



National Audit Office



Investigation into the government's contracts with Randox Laboratories Ltd

Department of Health & Social Care

REPORT

**by the Comptroller
and Auditor General**

**SESSION 2021-22
24 MARCH 2022
HC 1018**



We are the UK's independent public spending watchdog.

We support Parliament in holding government to account and we help improve public services through our high-quality audits.

The National Audit Office (NAO) scrutinises public spending for Parliament and is independent of government and the civil service. We help Parliament hold government to account and we use our insights to help people who manage and govern public bodies improve public services.

The Comptroller and Auditor General (C&AG), Gareth Davies, is an Officer of the House of Commons and leads the NAO. We audit the financial accounts of departments and other public bodies. We also examine and report on the value for money of how public money has been spent.

In 2020, the NAO's work led to a positive financial impact through reduced costs, improved service delivery, or other benefits to citizens, of £926 million.



National Audit Office

Investigation into the government's contracts with Randox Laboratories Ltd

Department of Health & Social Care

Report by the Comptroller and Auditor General

Ordered by the House of Commons
to be printed on 23 March 2022

This report has been prepared under Section 6 of the
National Audit Act 1983 for presentation to the House of
Commons in accordance with Section 9 of the Act

Gareth Davies
Comptroller and Auditor General
National Audit Office

22 March 2022

Investigations

We conduct investigations to establish the underlying facts in circumstances where concerns have been raised with us, or in response to intelligence that we have gathered through our wider work.

This investigation sets out the facts relating to how the government awarded and managed its contracts with Randox Laboratories Ltd for COVID-19 testing services and goods during the pandemic.

The material featured in this document is subject to National Audit Office (NAO) copyright. The material may be copied or reproduced for non-commercial purposes only, namely reproduction for research, private study or for limited internal circulation within an organisation for the purpose of review.

Copying for non-commercial purposes is subject to the material being accompanied by a sufficient acknowledgement, reproduced accurately, and not being used in a misleading context. To reproduce NAO copyright material for any other use, you must contact copyright@nao.org.uk. Please tell us who you are, the organisation you represent (if any) and how and why you wish to use our material. Please include your full contact details: name, address, telephone number and email.

Please note that the material featured in this document may not be reproduced for commercial gain without the NAO's express and direct permission and that the NAO reserves its right to pursue copyright infringement proceedings against individuals or companies who reproduce material for commercial gain without our permission.

Links to external websites were valid at the time of publication of this report. The National Audit Office is not responsible for the future validity of the links.



Contents

What this investigation is about 4

Summary 6

Part One

Background 14

Part Two

The first contract awarded
to Randox Laboratories Ltd
for COVID-19 testing services 28

Part Three

Subsequent contracts awarded
to Randox Laboratories Ltd 41

Appendix One

Our investigative approach 46

This report can be found on the National Audit Office website at www.nao.org.uk


If you need a version of this report in an alternative format for accessibility reasons, or any of the figures in a different format, contact the NAO at enquiries@nao.org.uk


The National Audit Office study team consisted of:


Leon Bardot, Iain Forrester and Pauline Ngan, with the assistance of Andrew Denney, Katie Taylor and Christopher Tipuric, under the direction of Lee Summerfield.

For further information about the National Audit Office please contact:

National Audit Office
Press Office
157-197 Buckingham Palace Road
Victoria
London
SW1W 9SP

 020 7798 7400

 www.nao.org.uk

 @NAOorguk

What this investigation is about

1 At the start of the COVID-19 pandemic, the government needed to act rapidly to create high-volume testing capacity in the UK. As part of these efforts, the government awarded contracts for testing services which included some to Randox Laboratories Ltd (Randox). Concerns have been raised in Parliament regarding the transparency and management of these contracts. Ministers commented in Parliament that the National Audit Office (NAO) had reviewed the government's first testing contract with Randox, although our previous work did not examine the contract with Randox in detail. To increase transparency and accountability, we have therefore carried out a more detailed review of government contracts let to Randox between January 2020 and December 2021. The report focuses on the actions of the Department of Health & Social Care (the Department) in awarding and managing those contracts.

2 This report sets out:

- a summary of the Department's procurement process (Part One);
- the procurement and performance of the Department's first contract with Randox for COVID-19 testing services (Part Two); and
- how the Department awarded subsequent contracts to Randox (Part Three).

3 Testing was crucial to understanding infection prevalence and containing its spread but in early 2020 there was very limited testing capacity and infrastructure within the NHS, Public Health England (PHE) and the private sector. From March 2020 onwards, the Department of Health & Social Care (the Department), supported by other government bodies, began to significantly scale up COVID-19 testing capacity in England. On 28 May 2020, the government announced the launch of a new NHS Test and Trace Service (NHST&T) with responsibility for leading the development and provision of the test and trace process. On 24 March 2021, the government announced that the health protection capabilities of PHE and NHST&T would combine into a new UK Health Security Agency (UKHSA). UKHSA was formally established in April 2021 and became fully operational on 1 October 2021. Our first report on the government's approach to test and trace acknowledged the significant efforts to scale up testing activity and set up a national contact tracing service from scratch.¹

¹ Comptroller & Auditor General, *The government's approach to test and trace in England – interim report*, Session 2019–2021, HC 1070, National Audit Office, December 2020.

4 The government's procurement of goods and services following the emergence of the pandemic took place in exceptional circumstances. It had to work at pace to procure the goods and services needed, with no experience of using emergency procurement on such a scale before, in the face of global competition. In emergency situations where extreme urgency is needed, such as the pandemic, the Public Contracts Regulations 2015 (the Regulations) allow public bodies to award contracts without competing or advertising the requirement. The Regulations also require public bodies to document their procurement decisions and actions fully and to ensure that risks such as conflicts of interest are managed appropriately. As noted in our earlier report on government procurement during the pandemic, the speed of procurement required brought with it increased commercial and propriety risks, which we found had not always been adequately addressed.²

5 The contracts that the government awarded to Randox during the pandemic have been for the supply of polymerase chain reaction (PCR) testing services and goods, and references to 'testing' in this report are to PCR testing. Randox is a UK-based global company offering a range of health diagnostics goods and services, including undertaking clinical tests that analyse samples taken from the human body, developing diagnostic solutions for hospitals and laboratories, and supplying reagents and equipment for laboratory medicine.

6 This report covers all the contracts the Department awarded between January 2020 and December 2021 to Randox and to its strategic partner, Qnostics Ltd, which was also the subcontractor for some of the contracts. The report focuses on the award of Randox's first COVID-19 testing contract and its subsequent variation, which together account for almost three-fifths of the total value of contracts the Department awarded to Randox over this period. All contract values in this report exclude Value Added Tax. Although this report covers considerations relevant to value for money such as unit costs of goods and services purchased, it does not seek to form an opinion on the overall value for money of the government's award and management of contracts to Randox.

7 In undertaking this work, we asked the Department and UKHSA to confirm that they had provided us with all the information and documents relevant to this investigation. A full list of the information and documents that we requested is set out in Appendix One, which explains our investigative approach. The Department and UKHSA confirmed that they had provided all relevant information for the purpose of this investigation.

² Comptroller and Auditor General, *Investigation into government procurement during the COVID-19 pandemic*, Session 2019–2021, HC 959, National Audit Office, November 2020.

Summary

Key findings

8 Between January 2020 and December 2021, the Department of Health & Social Care (the Department) and Public Health England (PHE) awarded 22 contracts to Randox Laboratories Ltd (Randox), or its strategic partner Qnostics Ltd, with a maximum value of £776.9 million. By value, almost all the contracts were for the provision of COVID-19 testing services, with less than 1% (£6.9 million) for the provision of testing-related goods. Awarding bodies used three main procurement routes, with 85% of the total value of contracts awarded directly without any competition:

- Direct awards without competition using emergency procurement rules: four contracts or contract variations with a combined value of £463.5 million (60% of the total value of contracts).
- Direct awards using variations to existing contracts: nine contract variations with a combined value of £197.0 million.
- Awards from framework agreements (both direct awards and mini competitions) where Randox had undergone a competitive process to be appointed onto the framework: nine contracts with a combined value of £116.5 million (paragraphs 1.16 and 1.17).

9 By 18 October 2021, the Department had paid Randox £407.4 million for providing COVID-19 testing services and clinical goods. Of the payments made by the Department to Randox, £403.3 million was for the provision of testing services and £4.1 million for clinical goods ordered. By 16 December 2021, Randox had processed more than 16 million tests (paragraphs 3.7 and 3.12, and Figure 9).

The first contract for COVID-19 testing services

10 The Department considered several private companies as potential suppliers of COVID-19 testing services in early 2020, including Randox. From January 2020, the Department was identifying and receiving approaches from several private sector companies, including Randox, to provide testing services and goods that would be needed as part of the government's pandemic response. The Department told us that it set up online portals to capture offers and central mailboxes to manage communications with potential suppliers. Prior to this, testing had been largely undertaken by academic and local NHS organisations. The Department assessed that these organisations would not be able to increase service levels quickly enough to meet the government's objectives to increase testing to 100,000 tests per day by the end of April 2020. The government consequently sought to buy as much testing capacity as possible (paragraph 2.2).

11 From January 2020, the Department was in discussions with Randox about developing a COVID-19 test and supplying testing services. In January 2020, the then MP for North Shropshire, who was also a paid consultant to Randox, contacted the then Secretary of State for Health and Social Care regarding Randox's proposal to develop a COVID-19 test. The then Secretary of State followed up progress on this with PHE, alongside other offers from testing companies. This was consistent with what he saw as his ministerial responsibility to build the unprecedented testing capacity for COVID-19 required in the UK. The Department told us that in mid-March 2020 it entered negotiations with Randox about providing testing services. The Department was unable to supply us with documentation on the contractual negotiations. The then Secretary of State and the then Minister for Life Sciences (who had responsibility for testing)³ told us that they were not involved in these negotiations and that these were handled by officials. The then MP for North Shropshire also told us he did not participate in negotiations relating to contracts (paragraphs 2.3 to 2.6).

3 The full ministerial title is the Minister for Technology, Innovation and Life Sciences.

12 The Department awarded a £132.4 million contract without competition to Randox on 30 March 2020 for the provision of COVID-19 testing services.

The contract was for 2,669,100 tests and covered a 12-week period due to end in June 2020. The Department told us that it 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. Randox was contracted to complete 300 tests per day at the contract's start in March 2020, increasing capacity to 60,000 tests per day from mid-May 2020. To deliver this contract, the Department knew that Randox would have to build additional laboratory space, recruit and train additional staff and purchase equipment and consumables to deliver this level of testing. The Department told us this was also the case for many of the other suppliers it awarded contracts for testing services to, as no facility in the UK was at that time equipped to handle the volume of COVID-19 testing required. Randox told us that in addition to providing contracted testing services and goods, it also provided free advice to the testing programme to support the development of a national testing infrastructure (paragraphs 2.8, 2.9 and 2.12, and Figure 3).

13 The Department was unable to provide some of the key evidence we would expect to see to support its decision-making on the first contract. Because basic information about the emergency procurement process, including evidence of approvals, was not recorded in the Department's established systems, the Department had to review several officials' email accounts to find evidence on its decision to award Randox the first testing contract. The Department provided an email to us in which the then Minister for Life Sciences gave his authorisation for civil servants to proceed with the contract, although the then Minister told us he did not consider he was being asked to formally approve the contract itself. We were also provided an email where officials consulted with the Departmental Accounting Officer on the value for money of the proposed contract with Randox. The contract was subsequently signed by the deputy director of the Department's commercial team. The Cabinet Office told us the Department did not seek its approval for the Randox contract before it was awarded, although the Department did later submit it for approval among a list of bulk retrospective spend control cases. The Cabinet Office did not provide approval for any of these retrospective cases. The Department and the Cabinet Office told us that ministers were aware of this decision and supported it. The Department gave us incomplete or no documentation on other significant aspects of the procurement, including detailed due diligence, detailed contractual negotiations leading to the first contract award, and consideration of potential conflicts of interest (paragraphs 2.6, 2.7 and 2.27 to 2.29).

14 The Department had very limited information on which to compare the price offered by Randox prior to the award of this contract. The Department agreed to pay Randox a unit price of £49.60 per test for almost 2.7 million tests but could not provide us with any documentation on the negotiations for this contract award. The Department told us it did not conduct a price benchmarking exercise because it lacked market comparators, given this type of testing was only being carried out on a small scale. It also did not consider any information on supplier profit margins. The Department and Randox have indicated that the price reflected the cost of capital investment required to deliver the level of testing set out in the contract. Randox told us that the original contract was for a limited duration and number of tests, with no guarantee of an extension. It felt that it was commercially prudent therefore that capital costs should be covered within that contract and told us that it spent £70 million on building additional laboratory space and other set-up costs (paragraphs 2.8, 2.10 and 2.11).

