement of additional supplies started prior to any contract announcement. Fast management approval, often from the MD, ensured items were secured early and commitments were made to suppliers to ensure future supply. But as testing increased so did the demand for goods at a time when supply was restricted by companies operating at reduced staffing, global supply chain blockages, and international demand for similar consumables. This was driving up the cost of purchasing supplies and consumables, with high demand items often costing a multiple of their usual cost.³²

To address these issues the procurement team at Randox brought their years of experience and good supplier relations to the fore. They talked to contacts in existing suppliers to secure goods, sought out secondary suppliers wherever they could find them, and even resorted to picking up items themselves if it would secure an item.

³²Department of Health and Social Care (2020) Coronavirus (COVID-19) Scaling up our testing programmes

Figure 3(5) Elements of the accessioning process



Another issue with the ramping up of testing and buying at scale was that certain items suddenly required more paperwork. In one example the requirement for ethanol meant purchasing quantities similar to those purchased by a brewery and it was essential that the correct HMRC licenses were in place for this level of use. To cope with the extra pressures the Procurement team at Randox would increase by 50% over the pandemic to 18 employees.

“lab processes were never delayed due to shortages”

It is a credit to the procurement team the laboratory processes were never delayed due to shortages. It is also a credit to the entire testing system in the UK that a culture of co-operation between laboratories often ensured that surpluses in one laboratory could be moved to avert shortages in another.

Alongside sourcing goods, it was essential that Randox could supply the laboratories with the correct materials in the correct quantities. Systems needed to be put in place to ensure the whole process was running smoothly and avoided any damaging breaks in testing. The absence of something as apparently insignificant as a label or pipette tip could have brought the whole operation to an abrupt halt. New storage areas for the immediate support of the laboratories were established (first-line) and supplies constantly monitored and topped up from second-line company stores to ensure testing never faltered.

The additional space within the Randox Science Park was invaluable for storing and managing the extra supplies needed. The team were able to acquire an extra building to create a centralised store - see figure 3(7), and then move again to a larger building as the scale of supplies continued to increase to match test demand. This ability to scale up the required storage space would not have happened as easily without the extra premises available on the Science Park.



Figure 3(7): Main hangar space immediately pre-pandemic – which was quickly converted to provide laboratory, logistic and engineering capabilities



An additional factor in managing essential supplies was the in-house IT team's ability to develop new systems. In March 2020, the IT system to deliver on the scale required by the pandemic did not exist and the IT team were required to pull on all their resources to design and develop multiple applications within timescales unheard of for IT projects. As one software development manager stated, thanks to the dedication and long hours of the team they were developing systems in three weeks that would normally take three months.

The scale of the challenge facing the IT team was significant. They had to develop platforms that were accessible and functional 24 hours a day/7 days a week. These platforms had to be user-friendly, compatible with a variety of devices, and be hosted on servers that could deal with high volume and fluctuating user traffic.

In actions typical of the culture within the company, the IT team would also spend weeks in the laboratory, analysing processes and shadowing laboratory staff to understand their needs and ways to optimise processes. This learning was then taken away and used to develop systems that could deal with unprecedented demand.

The achievement of the IT team is demonstrated by a number of innovations including:

- The team launched the first version of the COVID-19 kit registration portal within 48 hours of the original request. This allowed customers to register their test kit online and to assist the UK Government with contact tracing.
- The IT team reconfigured the Laboratory Information Management System (LIMS); in only two weeks, developing a full end-to-end process that never failed despite the huge increase in tests.
- Randox also managed the kit registration process for the UK Government National Testing programme while they spent four months building their own systems.
- In April 2020, the IT team launched the first version of the Randox sample accessioning platform to manage the sample receipt and formal chain of custody process. This allowed for scanning of samples and automatically updating their information onto Laboratory Information Management System (LIMS). This assisted the development of the traffic light system that ensured samples close to expiry were identified and fast-tracked through the testing process.
- The paperless Laboratory Information Management Application (LIMA) was custom developed in-house by the Randox IT team to manage the end-to-end sample workflow process. The system tracked hundreds of quality related data points as samples moved through the testing process.
- An automated report delivery service was developed to email customers with their results within five minutes of the result being authorised. In one 24-hour period this system communicated 114,000 results, and in total would communicate more than 25 million results.
- An online ordering and dispatch system for sample collection kits was created withing three weeks of the original idea. This would peak at 40,000 orders being processed in one day.

Alongside supplies and systems, the successful execution of the contract would require a significant increase in employment. Employment went from 1,360 in February 2020 to a high of 3,298 in December 2021 as Omicron surged across the country – a growth of 143% in just under two years.

Total Randox staff during the National Testing Programme
(by month)

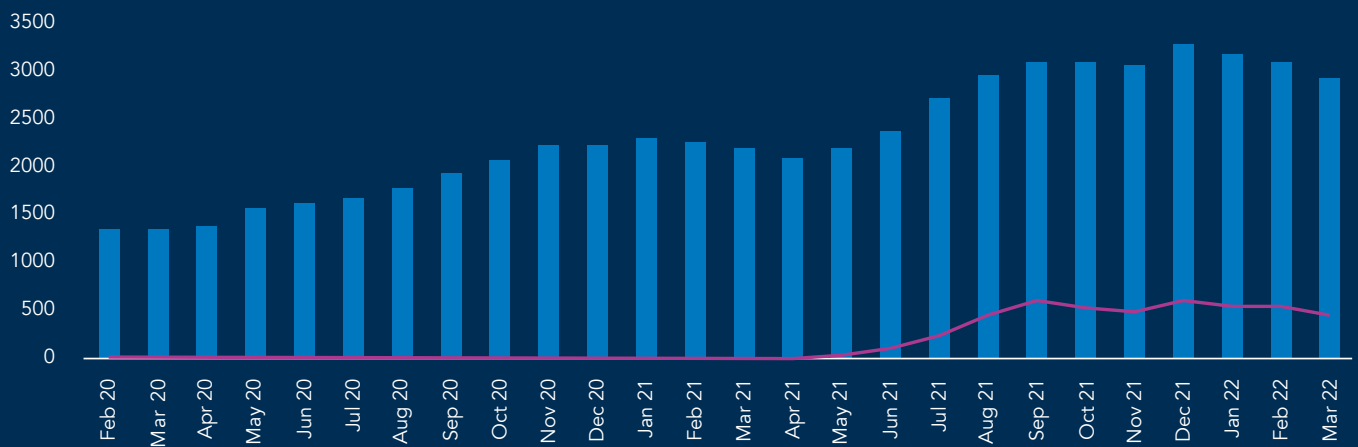


Figure 3(8) staffing at Randox

When lockdown was announced in the UK on 23 March the whole HR department was switched to help with recruitment, an ‘all hands to the pumps’ attitude that was present across the company and undoubtedly helped deliver the contracts.

Randox needed to recruit a lot of people in a short space of time and an Assessment Centre Programme was developed as an efficient and effective solution. Up to 60 people could be assessed in these centres each day, including initial screening (eligibility to work, ability to work shifts/on foot etc), tests for critical reasoning and detail, and one-to-one interviews with managers.

One of the biggest recruitment issues was where to find all the qualified scientists for the extra testing work, especially in a smaller geography like Northern Ireland at a time when travel was restricted? In an example of creative thinking, the company took a modular approach and identified what staff and qualifications were needed for each part of the testing process. By identifying processes that could be done without a specific life sciences qualification, the team could recruit from a broader range of applicants without sacrificing on quality for more technical roles.

While the HR team was totally focussed on recruitment, interviews with staff made it clear they felt valued at Randox. When operations shifted to 24/7 salaries were increased to compensate, promotion came from within and many staff experienced accelerated career development equivalent to five years over the two-year process. One example included promotion from R&D scientist to shift lead to deputy lead to laboratory manager to reporting manager in less than two years. It is revealing that all permanent recruits during the pandemic have either been retained after the testing programme finished, or naturally moved on.

3.2.3 Issues arising in the early months of the contract

Considering the speed with which events were unfolding, the exponential nature of the virus, and the fact that the country was in lockdown, it is not surprising that some issues emerged when getting up to full operational capacity.

During the initial contract negotiations Randox had stated that it currently had the resource to be able to reach targeted capacity up to week three and that it would scour their global supply chains for the required equipment and consumables, to go beyond the Week 3 capacity. However, government assistance may be required beyond Week 3 given the global demands and pressure. This was acknowledged in the contract that stated:

'Contractor anticipates that it will be able to cover supplies of raw materials, including reagents, until the end of Week 3 from the Contract commencement date. Authority support may be required in procurement chains thereafter (including access to third party items outside Contractor control as indicated in presentation sent to OLS).'³³

As early as the first week of April it was clear to Randox that global supply chains for PCR equipment were very heavily stressed and that once internal capacity had been maximised by week three the fastest way to increase capacity further would be to loan equipment from universities.

Requests for assistance to the DHSC, as anticipated in the contract, were not forthcoming and Randox elevated the issue to Ministerial level. A telephone conference call was held on 9th April 2020 to request Randox loan of available but unused RNA extraction systems.

To put this episode into context, on the day of the call there were 1,118 COVID-19 deaths in the UK (unknown at the time this was the Wave 1 peak) and equipment that was in high demand internationally and could be considered critical national infrastructure in a pandemic, was idling in university laboratories that were closed because of the lockdown.

Following the call, the then Minister for Technology, Innovation and Life Sciences initiated contact with several universities on 10 April 2020 to expedite equipment loans not just for Randox but across the developing Pillar 2 network.

Randox would receive four working RNA extraction systems on loan by 17 April (at the same time they had 26 on order). Subsequent analysis showed that while these machines were only responsible for 0.5% of the overall samples processed by Randox, at that moment in April 2020 the collaboration among universities and laboratories played a pivotal role in delivering the testing programme.

Randox ultimately ordered an additional 106 RNA extraction systems of which 99 were delivered. In total Randox received 185 items of equipment on loan, of which 62 were used. The bulk (82%) of loaned equipment was returned by the end of August 2020, with the remainder returned by mid-November 2020.

³³Appendix 1 of Randox contract with DHSC (30 March 2020)



3.3.4 The challenge of ramping up capacity

The early focus of the UK's National Testing Programme (March to September 2020) was primarily on rapidly building additional capacity. However rapid growth presents issues in large complex systems that were often felt by Randox.

Diagnostic laboratories operate best when capacity is understood and sample in-flow is smooth and well managed. In these circumstances work flows can be efficiently managed across all stages of the process (delivery, accessioning, extraction, amplification, testing, results reporting). Two issues in the early part of the contract that impacted Randox and undermined efficiency and operational delivery were forecasting and delivery of samples.

As the National Audit Office report into these contracts sets out, there was lower demand in the system than the Department had forecast³⁴ and a lack of sample projection accuracy created volatility in the system that affected smooth sample flows. Additionally, courier system inefficiency, and simple issues such as postal deliveries not happening on a Sunday, could impose inefficient peaks and troughs of high and low demand which were very difficult for Randox to predict. See Figure 3(9).

³⁴National Audit Office (2022) Investigation into the government's contracts with Randox Laboratories Ltd

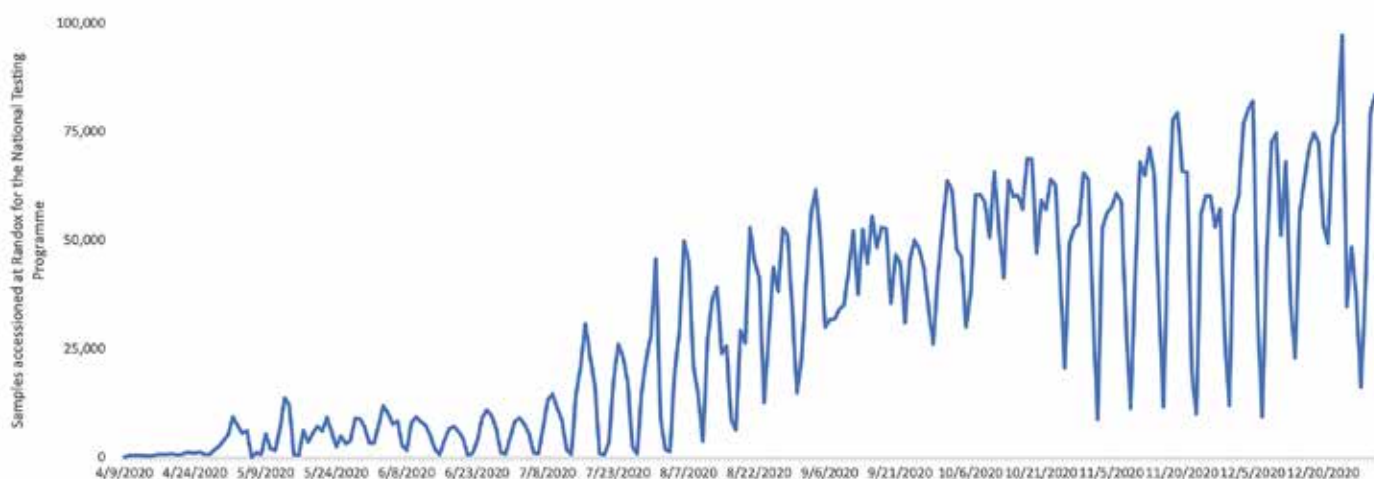


Figure 3(9): The number of samples accessioned each day shows the volatility of supply that could affect the smooth running of the laboratories

Randox, in common with all laboratories, had to contend with technical issues that impacted upon capacity from time to time. The installation of loan equipment, in particular, was not straightforward due to variable historic maintenance; associated equipment failures led to a temporary drop of capacity in early May 2020. In the post-incident review, and as a broader system efficiency, NHS Direct additionally requested that Randox transfer subjects from the Randox portal to the NHS Test and Trace portal, both to support registration and the issuing of results.³⁵

At this time, any reduction in the number of test results was an issue for government as the Prime Minister, other senior ministers, and senior health officials would be required to explain this on their daily televised briefing and questioning by journalists. This did place pressure on Randox from Ministers to prove their resilience, something that as figure 3(10) shows they would ultimately display over the coming months by significantly ramping up capacity. By the end of September 2020, Randox had increased capacity to 50,000 tests per day which was the highest volume of any of the laboratories which government had contracted to provide testing services.³⁶

³⁵Memo dated 6 May in parliamentary motion on Randox contracts passed on 17 November 2021

³⁶National Audit Office (2022) Investigation into the government's contracts with Randox Laboratories Ltd

In June 2020, a process was initiated by the Department to integrate Randox into the wider testing programme rather than their current 'closed-loop' of standalone kits and laboratory processing. As part of this process an assurance of safety checks in the supply chain in July identified one Randox supplier who lacked supporting documentation for sterility of their swabs.

The issue revolved around an incomplete European Commission certification (CE certificate), and the relevant test kits were placed on hold while Randox sought assurances from the supplier. This highlights one of the biggest challenges of sourcing supplies during the pandemic; a dramatic increase in global demand meant more suppliers were required, but

a ban on international travel meant supplier visits were not possible and companies were relying on suppliers and their agents for verification. By the start of August the supplier had been unable to provide evidence to satisfactorily support the CE marking for these swabs so Randox voluntarily committed to initiate a recall on the basis of a missing CE certificate.

Randox, at its own cost rather than an extra to the Department and taxpayer, recalled a total of 1.7m kits. This covered those that had been recalled plus those already in stock. In his associated statement to Parliament the Secretary of State confirmed that test results were not affected and that there would be no impact upon access to testing.³⁷

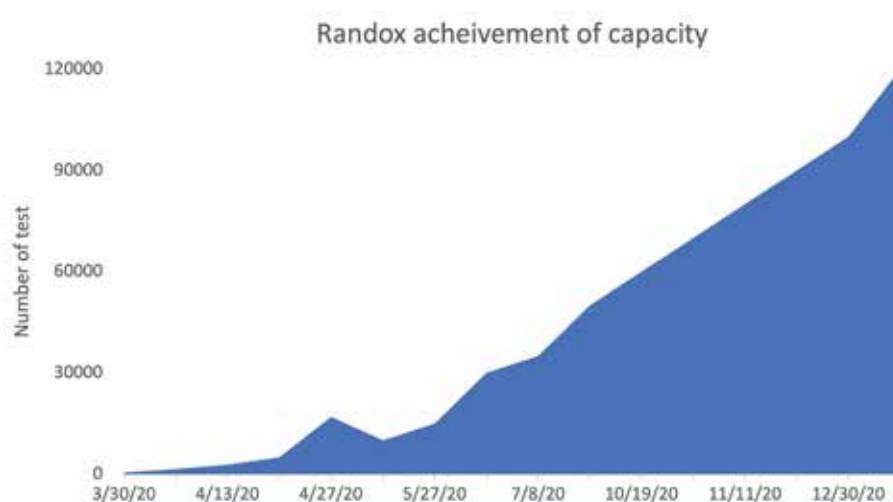


Figure 3(10): How the Randox capacity increased to 120,000 by January 2021

³⁷Hansard (2020) COVID-19 Update Volume 678: debated on Thursday 16 July 2020

3.3.5 Examining overall performance of the initial contract

In June 2020 Randox agreed to extend the contract period to ensure the Department was provided with the 2.7m tests that it originally contracted. This continuity was important as Randox was able to support the NHS Track and Trace system that had started on 28 May 2020. At this time, the company also agreed to test any sample sent to it rather than just its own kits and bore the financial costs of doing this.

This requirement for an extension within the first contract has been described as a 'performance issue' based on Randox's inability to increase testing capacity³⁸ but this fails to consider logistical issues beyond the company's control, or the fact that Randox could only test what was sent to them. It was noted in the subsequent review by the National Audit Office that 'throughout this period there were very few days on which the capacity Randox provided was fully utilised by the Department.'³⁹ This was because the number of tests Randox was receiving was affected by lower demand in the system than the Department had forecast. Randox was paid per test rather than capacity and therefore an under-utilisation was also a commercial issue that was not in the best interest of the company. Randox was also building capacity which would exceed all other Pillar 2 laboratories.

Although no specific performance indicators were included in the original contract there is evidence to show that Randox not only performed well but was one of the best performing laboratories across the National Testing Programme.

In June 2020 Newton, a UK-based specialist in operational improvement, was asked by DHSC to conduct an assessment of all laboratories in the Pillar 2 programme. Newton visited the main five laboratories and conducted process mapping, cycle time analysis and examined historical data analysis to understand current performance of processes.

