



Investigation into the government's contracts with Randox Laboratories Ltd

Department of Health & Social Care

REPORT

by the Comptroller and Auditor General

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Department of Health & Social Care

Report by the Comptroller and Auditor General

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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.

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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.

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).
- 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).

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).

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).
- 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).

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).

The Department did not disclose Randox's attendance at four ministerial 18 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

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).

- 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).
- 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.