15 Randox sought operational help to increase its testing capacity and the government acted to provide access to equipment it needed. Randox was unable to increase the number of tests provided without additional specialist testing machines. Both the Department and Randox told us that they had expected government support would be required to acquire these testing machines. The contract noted that government support for Randox to access third-party items might be needed but did not specify testing machines. No documentary evidence was provided to us by the Department that showed it had a clear understanding that this support would be needed when it considered the contract price and awarded the contract. On 8 April 2020, Randox's managing director asked for ministerial help to "unblock" this issue of accessing specialist equipment. The Department arranged a telephone meeting on 9 April 2020 to discuss the help to be provided, which was attended by the then Minister for Life Sciences, Randox's managing director and Randox's consultant (the then MP for North Shropshire). The then Secretary of State and Number 10 officials contacted several universities on 10 April 2020 to request equipment loans for a number of suppliers, including Randox. In total Randox received 185 items of equipment on loan, most of which were returned by the end of July 2020 and the remainder by mid-November 2020, apart from two items still awaiting collection as at March 2022 (paragraphs 2.10, 2.13 and 2.14).

16 The Department contracted for service levels which were not met until September 2020, in part because of factors outside of Randox's control. This was because it took Randox longer than it expected to increase capacity, there was lower demand in the system than the Department had forecast and various logistical challenges arose which prevented Randox from operating at full capacity. Randox experienced delays in securing the additional equipment and consumables needed to increase capacity because of a highly competitive market caused by the pandemic. The Department told us that Randox agreed to extend the period that it would test beyond the contract's expected end in June 2020. It also agreed to test any sample sent to it rather than just its own kits and bore the financial costs of doing this. A report commissioned by the Department in June 2020 had given a positive assessment of Randox's technical capacity, but Randox was unable to increase capacity in line with the projections set out in that report. By the end of September 2020, it had increased capacity to 50,000 tests per day. This was the highest volume of any of the laboratories which government had contracted with to provide testing services, but still below the 60,000 tests per day contracted for. Throughout this period there were very few days on which the capacity Randox provided was fully utilised by the Department. Randox met its total contracted number of tests on 25 September 2020 (paragraphs 2.15, 2.16 and 2.18).

17 The Department did not specify key performance measures in the contract. The Department told us that between March and September 2020, the focus of the testing programme was on rapidly building additional capacity. From the start of the contract, it received a daily performance summary from Randox. Performance measures, such as turnaround times (that combine the journey time from swab collection with the laboratory process time) were not initially specified in the contract. From 1 July 2020, the NHS Test and Trace Service (NHST&T) introduced a target that 60% of tests sent from organisations, such as care homes, should be turned around within 48 hours of kit registration. Of the 2.285 million tests sent by organisations and processed by Randox between 1 July and 1 October 2020, 14% were turned around within 48 hours. The Department and UKHSA were unable to provide equivalent data for other types of tests during this period, but Randox told us that 78% of all samples were processed within 48 hours of arrival at its laboratory. Turnaround performance was affected by several issues outside Randox's control, such as erratic flow of tests to Randox, courier efficiency and transportation times, and several issues that were within NHST&T's control, such as poor forecasting of sample numbers and NHST&T processes to manage backlogs during peak demand. Randox told us that it engaged daily with NHST&T to support the resolution of these issues (paragraphs 2.12 and 2.19).

18 The Department did not disclose Randox's attendance at four ministerial meetings as it should have done in line with transparency requirements. We have reviewed documents on ministerial contacts with Randox provided to Parliament on 3 February 2022, as well as additional departmental documents. From the information provided, we have identified four ministerial meetings for which the Department did not record Randox's attendance on its quarterly transparency releases. Meeting minutes were kept for two of eight meetings on testing involving ministers and Randox that took place in 2020 and 2021. Some private correspondence exchanges between the then Secretary of State and the then MP for North Shropshire have recently been made available to the Department. The then Secretary of State told us he did not forward all of these messages to the Department at the time as they were not substantive discussions and so he was not required to do so. These messages were not inconsistent with what the then Secretary of State saw as his ministerial responsibility to drive progress, rapidly building testing capacity with Randox and other suppliers (paragraphs 2.22 to 2.25, and Figure 8).

Subsequent contracts

19 In October 2020, the Department awarded without competition a contract variation to Randox worth £328.3 million, almost two and a half times the value of the original contract. The Department told us that it considered Randox to be an essential part of providing testing capacity at this point and awarded the contract variation under emergency procurement rules on 2 October 2020, six months after the original contract award. The Permanent Secretary of the Cabinet Office expressed disappointment that the Department had made another direct award for the contract variation, as it had had enough time to organise and conclude a competitive contract process. The Department and Randox agreed a significant reduction in the price per test for the contract variation. The Department told us that the reduction was achieved through negotiation using better price benchmarking. Randox told us that it was because capital investment had been covered in the first contract, and as a result of higher volume purchasing and improvements in Randox's manufacturing and process management systems. Randox said it also reflected the removal from the contract of requirements to supply sample collection devices and IT infrastructure for test registration and reporting. Randox reached its maximum level of capacity in January 2021 (paragraphs 3.2 to 3.5 and 3.7).

20 The Department awarded two contracts to Randox from a framework agreement for testing services covering the period April 2021 to March 2022 and three contract variations to the first of those contracts. In February and March 2021, PHE appointed Randox as one of the suppliers on all four lots of its National Microbiology Framework. This was a multi-supplier framework agreement involving more than 100 suppliers, subject to a competitive process. Between March and December 2021, the Department then awarded two contracts to Randox from lot four of this framework agreement: one direct award and one through a mini competition, with a combined value of £112.5 million. It also awarded three variations to contracts awarded directly with a combined value of £196.7 million. For these contracts, the price per test was significantly lower than the price paid during Randox's first contract. Since the first contract, turnaround times for tests sent by organisations and processed by Randox have improved. For example, between 2 October 2020 and 7 December 2021, 62% of tests were turned around within 48 hours. In 2021, Randox's void rate (the percentage of samples tested that returned an inconclusive result) was 2.1%, compared with 2.5% in 2020. The average void rate across all laboratories with government contracts for testing services was 2.5% in 2021 and 2.9% in 2020 (paragraphs 3.6 and 3.8, and Figure 3).

21 After the NHS Test and Trace Service was established in May 2020, it strengthened governance and spend controls. These included creating an Investment Board to approve all major spending decisions, agreeing spending delegations with HM Treasury and establishing controls to ensure that contracts could not be signed or contract values exceeded without explicit consent by the relevant officials. All Randox contract awards from the variation agreed in October 2020 were subject to this governance process. The Department also stopped using direct awards allowed in emergency situations for testing contracts once the National Microbiology Framework was established in 2021 (paragraphs 1.19 and 3.6, and Figure 5).

22 The government did not publish details of contracts awarded to Randox during the pandemic within its target of 30 days. Our previous work has highlighted that details of most contracts awarded by government during the early months of the pandemic were not published within the 30-day target. It took 49 days to publish details of Randox's first testing contract for £132.4 million and 55 days to publish details of the subsequent £328.3 million variation. The Department told us that it has subsequently made efforts to comply with government transparency obligations. It met the 30-day target for all four contracts awarded to Randox since the beginning of July 2021 (paragraphs 1.20 and 1.21, and Figure 6).

Concluding remarks

23 The government acted quickly at the start of the pandemic to increase significantly the scale of testing capacity from a very low base and let its first testing contract with Randox in March 2020. The speed of action required at the beginning of the pandemic to build high-volume testing capacity necessitated the use of emergency procurement without competitive tendering. However, the Department did not document key decisions adequately, disclose ministerial meetings with Randox fully or keep full records of ministerial discussions involving Randox. The gaps in the audit trail mean that it is not possible to provide positive assurance in the normal way, but we have not seen any evidence that the government's contracts with Randox were awarded improperly.

24 Our previous reports on COVID-19-related procurement and those of Nigel Boardman have already recommended improvements necessary to ensure that even when emergency procurement is necessary and the priority is speed of action, an adequate audit trail is maintained to ensure transparency, accountability and robust decision-making. Government has already started to implement some of these improvements, and we will follow up progress.

Part One

Background

1.1 Procurement by public bodies in the UK, such as government departments and their agencies, NHS organisations and local authorities, is subject to the regime set out in the Public Contracts Regulations 2015 (the Regulations) and related statutory instruments. This part sets out some of the rules and regulations around public procurement, and background on the government's test and trace programme in response to the COVID-19 pandemic and on Randox Laboratories Ltd (Randox), one of the suppliers the government contracted with to support the delivery of this programme. It also provides a summary of the contracts awarded to Randox during the pandemic, procurement routes used, approval processes in place and publication of contract awards.

Government procurement

1.2 The Regulations seek to ensure that in procuring goods, services and works, public bodies adhere to fair and reasonable timetables and procedures as well as encouraging open competition. **Figure 1** sets out relevant aspects of these Regulations, including procuring with extreme urgency, using modifications to existing contracts, documenting procurement processes fully and ensuring that risks such as conflicts of interest are managed. This should take place within the wider requirement to ensure value for money in the use of public resources as set out in HM Treasury's guidance on handling public funds, *Managing Public Money*.⁴

1.3 Public bodies also make use of framework agreements, which are agreements between one or more contracting bodies and one or more suppliers. These agreements establish the terms governing contracts to be awarded during a given period regarding price and, where appropriate, the quantity envisaged. Suppliers expect to go through a competitive tendering process to be placed on a framework and can then be awarded contracts either directly (under the specific circumstances set out in the framework), through a mini competition between the suppliers on the framework, or both.

⁴ HM Treasury, *Managing Public Money*, May 2012.

Figure 1

Key aspects of the Public Contracts Regulations 2015

The Public Contracts Regulations 2015 contain provisions that allow public bodies to procure goods, services and works with extreme urgency, as was required during the COVID-19 pandemic

Regulation	Area	Details
24	Conflicts of interest	Awarding bodies should take appropriate measures to effectively prevent, identify and remedy conflicts of interest arising in the conduct of procurement procedures. This includes any situations where the financial, economic or other personal interests of those involved in the procedure, or those able to influence its outcome, might be perceived to compromise their impartiality and independence.
32	Use of the negotiated procedure without prior publication	Regulation 32(2)(c) allows public bodies to award contracts without competing or advertising the requirement so long as they can demonstrate that: there are genuine reasons for extreme urgency; the events that led to the need for extreme urgency were unforeseeable; it is impossible to comply with the usual timescales; and the situation is not attributable to the public body making the award.
72	Modifications of contracts during their term	Allows public bodies to make changes to contracts rather than going through a new procurement process in specific circumstances. For example, the modification does not alter the overall nature of the contract and any increase in value, whether from price or volume, does not exceed 50% of the original contract or framework agreement.
84	Reporting and documentation requirements	Awarding bodies should document the progress of all procurement procedures, ensuring sufficient documentation is kept justifying decisions taken at all stages of the process.

Source: National Audit Office review of the Public Contracts Regulations 2015

1.4 The expectations of civil servants responsible for government procurement and contracting are set out in the government's commercial functional standard. This states that those engaged in commercial activities shall ensure public service codes of conduct and ethics, and those of associated professions, are upheld. As well as achieving value for money and ensuring the delivery of high-quality public services, the main components of effective commercial activity in government are described as including:

- defining the requirements to meet the business need;
- procuring those goods, works and services from the supply market; and
- managing the subsequent contracts and suppliers to deliver maximum benefit to the organisation.⁵

5 HM Government, *Government Functional Standard GovS 008: Commercial*, September 2021.

1.5 In practice, most commercial activity is delegated to civil servants and undertaken in the name of the relevant Secretary of State or other responsible government minister. The Cabinet Office told us that ministers are encouraged to be involved in commercial activity. Along with civil servants, ministers must abide by public law and procurement regulations. Existing central government policy describes how to manage conflicts of interest, while guidance and codes of conduct outline principles and expected behaviour for ministers, special advisers, civil servants, board members and accounting officers.^{6,7} For example:

- the Civil Service Management Code states that civil servants must not misuse their official position or information acquired in the course of their official duties to further their private interests or those of others; and
- the Ministerial Code sets out standards of conduct expected of ministers and how they discharge their duties. Under the terms of the Ministerial Code, Ministers must ensure that no conflict arises, or could reasonably be perceived to arise, between their ministerial position and their private interests, financial or otherwise.

1.6 The government's procurement of goods and services during the COVID-19 pandemic took place in exceptional circumstances. In the months following the emergence of the pandemic in March 2020 in the UK, the government awarded billions of pounds of contracts using emergency procurement regulations. The government had to work at pace, with no experience of using emergency procurement on such a scale before. It developed its approach at the same time as procuring large quantities of goods and services quickly, frequently from suppliers it had not previously worked with, in the face of global competition. This procurement activity secured unprecedented volumes of essential supplies necessary to respond to the pandemic. However, as noted in our earlier report on COVID-19 procurement, the speed of procurement required also brought with it increased commercial and propriety risks, which we found had not always been adequately addressed.⁸

6 Cabinet Office, *Procurement Policy Note 04/21: Applying Exclusions in Public Procurement, Managing Conflicts of Interest and Whistleblowing*, May 2021.