According to Shona Dunn, the Second Permanent Secretary at the Department of Health and Social Care, Newton's overall assessment 'had placed Randox at the top end of performance in terms of its testing provision on a number of different metrics'.⁴⁰ These include the provision of four green observations, three amber observations and no negative red observations.

A later performance indicator was added to the contract from 1 July 2020 when the NHS Test and Trace Service introduced a target that 60% of tests sent from organisations, such as care homes, should be turned around within 48 hours of kit registration. Between 1st July and 1st October 2020 Randox were able to process 78% of samples within 48 hours of arrival at its laboratory⁴¹ after which turnaround times reduced markedly (See Fig 3(16), Page 47).

While the first contract had experienced some issues, when looked at as a whole, Randox had made a significant contribution to the UK's testing infrastructure at the very outset of a national emergency, and in a time of unprecedented demand on global supply chains. By September 2020, they had delivered 2.7m tests, scaled their own business to handle 50,000 tests per day from a starting point of 300, and introduced processes and innovations that would help the UK meet some of the toughest COVID-19 challenges that were still to come in 2020 and 2021.

³⁸Memo Public Accounts Committee (20 July 2022) Government's contracts with Randox Laboratories Ltd

³⁹National Audit Office (2022) Investigation into the government's contracts with Randox Laboratories Ltd

⁴⁰Public Accounts Committee (20 July 2022) Government's contracts with Randox Laboratories Ltd

⁴¹National Audit Office (2022) Investigation into the government's contracts with Randox Laboratories Ltd

3.3 THE SECOND NATIONAL TESTING CONTRACT

In October 2020, a second contract was awarded to Randox as part of the National Testing Programme. This was a contract variation without competition and covered the period up to March 2021. The value of the contract was £328.3m but as with all these contracts, Randox would be paid per test carried out rather than receiving the published contract value.

This contract also included several variations such as capacity milestones, a mechanism to deal with under-utilisation of test capacity, and increased liabilities for Randox if contract milestones were not met. At the time there was criticism of the DHSC from the Permanent Secretary of the Cabinet Office who stated:

*"I am disappointed that despite entering into the original contract on 30 March DHSC have not moved to organise and conclude a competitive contract process and are now in a position where extension by direct award is the only viable option. Can we please insist on a written commitment from DHSC to initiate a competitive process in time for new contracts to be let from March 2021. At least the price has been negotiated down and is now comparable to benchmarks, and quality has been good."*⁴²

While the main public focus of this quote has tended to be on the departmental criticism, the last sentence is telling. It shows that the price had been reduced and costs had been benchmarked as far as possible. Critically, the overall performance of Randox was regarded as good.

Randox's performance was also acknowledged by Shona Dunn, the Second Permanent Under Secretary (2nd PUS) at the Department of Health and Social Care, who stated that one of the reasons for awarding the extension was that 'Randox was already an important part of the infrastructure and had the ability to scale and provide an even more important part of an infrastructure that we were still growing.'⁴³

Randox were also able to reduce the cost per test because of the additional volume being procured, and the removal of requirements to supply sample collection devices and IT infrastructure. On top of this, significant capital investment had been covered in the first contract, and improvements in manufacturing and process management systems were having a positive impact on delivery.

Whilst Randox commenced supporting the National Testing Programme at the end of March 2020 with 300 tests per day, the programme capacity requirement from Randox peaked at 120,000 test per day, which Randox achieved at the end of January 2021. Thereafter, as additional Pillar 2 laboratories came on-line in Great Britain, the requirement from Randox was progressively reduced to, eventually, 15,000 tests per day. During the Omnicron peak of December 2021/January 2022, this was rapidly increased to 105,000 tests per day to meet the surge in demand.

⁴²Email dated 25 September in parliamentary motion on Randox contracts passed on 17 November 2021

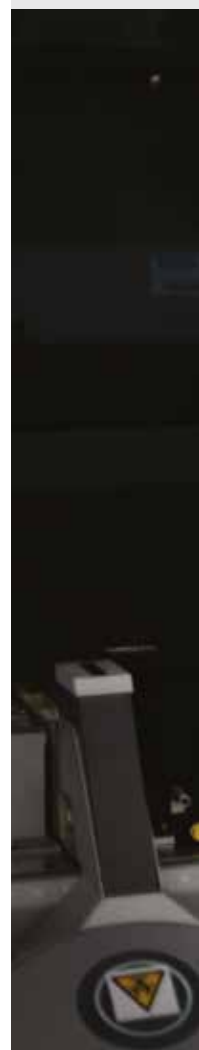
⁴³Public Accounts Committee (20 July 2022) Government's contracts with Randox Laboratories Ltd

3.3.1 Process improvement at Randox

Automation played a major part in Randox improving their manufacturing and processing. There are numerous examples of new systems being designed throughout the contract period to make processes more efficient, safer, and reduce the potential for human error.

These include:

- Designing the script for a robotic sample handling unit that allowed samples presented in standard PCR 96 sample plates to be screened for positive samples and for those positive samples to be automatically transferred to a 'positive only' sample plate for more detailed variant analysis. This process, known as 'cherry picking', removed the risk of human error and accelerated the identification of new variants.
- Developing robotic solutions to automate many of the more labour-intensive parts of the process was essential to meet the ever-increasing sample testing demand. As an example, to make the accessioning of samples prior to analysis more efficient two automated box cutters were developed to handle the tens of thousands of boxed sample tubes processed daily.
- Newly arrived sample tubes pose a risk from the COVID-19 virus on the outside. Originally, decontamination before release into the laboratory for testing was performed manually with a tissue sprayed with disinfectant. To avoid a bottleneck, an automated decontamination tunnel was developed. Sample racks were fed along a conveyor through a mist of disinfectant and by the time they reached the end they were virus free, dry and ready for sorting prior to entering the laboratory for testing.
- Gantry robots were programmed to pick up each sample and scan a barcode that logged the sample on LIMS and determined its age. The samples were then deposited in corresponding racks on the other side of the unit based on the time left before the sample would need voided. This helped Randox achieve a void rate better than the rest of the National Testing Program laboratories.
- The Extraction Automated Sample Transfer (EAST) instrument helped reduce process risk through a fully automated system for extracting RNA from the sample. This also freed up staff for other roles by removing the need for two staff in a biosafety cabinet unscrewing sample caps and pipetting samples with reagent into deep well plates.
- Digital tracking software developed by the IT team meant samples were scanned and tracked individually or collectively through each stage process. This meant priority samples could be tracked to ensure they did not get caught up or lost amongst the general flow of samples. It also allowed the Operations Team to monitor each stage of the process, identify potential bottlenecks, and redirect samples to other testing lanes to maintain the constant flow of samples.



The impact of this process improvement is evidenced in the reporting processes, which went from 96 samples in 12 hours at the start of the pandemic, to being able to process 5,000 samples in one hour by the end of the contract. To put this into context, between September 2020 and January 2021 Randox increased sample processing by 233% with only a 50% increase in laboratory operations staff.⁴⁴



Increases in tests processed

233%



Increases in staff to process tests

50%

Automation

- Robotic sample handling unit
- Automated box cutters
- Automated decontamination tunnel
- Gantry robots conducting visual checks
- Extraction Automated Sample Transfer
- Digital tracking

Source: OCO analysis based on interviews with Randox staff

Figure 3(11): Process improvement played a key role in driving testing efficiency



⁴⁴Interview with Lab Operations Manager conducted by OCO at Randox Science Park (22/07/2022)

Figure 3(12) Automation being used in the Randox laboratories

Alongside automation, the employees at Randox played a critical role in the process, and interviews with staff showed a culture of everyone helping out where necessary. From the MD and senior management unpacking boxes or working a shift on customer helplines, to HR staff moving into operations for the day.

The crisis created by COVID-19 broke down any silos that might have existed as the only way to achieve agility and stay on top of the rapidly changing environment was for departments to be

in constant contact. Examples include software developers visiting laboratories to get a better understanding of how it all works and what the laboratory technicians need, and daily discussions between teams to plan immediate requirements in staffing and supplies.

Collaboration and communication among staff should be recognised as an essential part of the Randox COVID-19 story, and it appears to have taken root rather than fade away post-crisis.



3.3.2 Examining overall performance of the second contract

In the first contract Radox achieved the one million test milestone in August 2020, a period of just over four months. When the second contract started in October, one million tests were completed within the space of 19 days. This growth would continue, with Radox hitting the 12 million test milestone before the end of the second contract.

This significant capacity and performance improvement in the second contract is an example of how Radox had developed its capabilities to become an integral part of the National Testing Programme. While their processes were still being stretched, a combination of innovation, staff commitment, and experience gained from the initial contract had allowed Radox to run an efficient operation that played a key role in the government's handling of the pandemic.

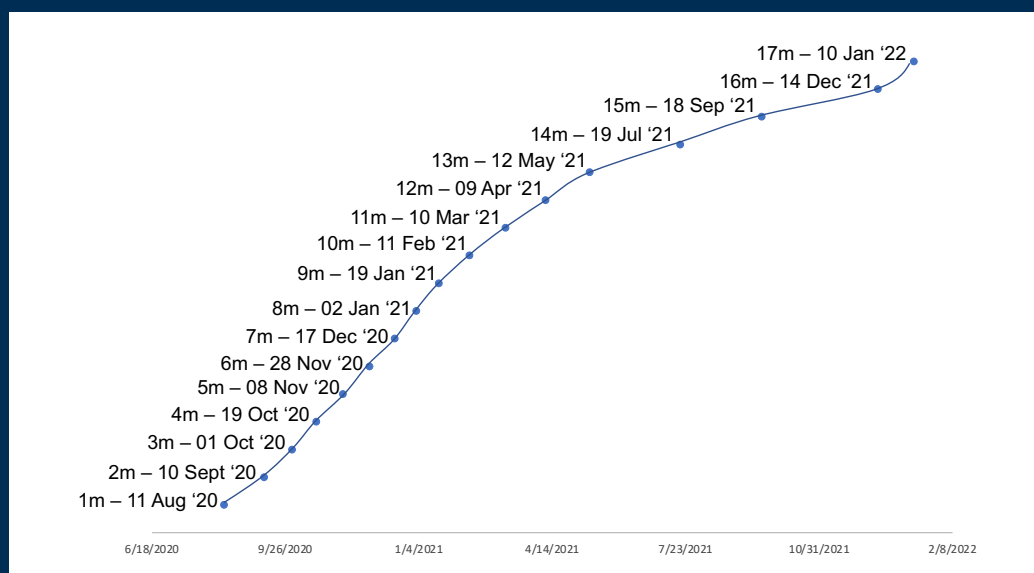


Figure 3(13): Million sample milestones show how the sharpest rises occurred at times of greatest demand

This is best summed up by Dr Jenny Harries, Deputy Chief Medical Officer for England, who stated in evidence to the Public Accounts Committee.

*"Ideally, it would have been lovely to have had that capacity ramp up immediately. I just point out that once that testing got going—this is the critical thing; this was quite new—it actually over performed later on. It was the work that Radox did that really got us through the next wave of that pandemic, through that winter [2020]. It was absolutely critical in the capacity that was provided."*⁴⁵

"It was the work of Radox that really got us through the next wave of that pandemic, through that winter."

⁴⁵ Public Accounts Committee (20 July 2022) Government's contracts with Radox Laboratories Ltd

3.4 THE THIRD NATIONAL TESTING CONTRACT

Due to the ongoing pandemic, and rise of variants, a third contract was let by the Department of Health and Social Care from March 2021. The Department had agreed with the Cabinet Office that this would be under a competitive process and the contract was let through Public Health England's (PHE's) National Microbiology Framework.

The National Microbiology Framework was a framework agreement that covered four strands - diagnostics, research and development, manufacturing of supplies and services and provision of laboratory testing capacity. The framework includes more than 100 suppliers and Randox successfully tendered to be involved across all four strands.

Randox was appointed to the different strands of this framework in February and March 2021. Between March and December 2021, the Department awarded two contracts to Randox which later included three variations. The price per test was reduced to £18, a significant decrease on the first contract of £49.60. This lower price was in part due to Randox no longer covering sample collection kits and IT requirement, but also due to the heavy capital commitment covered within the first contract and the ongoing drive for operational efficiencies. Overall, the average cost across the three contracts would be £26.07.

From April and May 2021 Randox's contracted capacity was decreased as other testing laboratories became available in the UK, and testing capacity could be more evenly distributed across the network of laboratories. However, Randox's ability, and reliability, to scale at speed would result in additional contract variations to deal with the Delta and Omicron variants.

3.4.1 Continuing to innovate throughout the contracts

Throughout all the contracts, Randox continued to build on experience and innovate new processes that would improve the whole National Testing Programme. By October 2021 they had developed the Randox Cube – a fully deployable robotic testing laboratory conducting the standard RT-PCR test. Utilising knowledge gained through their onsite PCR testing facility, Randox designed a compact testing line utilising a series of robots and liquid handling systems to handle and process samples taking them through the extraction, amplification and detection stages of the PCR test.

The modular design of the Cube meant it could be moved almost anywhere and be operational within weeks. The fully robotic system reduced manual input, error and risk to the process, and could be more flexibly deployed thanks to the less operational space required.

Randox had invested £30m in developing and building these Cubes, four of which were installed and fully operational across England within five weeks and contributed significantly to the overall testing capacity, providing up to 48,000 PCR tests per day. This innovation also made the testing process more accessible, reliable and cost-effective.



Figure 3(14): The automated Randox Cube

3.4.2 Contract performance and the rise of the variants

All viruses constantly and naturally change through mutation, usually having little impact on how the virus behaves. However, there are occasions when a mutation is beneficial to the survival of the virus, and variants emerge that are more transmissible or damaging to health.

Surge testing was used by the government in 2021 as a way to monitor and suppress the spread of COVID-19 and to understand these new variants. It involved encouraging everyone in listed postcode areas to take a test.

As the more transmissible Delta variant spread through the UK the level of surge testing increased, and so too did the testing capacity requirement. In August 2021 Randox was awarded a 12-week contract extension under the National Microbiology Framework to provide capacity for surge testing.

Three months later a second contract extension was awarded to Randox to deal with the Omicron variant, an even greater threat as the country moved towards the Christmas period and the increased risk caused by more socialising and household mixing.

The Department first asked Randox for additional capacity in November 2021, and by 21 December Randox had increased their capacity from 15,000 to 70,000 tests per day. 'Just before the New Year, in the face of the Omicron variant, the Department requested and Randox agreed to further increase capacity to 105,000 tests per day. In a period of 10 days, and over the Christmas period, Randox increased capacity by 700% to support the National Testing Programme.

These numbers increased even more as other UK laboratories struggled with increased requirements and staffing absences. The number of samples received rose rapidly after the Christmas break, almost doubling in three days to 138,000 on 30 December see Figure 3(15). By 03 January 2022, the number of samples being sent to Randox was well over their stated capacity and it was agreed that some samples would be frozen. This decision allowed Randox to reduce the potential void rate caused by over-supply.

A few days later (07 January) Randox was able to process the last of the surplus samples and the following day they started receiving additional samples from other laboratories in Great Britain that were unable to process their samples.

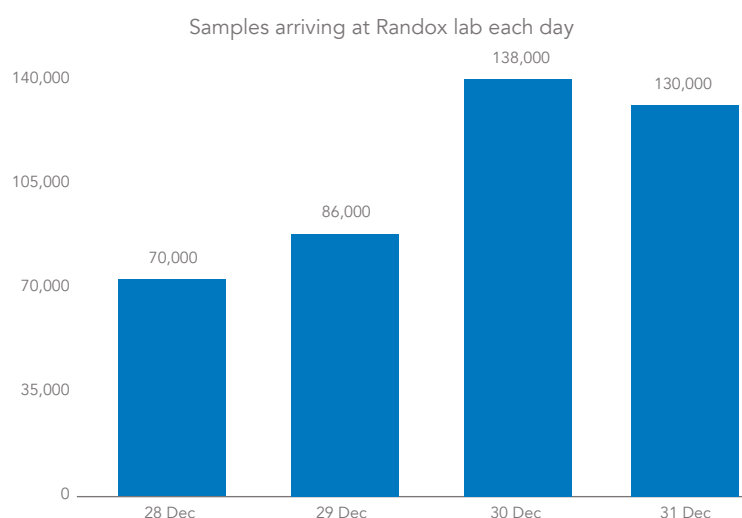


Figure 3(15): Samples arriving at Randox over Christmas 2021

The ability of Randox to scale up at short notice and support testing during the peak of the Omicron wave, when many other laboratories were struggling, would not have been possible without the experience and investment gained in the previous twenty-two months. As senior health officials have described to various governmental committees, by building up the UK's testing infrastructure the country had put itself in a position to be better able to deal with challenges that came along.

This capability within testing allowed more people to enjoy Christmas 2021 in a way that was not possible the year before and prevented a more serious scarring of the economy from another lockdown.

3.4.3 In-Laboratory Turnaround Times

Laboratory turnaround times and efficiency are greatly assisted by smooth sample flow, as this allows all laboratory systems and processes to run optimally. As Figure 3(9), Page 36, shows smooth sample flow was not a feature of the pandemic. Nevertheless, by the end of the third contract Randox had reduced in-laboratory turnaround times to 8.5 hours.⁴⁶ As Figure 3(16) below shows, the trend in Randox laboratory turnaround times was towards shorter times as processes continually improved. In-laboratory turnaround times did rise in the early part of the programme (when demand was rising while capacity was being built and key equipment remained in short supply). There were also two spikes caused by increased variant demand in July 2021 and in December 2021 / January 2022. In these cases, Randox were consciously over-stocked with samples in the face of very high national demand and it was understood by the programme that turnaround times would rise.

⁴⁶In-laboratory turnaround times cover laboratory activities - from the accessioning (receipt) of a sample in the laboratory, through sample processing, to the provision of a result; they exclude the time prior to the sample arriving in the laboratory. For Government contracts, DHSC were responsible for sample collection and for the logistics to deliver samples to Pillar 2 laboratories.

By way of example, in the case of dealing with the Omicron variant over Christmas 2021 and over that New Year, Randox were tasked with increasing capacity by 700% between 20th and 31st December 2021, from 15,000 to 105,000 samples a day, and on 30th and 31st December received over 138,000 and 130,000 samples respectively – clearly impacting turnaround times.

Overall, the average Randox in-laboratory turnaround time for National Testing Programme samples was 15.89 hours.

In July 2020 The National Testing Programme set end-to-end target turnaround times, from sample collection to result, from national Testing Centres of 80% within 24 hours, and in from the wider community setting of 60% within 48 hours. These end-to-end targets start at the point of sample collection and are inclusive of the logistics to deliver samples to laboratories, laboratory processing and the delivery of results.

Randox had responsibility for processing samples from Northern Ireland based Testing Centres and sample 'traffic lighting' allowed prioritisation of those samples to meet the required turnaround time. The numbers were relatively small.

For the much greater number of community samples, with a 48 hour end-to-end target, the average Randox in-laboratory turnaround time of just under 16 hours allowed an average of 32 hours for the pre-laboratory sample collection and sample delivery logistics processes. By 2022 this logistics timeframe had been increased to more than 36 hours thanks to Randox reducing their average turnaround time to 11.18 hours.

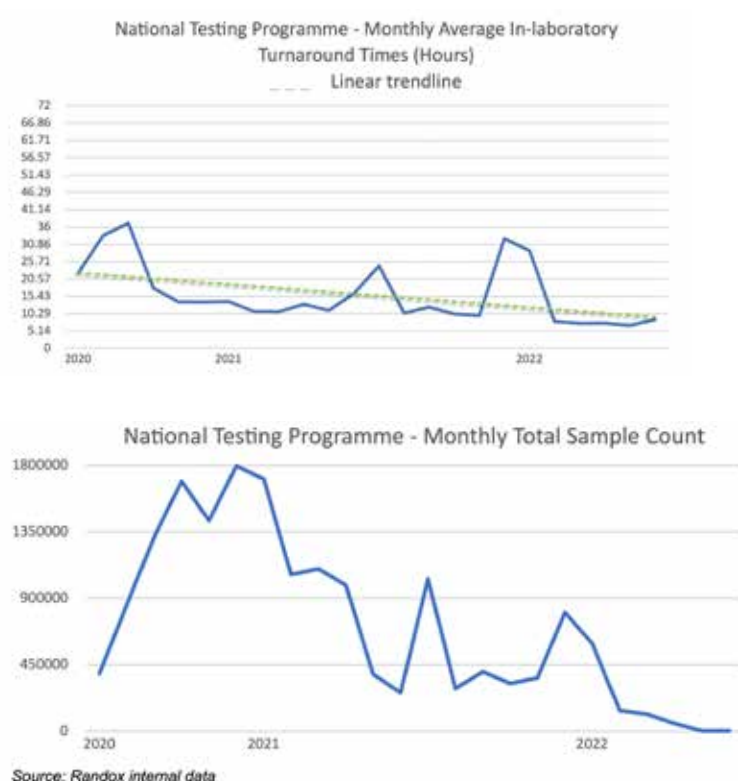


Figure 3(16): Randox in-laboratory turnaround times and samples received per month from July 2020 to June 2022

PRIVATE TESTING

In this section, we show how testing helped re-open the country, first with sport and key businesses and eventually with travel testing. Benchmarking Radox against other travel testing providers shows it was able to provide an excellent rated service at a lower cost.

4.1 THREE STAGES OF PRIVATE AND TRAVEL TESTING

Private testing through the pandemic can be broken down into three stages.

- From July 2020 testing allowed sports leagues and other corporate partners to return to work within a tight observation environment.
- This was followed from May 2021 with the return of international travel and a significant scale up of operations while trying to navigate the ever-changing regulations.
- As the country starts to emerge from the pandemic so private testing is evolving to meet the needs of consumers who have an ever-greater awareness of diagnostic testing as part of a healthy lifestyle.

4.1.1 Private testing up to May 2021

No sector of society escaped the impacts of the COVID-19 pandemic and lockdown, with tourism, hospitality and sport experiencing some of the biggest upheavals. In April 2020, 34 major airlines cancelled at least 90% of their flights, while only one percent of scheduled sports events with an attendance of at least 5,000 took place. The impact can be seen through commercial airlines announcing \$190 billion in net losses in 2020 and 2021⁴⁷ while revenues in the sport industry reduced by 54% in 2020.⁴⁸

The lack of activity in these sectors also created secondary issues both financially and in terms of personal wellbeing. A lack of air-travel restricts both tourism, visiting friends and family and international business, while people stuck at home in lockdown are unable to distract themselves watching live sport or other entertainment.

Sport was one of the first activities to return during the pandemic, typically behind closed doors or in 'bubble environments' with robust risk assessment and reduction. Radox was able to assist professional leagues by offering private testing services that were in line with regulations set out by the governing bodies and Department for Digital, Culture, Media and Sport.

From mid-2020, Radox was awarded the contract for testing 12 Premiership Rugby Teams and 12 Championship Rugby teams, alongside all professional Scottish rugby. This was a twice weekly throat and nose swab testing service with Radox responsible for providing an end-to-end solution including private road and helicopter transportation of samples, the fastest possible turnaround of samples, and bespoke private reports provided each week.

⁴⁷Statista (2022) Passenger airlines worldwide

⁴⁸Centre of Sports and Human Rights (2021) Call for Evidence: DCMS Select Committee on the Impact of COVID-19 on DCMS Sectors



Over the course of this contract, Randox would provide approximately 30,000 tests to English and Scottish rugby teams. It is unlikely that many people enjoying the distraction of a rugby game on a Saturday afternoon were aware of Randox staff working at 4am on a Tuesday morning to receive and prepare player samples for testing.

Another major sports undertaking for Randox was a two-year partnership with the British Olympic Association. As the official tester for TeamGB, Randox provided a test programme for each athlete, coach and official that included three pre-games PCR tests (Day 14, 96hrs and 72hrs pre-travel) and between one and three post games test on arrival in the UK.

A total of 4,262 tests were carried out across the Olympics and 2,400 for the ParalympicsGB squad. This was an end-to-end solution that included transportation of samples from test hubs, sports centres and training camps across the UK, testing, and the design and use of a bespoke dashboard to access results.

At this time, following another major innovation programme, Randox was also able to deploy accurate portable PCR testing systems to support corporate testing. Over 700 systems were provided to support nuclear power plants, film and TV production, energy providers, clinics and pharmacies, and major construction projects. Systems were also provided to Team GB during the Olympics to allow them to monitor athletes in-country, during competition.

4.1.2 Travel testing

A particular focus for the government was a return to international travel, to help the aviation industry, encourage international business, and allow for tourism to re-start. In early 2020 most countries had imposed border closures and lockdowns that made international travel almost impossible, but as the initial peak passed in the summer, countries were easing their restrictions.

On 22 May 2020, the UK government announced self-isolation (quarantine) plans for all arrivals (including returning British nationals) into the UK commencing on the 08 June. The Joint Biosecurity Centre was also established to assess the risks of inbound travel. By July a number of 'travel corridors' were established, meaning that people could return to the UK from low-risk countries without quarantine.

In the UK, the market for PCR tests for international travel did not exist before December 2020 when the UK Government launched 'test to release'. Accordingly, all international arrivals must be tested post-arrival and this testing must be PCR-based.

Prior to these announcement Randox had already been in initial discussions with airlines to provide a testing solution to clients. Again, the company had the advantages of providing an end-to-end solution and being able to scale quickly as government announcements opened up travel.

This ability to scale up is demonstrated by the logistics associated with travel testing. At Christmas 2020 there were 10 drop-off boxes around the country for customers of TUI, EasyJet and Jet2 to leave samples for collection and testing. By August 2021 this had increased to 220 drop off boxes, making Randox the only testing provider running a private delivery network on this scale.

Over this period, to facilitate personal access, Randox opened 32 Testing Centres in Great Britain, 12 in Ireland and 6 in Northern Ireland. At the height of testing surges, Randox were operating all these facilities, emptying drop boxes 4-5 times a day, and bringing in approximately 50,000 private samples each night to the laboratories. This was a logistics operation involving around 220 drivers, one helicopter, and three aeroplanes (one medium and two small).

As with the National Testing Programme, Randox was always looking for ways to improve this service and in August 2021 they entered into a partnership with Paypoint, an innovative services and technology company that connects consumers to over 60,000 retailer partner and SME locations. This partnership added additional convenience for customers through a click-and-collect service at 2,719 collection points. A key innovation for travel testing was the development of an express PCR test that could provide a result in less than three hours. This product meant Randox was a company that travel companies wanted to do business with.

In June 2021 Randox were awarded with 5 out of 9 contract lots from Manchester Airport Group (MAG) tender, for rolling out drive-through and walk-through testing sites across Manchester, Stansted and East Midlands airport. Interviews with MAG stated that they were impressed with how Randox spent time and money to make the customer experience as painless as possible and pointed to the one hour turn around



Figure 4(1) A Randox Express PCR laboratory, facilitating results within one hour. Over 30 Express PCR sites were opened across the UK and Ireland

as a key factor.

The express test would also lead to a partnership with Collinson, a provider of Priority Pass airport lounges and experiences programmes. The partnership made the testing process more seamless for passengers, enabling them to book to take their test as part of the journey to the airport. Using on-site Randox technology to process PCR tests in under one hour meant passenger could book to take the test on their day of departure and have their result in time for check-in, rather than needing to arrange for a test days in advance.

Randox was also able to develop consumer based technology solutions to help navigate the ever-changing rules for travel. For example, on 24 October 2021, it was announced that fully vaccinated arrivals into England, who had not been in a red list country in the last 10 days would be able to take a lateral flow test instead of a PCR test. Passengers were required to take a photo of their lateral flow test result and send it back to their private testing provider for verification. Randox provided a remote lateral flow testing app in October that allowed users to easily verify test results. The iOS version of the app was No1 in Health and Fitness Appstore section for eight consecutive weeks.

An aspect of travel testing that was different from the National Testing Programme was that all positive COVID-19 tests from travel samples had to be genetically sequenced by the testing provider and the report generated had to be shared with the Government (but not the individual) in order to monitor the development and source of possible new variants of the virus. To do this in-house Randox purchased a sequencer instrument, trained their staff in the necessary techniques and gained sequencing accreditation. This was a major undertaking, with an investment well in excess of £1m, but one that leaves Randox with strong capabilities for future diagnostic requirements.

4.1.3 The roll out of Randox Health Clinics

As pandemic restrictions have eased, so Randox has begun using the technologies and experience built in private and travel testing to develop a network of health clinics aimed at providing the same seamless experience for broader healthcare testing. The clinics include unique products aimed at promoting preventative healthcare.

As consumers become more aware of their own health, and the varied roles that diagnostic testing can play, these high street clinics will become a useful health facility for those interested in additional health screening. The company is aiming for 20 high street clinics by the end of the year, with plans to open more in Europe, the US and Australia.

4.2 THE DEVELOPMENT OF CUSTOMER SERVICES CAPABILITIES

Providing private testing represented a shift from contractual relationships with government, to a business-to-business relationship. With travel testing this pivoted further into business-to-consumer services, with a significant increase in customers and information requests.

The impact of this change is shown by the fact that the Customer Services team at Randox started with four re-deployed staff to deal with private testing, but eventually grew to 300 staff running 24 hours a day, seven days a week.

Figure 4(2) below shows the number customer enquiries received each week and the correlation between changes in government policy and enquiries. The two peaks represent the introduction to the “Day 2, Day 8 and Day 5” Testing system and the “Traffic Light System” in May and June, with the second peak related to the constant changes in requirements for “Test to Return” to the UK and numerous countries removing their requirement for testing.



At times the Randox customer services team felt like they had become a government advice line, even though they became aware of these announcements and changes at the same time as the general public. These staff were not in a position to give government advice, and did not do so, but it was still a time-consuming business to tell callers that Randox was not an official government advice line.

Figure 4(2): Number of customer service enquiries handled by Randox

This was especially true at busy times, when up to 15,000 enquiries could be received in a day. To handle these Radox was constantly employing new staff, increasing the number of shifts, training staff in two external call centres to help with demand, and drafting in staff from other departments.

4.3 THE PERFORMANCE AND IMPACT OF PRIVATE TESTING

By October 2022 Radox had processed over 9.5 million private COVID tests. Behind the scenes they had also built an online platform, grown a customer service department from 4 to 300 people, established an in-house logistics network, and redesigned test kits to suit the ever-changing regulatory environment – often at very short notice.

Radox also had to deal with 12 major international travel policy changes within 8 months, including frequent movement of major travel destinations across lists, re-definitions of testing requirements and the removal and subsequent reimposition of PCR testing for vaccinated travellers – all at very short, or no, notice. Ramping testing capability, up or down, at very short notice is challenging and causes considerable anxiety amongst the travelling public.

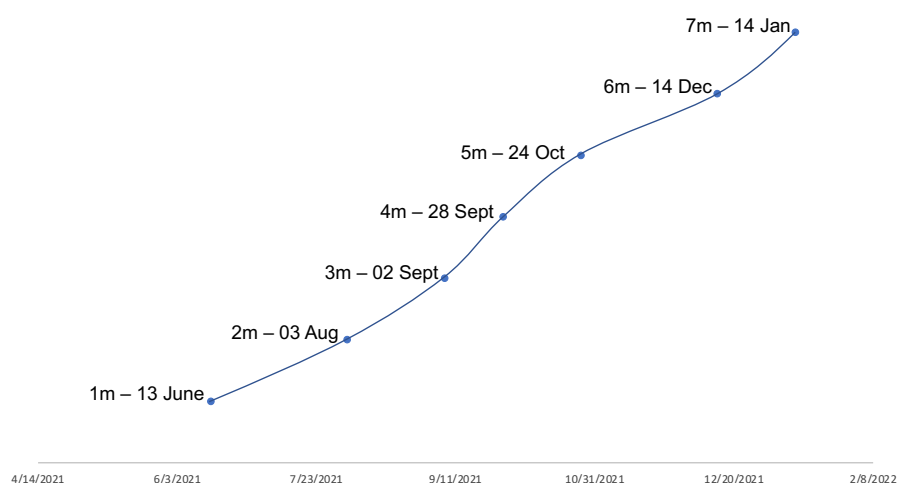


Figure 4(3) Travel and private testing milestones Source: Radox internal data

When the government introduced new rules for the resumption of international travel it created a completely new market for testing with little protection for consumers against unscrupulous firms. Between December 2020 and September 2021, the number of providers rose from 11 to at least 400. At this time a report from the Competition and Markets Authority concluded that even with the enforcement of consumer protection law, competition cannot be guaranteed to deliver the right outcomes for consumers in the PCR testing market.⁴⁹

A report from the consumer group Which? highlighted some of the problems with this market that was developing into a race to the bottom. As a travel testing market emerged some new companies deliberately chose a name that would put them at the front of the government's list of suppliers that was published alphabetically. When this was changed to listing by lowest price, new ways were found to monopolise positions at the front of the list. For example, it was found that five of the top 10 firms may have been connected.⁵⁰

To examine Randox's performance in such a disordered market, we have compared it against eight companies highlighted by Which? as test providers that consumers 'should consider'. Our analysis looked at technical aspects (whether the laboratories were fully accredited), customer service (refunds, limits etc), where the service was available, price, and consumer reviews. See Figure 4(4).

Three key points from this benchmarking exercise include:

- Breathe Assured were rated higher than Randox on Trustpilot but they did not in fact provide PCR tests. Their customers were given vouchers to book PCR tests through Randox. The difference in reviews for what was essentially the same service suggests Randox did suffer from the negative press it received with the National Testing Programme.
- Testing for All had a higher price point to Randox yet they are a not-for-profit organisation. This suggests Randox pricing was competitive rather than profiteering.
- Expert medicals, who offered tests at £20, were removed from the government's list after the Competition and Markets Authority announced that it was launching an investigation into whether its practices breach consumer law.

⁴⁹Competition and Markets Authority (2021) Advice on PCR travel tests

⁵⁰Which? (2021) The cheap testing firms that can't provide tests at the top of the government's day two and day eight provider list (accessed 24/08/2022)

Supplier	Fully accredited laboratory	Provide Refunds	Airline discount options	Limit on sales	Service Available			Price - Sept 2021*	Consumer review (out of 5)**
					At home	In-person	Airport		
Randox	Yes	Sometimes	Yes	No	Yes	Yes	Yes	43	4.1
Breathe Assured	Yes	No	Yes	Yes	Yes	Yes	No	45	4.9
C19 Testing	Yes	Yes	No	No	Yes	No	No	89	4.8
Chronomics	No	Yes	Yes	No	Yes	No	No	89	4.0
Collinson	Yes	Sometimes	Yes	No	Yes	Yes	Yes	69	3.9
Eurofins	Yes	Sometimes	Yes	No	Yes	Yes	No	55	3.7
Expert Medicals	No	No	No	No	Yes	No	No	20	2.9
Project Screen by Prenetics	Yes	Sometimes	Yes	No	Yes	Yes	No	79	4.4
Testing for All	Yes	Yes	No	Yes	Yes	No	No	48	4.5

* Price for day 2 PCR, ** Trustpilot (website accessed 24/08/2022)

Sources: Individual company websites (accessed 25 Aug 2022), Trustpilot website (accessed 25 Aug 2022) <https://uk.trustpilot.com/Which?> (2022) Should I book my cheap COVID lateral flow test with Randox, Collinson, Testing For All, or another company? (<https://www.which.co.uk/news/article/travel-news-cheap-pcr-covid-19-test-discount-randox-express-test-c19-expert-medicals-aqVmm3l52x24>)

Figure 4(4): benchmarking travel testing against competitors

They were able to lower costs across the industry

Overall, the benchmarking shows that Randox provided the widest range of services for consumers, and while their consumer rating is marginally below some competitors, they were still rated as 'excellent'. As a market leader Randox had considerable influence over market price and continuous improvements meant they were able to lower costs across the industry. For example, when the Department of Transport announced plans to open up overseas travel Randox announced a price reduction from £100 to £60 for the general public which had the effect of shifting all market prices lower.

International comparisons also demonstrate how Randox at that time provided lower priced tests. In April 2021 the PCR average cost across Germany, the Netherlands, France, Belgium, Spain, Portugal, Italy and Greece was £61.77, compared to £60 with Randox. Noting that the Randox price was inclusive of delivery and all return logistics, it is clear that Randox was providing a value for money service for UK customers.⁵¹

⁵¹The Times (14/04/2021) Firms begin to cut Covid test prices after 'profiteering' claims

As figure 4(5) below shows, Randox would continue to reduce the cost to consumers, and by October 2021 the cost of a PCR test (click and collect) would be £34.99. This represents a 70% decrease in costs from December 2020. The private test cost was higher than for the National Testing Programme due to additional costs such as marketing, logistics, airport/high street facilities, customer support and express laboratory development.