7 Cabinet Office, *Ministerial Code*, August 2019; HM Government, *Civil Service Management Code*, November 2016; Cabinet Office, *Code of Conduct for Special Advisers*, December 2016; Cabinet Office, *Code of Conduct for Board Members of Public Bodies*, June 2016; HM Treasury, *Managing Public Money*, May 2021.

8 Comptroller and Auditor General, *Investigation into government procurement during the COVID-19 pandemic*, Session 2019–2021, HC 959, National Audit Office, November 2020.

COVID-19 testing

1.7 The development of high-volume testing for COVID-19 was a key part of the government's response to the pandemic. Testing was crucial to understanding infection prevalence and containing the spread of COVID-19. In early 2020, there was very limited testing capacity and infrastructure within the NHS, Public Health England (PHE) and the private sector. From March 2020, the Department of Health & Social Care (the Department), supported by other government bodies, began to significantly scale up testing capacity in England and launched a new NHS Test and Trace Service (NHST&T), which we reported on in December 2020 and June 2021.⁹ On 24 March 2021, the government announced that NHST&T would form part of the newly created UK Health Security Agency (UKHSA). UKHSA was formally established in April 2021 and became fully operational on 1 October 2021.

1.8 Our first report on the government's approach to test and trace in December 2020 found that the government had achieved significant increases in testing activity and set up a national contact tracing service from scratch. The report noted that NHST&T relied on contractors for many of its supplies, services and infrastructure.¹⁰ Our progress update in June 2021 found that by the end of March 2021, the Department had signed 964 contracts with 454 suppliers for activity related to NHST&T.¹¹ Of the £14.1 billion total contract value, testing accounted for £12.7 billion, or 90% of the total contract value.¹² Ten of the largest suppliers accounted for more than half (£7.3 billion) of the total contract value, with Randox being the fifth largest supplier in terms of value of contracts at that time.

COVID-19 testing procurement

1.9 The Department set up its testing procurement processes from March 2020. It established online portals and central mailboxes for receiving supplier offers and communicating with suppliers and set up high-priority entry routes that some supplier offers went through. In early April 2020, the government issued a "call to arms" to private testing companies to help it achieve the target of 100,000 tests per day by the end of April 2020. As part of this call to arms, ministers and officials engaged with pharmaceutical and diagnostic companies to support the test and trace system being created.

⁹ Comptroller and Auditor General, *The government's approach to test and trace in England – interim report*, Session 2019–2021, HC 1070, National Audit Office, December 2020; Comptroller and Auditor General, *Test and trace in England – progress update*, Session 2021–22, HC 295, National Audit Office, June 2021.

¹⁰ Comptroller and Auditor General, *The government's approach to test and trace in England – interim report*, Session 2019–2021, HC 1070, National Audit Office, December 2020.

¹¹ Comptroller and Auditor General, *Test and trace in England – progress update*, Session 2021–22, HC 295, National Audit Office, June 2021.

¹² Testing contracts include contracts for testing infrastructure, laboratories, new testing technology, and testing-related consumables, reagents and equipment.

1.10 In January 2022, UKHSA conducted a retrospective analysis of how supplier offers had been received and 'triaged'. Supplier offers received priority status if they involved a referral from a 'high-ranked individual' such as a minister's office, MP or the Prime Minister's Office, or for other reasons such as where there were shortages or bottlenecks in supply. For the period 28 May 2020 to 31 March 2021, UKHSA identified more than 300 suppliers considered to be high priority that had come through one of the following routes:

- Offers that went through a high-priority email mailbox set up in April 2020 (covidtestingprioritycontacts@dhsc.gov.uk).
- Correspondence labelled 'FASTTRACK', 'VIP', 'High priority', or 'Referral'.
- Suppliers involved in email correspondence with a 'VIP' individual – as signified by a ministerial private office, parliamentary or Number 10 email address.

1.11 UKHSA's analysis of how supplier offers were treated noted that: "The extent to which a 'priority' status gave an advantage to suppliers in terms of expediting through internal processes is unknown, due to the variables involved (size and complexity of contract, stage of the pandemic etc)". However, UKHSA does not consider that these routes represented a separate "priority lane" through which suppliers could circumvent the standard processes it put in place for testing procurement. UKHSA told us that all supplier offers had to undergo the same technical validation process and commercial evaluation once they were in the system.

1.12 From May 2020 to March 2021, 50 suppliers that went through high-priority entry routes were subsequently awarded contracts worth £6.0 billion, 76% of the £7.9 billion of testing contracts awarded over this period (**Figure 2**). Of the contracts awarded to these high-priority suppliers, £4.8 billion were awarded directly without competition. UKHSA's analysis of supplier entry routes does not cover all testing contracts because it excludes those awarded before 28 May 2020.

1.13 Officials told us they do not consider that Randox came through the test and trace procurement high-priority entry routes created early in the pandemic to deal with supplier referrals from 'high-ranked individuals' such as ministers, MPs and the Prime Minister's Office. The analysis that UKHSA conducted retrospectively in January 2022 to identify high-priority suppliers focused on activity from May 2020 to March 2021, two months after the award of Randox's first testing contract.

Figure 2

Value of testing contracts awarded to suppliers by entry route, May 2020 to March 2021

Fifty suppliers that went through high-priority entry routes were awarded contracts worth £6 billion

Supplier entry route	Number of suppliers awarded testing contracts	Value of testing contracts awarded (£bn)
Priority entry route	50	6.007
Standard/non-priority entry route	50	1.667
Entry route not identified	58	0.180
Total	158	7.854

Notes

- 1 The period covered by these data is 28 May 2020 to 31 March 2021.
- 2 Of the £6.007 billion of contracts awarded to priority entry route suppliers, £4.822 billion were direct awards without competition under Regulation 32(2)(c) of the Public Contracts Regulations, and the remaining £1.185 billion were other contract award types.

Source: National Audit Office review of UK Health Security Agency documents

Randox

1.14 Randox Laboratories Ltd (Randox) was established in 1982 and is a global diagnostic provider. It offers a range of goods and services, including undertaking clinical tests that analyse samples taken from the human body; developing diagnostic solutions for hospitals and laboratories; and developing, manufacturing, and marketing reagents and equipment for laboratory medicine. Prior to the pandemic, it employed more than 1,500 staff. It now employs around 3,300 staff. In February 2018, Randox entered into a strategic partnership with Qnostics Ltd to access its molecular range of products. Randox's two directors are also directors at Qnostics Ltd.

1.15 The former Member of Parliament for North Shropshire (from 1997 to 2021) acted as a paid consultant to Radox from August 2015 to November 2021. He declared in the Register of Members' Financial Interests that he was paid £8,333 a month for this work for a monthly commitment of 16 hours.¹³ He sought advice on taking up his Radox role from the Advisory Committee on Business Appointments (the Committee), given the former ministerial positions he held from 2010 to 2014. The Committee provided advice to the then MP for North Shropshire under the government's business appointment rules in July 2015. This included the condition that he was not permitted to lobby government for two years after his last day in ministerial office or draw on privileged information available to him during his time in government. The Committee noted in its published advice letter: "Although Radox will have engagement with government in pursuit of its business, you have informed us that it will not be part of your role with the company to be involved in such engagement".¹⁴

Contracts awarded to Radox during the pandemic

1.16 Between January 2020 and December 2021, the Department and PHE awarded 22 contracts to Radox or Qnostics Ltd with a maximum value of £776.9 million.

- Ten contracts to Radox for the provision of COVID-19 testing services with a combined value of £770.0 million (**Figure 3** on pages 22 to 24); eight of which were for the provision of COVID-19 testing kits and analysis of those tests (£769.1 million) and two for additional services to test samples further to better understand the virus (£0.9 million).
- Twelve contracts to Radox and Qnostics Ltd for the provision of COVID-19 testing goods with a combined value of £6.9 million (**Figure 4** on pages 25 and 26).

1.17 Three main procurement routes were used by the Department to award these contracts (Figures 3 and 4). Of the £776.9 million total, 60% was awarded directly without any competition using Regulation 32(2)(c), 25% was awarded using amendments to existing contracts using Regulation 72, and 15% was awarded using framework agreements.

¹³ UK Parliament, *Register of Members' Financial Interests*, 1 November 2021.

¹⁴ Advisory Committee on Business Appointments, *ACOPA approval letter: Rt Hon Owen Paterson, Consultant, Radox Laboratories*, July 2015.

Spending controls

1.18 For the period March to May 2020, prior to the establishment of NHST&T, the Department told us that the procedure to approve business cases for test and trace contracts involved approval from the Second Permanent Secretary of the Department, followed by HM Treasury approval for spending on contracts above £150 million in value. Cabinet Office commercial spend controls for contracts worth more than £10 million also applied to testing contracts. However, the Cabinet Office confirmed that before early April 2020, the Department did not submit testing contracts that were more than £10 million in value for commercial spend approval as required. Instead, it submitted retrospective spending cases in bulk for Cabinet Office approval, which the Department told us was to avoid overwhelming the approval system with the volume and speed of contract approvals needed. The Cabinet Office told us it did not approve any of these retrospective cases and that ministers supported this decision.

1.19 **Figure 5** on page 26 sets out the procedures to approve business cases for test and trace contract awards that officials told us the Department introduced after NHST&T was established in May 2020. This included an Investment Board to approve all major spending decisions, delegations agreed with HM Treasury and the Department, and controls to ensure that contracts could not be signed, or contract values exceeded, without explicit consent by the relevant officials.

Publication of contract details

1.20 Transparency through the publication of contract details is fundamental to good government procurement practice. This is particularly important in the case of direct awards, where the assurance provided by a competitive process is absent. As we have noted previously, we recognise the early months of the pandemic involved exceptional circumstances where government had to act at speed to respond to the scale of the emergency. However, meeting expected standards of transparency is vital to maintaining public trust and providing the necessary assurance that government adequately mitigated the increased risks from emergency procurement.¹⁵

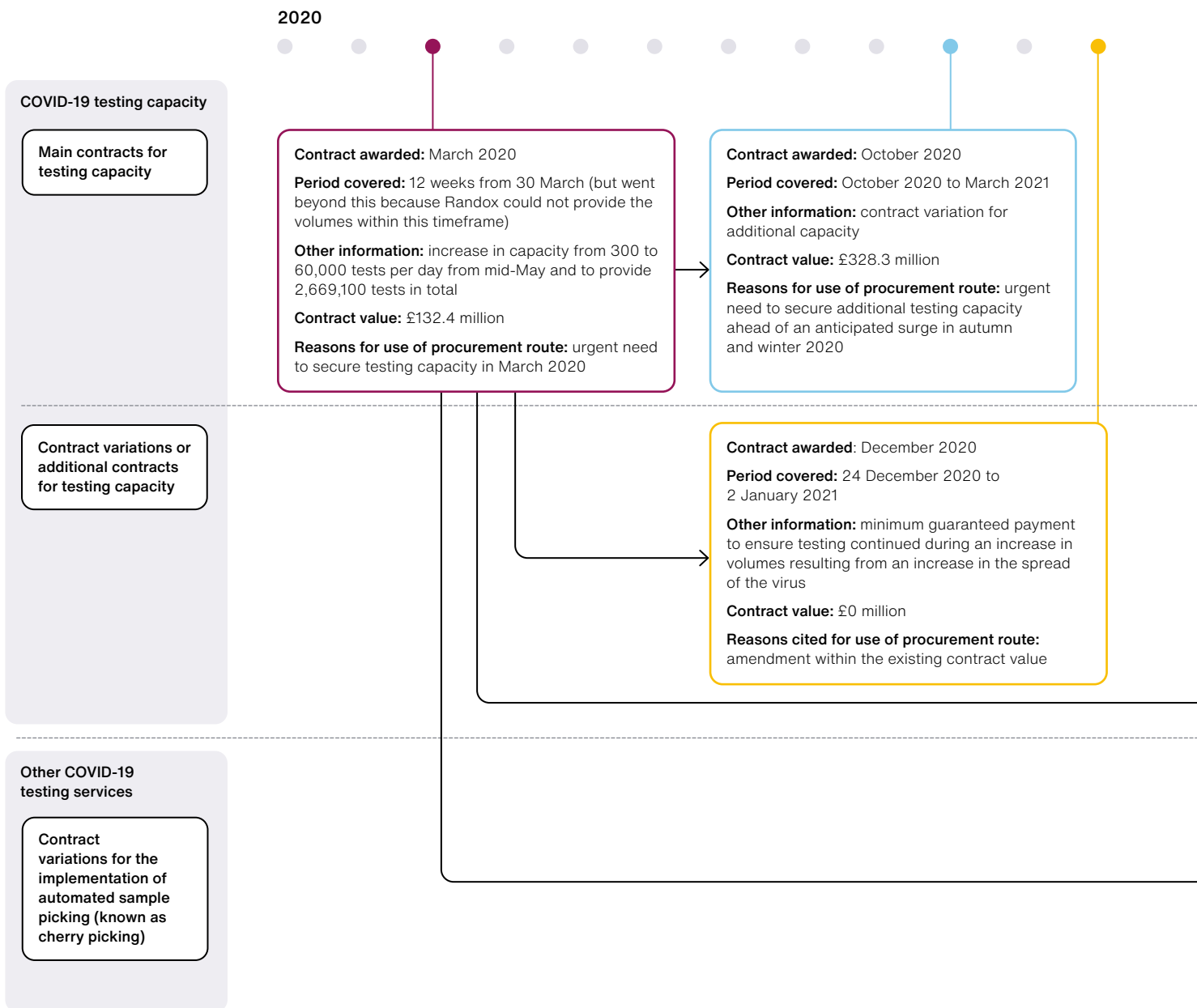
1.21 Public bodies have legal obligations under the Regulations to publish notices for supplies and services procurements above £122,976 within 30 days. Failure to do so can result in unfairness to other suppliers if it prevents or hinders their ability to challenge contract awards. Our previous work highlighted that between March and July 2020, most of the government's award notices were not published within 30 days. **Figure 6** on page 27 shows that most of the award notices for contracts or places on framework agreements awarded to Randox or Qnostics Ltd were also not published within the 30-day target. The Department told us that it has subsequently made efforts to comply with government transparency requirements.

¹⁵ Comptroller and Auditor General, *Investigation into government procurement during the COVID-19 pandemic*, Session 2019–2021, HC 959, National Audit Office, November 2020.

Figure 3

Government contracts awarded to Randox Laboratories Ltd for COVID-19 testing services, January 2020 to December 2021

Between January 2020 and December 2021, the Department of Health & Social Care (the Department) awarded 10 contracts to Randox Laboratories Ltd to provide COVID-19 testing services with a combined value of £770.0 million



Procurement route

- Direct awards under Regulation 32(2)(c)
- Mini-competition from a framework agreement³
- Contract variations under Regulation 32(2)(c)
- Contract variations under Regulation 72
- Call off (direct award) from a framework agreement²
- Contract variation

2021

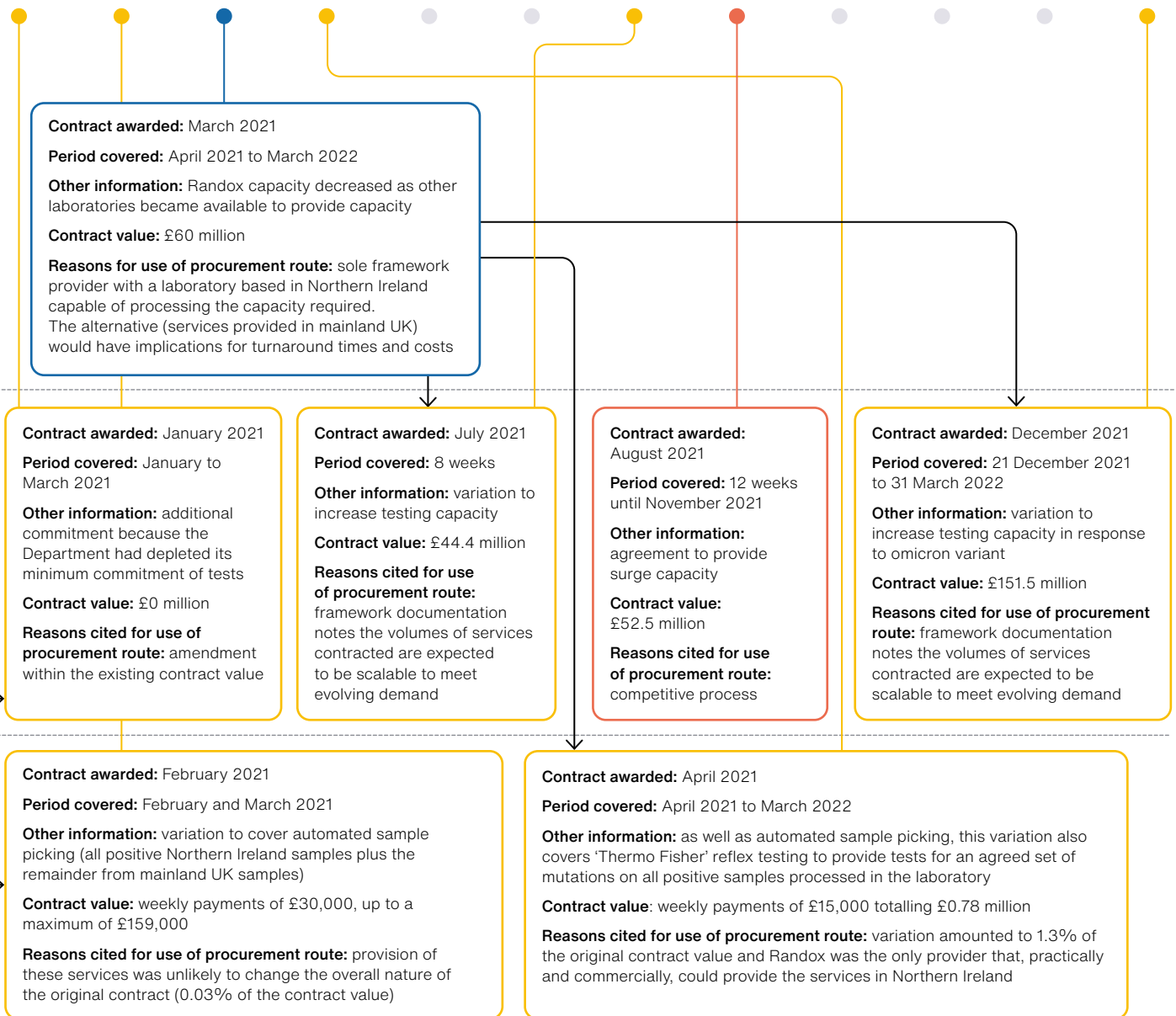


Figure 3 *continued*

Government contracts awarded to Randox Laboratories Ltd for COVID-19 testing services, January 2020 to December 2021

Notes

- 1 Regulation 32(2)(c) of the Public Contracts Regulations 2015 allows public bodies to negotiate with any supplier to provide their requirements without undergoing a formal competition under certain circumstances. Regulation 72 allows public bodies to make changes to contracts rather than going through a new procurement process for goods and services in specific circumstances. Framework agreements are agreements between one or more contracting bodies and one or more suppliers. Suppliers go through a competitive tendering process to be placed on the framework.
- 2 Lot four of Public Health England's National Microbiology Framework. The framework included a requirement, in accordance with the UK government's policy, to have a laboratory in each devolved administration and a requirement for the turnaround time from kit registration to result communication to be kept to the absolute minimum, with a target of less than 24 hours.
- 3 Lot four of the National Microbiology Framework. The Department received 16 bids from the 50 suppliers on this lot. It evaluated bidders on quality (based on responses around speed to mobilise, turnaround time and capacity) and on price. Eight suppliers, including Randox, were awarded contracts, with a combined value of £282.2 million.
- 4 All contract values exclude Value Added Tax.

Source: National Audit Office analysis of Department of Health & Social Care and UK Health Security Agency documents

Figure 4 Government contracts awarded to Randox Laboratories Ltd and Qnostics Ltd for the provision of COVID-19 testing goods, January 2020 to December 2021

The Department of Health & Social Care (the Department) and Public Health England awarded 12 contracts to Randox Laboratories Ltd and Qnostics Ltd to provide COVID-19 testing goods with a combined value of £6.9 million

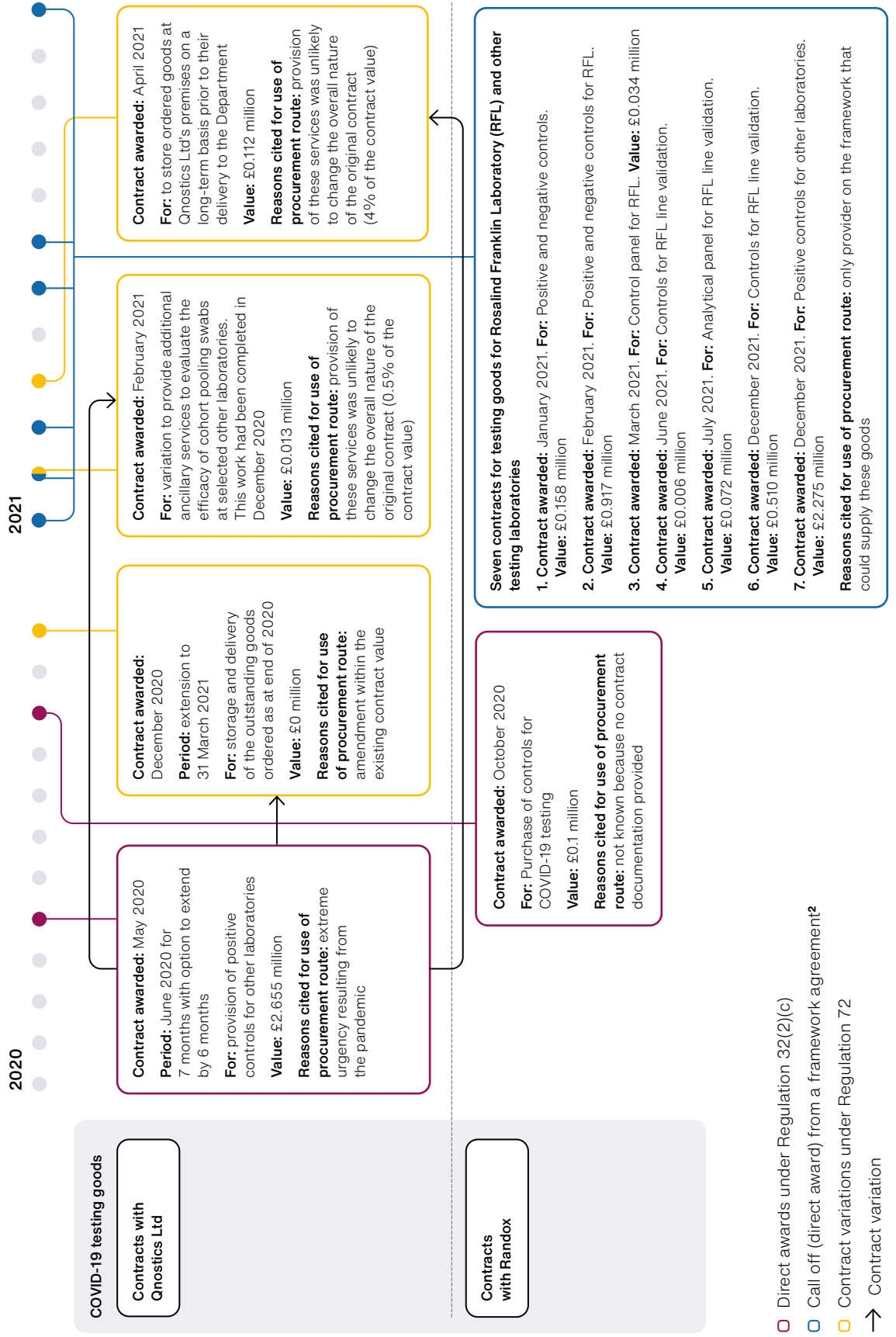


Figure 4 *continued*

Government contracts awarded to Randox Laboratories Ltd and Qnostics Ltd for the provision of COVID-19 testing goods, January 2020 to December 2021

Notes

- 1 COVID-19 testing goods are laboratory consumables needed for an end-to-end sample testing process.
- 2 NHS Supply Chain's framework agreement for pathology and point of care testing, associated equipment, instruments, consumables, accessories, and managed services. NHS Supply Chain told us that Randox passed all framework evaluation stages and that financial due diligence checks identified no concerns, and that it was one of 142 suppliers appointed to the framework. Qnostics Ltd was a subcontractor on all contracts awarded to Randox Laboratories Ltd from this framework agreement.
- 3 Regulation 32(2)(c) of the Public Contracts Regulations 2015 allows public bodies to negotiate with any supplier to provide their requirements without undergoing a formal competition in specific circumstances. Regulation 72 allows public bodies to make changes to contracts rather than going through a new procurement process for goods and services in specific circumstances. Framework agreements are agreements between one or more contracting bodies and one or more suppliers. Suppliers go through a competitive tendering process to be placed on the framework.
- 4 All contract values exclude Value Added Tax.