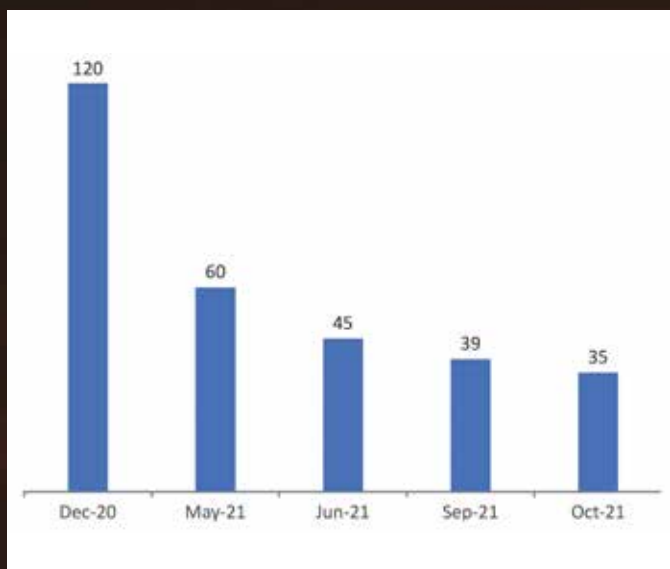


Figure 4(5): the cost of Randox PCR Private Testing Kits would reduce by 70% in less than a year

Source: Randox internal data

Randox was able to reduce these costs despite significant risks associated with delivering a travel testing service. The UK government never gave advance notice of changes to regulations, and these could often result in a test that was no longer required, leaving Randox with surplus stock, or even a service with no demand. In total, there were 12 different types of travel tests during the pandemic and each regulation change meant re-packaging or discarding supplies.

As with the National Testing Programme, Randox's willingness to take and manage risk was a key part of the success in the private testing market.



ANALYSIS AND IMPLICATIONS

In this section, we evaluate, model and quantify the health, social and economic impacts of Randox's testing programmes.

There are principally three reasons for attempting to quantify the impact of Randox's COVID-19 testing programme:

i. To reflect on value for tax payers

There has inevitably – and rightly – been scrutiny into how goods and services were contracted by the government without competitive tender under emergency legislation during the pandemic. Few would argue that the nature of the emergency did not demand some temporary relaxation of the time-consuming checks and balances that usually accompany government procurement. However it is appropriate now that the emergency has abated to ask: did these contracts represent value for money for the taxpayer? In this sense, this impact assessment can function as a retrospective cost benefit analysis. And, of course, given the significant cost of the National Testing Programme address the question: was it worth it?

ii. To inform future public health decisions

A related but distinct motive for analysing the impact of the testing program is to shine a light on the importance of retaining a diagnostic testing capability for future pandemics and, potentially, for other applications. We discuss this further in the discussion on legacy in Section 6.

iii. For internal purposes

As is evident from this report, Randox employees made significant sacrifices to stand up its pandemic testing programmes. Like many others across the public and private sectors they were motivated as much by a sense of public spiritedness as by commercial reward. It is important now, as we transition from an emergency response to something more like 'living with Covid', that we reflect on what a difference these programmes made to the course of the pandemic and its impact upon our lives. What did those sacrifices help to achieve?

5.1 THE IMPACT OF TESTING ON THE COURSE OF THE PANDEMIC

Five days after the World Health Organisation declared COVID-19 a pandemic in March 2020 its Director General, Tedros Adhanom Ghebreyesus, implored the world to “Test, test, test.” Warning that social distancing and handwashing would not be sufficient to control the pandemic, he likened trying to stop the spread of the disease without testing with trying to fight a fire blindfolded.

In evaluating the impact of testing it is important to remember that for effectively the first year of the pandemic the only effective option for governments to control transmission was to reduce social contact. The most effective tool to achieve this was to lock down large swathes of the economy. But it was also a blunt tool. By mandating (almost) everyone to stay at home, transmission of the disease could be reduced, but only at enormous social and economic cost.

Testing allowed the country to be more targeted in its social distancing. Those who tested positive for the disease - and to a lesser extent those who had recently come into contact with someone who had tested positive - were more likely than the average person to be contagious. By encouraging (or mandating) those people to reduce their social contact, the government was able to achieve the same level of transmission reduction as would have been achieved with wider, non-targeted social distancing measures.

Of course, in the UK, the government did, at times, resort to blanket lockdowns, but without testing these lockdowns would have been less effective, or longer, or both. We model these relationships in section 5.3.1 below.

To the extent that Randox delivered a share of the National Testing Programme, then, it can be considered responsible for a commensurate share of these impacts.

Separately, and in parallel, as the pandemic progressed, international travel was one of the sectors of the economy most severely affected, with almost all flights grounded for the first few months.

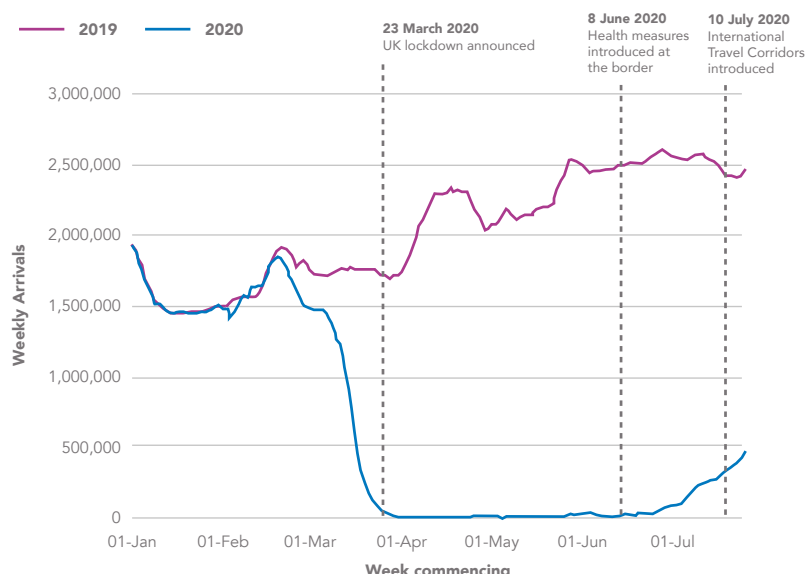


Figure 5(1): UK weekly arrivals 2019-2020

Source: Home Office (2020) Statistics relating to passenger arrivals since the COVID-19 outbreak, August 2020

Once economies reopened and blanket travel bans were lifted, countries began to introduce targeted measures to inhibit the spread of COVID-19 across borders. These measures sometimes attempted to discriminate between travellers from different locations but, increasingly, took the form of requirements to test: either prior to departure, or a number days after arrival to release from quarantine. Doubt has subsequently been cast over the effectiveness of these measures⁵² but notwithstanding this debate, once countries had introduced such restrictions, it is clear that international travel to and from these countries could only occur thanks to testing.

Each of the travel tests Randox provided can be considered responsible for helping to facilitate an international journey. Enabling international travel clearly delivered social benefits by allowing individuals and families to visit one another and holiday together but it also delivered economic benefits, not just from tourism but also from international trade and investment. We estimate these benefits in section 5.3.2, below.

⁵²For example, see <https://publications.parliament.uk/pa/cm5803/cmselect/cmpubacc/29/report.html>

5.2 APPROACH TO THE IMPACT ANALYSIS MODELLING

The outputs of the impact analysis depend first on how the question of impact is interpreted and, then, on the assumptions that underpin the model. We have interpreted the question of impact to be: what would have happened in the absence of Randox's testing, without any compensatory uplift in testing from other providers. For a discussion of why we have interpreted the question in this way, and for an explicit set of assumptions that underpin our impact model, see Appendix B.

5.3 MODELLING THE IMPACT OF RANDOX'S COVID-19 TESTING

Randox's testing during the pandemic fell into two categories:

National Testing Programme. As one of a number of "Pillar 2" providers within the National Testing Programme, under a contract with central government.

Private testing. Paid for by individuals and businesses for the purposes of facilitating travel, work, sporting events, elective surgery etc.

We treat these two categories separately, both because they were funded separately (one publicly, the other privately) and also because the mechanisms by which they each led to positive health, economic and social outcomes are substantively different.

5.3.1 The National Testing Programme

For details of Randox's participation in the National Testing Programme, see section 3, above. We assume that the National Testing Programme led to positive impacts in three distinct ways:

1. Reduced Transmission. Positive tests led to reduced transmission of the virus by encouraging those correctly identified as carrying COVID (and later those identified through Test and Trace as being likely to have come into contact with a positive case) to isolate or reduce their level of social contact.

2. Expedited return to work. Negative tests facilitated a (faster) return to work, especially for subjects reporting symptoms, who might otherwise have isolated unnecessarily or for longer than was necessary.

3. Epidemiological intelligence. Accurate tests in general provided epidemiologists with intelligence needed to model transmission. These models in turn informed public health measures. We do not attempt to quantify this effect and it is therefore excluded from this analysis but we note this is likely an additional positive impact of testing beyond that which is modelled below.

The mechanism of action by which 1) and 2), above, delivered positive health, economic and social outcomes is illustrated in Figure 5(2) below.

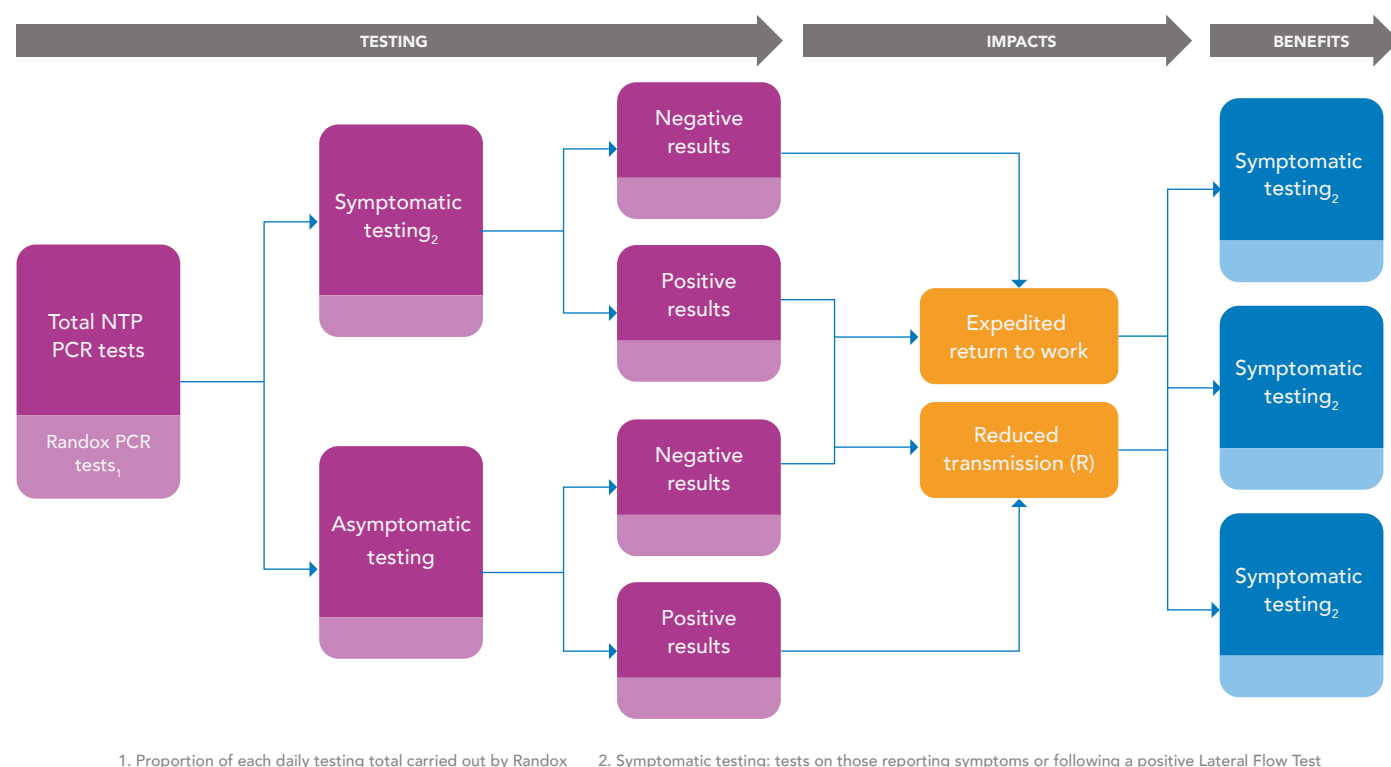


Figure 5(2): The impact model. NTP – National Testing Programme.

In order to estimate the impact of changes to transmission brought about by testing, we build a generative model using as inputs a few simple parameters:

- R_0 ⁵³, which we allow to take four different levels according to the level of government restrictions at the time.
- The average number of days each case is contagious.
- The time between infection and a positive test.
- The duration of effective immunity following infection.
- The duration of effective immunity following vaccination.
- The proportion of total cases captured by a positive test.

This allows us to build a model of transmission that exactly matches total numbers of cases and deaths with those observed and represents a good approximation of daily case numbers over time - see Figure 5(3).

⁵³There is debate over whether the term R_0 should refer to the 'basic reproduction number – in the absence of any deliberate intervention'. Clearly, here, we use the term in the context of deliberate intervention and, hence, it is free to take different values depending on the level of intervention

To model the impact of testing we then assume that someone who receives a positive test for COVID-19 is less likely to transmit the disease once they have received the test result than they would have been in the absence of a test. This is because they will, on average, reduce their social contacts in response to the knowledge that they are probably infectious.

A number of existing studies have attempted to estimate the magnitude of this effect.⁵⁴ They depend on the values assigned to three important variables:

1. The number of days of infectiousness that has typically occurred prior to the receipt of a test result (d_t).
2. The proportion of an individual's total transmission that occurs after d_t .
3. The extent to which a positive test result leads to enhanced social distancing.

There is significant uncertainty over the magnitude of these variables.

Although there is data to suggest that compliance with isolation following a positive test was robust⁵⁵, this must be compared to a counterfactual scenario in which those who experienced symptoms would have been likely to socially distance to at least some extent even in the absence of a test.

If, in this counterfactual scenario of non-testing, symptomatic people were to display a strong tendency to isolate anyway then the impact of testing on transmission would be smaller; conversely, if their tendency to isolate anyway were lower, the impact on testing would be greater.⁵⁶

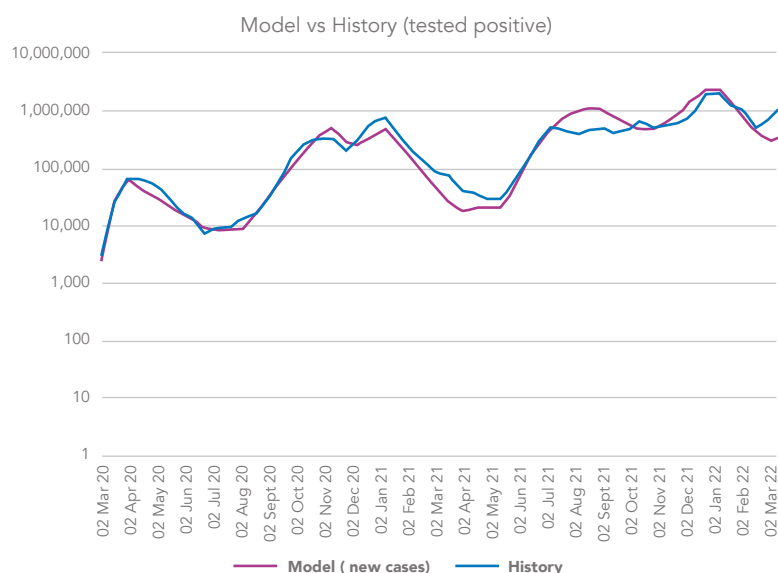


Figure 5(3): Generative model fit with observed data

Source: OCO Analysis

⁵⁴See Appendix B for a review of existing attempts to estimate the impact of testing on R

⁵⁵[https://www.thelancet.com/journals/laninf/article/PIIS1473-3099\(20\)30630-7/fulltext](https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(20)30630-7/fulltext)

⁵⁶On the other hand, given that a large majority (in the region of 94%) of test results were, in fact, negative, a high tendency for the symptomatic to isolate in the counterfactual scenario would indicate a greater impact of testing on expedited return to work. In other words, either tests significantly abated transmission or they significantly abated unnecessary isolation, or some combination of the two. So although the model outcomes are sensitive to the values ascribed to these variables, there is an automatic stabiliser that mitigates this sensitivity.

For our model, we assume that the impact of testing on the rate of transmission at each point in time, R_t , is between 0.9 and 0.14⁵⁷, compared to the counterfactual; this is at the lower end of a range of estimates made by existing academic studies - see Appendix B.

We find that even apparently small increases in transmission in the counterfactual scenario give rise to significant knock-on impacts. The increased transmission in a scenario with no testing – and no additional measures to mitigate transmission from either government or individuals - compounds over time and results in significantly higher peaks of transmission and total case numbers.

This is complicated by the unknown extent to which both the government and individuals might, in fact, adjust their behaviour in response to higher case numbers and transmission rates.

In reality we know that a key driver for government policy was concern that the NHS should not be overwhelmed. A breach of NHS hospital capacity would have been not just politically troubling; it would have had a material impact on infection fatality rates since some of those needing life-saving treatment for COVID-19 would not have received it.

This was of particular significance in the UK, where hospital capacity was more limited than in most comparably rich counties – see Figure 5(4).