Source: National Audit Office analysis of Department of Health & Social Care and UK Health Security Agency documents

Figure 5

Procedures to approve business cases for test and trace contract awards

The NHS Test and Trace Service (NHST&T) had four approval processes depending on the value of contract

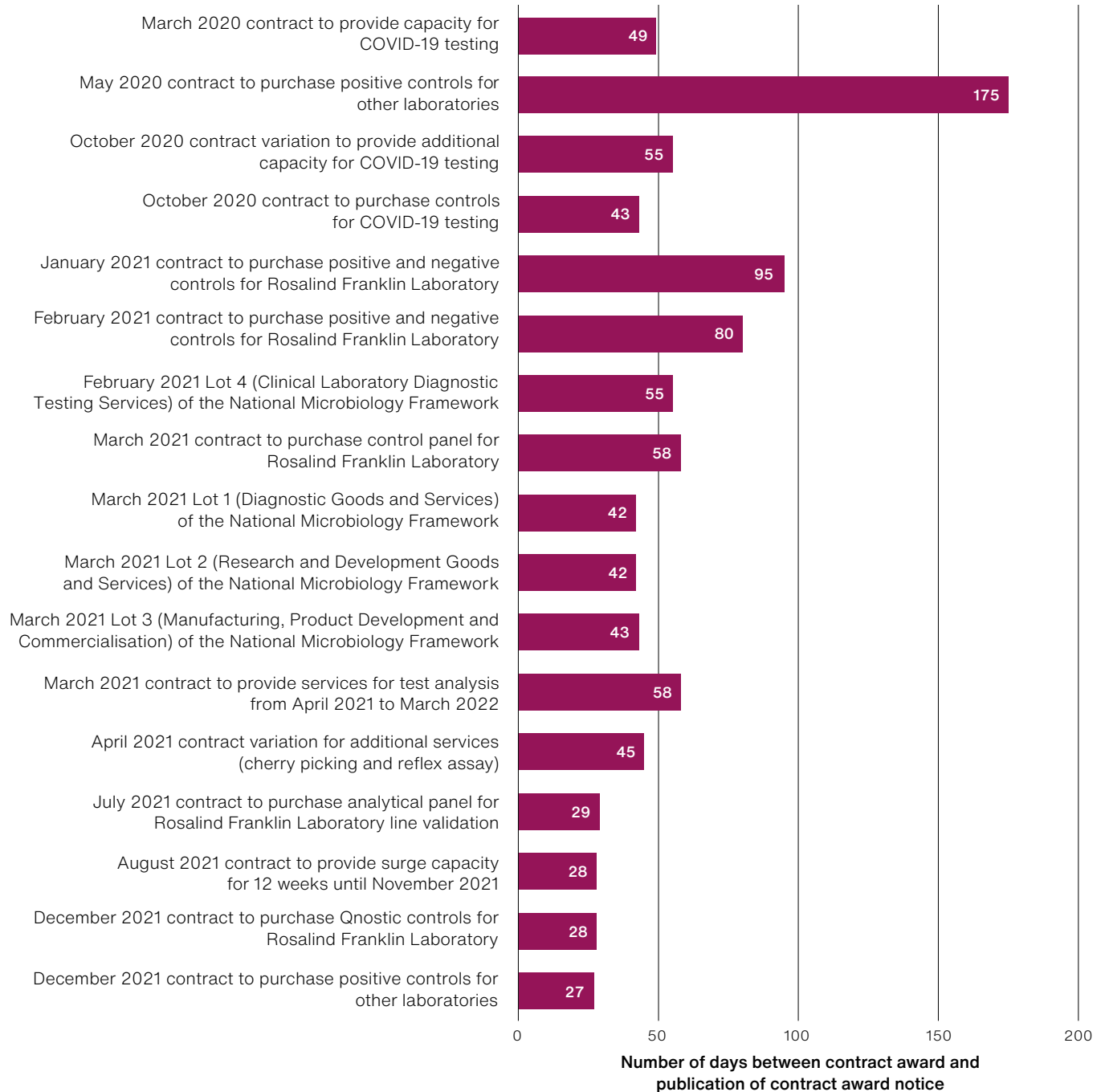
Value of contract	Approved by
£2 million or less	Budget holder, finance business partner and commercial lead within NHST&T.
More than £2 million but less than or equal to £25 million	Test and Trace Approval Board.
More than £25 million	Test and Trace Investment Board, chaired by Public Health England and containing representatives from the Department of Health & Social Care, the Cabinet Office, HM Treasury and the devolved administrations.
More than £150 million	Additional approval by the Cabinet Office, HM Treasury and Department of Health & Social Care Investment Committee.

Source: National Audit Office review of UK Health Security Agency documents

Figure 6

Number of days taken by awarding bodies to publish Randox Laboratories Ltd or Qnostics Ltd contract award notices, awarded between January 2020 and December 2021

Most contract award notices were not published within 30 days of the award, as legally required

**Note**

1 Some contract variations awarded to Randox were not published on Contracts Finder because transparency guidance does not require variations under Regulation 72 to be published.

Source: National Audit Office analysis of data published on Contracts Finder. Available at: www.gov.uk/contracts-finder

Part Two

The first contract awarded to Randox Laboratories Ltd for COVID-19 testing services

2.1 This part examines how the government awarded its first contract to Randox Laboratories Ltd (Randox) for COVID-19 testing services in March 2020. It covers how the government identified Randox as a supplier that could provide capacity for testing services, its award of the contract, and how it monitored Randox's performance in fulfilling its contractual obligations.

Identification of Randox as a supplier of testing capacity

2.2 Prior to the COVID-19 pandemic, Randox was on several NHS framework agreements for diagnostic goods and services. It had been awarded contracts by a range of public bodies, local authorities and universities, with values typically less than £100,000, consistent with the smaller demand for testing services before the pandemic. From January 2020, the Department of Health & Social Care (the Department) started to identify and receive direct approaches from private sector suppliers that could provide testing services and goods needed as part of the government's pandemic response. Prior to this, testing was largely undertaken by academic and local NHS organisations. The Department assessed that these organisations would not be able to increase service levels quickly enough to meet the government's objective to increase testing to 100,000 tests per day by the end of April 2020. The government consequently sought to buy as much testing capacity as possible. The number of approaches from private testing suppliers increased substantially after the government issued a "call to arms" to companies in early April 2020 to support its efforts to increase testing capacity, and the Department set up online portals to capture offers and central mailboxes to manage communications with potential suppliers.

2.3 On 26 January 2020, the then MP for North Shropshire, who was also a paid consultant to Randox, emailed the then Secretary of State for Health and Social Care at his private email address. He asked the then Secretary of State to contact Randox about its proposal to develop a diagnostic test for COVID-19. The same day, the then Secretary of State emailed Randox's managing director from his official email account, asking for further detail about its proposal. He then asked his ministerial office to forward Randox's response to the Chief Medical Officer's office for a view. On 29 January 2020, the Chief Medical Officer's office replied that it was dealing with Randox's proposal alongside others received from several groups and companies. It noted that there was not enough information at that time to make an initial assessment on Randox's specific proposal.

2.4 Following Randox's initial approach, on 6 February 2020, the then Secretary of State's ministerial office sent emails to a senior Public Health England (PHE) official asking whether PHE had been in touch with Randox, noting: "SofS [Secretary of State] keeps asking me about this". Randox told us that from 10 February 2020 it engaged with PHE on its proposal but felt that the response lacked urgency given the context of the pandemic and that it needed to alert ministers accordingly. On 18, 25 and 27 February 2020, the then MP for North Shropshire sent WhatsApp messages to the then Secretary of State, raising concerns about how PHE was handling Randox's proposal and asking him to chase the matter. The then Secretary of State forwarded two of these WhatsApp messages to his civil service team with his own comments: "could you please ensure PHE get on this" and "I am very worried about this. 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". The then Secretary of State told us he saw it as a key part of his ministerial responsibilities to push progress in this way in order to build the unprecedented testing capacity required. On 1 March 2020, PHE reported to the then Secretary of State's ministerial office that Randox's proposal had been identified through technical 'horizon scanning' and was being considered among those from other companies, with the most promising being prioritised for testing. PHE confirmed that Randox's proposal had been prioritised alongside others, and it subsequently approved Randox's test.

2.5 On 17 March 2020, Randox attended a testing summit at Number 10 also attended by the Prime Minister, the then Secretary of State and several other companies. Officials told us that on 18 March 2020 a meeting was held with the then Minister for Life Sciences,¹⁶ government officials responsible for testing services, a representative of the Prime Minister's Office, Randox and another supplier. The Department was unable to provide documents recording what was discussed at this meeting or any agreements made. However, officials who had attended told us the meeting discussed concerns that it would not be possible to increase existing NHS and PHE testing services quickly enough.

16 The full ministerial title is the Minister for Technology, Innovation and Life Sciences.

2.6 The Department told us that following the 18 March 2020 meeting, it began discussions with Randox about how the company could increase its capacity to deliver testing to support the government's testing programme. This led to contractual negotiations with the company to establish the number of tests that Randox could deliver per day, the cost per test and any support that it might need to fulfil its contractual commitments. The Department was unable to provide us with supporting documentation relating to these initial discussions and negotiations. The then Secretary of State and the then Minister for Life Sciences told us that they were not involved in these negotiations and that these were handled by officials. The then MP for North Shropshire (and then consultant to Randox) also told us he did not participate in negotiations relating to contracts. On 24 March 2020, the then Minister for Life Sciences was asked by civil servants to formally approve the following:

- “The commitment to order a minimum quantity of 2.7m tests @£49.60 each (£133,000,000 total).”¹⁷
- “A payment on account of £50,000,000 as security for their commitment.”
- “An upfront payment of £5,000,000 to contribute towards capex [capital expenditure].”

2.7 The then Minister for Life Sciences gave his “authorisation to proceed” on the basis that this met the expectations of government policy. However, he told us he did not consider he was being asked to formally approve the contract itself and that civil servants were responsible for then approving the contract. Officials then consulted with the Departmental Accounting Officer on the value for money of the proposed contract with Randox. A deputy director in the Department's commercial team signed the contract on the Department's behalf on 30 March 2020.

Award of Randox's first COVID-19 testing contract

2.8 On 30 March 2020, the Department awarded Randox a £132.4 million contract for the provision of COVID-19 testing services. The contract was for the provision of 2,669,100 tests and covered a 12-week period from the end of March 2020 to the end of June 2020. Randox was contracted to complete 300 tests per day at the contract's start, increasing capacity to 60,000 tests per day from mid-May 2020.

¹⁷ The contract was for 2,669,100 tests at £49.60, with a value totalling £132,387,360.

2.9 The contract was directly awarded without competition under emergency procurement procedures due to the urgency of the pandemic response. The Department told us that it 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. Prior to the direct award of this contract, the Department had expressed concerns about Randox's financial position because the value of the contract was larger than the company's annual turnover. To mitigate this, the Department made an upfront payment of £55 million (£50 million as security for Randox's commitment to supply the tests and £5 million towards the capital expenditure commitment Randox made to suppliers for additional laboratory hardware), to be recovered over the life of the contract.

2.10 The unit price specified in the contract was £49.60 per test processed. The Department told us that it had very limited information on which to compare the price offered by Randox during negotiations prior to the award of this contract because this type of testing was only being carried out on a small scale. It did not conduct a benchmarking exercise prior to the contract's award or consider any information on supplier profit margins. However, the Department prepared a limited market price comparison using price information from one other supplier at that time. This indicated that Randox's unit price was higher than that of the other company, although the Department has clarified that this was not a like-for-like comparison. The comparison noted that Randox's bid offered an end-to-end testing service and was not expected to involve any additional costs. In contrast, the comparator company's price was for testing reagents only, and it would need government support to secure testing machines, buildings and additional staff. The contract with Randox included a clause indicating that government may be required to offer support to procure "third-party items" such as reagents from three weeks after the contract began but did not make specific reference to providing testing machines. The Department and Randox told us, however, that the potential need to support Randox and other suppliers to secure testing machines was known at the time of the contract award but have been unable to provide evidence to demonstrate this or how this was taken into account in determining unit prices.

2.11 Randox told us that the original contract was for a limited duration and number of tests, with no guarantee of an extension. It felt that it was commercially prudent therefore that capital costs should be covered within that contract, and these were reflected in the price. The UK Health Security Agency (UKHSA) let four testing services contracts in May and June 2020 which it said provided a partial price comparator to Randox's contract in terms of cost structure. Randox's unit price was lower than the prices in three of these contracts and higher than the other one. Government's contracts with these providers were for significantly smaller volumes of tests than Randox's, with the value of these contracts ranging from £3.4 million to £28 million.

Contractual performance

2.12 To deliver this contract, the Department knew that Randox would have to build additional laboratory space, recruit and train additional staff, purchase equipment to deliver this level of testing and buy consumables to run the forecast test volumes. The Department told us this was the case for many of the suppliers to which it awarded contracts for testing services, as no facility in the UK was at that time equipped to handle the volume of testing required. Randox told us that it spent £70 million on building additional laboratory space and other set-up costs including setting up new packing lines for the delivery of the COVID-19 testing kits and new manufacturing lines for the formulation of reagents. The Department told us that between March and September 2020, the focus of the testing programme was on rapidly building additional capacity and that Randox provided daily performance reports from March 2020. Randox told us that in addition to providing contracted testing services and goods, it also provided free advice to the testing programme to support the development of a national testing infrastructure.

2.13 Randox was unable to increase the number of tests it was providing without additional specialist equipment. On 1 April 2020, two days after the contract was signed, the then Secretary of State's ministerial office contacted several senior officials to ask if Randox had been given a remit to remove laboratory equipment from two Northern Ireland universities and another facility. A senior official from the Office for Life Sciences replied to confirm that "no one has given anyone permission to remove anything against the wishes of NI and the universities involved". Randox told us that it had not attempted to remove laboratory equipment from any university or other facility. It said that unused equipment was located in UK universities and that it provided a schedule of equipment held at universities to the Department and the Cabinet Office, so they could make arrangements to support the loan of equipment to the UK government.

2.14 Randox then sought ministerial help to access equipment it needed to increase its testing capacity, as it told us it had made little progress after engaging with officials. On 8 April 2020, in a government meeting with ministers, officials and other suppliers, Randox asked for ministerial help to “unblock” this issue. The Department arranged a telephone meeting on 9 April 2020 to discuss the help to be provided, which was attended by the then Minister for Life Sciences, Randox’s managing director and Randox’s consultant (the then MP for North Shropshire). The then Secretary of State wrote to several universities on 10 April 2020 to request equipment loans for a number of suppliers, including Randox. This was followed up by the Prime Minister’s Office calling university vice-chancellors to support the request. In total, Randox received 185 items of equipment on loan. These included four working ribonucleic acid (RNA) extraction systems, which were the most critical items for Randox (the company said it had 26 RNA extraction systems on order at the time, but that the supply of this equipment from manufacturers was controlled by the Department due to global shortages). Randox told us that less than 0.5% of samples it processed were on loaned equipment. It also told us that most of the loaned equipment was returned by the end of July 2020 and all loaned equipment was returned by mid-November 2020, apart from two items still awaiting collection as at March 2022.

2.15 By late April 2020, the Department was in discussions with HM Treasury about further funding for COVID-19 testing. As part of these discussions, the Department noted that Randox was not able to provide the daily level of service envisaged because it was unable to scale up its operations to the extent required – in part because of the problems accessing the specialist machines. Randox also experienced delays in securing the consumables needed to increase capacity because of a highly competitive market caused by the pandemic. At that point, the Department expected to spend £60 million less than it had originally anticipated on the £132.4 million contract because it had not agreed to extend the time period of the contract.

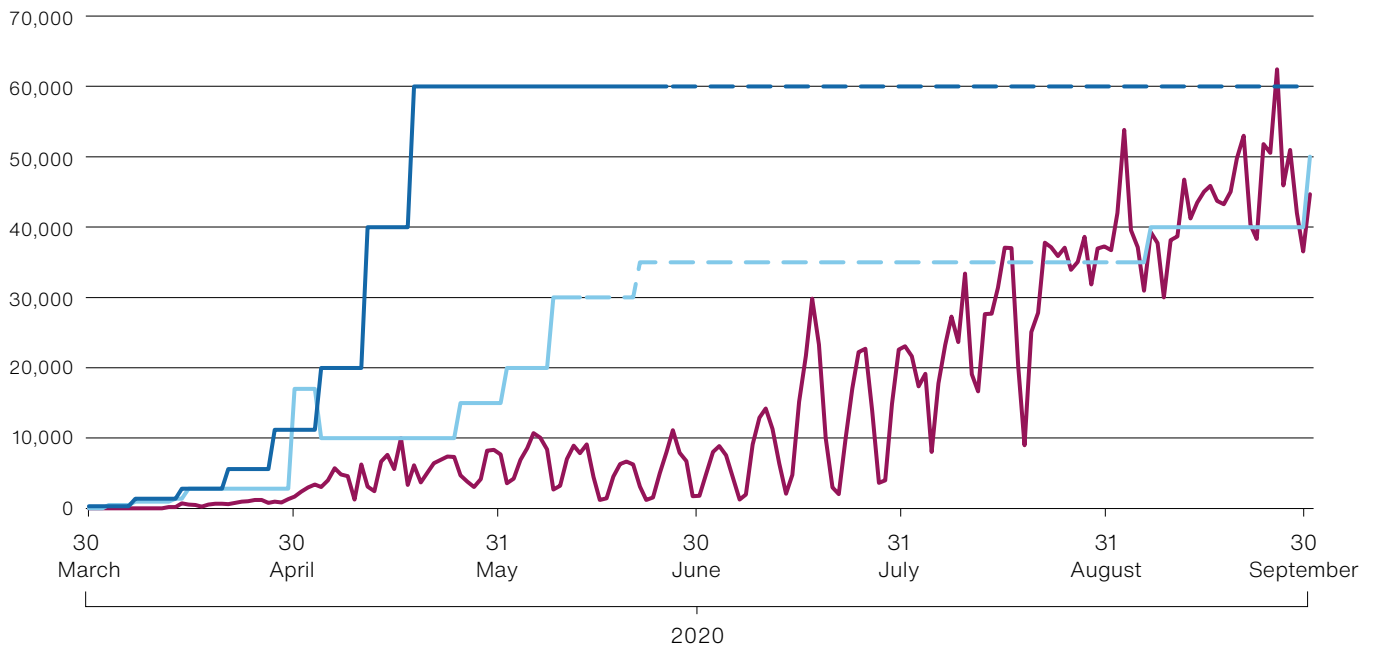
2.16 By early June 2020, Randox had increased capacity to 30,000 tests a day (**Figure 7** overleaf), but throughout this period there were very few days where its capacity was fully utilised by the Department. This was because the number of tests it was receiving was affected by lower demand in the system than the Department had forecast and there were logistical challenges in delivering samples to Randox quickly. These factors were outside of Randox’s control.

Figure 7

Contractual requirement for daily number of tests, estimated capacity, and the number of daily tests Randox Laboratories Ltd carried out, March 2020 to September 2020

Randox Laboratories Ltd did not provide the contracted number of tests until September 2020, three months after the contract was due to end

Number of tests per day



- Number of tests carried out
- Capacity
- - - Estimated capacity
- Contractual requirement
- • • Assumed contractual requirement

Notes

- 1 The Department of Health & Social Care’s (the Department’s) contract with Randox Laboratories Ltd included a schedule indicating the number of tests to be delivered daily up to the end of June 2020. This figure assumes that the June 2020 requirement of 60,000 tests a day continued beyond that point.
- 2 Capacity figures up to 10 June 2020 are estimates based on a graphic provided by the Department. The Department was unable to provide the data supporting the graphic. The only capacity data the Department provided between 10 June 2020 and 1 September 2020 was a capacity of 35,000 on 21 June 2020. We have assumed that the increase to 35,000 occurred on 21 June 2020 and that it then remained constant until 1 September 2020.

Source: National Audit Office analysis of UK Health Security Agency and Randox Laboratories Ltd data

2.17 On 15 July 2020, the Department instructed care homes and the public to immediately stop using sample collection kits supplied by Randox, following concerns that the swabs Randox was using in these sample collection kits were not sterile. Randox had purchased these swabs from another company not based in the UK. This was followed by a recall of 740,000 Randox test kits on 7 August 2020. The kits were removed from the market, and Randox agreed to replace 1.7 million kits that covered the recalled kits that had not been processed and ones it had in stock. This agreement was covered in the contract variation awarded to Randox in October 2020. PHE carried out a risk assessment of the public health risks of using these swabs, noting that based on the information available at that time, it assessed the risk of harm to public health to be very low. It did not identify any actual or potential harm that required public health action in those who had a Randox sampling kit.

2.18 The Department told us that Randox agreed to extend the period that it would test beyond the contract's expected end in June 2020 to reach the volumes set out in the contract. It also agreed to test any sample sent to it rather than just its own kits and bore the financial costs of doing this. The Department continued to use these services for some months without amending the contract. In June 2020 the Department commissioned a consultant to review Randox's potential capacity. The consultant reported observations that Randox staff were passionate about delivering the tests and improving processes, that Randox achieved "cycle times as fast as the speeds targeted in other labs", that investment in developing technologies had increased sustainability, and that there was opportunity in some areas to optimise processes further. It also reported that Randox's capacity was around 35,000 tests per day with a plan to reach 60,000 tests per day by early July 2020. Randox's capacity did not increase above 35,000 tests per day until September 2020, when it reached 50,000 tests per day (the highest volume of any of the laboratories government had contracted with to provide testing services). On 26 September 2020, Randox met the contracted commitment to provide almost 2.7 million tests. The Department paid Randox a total of £128.4 million for testing services provided under this contract, compared with an expected contract value of £132.4 million.

2.19 Key performance measures were not specified in the contract and were not initially measured. The NHS Test and Trace Service (NHST&T) began monitoring turnaround times, that combine the journey time from swab collection with the laboratory process time, for tests sent from organisations such as care homes from 1 July 2020. Its target was for 60% of tests to be turned around within 48 hours. Of the 2.285 million tests sent from organisations and processed by Randox between 1 July and 1 October 2020, 14% were turned around within 48 hours of kit registration. The Department and UKHSA were unable to provide equivalent data for other types of tests during this period, but Randox told us that 78% of all samples were processed within 48 hours of arrival at its laboratory. Turnaround performance was affected by several issues outside of Randox's control, such as erratic flow of tests to Randox, courier efficiency and transportation times, and several issues that were within NHST&T's control, such as poor sample forecast accuracy and processes implemented by NHST&T during peak demand to manage backlogs. Randox told us it engaged daily with NHST&T to support the resolution of these issues.

Transparency requirements

Ministerial contacts and meetings with Randox

2.20 Ministers have been involved in discussions with private testing companies since the start of the pandemic. The ministers involved at the time told us that they saw it as an integral part of their role to encourage efforts to increase testing capacity. This included working with suppliers to resolve any difficulties they faced in developing tests and providing their testing services.

2.21 To meet transparency rules on lobbying, departments are required to publish quarterly releases on gifts, hospitality and external meetings of ministers and permanent secretaries. Other transparency obligations on ministers and officials are set out in their respective codes of conduct. For example, the Ministerial Code notes that if ministers find themselves discussing official business with an external body or individual without a civil servant present, any “significant content” should be reported back to the department as soon as possible.¹⁸ The Cabinet Secretary has said publicly that the underpinning principle regarding any ministerial discussions with external parties is that “government business is government business however it is conducted and by whatever means of communication”.¹⁹ The Committee on Standards in Public Life noted that under this principle, any lobbying of ministers through informal channels or alternative technologies, such as WhatsApp or Zoom, should be reported to civil servants.²⁰

2.22 We have reviewed documents provided by the Department detailing correspondence between Randox and ministers, special advisers, MPs and civil servants from January 2020 to March 2021. The documents included emails, screenshots of WhatsApp messages and internal government briefings. This documentation is wider than the set of ‘Humble Address’ material provided to Parliament on 3 February 2022, in response to a parliamentary motion passed on 17 November 2021.

¹⁸ Cabinet Office, *Ministerial Code*, August 2019, paragraph 8.14.

¹⁹ Public Administration and Constitutional Affairs Committee, *Oral evidence: The work of the Cabinet Office*, Session 2019–2021, HC 118, 26 April 2021, Q 754.

²⁰ Committee on Standards in Public Life, *Upholding Standards in Public Life*, November 2021.

2.23 Some of the correspondence contacts between the then Secretary of State and Randox's consultant (the then MP for North Shropshire) about Randox took place using private email or WhatsApp accounts. Both the Cabinet Office and the Information Commissioner's Office (ICO) have issued guidance on the use of private email acknowledging that it may sometimes be necessary to use private messages to discuss official business.²¹ The Cabinet Office guidance states that: "The originator or recipient of a communication should consider whether the information contained in it is substantive discussions or decisions generated in the course of conducting government business and, if so, take steps to ensure the relevant information is accessible (e.g. by copying it to a government email address)". The ICO told us that where private messages are used, public authorities need to manage potential additional associated risks, such as the risk of not preserving official records of decision making. Its guidance to public authorities states that: "It is accepted, that in certain circumstances, it may be necessary to use private email for public authority business. There should be a [records management] policy which clearly states that in such cases an authority email address must be copied in to ensure the completeness of the authority's records".

2.24 We have seen eight exchanges between the then Secretary of State and Randox's consultant (the then MP for North Shropshire) using private email or WhatsApp messages between January and October 2020. Two of these messages were subsequently forwarded to the then Secretary of State's ministerial office to follow up and none were copied into an official address at the time. The then Secretary of State told us he did not discuss anything substantive in the messages not forwarded at the time and so did not need to inform the Department of their content. The messages not forwarded at the time were kept by him and made available to Parliament as part of the publication of the Humble Address material in February 2022. These messages were not inconsistent with what the then Secretary of State saw as his ministerial responsibility to drive progress, rapidly building testing capacity with Randox and other suppliers. The ICO has been conducting an investigation on the use of private correspondence channels at the Department since July 2021 and has yet to report on this investigation.

²¹ Cabinet Office, *Guidance to departments on the use of private email*, June 2013; Information Commissioner's Office, *Official information held in private email accounts*, 2017. The Cabinet Office guidance notes that it should be read in conjunction with the ICO's guidance.