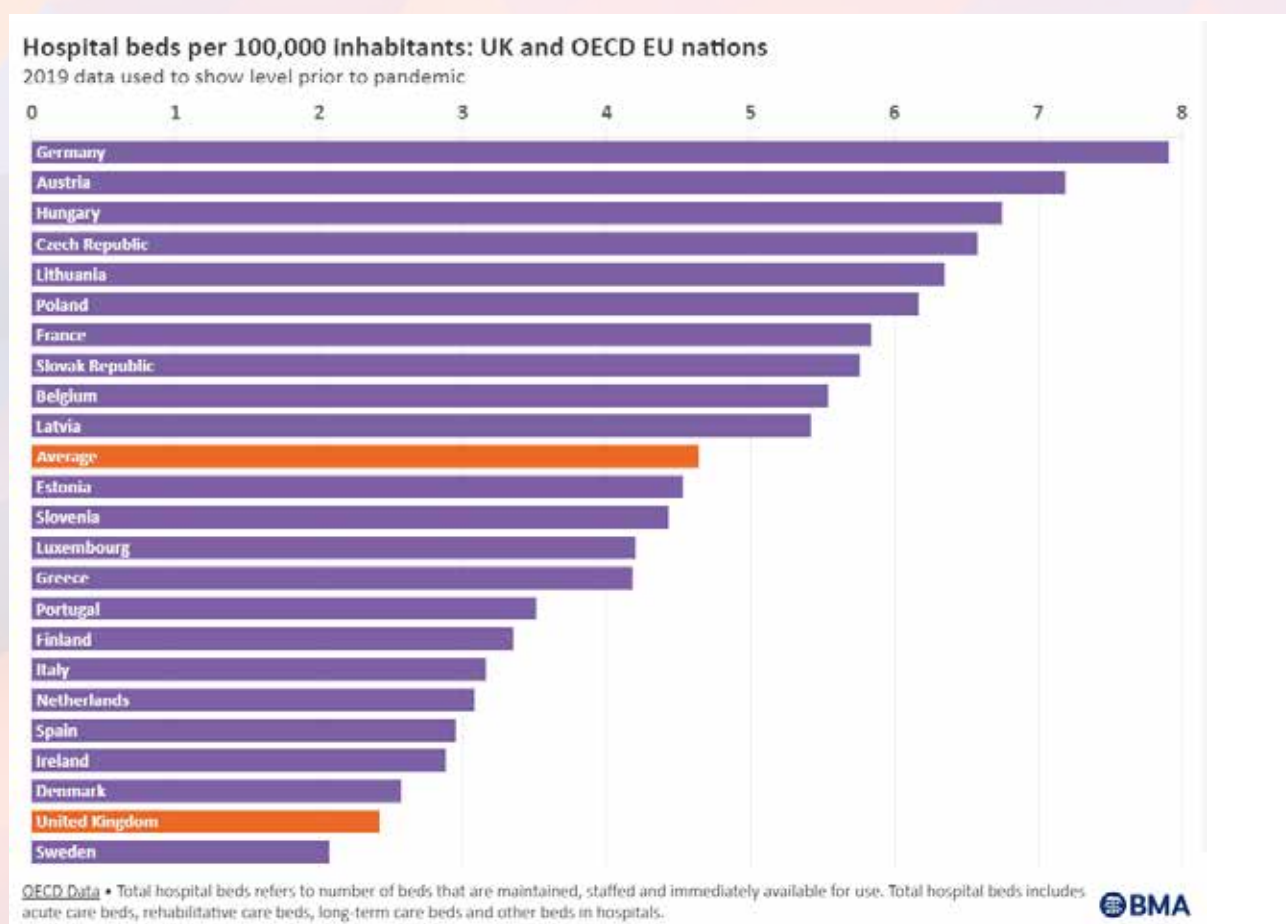


Figure 5(4) Comparisons of hospital beds across selected countries

⁵⁷The impact on R_t varies over time – in general it is larger when case numbers are higher.

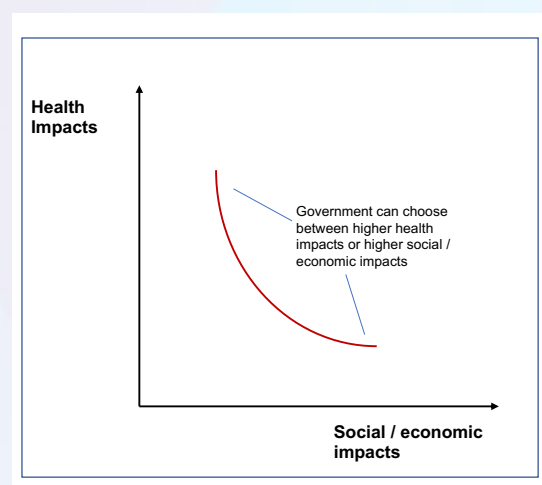


Figure 5(5) - COVID impact frontier

With less capacity to start with, the threshold for running out of hospital beds was lower for the UK than for most of its European counterparts. Although we do not attempt to model the effect of breaches of hospital capacity on fatality rates, it should be noted that this would likely increase the number of deaths in scenarios where much higher peaks of transmission are indicated.

In truth, this dilemma over NHS capacity is only a particularly vivid example of a more general conundrum for government. For a given level of

natural transmission amongst the population, the government could control with policy, to some extent, how to share the pain of the pandemic between health, social and economic impacts. In simple terms, more lockdowns could mitigate the worst health outcomes but only at the cost of more social isolation and economic pain. Removing restrictions could stimulate the economy but only at the cost of more transmission and the health outcomes that would entail.

This trade-off is illustrated in Figure 5(5).

The government could strengthen or relax social distancing measures to choose a point on the impacts frontier. However, moving to a different frontier altogether could not be achieved with stronger or weaker social distancing measures, but only with interventions that changed the baseline rates of transmission, or the clinical outcomes, for a given level of social distancing. Examples of this type of intervention are testing and vaccines.

Given this uncertainty over how individuals and the government would have responded to higher rates of infection, we have modelled three alternative scenarios for the non-testing counterfactual to illustrate the range of possibilities. In Figure 5(6), the impact of testing is represented by the shift from Frontier(i) to Frontier(ii). The position on Frontier (ii) that the government chooses to take is then illustrated by the three scenarios: A, B and C.

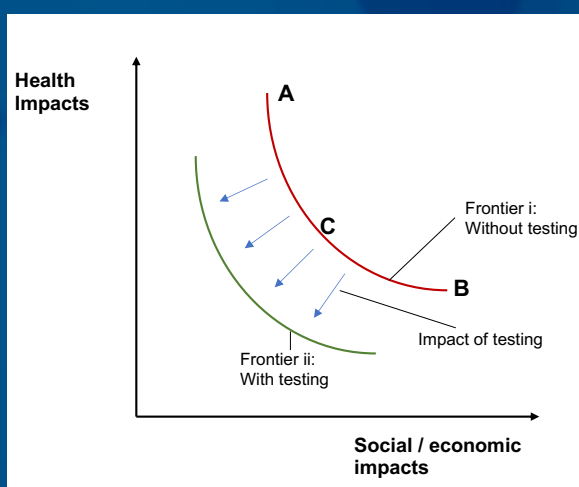


Figure 5(6)- COVID impact frontier with non-testing scenarios

These alternative scenarios are described in the boxes below.

SCENARIO A: NO FURTHER SOCIAL DISTANCING MEASURES

Governments and individuals do not adjust their behaviour at all in the counterfactual scenario as compared to the observed scenario; exactly the same social distancing measures and approaches are adopted.

SCENARIO B: STRICT LOCKDOWNS

Government attempts to limit health impacts to no greater than those tolerated in the observed scenario. In this scenario, we assume that the government's tolerance for case numbers and their knock-on effects on the NHS are the same as they were in the observed scenario. Therefore when case rates reach numbers that were sufficient to trigger a lockdown in the observed scenario we assume a lockdown in the counterfactual scenario.

SCENARIO C: THE CENTRAL PROJECTION

In this scenario, we assume that in response to higher rates of transmission, individuals and government do take steps to mitigate transmission on top of those taken in the observed scenario but that these stop short of the extreme lockdowns envisaged in Scenario A. That is, we assume that governments and individuals are prepared to tolerate both somewhat worse health outcomes and somewhat worse social and economic outcomes in order to avoid the most extreme impacts from either.

Scenario A outputs:

NO FURTHER SOCIAL DISTANCING MEASURES

Without individuals or governments adapting their behaviour in response to higher rates of transmission in a non-testing scenario, we find that the total number of recorded cases between 01 March 2020 and 28 March 2022 would be 3.9m higher; there would be a further 218,457 hospitalisations and 100,079 extra deaths. This represents an 18% increase in cases and a 60% increase in deaths. The relatively high increase in deaths occurs because the cases occur at an earlier point in the pandemic, when the absence of vaccines and the lack of clinical treatments meant the fatality rates were much higher (Figure 5(7)).

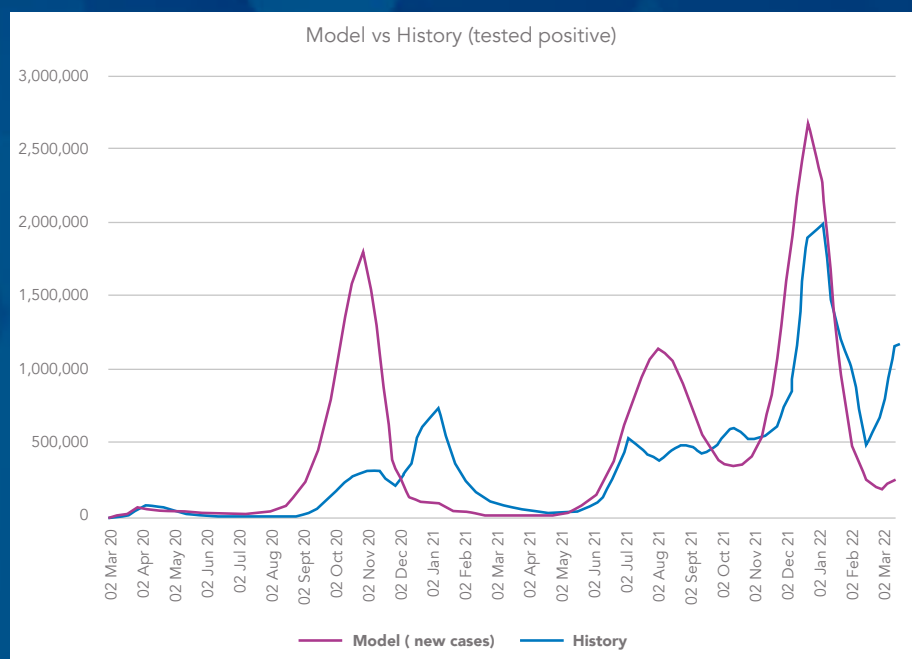


Figure 5(7): Transmission in the absence of testing in Counterfactual Scenario A (OCO analysis)

Even without extra government restrictions on social contact, these more severe health outcomes would have knock-on social and economic effects. The extra infections would mean more isolations, and more long-term health impacts. In financial terms, the direct cost of treating the increased number hospitalised and the indirect cost of the additional absence from work caused by these extra infections is estimated to be a further £14.4bn.⁵⁸

⁵⁸Based on average cost of COVID-19 absence per recorded case of £559. See <https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/labourproductivity/articles/sicknessabsenceinthelabourmarket/2021/pdf>

With Randox accounting for some 12.2% of the total National Testing Programme (NTP) tests, it is reasonable to apportion to Randox an equivalent proportion of these positive estimated impacts from the National Testing Programme (see box).

However, it was clear from UK government announcements that staying within NHS capacity limits was a key driver of government policy. When the NHS was in danger of being overwhelmed, the government typically introduced more severe social distancing regulations or laws to reduce transmission. The counterfactual in which the government did nothing in response to higher levels of transmission to those which actually occurred is arguably, therefore, implausible.

Impacts of testing Scenario A

	Impact	NTP as a whole	Randox Contribution
Health	COVID-19 cases averted	3,938,526	480,500
	Hospitalisations averted	218,457	26,652
	Deaths averted	100,079	12,210
Social	Lockdown weeks averted	0	
Economic	Boost to GDP	£14.4bn	£1.76bn

Scenario B outputs:

STRICT LOCKDOWNS

At the other extreme we assume that in order to avoid more severe health outcomes the government introduces lockdowns at the same trigger points in terms of case numbers as it did in the observed scenario. We find that with the increased levels of transmission in the non-testing scenario this gives rise to an earlier, and longer, second lockdown and a longer third lockdown.

In this scenario, the health impacts are limited, since increased lockdowns are largely effective in mitigating the case numbers. We find that cases remain largely unchanged but hospitalisations increase by 8563 and deaths by 6097.

However, the social and economic consequences are severe. The loss of output associated with more than twelve weeks of extra lockdown, plus the modest costs associated with hospitalisations give a total additional cost to the economy of £63.7bn. And the social costs of the increased lockdowns include an increase in the number of pupil-days lost to school closures of 298 million.

In practice, this scenario too may be considered implausible. It is arguable that even if the government judged it in the public interest to lock down the economy for such an extended period, compliance amongst the general population may not hold.

We therefore model a third sub scenario which we judge to be the most plausible of the three.

Impacts of testing in Scenario B

	Impact	NTP as a whole	Randox Contribution
Health	COVID-19 cases averted	2,358	288
	Hospitalisations averted	8,563	1,045
	Deaths averted	6,097	744
Social	Lockdown weeks averted	12.3	N/A
	Pupil days of school	298 million	N/A
Economic	Boost to GDP	£63.65bn	£7.77bn

Scenario C outputs:

THE CENTRAL PROJECTION

In this scenario, we hypothesise that the government takes measures to reduce social contact in relation to the observed scenario but is also prepared to accept worse health outcomes than in the observed scenario. i.e. it opts to share the pain of increased transmission in a non-testing scenario between health, social and economic impacts.

This, we argue, is the most realistic scenario, where the most extreme health impacts are averted, but in which an unfeasible lockdown is not postulated.

In this scenario, there are an additional 1,303,191 cases; with 115,576 additional hospitalisations and 25,706 extra deaths. There are nine weeks of additional lockdown and the extra loss of GDP compared to the observed scenario is £53.1bn. The social impacts include a further 234 million pupil-days of school missed. The share of these impacts attributable to Randox is shown in the box below.

Impacts of testing in Scenario C

	Impact	NTP as a whole	Randox Contribution
Health	COVID-19 cases averted	1,303,191	158,989
	Hospitalisations averted	115,576	14,100
	Deaths averted	25,706	3,136
Social	Lockdown weeks averted	9.4	
	Pupil days of school	234 million	N/A
Economic	Boost to GDP	£53.12bn	£6.48bn

5.3.2 Private testing

With travel testing, the mechanism by which testing led to improved health social and economic impacts is essentially different. Although it is the case that some people who received a positive test prior to travelling may have reduced their social contacts as a result, this is not the primary mechanism by which travel testing delivers benefits.

With the National Testing Programme there is a presumption that those who take tests have an elevated likelihood of testing positive either by virtue of having reported symptoms or, because they have been in recent contact with a positive case. By contrast, those who take travel tests or other private tests are usually, by assumption, less likely to be positive, as those with symptoms would be less likely to attempt to travel anyway. This is borne out by the proportion of positive tests in the travel testing program (1.8%) compared to the proportion of positive tests in the National Testing Programme (6%).

Instead, the positive benefits of the travel testing program accrue from the activities they facilitated that would not have taken place were it not for the reassurance a negative test provided.

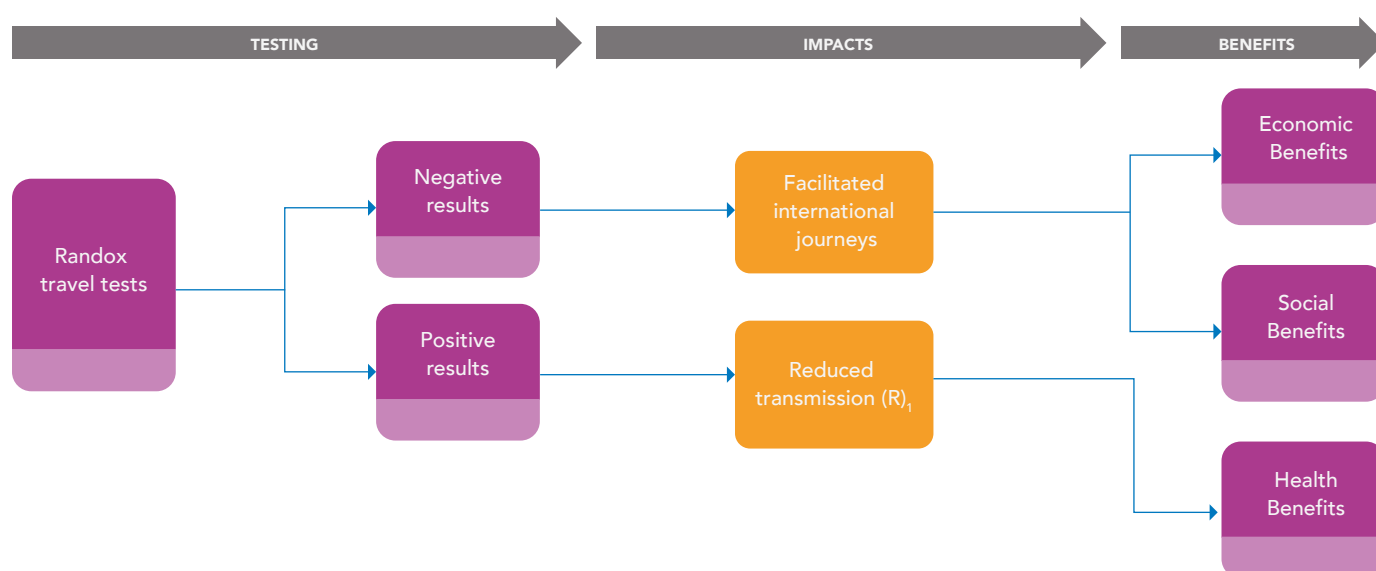


Figure 5(8): Mapping travel testing impacts

Between 1 May and 31 December 2021, 21.06m passengers arrived in the UK, including 9.44m non-UK residents.⁵⁹ Once government travel restrictions had been introduced, these flights could only take place because of COVID-19 tests provided by Randox and others. The UK airline industry is estimated to have lost £20.1bn in revenue in 2020⁶⁰ and similar losses would have occurred in 2021 were it not for the travel that testing facilitated.