2.25 Since the start of the pandemic, the government has reported four meetings on COVID-19 testing involving ministers and Randox on its quarterly releases of ministers' meetings with external organisations (**Figure 8**). Three of these were large meetings also involving other suppliers and organisations. The other reported meeting was a telephone call between the then Minister for Life Sciences, Randox, its consultant (the then MP for North Shropshire) and civil servants on 9 April 2020 to discuss government help to access equipment. From departmental documents and interviews, we have identified four other instances of ministerial meetings involving Randox where the Department did not record Randox's attendance on its quarterly transparency releases:

- an 18 March 2020 meeting with the then Minister for Life Sciences, Randox and another supplier;
- an 8 April 2020 Testing Taskforce meeting where Randox first asked for ministerial help to access equipment;
- a telephone call on 13 May 2020 with the then Minister for Life Sciences and Randox on Randox's backlog in processing tests and how they could be best processed; and
- an online meeting on 7 August 2020 between the then Minister for Life Sciences and Randox about the potential recall of Randox's test kits on safety grounds.

The Department provided minutes or records of meeting discussions for two meetings: the 8 April 2020 Testing Taskforce meeting and the 9 April 2020 call between the then Minister for Life Sciences, Randox and its consultant (the then MP for North Shropshire).

2.26 Departmental documents also indicate other instances where arrangements were made for one-to-one telephone calls between ministers and Randox or its consultant (the then MP for North Shropshire):

- a call between the then Secretary of State and the then MP for North Shropshire on or before 26 January 2020;
- a call between the then Minister for Life Sciences and Randox's managing director on 25 March 2020;
- a call between the then Minister for Life Sciences and Randox's managing director on 3 or 4 April 2020; and
- a call between the then Minister for Life Sciences and the then MP for North Shropshire between 11 and 13 May 2020.

The Department could not confirm whether these calls took place or provide notes of any of these calls (which would have been required if any substantive discussions had taken place).

Figure 8

Ministerial meetings on testing with Randox Laboratories Ltd

Government ministers met with Randox Laboratories Ltd (Randox) several times in 2020 and 2021 to discuss testing

Date	Meeting details	Participants	Reported in government transparency releases	Record taken of meeting discussion
17 March 2020	Roundtable on mass testing for COVID-19, Prime Minister's Office.	Prime Minister, Secretary of State for Health and Social Care, Minister for Life Sciences, Randox, other suppliers, civil servants.	Yes.	None provided.
18 March 2020	Meeting to discuss COVID-19 testing capacity, Department of Health & Social Care (the Department).	Minister for Life Sciences, Randox, one other supplier, civil servants.	Yes, but Randox not reported among participants.	None provided.
8 April 2020	Meeting of COVID-19 Testing Taskforce, the Department.	Secretary of State for Health and Social Care, Minister for Life Sciences, Randox, other suppliers and organisations, civil servants.	Yes, but Randox not reported among participants.	Yes.
9 April 2020	Telephone call between the Department and Randox, to discuss Randox's request for government help to access equipment.	Minister for Life Sciences, Randox, MP for North Shropshire (paid consultant to Randox), civil servants.	Yes.	Yes.
13 May 2020	Telephone call between the Department and Randox, to discuss Randox's backlog in processing tests.	Minister for Life Sciences, Randox, civil servants.	No.	None provided.
7 August 2020	Online meeting between the Department and Randox, to discuss the potential recall of Randox's test kits on safety grounds.	Minister for Life Sciences, Randox, civil servants.	No.	None provided.
29 April 2021	Meeting to discuss laboratory testing provision for international arrivals, the Department.	Minister for Life Sciences, Randox, other suppliers and organisations.	Yes.	None provided.
11 May 2021	Meeting to discuss upcoming legislation to validate COVID-19 tests on the market, the Department.	Minister for Life Sciences, Randox, other suppliers and organisations.	Yes.	None provided.

Notes

- 1 The Ministerial Code sets out the requirement for government departments to publish details of ministers' meetings with external organisations on a quarterly basis.
- 2 Meeting participants in this table are those office-holders who were in post at the time of the meeting.

Source: National Audit Office analysis of government transparency releases and Department of Health & Social Care documents

Documentation of contract decision-making

2.27 For Radox's first testing contract, we requested key evidence and documents relating to the contract procurement and decision-making process. The Department had to review several key government officials' email accounts because supporting documentation had not been saved in the Department's established systems. However, despite its review, it was still unable to provide information on important parts of the emergency procurement process, such as detailed due diligence reports and detailed contractual negotiations leading to the first contract award. The Department could not explain why important information was not saved or maintained for the evidence trail to support decision-making on this contract. Our previous report on government procurement during the COVID-19 pandemic found similar issues with insufficient documentation of key procurement decisions.²²

2.28 On HM Treasury and Cabinet Office approvals, the Department provided evidence that it shared information on the Radox contract with HM Treasury. As the contract's value was less than the Department's delegated spending limit of £150 million, the spending involved did not require Treasury approval. The Cabinet Office told us the Department did not seek commercial spending approval for the Radox contract before it was awarded, as it was required to do. The Department did later submit it for approval among a list of bulk retrospective spend control cases, but the Cabinet Office did not provide approval for any of these. The Department and the Cabinet Office told us that ministers were aware of this decision and supported it.

2.29 There was no identification of potential conflicts of interest relating to the contract. The records of the procurement process state that consideration of conflicts of interest was deemed "not applicable" because the contract was a direct award under Regulation 32(2)(c) of the Public Contracts Regulations 2015 (the Regulations). This reflects an incorrect understanding of the relevant Regulations, as potential conflicts of interest still need to be considered where contracts are directly awarded.

2.30 UKHSA provided documentation supporting the procurement decisions taken by NHST&T and UKHSA in the award of contracts to Radox after September 2020.

²² Comptroller and Auditor General, *Investigation into government procurement during the COVID-19 pandemic*, Session 2019–2021, HC 959, National Audit Office, November 2020.

Part Three

Subsequent contracts awarded to Randox Laboratories Ltd

3.1 This part sets out the remaining contracts awarded to Randox Laboratories Ltd (Randox) for COVID-19 testing services and goods, including the £328.3 million variation to Randox's first £132.4 million testing contract. It covers the contracts and contract variations, costs and performance.

Further contracts for COVID-19 testing services

Award of the £328.3 million contract variation and further testing services contracts

3.2 On 2 October 2020, the Department of Health & Social Care (the Department) directly awarded Randox a £328.3 million variation to its first testing contract. The value of the contract variation was almost two and a half times the value of the original £132.4 million contract. The Department told us that it considered Randox to be an essential part of providing testing capacity at this point. The variation was awarded days after Randox met the contracted volume of tests in September 2020, which was three months later than originally anticipated. It was also less than two months after the recall of 740,000 Randox-supplied testing kits in August 2020. Under the Public Contracts Regulations 2015 (the Regulations), the government may consider a supplier's past performance in decisions on whether to make a direct contract award to that supplier or the details of that award. The variation included several additions to the contract which the Department told us were in response to issues it had experienced with the first contract. These included capacity milestones, a mechanism to deal with under-utilisation of test capacity, and increased liabilities for Randox if contract milestones were not met. The Department awarded Randox three further variations to its first testing contract with a combined value of £0.159 million (see Figure 3 on pages 22 to 24).

3.3 In the lead-up to the award of the October 2020 contract variation, the Cabinet Office advised the Department to negotiate a lower price. During discussions on the Cabinet Office's approval for the contract spend, the then Minister for Efficiency and Transformation said he was "very worried" about pricing and that given the volumes involved, the government was "paying dramatically over the odds". As one of the conditions of Cabinet Office approval, the Department was asked to carry out international price benchmarking within a month, although the Department could not confirm if that was done. The Department and Randox agreed a significant reduction in the price per test in September 2020. The Department told us that the reduction was achieved following price benchmarking. Randox told us that it was due to capital investment being covered in the first contract, higher volume purchasing and improvements in Randox's manufacturing and process management systems. Randox said it also reflected the removal from the contract of requirements to supply sample collection devices and IT infrastructure for test registration and reporting. This lower price applied to the contract variation awarded in October 2020 and reduced further in later contracts.

3.4 In February 2021, the Department prepared a contract overview document, which noted the risk that prices agreed with Randox might be considered poor value for money. The risk mitigation set out in the contract overview states that benchmarking was done after the original contract was awarded and a price reduction agreed with Randox in September 2020. The contract overview further noted: "The prices agreed with Randox since 2 October 2020 also represent a significant saving over the prices that were included in the original contract covering the period 30 March 2020 to 2 October 2020". The Department told us that it paid a total of £128.4 million for tests at the £49.60 unit price.

3.5 As with the original testing contract awarded to Randox in March 2020, the contract variation was a direct award under Regulation 32(2)(c) of the Public Contracts Regulations 2015, which enabled goods and services to be procured with extreme urgency for the pandemic response. Prior to the award of this contract variation, the NHS Test and Trace (NHST&T) Finance and Investment Board noted that "it would not be preferable to do a tender for this work" at that time because Randox was a fundamental part of meeting testing targets over the following weeks. However, the Permanent Secretary of the Cabinet Office expressed disappointment that the Department had made another direct award for the contract variation, given that it had had time to organise and conclude a competitive contract process. The Cabinet Office insisted on a written commitment from the Department that it would initiate a competitive process in time for new contracts to be let from March 2021. This took the form of Public Health England's (PHE's) National Microbiology Framework.

3.6 The National Microbiology Framework is a four-lot framework agreement for diagnostics, research and development, manufacturing of supplies and services and provision of laboratory testing capacity. The framework includes more than 100 suppliers. In February and March 2021, Randox was appointed as a supplier on all four lots through a competitive process. Between March and December 2021, the Department awarded two contracts to Randox from lot four of this framework agreement and three variations to the first of these two contracts. For these contracts, the price per test was significantly lower than the price paid during Randox's first contract.

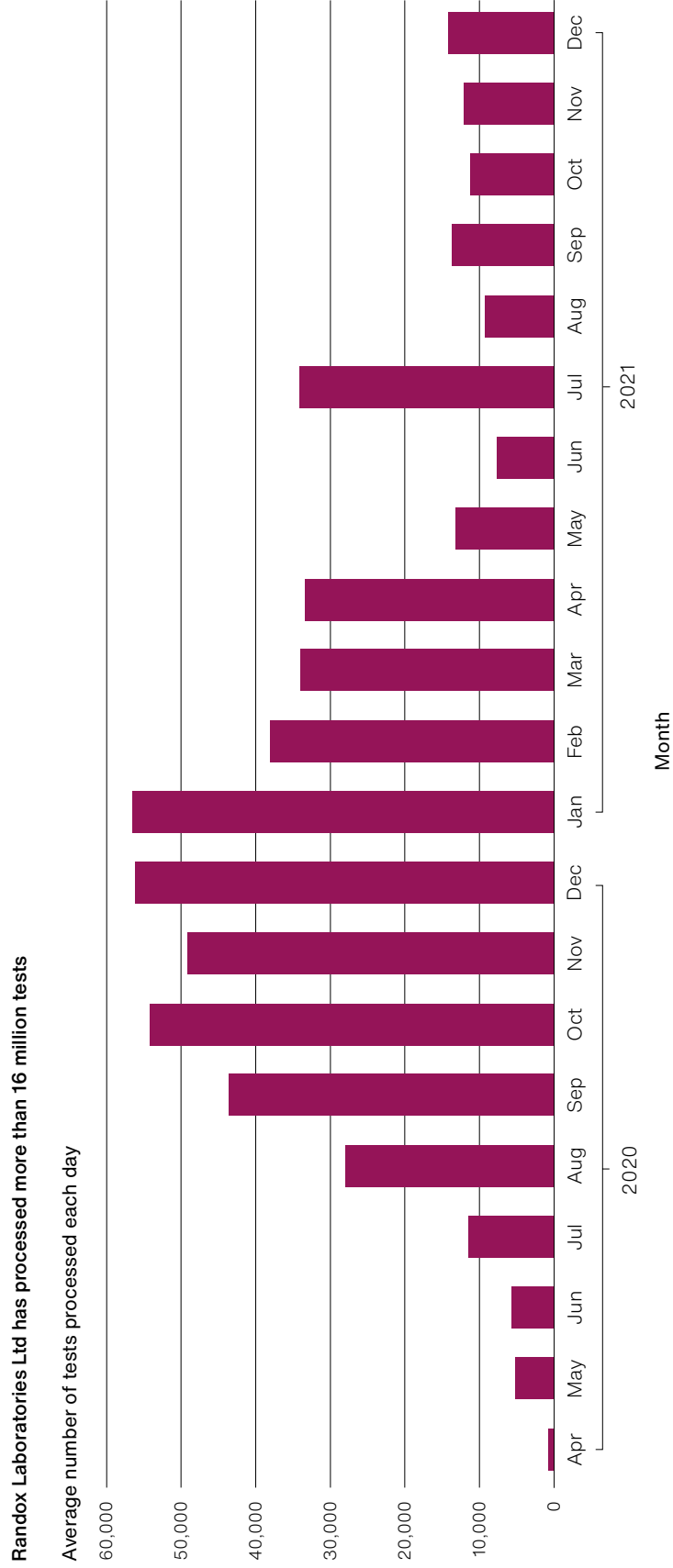
Performance and contract management

3.7 By 18 October 2021, the Department had paid Randox £403.3 million for the provision of testing services under all its testing services contracts, including additional services. Randox reached its maximum contracted capacity level in January 2021. Randox's contracted capacity was decreased in April and May 2021, as other testing laboratories became available and testing capacity could be more evenly distributed across the network of laboratories. By 16 December 2021, Randox had processed more than 16 million tests (**Figure 9** overleaf). The Department and the UK Health Security Agency (UKHSA) were not able to provide us with data on how Randox's capacity compared to the contracted levels.