However, the total economic benefits of the facilitated travel extend further still. Overseas visitors to the UK spent an average of £696 per trip in addition to their air travel in 2019⁶¹, whilst a 2016 report from Oxford Economics⁶² estimates that a 1% increase in business travel boosts trade volumes by 0.05% (or

⁵⁹<https://www.gov.uk/government/statistics/statistics-relating-to-passenger-arrivals-since-the-COVID-19-outbreak-august-2022/statistics-relating-to-passenger-arrivals-in-the-united-kingdom-since-the-COVID-19-outbreak-august-2022>

⁶⁰<https://ukparliament.shorthandstories.com/coronavirus-impact-aviation-transport-report/index.html>

⁶¹<https://www.visitbritain.org/2020-inbound-data>

⁶²<https://www.businessvisitsandeventspartnership.com/component/phocadownload/category/5-industry-research?download=329:the-value-of-international-business-travel#:~:text=It%20encourages%20domestic%20and%20foreign,benefits%20accrue%20to%20an%20economy.>

approximately £400 million in the UK) and increases FDI by 0.3% (equivalent to a £100 million boost to inward investment in the UK). Factoring in the impacts on the aviation industry directly, the impacts on tourism and the international trade and investment facilitated we estimate that the average uplift in GVA from international travel amounts to £980 per international journey.⁶³

With over 9.6 million private tests completed, including 8.8 million travel tests, Randox's private testing is estimated to have facilitated 4.4m international passenger journeys (about 1 in 6 of the UK total), with an estimated total economic benefit of just over £4.3bn. We further estimate that £1.82bn of this benefit would be attributable to the UK economy, with the remainder split between the Republic of Ireland, where Randox delivered about 0.5m PCR tests, and the rest of the world.⁶⁴

5.3.3 Impact on the Northern Ireland economy

Randox is one of Northern Ireland's major employers and had invested substantially in the region even before the pandemic. However, over the course of the pandemic, Randox recruited greatly, at one point more than doubling its pre-pandemic headcount. Between February 2020 and May 2022, it employed an average of 1594 people in Northern Ireland, with hundreds more employed elsewhere. Its expanded headcount included a large number of life sciences graduates but also included employees with non-scientific backgrounds employed to perform non-technical parts of the testing process.

In addition, Randox was indirectly responsible for the employment of large numbers of construction workers, cleaners, gardeners, waste disposal operatives and delivery drivers.

In addition to those directly employed, further jobs were created in the Randox supply chain. The total economic impacts on the Northern Ireland economy are wider still, with those employed, either directly or indirectly by Randox, spending a proportion of their money in the regional economy too. To aggregate the direct, indirect and induced effects of Randox activity in Northern Ireland throughout the pandemic we use established multipliers for the Life Sciences sector that range between 2.5 and 3.4.⁶⁵ On this basis, we estimate that the total economic impact on the Northern Ireland economy from Randox's economic activity during the pandemic⁶⁶ as £182m. For context, this is approximately equivalent to c. 0.4% of Northern Ireland's annual GDP or, on an annualised basis, around 0.2% of Northern Ireland's GDP.

Beyond the headline economic impact, the career opportunities offered by Randox are noteworthy in an economy that has historically suffered from a 'brain drain' to other parts of the UK and elsewhere. A 2018-19 report found that about two thirds of students from Northern Ireland continued to live and work away from home after they graduated.⁶⁷ Not only does Randox offer top life sciences graduates the opportunity to remain in Northern Ireland after they finish their studies at Queen's or Ulster University; the pandemic has, in many cases, provided Randox recruits with an accelerated career progression. The majority of pandemic recruits have been kept on to work in R&D now that free national COVID-19 testing has finished and, as one life sciences graduate put it, five years of experience has been condensed into two years working at Randox during the pandemic.

⁶³<https://www.atag.org/our-activities/social-and-economic-benefits-of-aviation.html>;

⁶⁴Data on the geographic breakdown of travel test from Randox internal data
⁶⁵<https://www.sciencecampaign.org.uk/static/uploaded/bdcdd36f-e131-4c9d-880cbfa0fd36ac12.pdf>;
<https://www.pwc.co.uk/industries/assets/life-sciences-2030-report.pdf>

⁶⁶i.e this is separate from the UK-wide testing impacts identified above

⁶⁷<https://www.pivotalppf.org/cmsfiles/Retaining-and-Regaining-talent-report-V1.pdf>

5.4 DISCUSSION AND SENSITIVITY ANALYSIS

The sensitivity of the model outputs to its various inputs can inform the confidence with which we should hold the conclusions. Central to the projections of all types of outcome - health, social and economic – is the impact testing had on transmission. In particular, the model is especially sensitive to the impact testing is assumed to have on R_t . This is simply a function of disease transmission being an exponential process: it compounds over time, so that even relatively small differences in the rate of transmission have large impacts over long periods of time.

It should be noted, however, that in the case of COVID-19, the impacts from higher rates of transmission (whether due to an absence of testing or any other reason) stem less from the total number of cases in the long run and more from the timing of those cases. Higher rates of transmission lead to larger and earlier peaks but the immunity these extra cases confers on the population can in turn lead to lower case numbers later.

In a sense, then, testing (and other transmission-lowering measures) can be thought of less as preventing cases and more of deferring them. The large impacts from deferring cases stems from the dramatically improved clinical outcomes for those who contracted the virus post-vaccination and, to a lesser extent, after new clinical treatments had been pioneered, compared to those who caught the virus in the first waves.

The impact of testing on R_t is, in turn, sensitive to three factors:

i) The proportion of / extent to which people with COVID-like symptoms would spontaneously isolate in the absence of a test.

Notably, however, if this proportion is high, it would imply a reduced impact of testing on transmission but an increased impact of testing on expedited return to work. If many are isolating with COVID-like symptoms, negative tests may allow them to curtail their isolation.

ii) The proportion of total infectiousness that occurs after a positive test.

This is, in part, a feature of the virus – and there is evidence to suggest both total duration of infectiousness and the period between contagion and the onset of infectiousness vary with different variants of the virus.⁶⁸ However, it is also, of course, a function of how quickly after contagion people take a test and then how quickly that test is processed. Any behavioural response to a positive test can only occur after the result is received.

iii) The accuracy of the test.

The positive impacts of testing are very sensitive to the accuracy of the test itself. False positives can lead to people unnecessarily isolating, whilst – more seriously – false negatives can encourage those who are genuinely infectious to resume or increase social contact.

⁶⁸<https://hospitalhealthcare.com/COVID-19/incubation-time-for-COVID-19-variants-reducing/#:~:text=A%20systematic%20review%20and%20meta,days%20for%20the%20omicron%20variant.>



Legacy

In this section, we consider the legacy of Randox's pandemic testing and its implications for the future of Randox and the future of diagnostic testing and public health more generally.

Even before the pandemic, the future importance of diagnostic testing had been identified by Public Health England among others. Market forecasts are predicting double-digit growth and a new digitised future. But the reality remains that health services have been pushed to the limit by the pandemic and will struggle without outside assistance. This positions an R&D enabled company like Randox as a core enabler of future diagnostic developments . They have the benefit of multiple equipment and data innovations developed during the testing programme, they are at the heart of research co-operation across the sector, and they are at the forefront of empowering individuals to take control of their own health.



6.1 THE FUTURE ROLE OF DIAGNOSTICS IN IMPROVING HEALTH CARE OUTCOMES

Since its formation in 1982, Randox has been dedicated to improving healthcare using innovative diagnostic technologies. Its origins in R&D and Manufacturing of reagents and molecular products are recognised as being 'best in class' and used across public and private healthcare participants across the globe. As the firm has expanded, it has evolved into the additional development of testing software and hardware solutions, as well as significant capabilities in the delivery of testing services, as strongly evidenced by the National Testing Programme.

This has placed Randox in a strong position to take advantage of a market that is forecast to be valued between \$24bn to \$31bn by 2030, with close to double digit compound average growth in this period.⁶⁹

The assay, reagents and kits segment is forecast to account for the largest share in the market owing to easy accessibility of reagents and their usage across a wide range of therapeutic applications. Followed by this, the molecular diagnostics software and services is growing quickly due to the entry of new diagnostic laboratories, increasing prevalence of chronic diseases and growing demand for early diagnostic tests and treatments.

A report by Healthcare Transformers⁷⁰ on diagnostic trends shaping the future of healthcare shows how innovations Randox developed during the National Testing Programme place it at the forefront of development in this area.

The report suggests that the convergence of digital technologies and diagnostic tests sets the stage for advancing and improving patient experience and outcomes. At the same time, it may help to alleviate some of the capacity and resource pressures on the health system and help to improve the speed and efficiency of the testing process.

⁶⁹Growth+ Market Reports (2022) Molecular Diagnostics Market by Product & Services, Global Outlook and Forecast 2020-2030 & Allied Market Research (2022) Molecular Diagnostics Market by Type, Global Opportunity Analysis and Industry Forecast, 2020-2030

⁷⁰Healthcare Transformers (2021) 6 diagnostic trends shaping the future of healthcare

Key enablers that the report points to include: point of care testing and emerging at-home diagnostic solutions; predictive and personal genetics; real-time diagnostics; clinical decision support solutions; data-driven laboratory optimisation solutions; and artificial intelligence in medical imaging.

In the UK, this emerging market was identified just as the pandemic was taking in root in the UK when NHS England published the Chief Scientific Officer's strategy in March 2020. ⁷¹

In the foreword to this report⁷¹ the CSO commented:

"We are currently experiencing, and will continue to see, an exponential pace of change in scientific and technological advances, coupled with an ability to compare and interrogate large datasets. These developments have the potential to revolutionise many areas of healthcare delivery and benefit patients through more personalised and evidenced based interventions. These advances are happening at a time when the health system is facing a number of challenges.

Our ambition is to provide scientific leadership within the system, encourage and attract research and innovation, embrace digital advances and technology in NHS services and work in collaboration with stakeholders, patients and partners to deliver this ambition."

The report goes on to note that the pace of change within innovation, and the demand for diagnostic services will increase significantly, and that working in partnership will be critical to fully realise the opportunity that diagnostics presents.

"A challenge for the system is that demand for diagnostics has increased by 26% in the last 5 years (HES data 2014 to 2018) and an average yearly increase of 8% is predicted...This (ie the strategy) will be supported by building on the universal language of science and expanding partnerships across other scientific sectors including academia, industry and public sector charities."

⁷¹NHS England (2020) Science in Healthcare : Delivering the NHS Long Term Plan, The Chief Scientific Officer's strategy

The need to deliver upon this strategy is only heightened post COVID. A recent (April 2022) article published in the Lancet⁷², notes:

"We recognise the commitment of Pathology and Laboratory Medicine (PALM) services in the face of a global health-care emergency to contribute through the development of dedicated and accredited biobanks, artificial intelligence-based innovations, and medical technology solutions. However, most of these services have had chronic scientific-expertise depletion, making innovation and adoption a challenging goal. Nevertheless, mature partnerships with academia and industry have been a major driver to NHS-led innovation. This collaboration identifies a major focus on the transformation roadmap and makes a strong case for strengthening such collaborative interactions in the future."

Randox, with their COVID experience, skills and resources, are very well positioned to take advantage of this growth.

⁷²Grammatopoulos, D., Young L., & Anderson, N (2022) Transforming the UK's diagnostics agenda after COVID-19. The Lancet 399 (issue 10335) p1606.



6.2 RANDOX IS WELL POSITIONED TO MEET FUTURE DIAGNOSTIC DEMAND

As a privately owned company Randox have always had the freedom to invest heavily in R&D and, from inception, have always done so. Routinely, some 25% of the company's staff have been research scientists and engineers and up to 25% of turnover is reinvested in R&D each year. Randox have been awarded the McRoberts Award for Engineering and have been actively engaged in research collaboration with universities and NHS Trusts across the UK, and internationally. To date Randox have spent in excess of £350 million on research and innovation associated with its unique biochip array technology. Innovation and quality improvements are a central pillar within Randox's mode of operation, and flowed naturally into the COVID testing programme.

Throughout the COVID testing programme, Randox developed and implemented a series of innovations, and a culture of continuous improvement that will serve the company and the industry in the longer term.

Randox has invested £226m in combined infrastructure and R&D from January 2020 to June 2022. This included state-of-the-art laboratory facilities, totalling 80,000 square foot of space with capacity to process well in excess 120,000 PCR tests per day, alongside 50,000 square feet of supporting logistics and engineering space. Whilst these facilities will inevitably be re-purposed they will remain a core part of the Randox infrastructure and will be part of the Randox plan for enhanced diagnostic capabilities going forward. This compares to other National Pillar 2 laboratories, with the exception of the Rosalind Franklin laboratory in Royal Leamington Spa that have largely been disbanded. Should the nation face another requirement for surge diagnostic testing in the short, medium or long term, Randox are now better positioned to support than they were in March 2020.

The overall testing programme also gave rise to several specific innovations that will play a key role in the future of diagnostic provision:

The Randox Cube

The Randox cube is a deployable fully robotic testing laboratory set up initially to conduct the standard RT-PCR test. The reduced space and staff required for the Cube provides enormous potential for future scenarios where rapid deployment of multiple smaller scale applications might be required.



Figure 6(1): Automated samples in the Randox Cube



Figure 6(2): The Randox Discovery, a fully automated, benchtop PCR system



Figure 6(3): The versatile Randox Vivalytic can be used in any clinic without the need for laboratory personnel training

The original Cube concepts are 'capable of performing 12,000 PCR tests per day each, and the initial four cubes were installed and fully operational within 5 weeks'. These Cubes can also be repurposed to take on a much wider range of testing – including, clinical chemistry, immunoassays and hematology.

Randox Discovery

A specialised, fully automated PCR analyser, the Randox Discovery, is also under development to improve the efficiency of a full range of PCR tests. The analyser consolidates the normal workload of multiple laboratories into one compact benchtop analyser.

The Randox Discovery can process 48 patient samples every hour, and can be adapted for multiple other areas of testing including respiratory and sexually transmitted infections.

Vivalytic platform

A universal, fully automated all in one solution for molecular diagnostics, Vivalytic is a cartridge-based platform enabling Hi-Plex and Low-Plex testing developed in partnership with Bosch.

Vivalytic consolidates the full molecular workflow into a small benchtop platform, capable of RNA extraction, PCR amplification and detection, enabling multiple results from one patient sample. For the Respiratory Array, for example, the Vivalytic reports on 23 viral and bacterial pathogens, providing clinicians with the information required to correctly identify infections and prescribe the appropriate treatment - reducing the misuse of antibiotics and supporting their targeted use.

Real-time PCR (RT-qPCR) Test

As the pandemic worsened, Randox developed its own real-time PCR test for COVID-19. This was a first for Randox with the test providing PCR results in real-time negating the need for the biochip analysis of the PCR product. This ability to innovate existing practice reduces the time to results and dramatically increases capacity will be critical in the future health service leading to efficiency savings.

Digital innovation and automation

The unique demands of the National Testing Programme both necessitated, but also provided an environment for continuous improvement, which Randox embraced. As a result, they were able to implement a series of continuous improvement initiatives that increased both the efficiency and the effectiveness of the testing programme, and can be re-applied to future applications

Examples of this included:

- **Use of Robotics.** Randox have greatly expanded the use of robotics within their processes, both in the main laboratory processes and in the Cubes. Significant experience has been gained and these capabilities will be rolled out across manufacturing and logistics to improve overall productivity.
- **Use of Data Analytics.** Associated with the growth of robotics the greater accessibility of data, and the ability to quickly interrogate that data, has supported management processes and critical decision making to an extent not utilized previously – again increasing productivity.

On a more operational level:

- An **automated decontamination tunnel** was developed to process potentially contaminated sample tubes which posed a risk from COVID-19 virus on the outside and had to be decontaminated before being released into the laboratory for testing. This was originally done manually with a tissue sprayed with disinfectant but this created a significant bottleneck in the process which the development of the tunnel alleviated.
- A **digital tracking software system** was developed to ensure a steady flow of samples through all stages of the testing process, as well as identifying where there were bottlenecks and areas requiring an intervention and resolution.

6.3 RANDOX IS INVESTING IN THE UK'S DIAGNOSTIC RESEARCH CAPABILITIES

Randox is clear that diagnostics are unquestionably critical to future improvements within healthcare and is committed to playing a leading role within the industry. In May 2022, Randox was announced as an industry partner in the 'Our Future Health' programme, which is the UK's largest ever health research programme.

The scale, depth and detail of the Our Future Health programme will make it a world-leading resource for health research. The programme is designed to truly reflect the UK population, including groups of people that have previously been under-represented in health research.

Our Future Health may hold the key to huge numbers of discoveries, such as:

- New signals that could be used to detect disease much earlier than is currently possible, leading to new or improved screening and prevention programmes and earlier treatment.
- New ways to predict with better accuracy who is at higher risk of diseases and would benefit from faster access to screening and prevention interventions.
- More targeted or personalised treatments, tools and technologies to delay the onset of disease, or change the course of disease progression; to reduce disease risks; and more targeted ways to investigate diseases for people at higher risk.

Randox will deliver a £10m investment in the programme which will discover and develop new methods of prevention, early detection and treatment of diseases and health conditions, and it joins a group of other life sciences companies in the collaborative programme.

As part of its participation, Randox will also make its high street Randox Health outlets available to test volunteers from across the UK taking part in the OFH project, which aims to monitor the long-term health of five million volunteers in the coming years, starting this autumn.

Andrew Roddam, chief executive of Our Future Health, said:

*"We welcome Randox as one of our industry partners, knowing their long-term commitment to diagnostics, and look forward to working with them in the months and years ahead. Our industry partners together will provide significant funding to further our objective to develop new ways to prevent, detect and treatments enabling people to live healthier lives for longer."*⁷³

In order to further advance its research agenda, Randox is also committing £40m to establish the Randox Institute of Personalised Health in London, in addition to recently funding the inaugural Randox Professor of Medicine at Ulster University. The Institute will drive Randox's agenda to improve diagnosis at a personal level. This location in London will also assist collaboration within the UK's 'Golden Triangle' in the London-Oxford-Cambridge region.

⁷³Diagnostics and personalised health company Randox to deliver £10m investment for major UK research project Our Future Health <https://www.randox.com/diagnostics-and-personalised-health-company-randox-to-deliver-10m-investment-for-major-uk-research-project-our-future-health/>

6.4 FURTHER INVESTMENT TO EMPOWER INDIVIDUALS TO TAKE CONTROL OF THEIR OWN HEALTH

Within the changing dynamics of Healthcare delivery, and the increasingly important role of diagnostics, Randox have sought and continue to make large investment in the development of services that are more accessible to partners and the public, empowering individuals to take control of their own health.

Early diagnosis of disease and lifestyle changes are key to improving global healthcare and saving lives. The range of comprehensive health checks offered by Randox Health can provide individuals with an accurate and actionable profile of current and future health. This will improve health outcomes whilst reducing the burden on healthcare services.

Randox Health brings the expertise of Randox directly to the public via a network of high street clinics, currently being rolled out across the UK. There were four Randox Health Clinics before the pandemic, but this has since grown to 16 outlets across the UK. The majority of these have been opened in 2022, with confirmed plans for further significant growth in the next 24 months.

COVID-19 has also changed the public perception that a hospital laboratory is the only place where diagnostic tests should be performed. The Vivalytic instrument is an examples of easy-to-use equipment that can be used in primary care, pharmacies, care homes and other sites - further reducing demand on primary care and healthcare resources.

These instruments can be used to identify bacteria and viruses causing respiratory and sexually transmitted infections using PCR and biochip in less than one hour. Treatment can be provided without the need to meet directly with a GP, thus reducing visits to GPs.





Radox is also increasing access to diagnostic tests by opening up the market to enable people to take a blood sample at home using home blood collection kits. These kits take advantage of the public's increased awareness of testing and confidence in their own ability to collect samples, alongside Radox's experience from COVID testing kits.

The blood is returned to Radox Laboratories and accessioned using the same process as accessioning during COVID-19. The client uses a portal similar to that developed during COVID-19 to register their sample (URN). The laboratory processes the sample, and results are reviewed and returned to the individual using knowledge gained from the processes developed at Radox during the pandemic.

To date Heart Health, Thyroid Health, Vitamin D, Vitamin B12, Male Health and Anti-Mullerian Hormone home blood collection kits are available to the public online, at pharmacies, and Radox Health

Clinics, with others being validated. This new business model for Radox empowers individuals to take control of their own health and reduces demand on healthcare resources.

Radox plans to continue investing in the R&D behind the science, diagnostic possibilities, technology, and service models that underpin the Radox Health business model. As the business evolves and scales, the data and insight gathered can (in the same way as the Our Future Health programme) serve as an important input into healthcare delivery, targeting ever more scarce resources and intervention to where it matters most.

Radox is also exploring how the Radox Health proposition can be rolled-out within international markets. The additional scale and connectivity this would create can provide additional investment capacity to deliver upon the ambition of patient and healthcare outcomes.

Figure 6(4): Radox Health on the High Street

6.5 DEVELOPING THE SECTOR AND THE ECONOMY

The UK has long been a powerful global centre for research in life sciences. In the post COVID-19 environment, investment in life sciences has never been more important. Indeed it was the accumulated research capability of firms like Randox that allowed the UK to deliver a testing programme and overall response that was the envy of the globe.

Randox has significantly strengthened its workforce since 2020 and now employs over 2,500 people across the globe. The company intends to maintain its workforce despite the ramping down of the National Testing Programme, as it continues to invest significantly in expanding its products and services and introducing them to a broader set of markets.

Randox is recognised amongst the global leading players within the diagnostics sector, and a visible and active participant within the sector in the UK. UK government has set out an ambitious strategy in this area⁷⁴ – with initiatives ranging from Clinical Research delivery, to improving accessibility and linkages of NHS and related healthcare data.

In its home economy of Northern Ireland, Randox ranks as a significant contributor to the economy and a Top 30 employer⁷⁵. As the business has grown both globally and in the UK context, it is notable that Northern Ireland remains very largely the centre of gravity for the business and has been where the majority of its recent significant investment, such as the laboratory space that delivered the National Testing Programme, has been located. In May 2021, the Northern Ireland Department for the Economy published its '10x Economy – an economic vision for a decade of innovation' strategy. Randox exemplifies the key components of this strategy – operating in a priority sector (Life Sciences), and investing heavily in R&D creating high value jobs within the local economy. More broadly Randox's innovations within Robotics, Artificial Intelligence and Data Analytics are all aligned with the ambition to focus on those technologies and clusters where Northern Ireland, within the context of the UK, can be a global leader.

⁷⁴Department for International Trade, Life Sciences Competitiveness Indicators 2022 (published 21 July 2022)

⁷⁵Belfast Telegraph (2021) Northern Ireland's 50 biggest employers (Note: this was based on Equality Commission date from 2019 where Randox was ranked 46. A more modern estimate is included in the text above to take account of where Randox would be ranked given their almost doubling of Northern Ireland workforce)









Appendices

APPENDIX A – PROJECT METHODOLOGY

To deliver this work, we adopted a four-phase process as shown in figure A(1).

Phase 1: Identify

After an initial meeting to agree expectations, scope and timeline we held a workshop with Radox to understand the internal information held regarding its COVID-19 testing programme.

We were given access to key internal Radox data such as the number of tests held under each category and the results of those tests. We then gathered external health data from a variety of publicly available sources, such as central government, devolved administrations, the NHS and public health bodies concerning the levels of infection, the R number, hospital and intensive care unit admissions, and deaths. We were also given a tour of the Science Park laboratories, where we were able to observe the testing process and equipment first hand. This was supplemented with a cache of internal documents and photographs that provided timelines of testing delivery and technical details of the laboratory processes.

Phase 2: Analyse

We then conducted a thorough literature review and meta-analysis of existing primary research into the impact of COVID-19 testing on transmission rates. Combining the internal Radox testing data with external health data and estimates on the rates of the impact of testing on rates of transmission from the literature review, we built a model to illuminate how the pandemic would have developed without the impact of testing in general on the course of the pandemic. From this, we estimated the ultimate health, social and economic impacts impact of Radox's particular contribution to testing programme.

Phase 3: Engage

To gain a thorough understanding of the role different departments and individuals within Radox played in standing up its testing programme we interviewed twenty-two Radox employees and ten external stakeholders with whom Radox engaged during the pandemic. These included senior public health officials, travel operators, and consultants.

Phase 4: Report

Finally, drawing on the data, research, modelling and interviews we presented our findings in a final report, bringing together the narrative of Radox's testing programme, the estimated health, social and economic impacts and its future legacy.

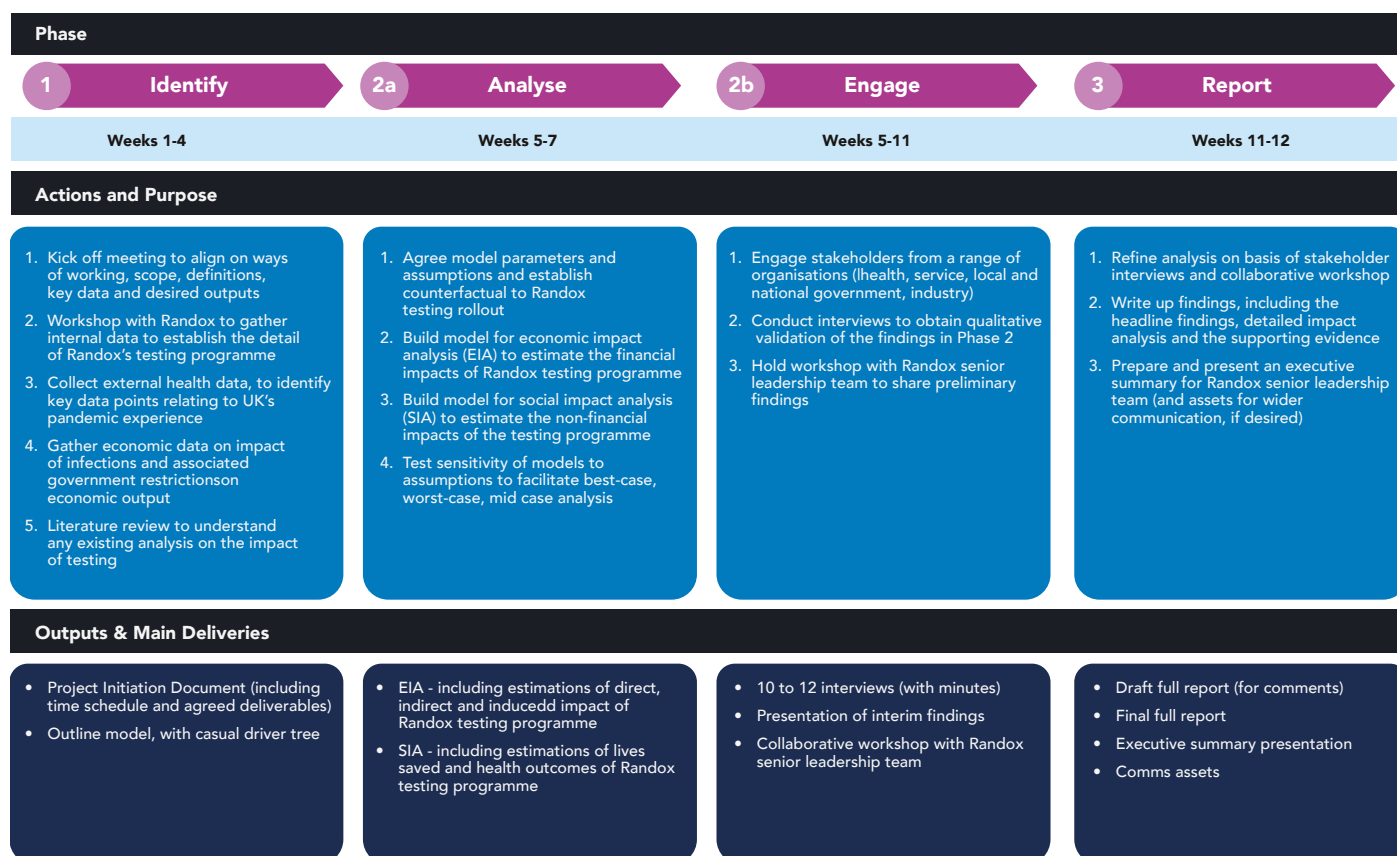


Figure A(1): Mapping travel testing impacts

APPENDIX B – MODEL APPROACH, ASSUMPTIONS AND PARAMETERS

Interpreting the question

What were the health, social and economic impacts of Randox's testing programme? This is a challenging question to answer for two reasons. First, because the question itself is not unambiguously defined. Secondly, because the pandemic affected our lives in profound and various ways and hence the impact of the measures that mitigated its effects, such as testing, are wide-ranging and complex too.

Dealing with the first of these challenges, the impact question can be reframed as: what would have happened were it not for Randox's testing program? The differences between this counterfactual and the observed outcome, i.e. what happened with Randox's testing, can be properly described as its impact.

Expressed like this, the challenge becomes more apparent. The world in which Randox's testing did not occur is a hypothetical one; it did not, in fact, happen. Trivially, then, it cannot be directly observed. And though we talk about 'estimating the impact', this is not an estimate in the normal sense. It is not an approximation of something that has happened and neither is it a forecast or something that will happen.⁷⁶ Instead, we build a model that posits a causal relationship between testing and variables that have implications for health, economic and social outcomes, such as transmission rates, case numbers, hospitalisations and deaths.

There is a school of thought that economic models are simplified versions of reality; that they should stand or fall on their ability to make accurate predictions. If that is sometimes the right way to think about economic models it is not the right way to conceive of this type. This model does simplify in the sense that it seeks to explain the majority of variance in observed outcomes using a few simple inputs. But its outputs are not a simplified version of reality but, rather, a description of a hypothetical world: one that can be imagined though it did not occur. And since it does not seek to make testable predictions it cannot be evaluated on the basis of their accuracy.

Instead, it stands or falls on the plausibility of the assumptions that underpin it. As such, in our analysis we make explicit our assumptions and the basis on which they are made, so that the reader may form his own view on their plausibility.

However, it is not only the plausibility of the counterfactual(s) we must consider but also their usefulness. There are many possible counterfactual worlds in which Randox testing did not occur. Consider the following hypothetical scenarios:

- i. There was no Randox COVID-19 testing because there was no pandemic.
- ii. There was no Randox COVID-19 testing because another company performed the same function instead.
- iii. There was no Randox COVID-19 testing and as a result fewer tests were carried out.

Of course we could also conceive of many others. Choosing between such possible worlds is not a matter of plausibility but rather one of purpose.

The first counterfactual is entirely plausible but unilluminating with respect to the task in hand.

The second counterfactual may also be plausible⁷⁷ but is also not useful given our purposes outlined in section 5.1. It would simply beg the question: what was the impact of the testing carried out by the alternative company?

⁷⁶Though it could usefully inform such a forecast should another pandemic arise.

⁷⁷Although there is serious doubt that early capacity limits would have been reached without making use of Randox's specific pre-pandemic capabilities

In selecting the third counterfactual for the basis of this analysis, then, we must acknowledge that, in all likelihood, had there been no Randox testing then some of those tests may have been carried out by other providers, at least once national testing capacity had expanded to meet demand. However, given our purposes outlined in section 5.1, we want to consider the value provided by Randox's testing to be evaluated alongside the cost of this testing.

Had some other provider stepped in to perform some portion of Randox's testing, they too might have made sacrifices and incurred costs against which to evaluate the benefits of their testing.

The proper target of this analysis, then, is the comparison of observed reality with a scenario where the need for testing was just as great as it was but the tests carried out by Randox were not delivered. This is the most natural, and useful, interpretation of the question 'what would have happened were it not for Randox's testing?'

Turning now to the second challenge, any impact analysis must deal with how to factor costs or benefits that are not directly expressed in comparable terms. This analysis is no exception: COVID-19 testing affected health outcomes most obviously but indirectly it also affected the ability of people to work and to socialise. Quantifying these requires a series of judgements and assumptions to be made.

What is unusual about this case, however, is that the health impacts of the pandemic were so severe that government policy was expressly designed to limit social contact, including economic activity, in order to slow the transmission of the disease. Although a simplification, it is not a gross distortion to suggest that the government used lockdowns and mandated closures of businesses to trade off health impacts for economic and social impacts.

This means that the modelling of health, economic and social impacts cannot be treated individually, in isolation, but should rather be treated collectively and considered interdependent.

Furthermore any attempt to model these impacts in a counterfactual scenario, as we do here, must consider how individuals and government might have responded to significant departures from the observed scenario in the counterfactual. For example, had transmission rates and hospital admissions been higher, would the government have locked down the economy for longer? In such a way, it may have been possible for the government to avoid the worst-case scenarios in terms of health outcomes but only at the expense of worse economic and social outcomes. The nature of this trade-off is explored more fully in section 5.3.

The table below provides details of the assumptions and parameters used in our model that forms the basis of our estimation of the impacts.

Parameter / assumption	Value	Rationale / source
Impact of testing on Rt	Rt /1.1 (or absolute impact on Rt of 0.9-1.4)	We use a multiplier because, in general, when transmission is higher, the impact of testing will be higher as a higher proportion will test positive. Our estimate is at the lower end of a range of estimates in the academic literature – see Appendix B for more details
Average cost to NHS of COVID-19 hospitalisation	£9712	Based on a range of estimates and sources https://www.england.nhs.uk/statistics/statistical-work-areas/COVID-19-hospital-activity/ ; https://www.nhsconfed.org/sites/default/files/2021-09/A-reckoning-continuing-cost-of-COVID-19.pdf ; https://www.medrxiv.org/content/10.1101/2020.12.14.20248201v1.full.pdf ; https://www.nature.com/articles/s41598-021-97259-7
Cost of lost economic activity to COVID absence	£128 per person per day	This is an average of the daily productivity across the whole population (including economically active and economically inactive). Based on total population and GDP
Days of absence avoided from negative test	3.36	Based on an average 5.6 days of post-test isolation avoided and a 60% symptomatic isolation rate
Cost of lockdown in lost output	£4,480,538,462 per week	Based on average drop in output across all three lockdowns
Randox share of NTP	12.28%	Based on total Randox tests of 17.1m out of a total Pillar 2 PCR total of 139.6m. We have assumed that Randox tests are a representative sample of the total.
Economic value of international journey	£980	Based on various estimates: https://www.icao.int/meetings/wrdss2011/documents/jointworkshop2005/atag_socialbenefitsairtransport.pdf ; https://wtcc.org/research/economic-impact ; https://www.oxfordeconomics.com/resource/not-all-visitors-are-created-equal-which-tourists-give-destinations-the-most-bang-for-their-buck/
Number of tests per journey	2	Travel testing policy varied between countries, and over time (with over fifty amendments to UK policy between March 2020 and August 2021). We have assumed, conservatively, that each private PCR test facilitated 0.5 international journeys.



A key input into the impacts model is an estimation of the extent to which testing reduces the overall rate of COVID-19 transmission. Various attempts have been made to discuss and quantify this impact using comparative studies between different locations and times; or primary research to estimate the causal drivers of testing impact, such as isolation compliance levels. We have treated the impact on R_t as an exogenous variable in our model, based on a review of existing literature.

Here we review a selection of existing studies, noting their estimate of the impact of testing (and tracing) on R_t , where given, and provide a brief commentary on each.

Year Published	Author	Source	Objectives	Methods	Findings	Limitations	Conclusions	Year Data Collected	Types of Resources
2020	Nicholas C Grassly, Margarita Pons-Salort, Edward P K Parker, Peter J White, Neil M Ferguson	The Lancet Infectious Diseases VOLUME 20, ISSUE 12, P1381-1389	Investigating the potential impact of different testing and isolation strategies on transmission of SARS-CoV-2	Development of a mathematical model of SARS-CoV-2 transmission based on infectiousness and PCR test sensitivity over time since infection, to estimate the effectiveness of alternate strategies	If all individuals with symptoms compatible with COVID-19 self-isolated and self-isolation was 100% effective in reducing onwards transmission, self-isolation of symptomatic individuals would result in a reduction in R of 47%	Uncertainty around the contribution of asymptomatic infections to SARS-CoV-2 transmission	Molecular testing can play an important role in prevention of SARS-CoV-2 transmission, especially among health-care workers and other high-risk groups, but no single strategy will reduce R below 1 at current levels of population immunity. Testing could also contribute to prevention of SARS-CoV-2 transmission in the general population. It might promote adherence to self-isolation by individuals showing COVID-19 symptoms who test positive.	2020	Estimate and range for model parameters of SARS-CoV-2 transmission from published literature: https://doi.org/10.1101/2020.05.9.20096289
2022	Laura C. Rosella, Ajay Agrawal, Joshua Gans, Avi Goldfarb, Sonia Sennik, Janice Stein	Science Advances Volume 8	identifying and reporting the process for establishing a workplace frequent rapid antigen test programme.	Testing programme statistics to identify the number of RATs deployed, presumptive positive, and reported PCR confirmation results Survey of 163 project leads working in organisations with a frequent RAT testing programme. An unspecified amount of feedback was requested from employees in a wide range of roles	One in 4300 RATs was presumptive positive but later tested PCR negative, therefore false positives did not meaningfully disrupt workplace operations 68% of 116 survey participants were very satisfied with the programme and an additional 31% were satisfied. Employees reported feeling safe and more comfortable and confident in the workplace. Several commented on the importance of this programme for keeping their families safe.	Unspecified, low number of employee feedback	High frequency testing programmes is highly effective at identifying asymptomatic COVID-19 infections. Testing offers the potential to break the chain of transmission and act as an extra layer of protection in a comprehensive public health response.	11 January 2021 - 25 June 2021	Statistics (number of participating organisations, screenings, positive cases identified) from the CDL RSC data system. Employee surveys were collected by the authors and approved by the University of Toronto Research Ethics Board

Screening should prioritize accessibility, frequency, and sample-to-answer time; analytical limits of detection should be secondary.