3.8 NHST&T had daily and weekly calls with Randox in which it discussed daily performance and performance over a rolling two-week period respectively. Performance indicators covered included utilisation; turnaround times for tests sent from test sites, organisations such as care homes, and home tests; and the rates of test results returned as void. Since the first contract, turnaround times for tests sent by organisations and processed by Randox have improved. For example, between 2 October 2020 and 7 December 2021, 62% of tests were turned around within 48 hours, compared with 14% between 1 July and 1 October 2020. In 2021, Randox's void rate (the percentage of samples tested that returned an inconclusive result) was 2.1%, compared with 2.5% for 2020. The average void rate across all laboratories with government contracts for testing services was 2.5% in 2021 and 2.9% in 2020.

3.9 In November 2020, Channel 4 broadcast a programme highlighting concerns about practices in Randox's laboratory. The Health and Safety Executive Northern Ireland (HSENI) conducted a visit to the site on 9 December 2020 and directed the site management to take immediate action to address significant safety concerns, both COVID-19-related and general, observed at the site. The situation was escalated to HSENI's senior management due to the concerns observed and the fact that an enforcement notice had previously been served on the company on 21 August 2020 relating to similar matters.

Figure 9
Average number of tests processed each day by Randox Laboratories Ltd, by month, April 2020 to December 2021



Note
1 Data cover the period 11 April 2020 to 16 December 2021.

Source: National Audit Office analysis of UK Health Security Agency data

3.10 The site was revisited by HSENI on 11 December 2020 and, as a result of the identification of continued serious issues, an urgent meeting with senior management of the site was undertaken. Further improvements required to address the observed issues were outlined and the company was informed that additional enforcement was being considered. Subsequently a meeting was held on 12 December 2020 between Randox, HSENI and other relevant government bodies to identify actions necessary to address the observed issues and underlying management failures.

3.11 To address HSENI's concerns, Randox established an improvement plan and HSENI made a further visit on 14 December 2020 to assess compliance with minimum legal requirements. Randox stated in a letter to UKHSA on 16 December 2020 that HSENI had confirmed it was satisfied Randox was now COVID-19-compliant.

Contracts for COVID-19 testing goods

3.12 Between January 2020 and December 2021, the Department, PHE and UKHSA 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 (see Figure 4 on pages 25 and 26). By December 2021, the Department had spent the full contract value (£4.1 million) on the testing goods contracts awarded before December 2021, and all these contracted goods had been delivered. UKHSA told us contracts of less than £0.1 million were one-off orders and required no further monitoring or reporting. For contracts above £0.1 million, NHST&T held weekly meetings with Qnostics Ltd, which was either the main contractor or subcontractor, but no explicit key performance indicators were set out in the contracts.

3.13 UKHSA told us that its approach to quality control for clinical products, such as those ordered through these contracts, was in line with procedures used across the industry for clinical testing technologies or products such as blood tests. UKHSA confirmed that for all of Randox's contracts for testing goods, there were no examples of any contractual non-performance or failures to meet contract specifications, and no other issues were raised.

Appendix One

Our investigative approach

Scope

1 We conducted an investigation into the government's contracts with Randox Laboratories Ltd (Randox) during the pandemic in response to concerns raised in Parliament regarding the transparency and management of these contracts. Ministers commented in Parliament that the National Audit Office (NAO) had reviewed the government's first testing contract with Randox, although our previous work did not examine the contract with Randox in detail. To increase transparency and accountability, we therefore carried out a more detailed review of government contracts let to Randox between January 2020 and December 2021. The report focuses on the actions of the Department of Health & Social Care (the Department) in awarding and managing those contracts. It sets out:

- a summary of the contracts awarded to Randox during the pandemic and the procurement routes used (Part One);
- the procurement and performance of the first contract awarded to Randox for COVID-19 testing services (Part Two); and
- subsequent contracts awarded to Randox (Part Three).

2 This investigation covers all the contracts awarded between January 2020 and December 2021 to Randox and to its strategic partner, Qnostics Ltd, which was also the subcontractor for some of the contracts. The report focuses on the award of Randox's first COVID-19 testing contract and its subsequent variation, which together account for almost three-fifths of the total value of contracts the Department awarded to Randox over this period. All contract values in this report exclude Value Added Tax. Although this report covers considerations relevant to value for money such as unit costs of goods and services purchased, it does not seek to form an opinion on the overall value for money of the government's award and management of contracts to Randox.

3 The report refers to all individuals by their titles or former titles for consistency. The former MP for North Shropshire asked that the report note he requested to be referred to in the report by name.

4 We provided Randox, the former Secretary of State for Health and Social Care, the former Minister for Life Sciences and the former MP for North Shropshire the opportunity to review this report to confirm its factual accuracy. The report takes into account the comments they provided.

Methods

5 Our fieldwork took place between December 2021 and February 2022. In examining these issues, we drew on a variety of evidence sources.

6 We requested the following information from the Department and the UK Health Security Agency (UKHSA).

- A list of government contracts (including contract variations and extensions) awarded to Randox and its strategic partner, Qnostics Ltd, between January 2020 and December 2021 with details on the contract title, award date, value and awarding body. For contracts awarded from framework agreements, details of the framework name, date of addition to framework and awarding body. Details of any rejected, cancelled or terminated contracts. For each of these contracts, we requested:
 - contract documentation covering: signed contract; award letter; contract notice; procurement record or log (Regulation 84 report or equivalent); record of publication of contract details (on Contracts Finder or elsewhere); commercial strategy covering the contract; and any formal contract change notices that have been agreed;
 - documentation setting out how conflicts of interest relating to Randox were identified and managed; due diligence conducted on Randox, including consideration of issues relating to politically exposed persons; consideration of previous contractual performance in subsequent contract awards; consideration of pricing information, including pricing comparisons and any consideration of supplier profit margins, in contract awards;
 - evidence of contract approvals, including approval dates within the awarding body and who was involved; review or confirmation of contract approval by a clearance or governance board; review or confirmation by HM Treasury or Cabinet Office, including application of spending controls;
 - details of the actual contract spend to date versus forecast cost, and a breakdown of actual spend by categories of spend;

- records of how the contracts were managed, including: what was delivered against the contract; performance reporting and monitoring against key performance indicators; details of checking regimes to assure quality of goods or services provided; details of any contractual non-performance or failure to meet contract specifications, action taken, and remedies sought; and any other issues identified and how these were dealt with;
 - details of contractual redress mechanisms, if relevant, and estimates of the potential financial exposure involved, including details of any payments to date, including advance payments; any analysis of the net financial impact of those contracts where the goods or services supplied did not meet the contract specification; and latest estimates of write-offs related to purchased goods or services; and
 - details of legal advice sought, including dates sought and how advice was acted upon.
- Documentation of contacts between ministers, officials and Radox (including Radox representatives) from 1 January 2020 to 30 November 2021, including details of face-to-face meetings, who was present and minutes recorded; emails (including from non-official email accounts); letters; other communications, such as text or WhatsApp messages (including those sent from non-official phones); and details and records of telephone calls (including those made from non-official phones).
 - Internal government communications (such as emails, letters, briefings, memoranda) about Radox or contracts with Radox, from 1 January 2020 to 30 November 2021.
 - Details of procurement procedures for the test and trace programme, including details on the high-priority procurement lane, including how the lane operated, such as dates of operation, which departments and bodies were involved and criteria for referral; list of companies referred to the high-priority lane and list of companies in the standard procurement lane; list of companies in the high-priority lane awarded contracts, list of companies in the standard procurement lane awarded contracts, and values of the contracts awarded through each lane; internal government communications (such as emails, letters, briefings and memoranda) relating to Radox and the high-priority lane; communications with Radox (and Radox representatives) concerning the high-priority lane.
 - Departmental or organisational policies on lobbying, including requirements on recording details and minutes of ministerial meetings with private companies and on the use of private or personal email or communications accounts for official business.
 - Internal reviews or audits relating to Radox or the contracts awarded to Radox, such as those carried out by the Government Internal Audit Agency.

7 We reviewed the contract documentation received in response to the request set out above. For the procurement documentation received for each contract, we reviewed this documentation against a framework of questions drawing on the requirements in regulations for recording of information. We asked further questions to understand the facts about the process by which each contract was awarded and information published, including interviews with those responsible where required. This report should not be considered as offering positive assurance over aspects of any of these contracts which are not detailed in the report or as offering any legal opinion on the use of public procurement regulations. We have not drawn conclusions regarding the overall value for money of these procurements.

8 We reviewed documents collected to respond to a parliamentary motion on Randox contracts passed on 17 November 2021, known as the 'Humble Address' material. We reviewed documents provided by the Department detailing correspondence between Randox and ministers, special advisers, MPs and civil servants from January 2020 to March 2021. This documentation includes the set of Humble Address material provided to Parliament on 3 February 2022 (in response to the parliamentary motion passed on 17 November 2021), as well as other documents collected as part of the Humble Address process but not published. The wording of the 17 November 2021 parliamentary motion is:

That an Humble Address be presented to Her Majesty, that she will be graciously pleased to give directions that there be laid before this House the minutes from or any notes of the meeting of 9 April 2020 between Lord Bethell, Owen Paterson and Randox representatives, and all correspondence, including submissions and electronic communications, addressed or copied to, or written by or on behalf of, any or all of the following:

- (a) a Minister or former Minister of the Crown,
- (b) a Special Adviser of such a Minister or former Minister, or
- (c) a Member or former Member of this House

relating to the Government contracts for services provided by medical laboratories, awarded to Randox Laboratories Ltd. by the Department for Health and Social Care, reference tender_237869/856165 and CF-0053400D00000000rwmUAA1, valued at £133,000,000 and £334,300,000-£346,500,000 respectively.

9 The Department's Humble Address methodology noted it conducted a search of departmental private office and special adviser email accounts between 1 January 2020 and 31 March 2021 for the search term 'Randox'. The Department also asked current and former ministers and any special advisers potentially involved in correspondence about Randox to search their private systems for correspondence over the same time period. These searches resulted in around 11,000 records which were then manually reviewed for relevancy according to criteria set by the Department. The Department's relevancy review criteria included whether correspondence related to the events described in the parliamentary motion or other key events such as Randox's identification as a possible testing supplier and ministerial meetings held before and after the first contract was awarded to Randox in March 2020.

10 We requested more specific information on senior officials' discussions about or with Randox in February 2022. In response to our request for information on civil servants' discussions with or about Randox, the Department provided documentation containing little or no evidence of correspondence with some key officials responsible for important aspects of the testing programme or procurement. In February 2022 we therefore requested correspondence between specified senior officials and Randox, as well as key internal documents such as briefings about Randox prepared for, or by, those officials, from 1 January to 31 October 2020. The senior departmental officials we specified were: the Head of the NHS Test and Trace Service (NHST&T), the Department's Director General of Finance, and the Department's Chief Commercial Officer. The Department confirmed that it provided all relevant correspondence from its searches of the email inboxes of the Director General of Finance and the Chief Commercial Officer relating to the award of the first contract to Randox in March 2020 and its extension in October 2020. The Department did not review the email inbox of the Head of NHST&T.

11 We collected data on the transparency of contract awards. For the contracts or places on framework agreements awarded to Randox or its strategic partner Qnostics Ltd between January 2020 and December 2021, we reviewed whether basic details for each award were published on Contracts Finder, available at www.gov.uk/contracts-finder.

12 We interviewed key officials from the Department, UKHSA and the Cabinet Office. The work was designed to understand:

- how Randox was identified as a potential supplier to support the government's objective of increasing testing capacity;
- the processes involved in awarding and managing the first contract to Randox and subsequent variation to that contract; and
- testing procurement processes, including the entry routes for supplier offers.

This report has been printed on Pro Digital Silk and contains material sourced from responsibly managed and sustainable forests certified in accordance with the FSC (Forest Stewardship Council).

The wood pulp is totally recyclable and acid-free. Our printers also have full ISO 14001 environmental accreditation, which ensures that they have effective procedures in place to manage waste and practices that may affect the environment.



National Audit Office

Design and Production by NAO Communications Team
DP Ref: 012079-001

£10.00

ISBN 978-1-78604-412-9



9 781786 044129