Effective screening depends largely on frequency of testing and speed of reporting and is only marginally improved by high test sensitivity.

Assessing the effectiveness of repeated population screening on controlling the spread of COVID-19

Science Advances
Volume 7, Issue 1

Daniel B. Larremore,
Bryan Wilder, Evan
Lester, Soraya
Shehata, James M.
Burke, James A.
Hay, Milind Tambe,
Michael J. Mina, Roy
Parker

2021

Several assumptions are made which affects the results of the model. The model assumes that all patients and HCWs are susceptible to infection at the beginning of the epidemic, the test accuracy is 100% and that patients and HCWs are fully immune once infected. The model is parameterized for an 'average' English hospital with 1000 beds and 8000 HCWs to reflect the average bed size to staff ratio in English NHS Trusts

Periodic testing of health care workers has a smaller effect on the number of hospital-acquired COVID-19 cases in patients, but reduces infection in HCWs by as much as 37%. Periodic testing and further results in only a small proportion of staff absences (approx. 0.3% per day); considerably less than the 20-25% of staff reported to be absent from work owing to suspected COVID-19 and self-isolation

Model simulations to examine the efficacy of HCW testing and patient isolation strategies. The study considers periodic testing of the HCW population every 1, 7, 14 or 28 days, and assume that an equal proportion of the population are tested each day (so 1/7 of all HCWs will be tested every day for 7 day periodic testing).

Assessing the impact of testing and infection prevention and control strategies on within-hospital transmission dynamics of COVID-19 in English hospitals

Philosophical Transactions of the Royal Society B: Biological Sciences
Volume 376, Issue 1829

Stephanie Evans,
Emily Agnew, Emilia
Vynnycky, Julie
Robotham

2021

modelling study
- hypothetical results that do not necessarily reflect the effectiveness of Randox testing

Assessing the impact of delays in testing on the R rate of infection

The Lancet Public Health
Volume 5, Issue 8,
E452-E459

Miriam E.
Kretzschmar, Gama
Rozhnova, Martin
Bootsma, Michiel
van Boven, Janneke
van de Wijgert, Marc
Bonten

2020

Year Published	Author	Source	Objectives	Methods	Findings	Limitations	Conclusions	Year Data Collected	Types of Resources
2020	Yuemei Zhang, Sheng-Ru Cheng	JMIR Public Health and Surveillance Vol 6, No 4	Quantitative analysis of the predicted impact that regular testing of health care workers for COVID-19 may have on the prevention of the disease among emergency department patients and staff.	Using publicly available data on COVID-19 cases and emergency department visits, as well as internal hospital staffing information, the study developed a mathematical model to predict the impact of periodic COVID-19 testing of asymptomatic staff members of the emergency department in COVID-19-affected regions.	The model predicts that after 30 days, with a transmission constant of 1.219e-4 new infections per person, weekly COVID-19 testing of healthcare workers (HCW) would reduce new HCW and patient infections by 5.1% and bi-weekly testing would reduce both by 2.3%. At a transmission constant of 3.660e-4 new infections per person, weekly testing would reduce infections by 21.1% and bi-weekly testing would reduce infections by 9.7–9.8%. For a lower transmission constant of 4.067e-5 new infections per person, weekly and biweekly HCW testing would result in a 1.54% and 0.7% reduction in infections respectively.		Periodic COVID-19 testing for emergency department staff in regions that are heavily-affected by COVID-19 and/or facing resource constraints may reduce COVID-19 transmission significantly among healthcare workers and previously-uninfected patients	2020	Various transmission constants based on the Diamond Princess cruise ship data
2021	MARTIN PAVELKA, KEVIN VAN-ZANDVOORT, SAM ABBOTT, KATHARINE SHERRATT, MAREK MAJDAN, CMMD COVID-19 WORKING GROUP, INŠTITÚT ZDRAVOTNÝCH ANALÝZ, PAVOL JARČUŠKA, MAREK KRAJČÍ, STEFAN FLASCHE, SEBASTIAN FUNK	Science Vol 372, Issue 6542, pp. 635-641	Assessing the impact of mass testing on COVID-19 infection rates in Slovakia	Observation and analysis of mass testing results across 41 counties in Slovakia, compared against a statistical model with a microsimulation approach	Repeated mass antigen testing reduced infections by about 25-30% and decreased R0 by 0.3 two weeks after the re-testing; the effects on incidence peaked around that time and all effects gradually dissipated afterward. Adjusting for epidemic growth of 4.4% (1.1 to 6.9%) per day preceding the mass testing campaign, the estimated decrease in prevalence compared with a scenario of unmitigated growth was 70% (67 to 73%). Modeling indicated that this decrease could not be explained solely by infection control measures but required the addition of the isolation and quarantine of household members of those testing positive	The observational nature of this study makes it difficult to separate the effects of mass testing from other interventions introduced during the period	Mass testing could be an effective tool in curbing the spread of COVID-19, but for lasting effects regular retesting would be necessary.	October 2020 - November 2020	The results of 5,276,832 SD-Biosensor Standard Q rapid antigen tests, taken across 41 counties in Slovakia

2021	Tim R. Mercer, Marc Salit	Nature Review Genetics Vol 22, pp. 415-426	An analysis of the changing role of testing during the COVID-19 pandemic, including the use of contact tracing to contain disease outbreaks					
2020	Joe Hasell, Edouard Mathieu, Diana Beltekian, Bobbie Macdonald, Charlie Giattino, Esteban Ortiz-Ospina, Max Roser, Hannah Ritchie	BMJ Open Journal Vol 22, pp. 415-426	Compiling the official data on the extent of PCR testing over time for 94 countries.	Official government sources: press releases, government websites, dedicated dashboards and social media accounts of national authorities	Limitations to the amount of information available on the public record	March 2020 onwards	Official country data on PCR tests administered in 94 countries	
2021	Marta Wanat, Mary Logan, Jennifer A. Hirst, Charles Vöcay, Joseph J Lee, Rafael Perera, Irene Tracey, Gordon Duff, Peter Tufano, Thomas Fanshawe, Lazaro Mwandigha, Brian D Nicholson, Sarah Hobbs	BMJ Open Journal	An examination of the experiences of university students and staff of regular asymptomatic self-testing using LFTs, and their subsequent behaviours.	A qualitative study using semistructured remote interviews and qualitative survey responses, which were analysed thematically.	Participants were motivated to regularly self-test as they wanted to know whether or not they were infected with SARS-CoV-2. Most reported that a negative test result did not change their behaviour, but it did provide them with reassurance to engage with permitted activities. In contrast, some participants reported making decisions about visiting other people because they felt reassured by a negative test result.	October 2020 - January 2021	People who were participating in weekly testing feasibility study, between October 2020 and January 2021, at the University of Oxford. 18 interviews, with 214 participants	
2021	Martin Kahanec, Lukáš Laffers, Bernhard Schmidpeter	Journal of Population Economics Vol 34(4), pp. 1105-1140	Assessing the potential benefits of repeated mass testing on the COVID-19 pandemic	Empirical approach studying the outcome of the Slovakia mass testing programme. Two days of mass testing was conducted in autumn 2020, and a second round of testing was conducted for districts where the share of COVID-19 tests was equal or above 0.7%	In those districts above the 0.7% threshold, the measured number of infections fell on average by up to about 30% and the R rate decreased by about 0.3 two weeks after the second mass testing event, compared to districts below the threshold. The results indicate a maximum reduction in COVID-19 incidence around 15 days after the second mass testing and a reversal to zero afterward. Three weeks after the second round of mass testing all the measured effects disappeared.	Repeated mass testing can be an effective policy tool for decreasing the spread of the disease when coupled with an effective airtight regime of positive cases and their contacts. The mitigating effect is temporary. Therefore, mass testing would need to be conducted on a regular bases if a sustained mitigation of the pandemic were to be achieved.	Data from the first ever nationwide rapid antigen testing implemented in Slovakia in autumn 2020	

Year Published	Author	Source	Objectives	Methods	Findings	Limitations	Conclusions	Year Data Collected	Types of Resources
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2021	Kevin L. Schwartz, Allison J. McGeer, Isaac I. Bogoch	Canadian Medical Association Journal Vol 193, Issue 13			People who are either presymptomatic or paucisymptomatic are major contributors to transmission. Rapid antigen tests have shown adequate sensitivity in identifying cases of infection with higher viral loads and can be used to good effect in screening programs to regularly identify people with SARS-CoV-2 infection who are asymptomatic.		Frequent rapid antigen testing is a scalable public health tool that can effectively identify asymptomatic and paucisymptomatic people with SARS-CoV-2 infection and improve contact tracing and control of outbreaks.	1 August 2020 - 15 December 2020	
2022	Jitka Polechová, Kory D.Johnson, Pavel Payne, Alex Crozier, Mathias Beiglböck, Pavel Plevka, Eva Schenhammer	Journal of Clinical Epidemiology Volume 145, pp 14-19	A justification of the use of antigen tests for epidemic control as distinct from a diagnostic test.						

2021	Rebecca L Smith, Laura L Gibson, Pamela P Martinez, Ruian Ke, Agha Mirza, Madison Conte, Nicholas Gallagher, Abigail Conte, Leyi Wang, Richard Fredrickson, Darci C Edmonson, Melinda E Baughman, Karen K Chiu, Hannah Choi, Tor W Jensen, Kevin R Scardina, Shannon Bradley, Stacy L Gloss, Crystal Reinhart, Jagadeesh Yedotore, Alyssa N Owens, John Broach, Bruce Barton, Peter Lazar, Darcy Henness, Todd Young, Alastair Dunnett, Matthew L Robinson, Heba H Mostafa, Andrew Pekosz, Yukari C Manabe, William J Heetderks, David D McManus, Christopher B Brooke	The Journal of Infectious Diseases Vol 224, Issue 6, pp. 976-982	Longitudinal assessment of 43 individuals newly infected with COVID-19		Both RT-qPCR and Quidel SARS Sofia antigen FIA peaked in sensitivity during the period in which live virus was detected in nasal swabs, but sensitivity of RT-qPCR tests rose more rapidly prior to this period. antigen testing's sensitivity reached >98% when conducted at least every 3 days, bringing it on par with PCR testing at the same frequency.		RT-qPCR tests are more effective than antigen tests at identifying infected individuals prior to or early during the infectious period and thus for minimizing forward transmission (given timely results reporting). Frequent antigen testing while the individual has a high viral load has similar effects to PCR testing	Undisclosed	Daily saliva and nasal swabs of 43 adults newly infected with COVID-19. Of the 43 participants, 23 provided 14 days of observations, 10 provided 13 days of observation, and only 3 provided fewer than 10 days of observation.
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Rapid antigen tests detect proteins at the surface of virus particles, identifying the disease during its infectious phase. In contrast, PCR tests detect viral genomes: they can thus diagnose COVID-19 before the infectious phase but also react to remnants of the virus genome, even weeks after live virus ceases to be detectable in the respiratory tract. Furthermore, the logistics for administering the tests are different. Large-scale rapid antigen testing in Austrian schools showed low false-positive rates along with an approximately 10% lower effective reproduction number in the tested cohort.

This paper motivates and justifies the use of antigen tests for epidemic control as distinct from a diagnostic test.

Literature review and the results of frequent mass antigen testing in Austrian schools during the spring of 2021.

Using antigen tests at least 2-3 times per week could become a powerful tool to suppress the COVID-19 pandemic.

Spring 2021

Jitka Polechová, Kory D. Johnson, Pavel Payne, Alex Crozier, Mathias Beiglböck, Pavel Plevka, Eva Schenhammer

Journal of Clinical Epidemiology
Vol 145, pp. 14-19

2022

Review of government contracts let to Randox, focusing on the actions of the Department of Health and Social Care in awarding and managing those contracts.

January
2020 -
December
2021

National Audit Office

N/A

2022

Francesc López Seguí, Jose Maria Navarrete Duran, Albert Toldrà, Maria Sarquella, Boris Revollo, Josep Maria Llibre, Jordi Ara Del Rey, Oriol Estrada Cuxart, Roger Paredes Deirós, Guillem Hernández Guillamet, Bonaventura Clotet Sala, Josep Vidal Alaball, Patricia Such Faro

International Journal of Environmental Research and Public Health
Jul 3;18(13):7129

2021

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2020	Elizabeth T Chin, Benjamin O Huynh, Matthew Murrill , Sanjay Basu, and Nathan C Lo	National Institutes of Health, medRxiv Vol. 3	To estimate the effectiveness of routine testing with SARS-CoV-2 polymerase chain reaction (PCR) to reduce workplace transmission of COVID-19.	Using a simulation model to estimate the effect of testing on the effective reproductive number (R)	The model indicated that if workers were tested daily by PCR, there was an estimated 59.8-64.5% reduction in the number of infectious days worked. When testing every three days, the reduction was 37.7-41.7%. When testing weekly the reduction was 19.8-23.8%. When testing monthly the reduction was 2.8-7.4%. The model also suggested that with R=2, workers should be tested every 2 days to prevent outbreak (R <1). This increased to every day with R=2.5, and decreased to every 3-4 days with R=1.5.	Study considers only high-incidence settings, rather than the population at large.	Routine testing strategies can provide benefit to reduce transmission in high-risk environments with frequent testing.		Statistical model of impact of testing using statistics available at time.
2021	Dame Carol Black and David Frost CBE		To minimise the loss of work resulting from ill health and to find ways of reducing the burdens and costs		140 million sick days lost in an average year. Cost businesses £9 billion and the government £13 billion. Thus costing businesses on average £64.29 per sick day, and the government £92.86 (£157.15 in total pp). Calculation not in report				
2021	Beatriz Gonzalez Lopez-Valcarcel and Laura Vallejo-Torres	Applied Economic Analysis Vol 29, No. 85, p.77-89	To provide an estimation of the costs of the coronavirus (COVID-19) pandemic with a special focus on Spain.	The total cost of COVID-19 for Spain in 2020 was obtained using the cost of illness approach with a bottom-up process. A cost effectiveness analysis of the TTQ strategy in Spain is based on the estimation of the total costs of TTQ and the health gains and avoided health-care costs associated with the TTQ strategy	Based on the estimated cost of the disease in Spain, and the estimated direct and indirect health costs of the pandemic, a TTQ (Test, Track, Quarantine) strategy was proven to be cost-effective. For every euro spent, €7 were saved in health-care costs. In all variants of the model (different PCR positivity rates etc.) the TTQ strategy was profitable in the long-term.	A number of assumptions are required to arrive at the estimates provided in this study e.g. estimating COVID hospital care costs	TTQ is a key strategy for the control of the pandemic and it is justified from the economic perspective		
2020	Andrew Atkeson, Michael C. Droste, Michael Mina, James H. Stock	NBER Working Paper Series Working Paper 28031	To assess the economic value of screening testing programs as a policy response to the ongoing COVID-19 pandemic	A macroeconomic cost-benefit analysis of a hypothetical U.S. program of imperfect screening testing with partial adherence. We extend the behavioural SIR model in Baqaee, Farhi, Mina, and Stock (2020b) (BFMS) to incorporate diagnostic and screening test regimes and partial adherence to self-isolation.	Scenario A - 98.5% specificity LFT, 50% take alone adherence 25% - \$244 billion GDP increase Scenario B - 98.5% specificity LFT, all take alone adherence 25% - \$54.1 billion GDP increase Scenario C - Two-stage 99.7% specificity LFT, no confirmatory PCR, LFT adherence 50% - \$395 billion GDP increase	The model does not include contact tracing outcomes. It does also not account for behavioural changes such as attitude to risk with tests in place.	For all scenarios (combinations of LFT or PCR tests) with only partial LFT adherence, the economic benefits outweighed the costs by 5-10x with weekly testing		

2021	Kobi Cohen, Amir Leshem	Scientific Reports Vol. 11 Article 6279	To develop a controlled testing framework to exploit limited testing efficiently to improve the outcome of contact tracing	Using a Stochastic model to estimate the likelihood of a person being infected with COVID-1	The model shows that targeted testing can reduce the quarantine period by up to 50%, while reducing both the peak number of infected people per day and the total morbidity	Model uses the WHO specified 1m distance for 15 minutes qualification for infection.	Targeted testing is a key measure to reduce infections, but also to reduce quarantine times, which has an economic impact.	Stochastic model of disease spread
2021	Thomas Gries & Paul J. J. Welfens	International Economics and Economic Policy Vol. 18, p. 1-24	To consider the potentially crucial role of a Corona testing approach in combination with a quarantine approach as a substitute for lockdowns, considering their cost of \$729.80 million per day in the UK	Using a model to evaluate the cost of lockdowns compared to test and quarantine strategies in the OECD.	Showed that a test and quarantine (T&Q) approach was effective in reducing cases of COVID-19 in Germany. The GDP reduction incurred by Germany in Q2 2020 was 10% because of lockdown, but the T&Q approach cost less than 2% of GDP	Model estimates the costs involved in testing, and the method of estimation of lockdown costs is not country specific	T&Q approach is effective and of lower cost than full lockdowns	
2022		Office for National Statistics		149.3 million days lost in 2021 (4.6 days per worker). COVID accounted for 1/4 of these (37.33 million days or 1.15 days per person).				
2022		Centre for Economics and Business Research	To find the impact of the June 2022 rail strikes on economic output		Estimates that 0.8% of the workforce (250,000 people) were unable to work on the first day of strikes. This will cause a £45.1 million drop in Gross Value Added (GVA). This takes into account the increase in people working from home because of the pandemic (46.5% of workers cannot work from home).	Figures not from COVID lockdown, but are a similar case.		

CHALLENGE.
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