IN THE UK COVID-19 INQUIRY
MODULE SEVEN

IN RESPONSE TO REQUEST FOR EVIDENCE UNDER RULE NINE OF THE INQUIRY RULES 2006

REQUEST REFERENCE - M7/RANDOX/01

WITNESS STATEMENT OF DR PETER FITZGERALD

INDEX

TOPIC	PAGE
Background	2
Initial Interaction with the TTI Strategy	8
Randox's Responses	14
Randox's Data Sharing with the Network	29
Effectiveness of Response	31
UK Government's Oversight and Scrutiny of Randox	34
Centralisation of the National Testing Programme and TTI	38
Contracts, Costings, Value for Money and Profitability	40
Additional Context	48
Randox - Key Decision Makers, Structure and Capacity in Respect of TTI	52
Observations and Conclusions	53
Statement of Truth	66
List of Annexes	67
Annex A – Ministerial Meetings	68
Annex B - Loan Equipment	73
Annex C – Withdrawal of Sample Collection Kits	77
Annex D – The Randox Approach to Testing Private and TTI Samples	87

I, Dr Peter Fitzgerald of 55 Diamond Road, Crumlin, County Antrim BT29 4QY will say as follows:

1. I am the Founder and Managing Director of Randox Laboratories Limited ('Randox'). I make this statement in response to the request for evidence by the Covid-19 Inquiry under Rule 9 of the Inquiry Rules 2006. The facts set out in this witness statement are true to the best of my knowledge and belief and are within my own knowledge unless stated to the contrary.

Background

2. Randox is a privately owned company based in the UK. It is a manufacturer of laboratory diagnostic tests, quality control systems and laboratory analysers. Randox supplies products to healthcare laboratories in the UK and overseas, supported by in-house research and development, data handling, engineering, regulatory and logistic capabilities. Under the Randox Health brand, Randox also provides direct-to-consumer testing services in the UK.

3. Randox was formed in 1982. By early 2020, and prior to the COVID-19 pandemic (the 'pandemic'), the company had accrued 38 years of UK and global diagnostic experience and employed just under 1400 staff. These staff were agile, adaptable and diagnostically aware. Around a quarter of those staff were research scientists and engineers. Prior to the pandemic, the company supplied diagnostic products both within the UK and for export – with links and distribution networks covering well over 100 countries. The nature of diagnostic research and development and manufacture requires the supply of raw materials from across the world, so Randox had an active global diagnostic supply chain network.

4. Randox's production facilities were largely concentrated in 5 sites in the south of County Antrim, Northern Ireland, with additional facilities in County Donegal, Ireland, Bangalore, India and in West Virgina in the US. Offices are maintained in over twenty countries with supporting distributor networks facilitating a wider global reach. The Northern Ireland facilities are located close to an international airport, facilitating freight and personnel movement.

5. Randox's diagnostic healthcare laboratory portfolio provided a range of products for clinical chemistry, immunoassay and molecular polymerase chain reaction (PCR) testing. Additional assets included Toxicology and Food Diagnostics divisions, the latter testing for drug residues and toxins within foodstuffs. Within the clinical healthcare area, the product range developed and manufactured by Randox included assays (tests), internal quality control materials, external quality assurance systems and, as required, the analyser systems to run the tests.

6. Randox manufactures diagnostic products both under its own brand and as manufactured product for other global diagnostic companies under their brands – holding the required accreditations and submitting to extensive external auditing processes in order to do so.

7. Pre-pandemic, Randox's manufacturing processes were accredited to ISO 13485. Randox's International Quality Assessment Scheme (RIQAS) was accredited to ISO17043. At that time, Randox had two service laboratories holding accreditations to ISO 17025, both located in County Antrim. Randox's Quality Assurance and Regulatory Department had successful experience in dealing with the accreditation requirements of external bodies such as the United Kingdom Accreditation Service (UKAS) and also the regulatory demands of export markets including MDSAP, FDA (US), SFDA (China), Anvisa (Brazil), TGA (Australia) and others.

8. The Randox IT department was responsible for data security and global connectivity, including the development and maintenance of applications and software programmes for its global customer base. The Company's IT products ranged from interactive consumer facing software required for the processing of personal data that had been developed for Randox Health, to real-time and high-volume input for laboratory professionals that had been developed for Randox's Acusera 24/7 programme, and for all its RIQAS programmes globally. Therefore, by early 2020, Randox's IT team were very experienced in dealing with high volumes of secure data and a wide range of interactive software development and connectivity issues. Randox was well placed to evolve and scale its systems to meet the requirements of the Pandemic.

9. In order to provide products to market Randox have, from inception, run quality assurance and assay development laboratories and gained significant experience in that area. From 2008 onwards Randox established the Randox Health brand in order to bring

testing innovations direct to the consumer. This initiative required the establishment of our consumer facing laboratories, with appropriate laboratory Quality Management Systems and UKAS accreditations to ISO17025 and later ISO15189. The laboratories were regularly audited both internally and externally as part of the process for attaining and maintaining accreditation. These audits included assessment of the qualifications, training and experience of the staff, the calibration and maintenance of equipment, the adequacy of quality assurance procedures, sampling practices, the traceability of measurements, the accuracy of recording and reporting as well as the overall suitability of the testing facilities. Well before the onset of the pandemic Randox had established and accredited consumer-facing diagnostic laboratory services.

10. A separate toxicology laboratory capability within the Business had additional experience of providing ISO17025 accredited testing facilities for forensic and workplace drug and alcohol testing. This provided additional experience of high-volume sample chain of custody and accessioning requirements which proved exceptionally beneficial during the pandemic.

11. Randox had also expended considerable resource in developing a 'biochip' testing capability – whereby multiple tests can be processed simultaneously on a 9mm x 9mm solid-state chip, improving the diagnostic information available to clinicians. Randox manufactured both the biochips and the analysers used to process the chips and produce results. The biochips were developed to provide comprehensive testing of samples for PCR and immunoassay purposes. Overall, the development of biochip capability had required an investment of £400m over twenty years.

12. Whilst Randox initially focussed on the clinical chemistry and immunoassay diagnostic disciplines from around 2010 progressively developed molecular, or PCR, testing capabilities. Prior to the pandemic Randox had an established PCR testing capability, using the biochip, to test for ten sexually transmitted infections (STIs) simultaneously from a single undivided patient sample.

13. During the course of developing a biochip for respiratory diseases, Randox had developed two tests for previous coronavirus variants. These had been specifically developed by Randox R&D scientists to detect coronavirus 229E/NL63 and coronavirus OC43/HKUI. Coronavirus assays for these subtypes were first developed by Randox in 2012, with an additional Randox respiratory infection testing array released in mid-2016.

Thus, Randox was well placed to be able to bring a COVID-19 test to operational use at pace.

14. Whilst the Respiratory biochip capability was largely designed as a business-to-business capability for laboratory providers, Randox made the decision pre 2020 to offer the STI service directly to the consumer. This could be provided in two ways – a walk-in service at Randox Health clinics or through ordering a sample self-collect and return kit, under the brand name 'Confidante'. After ordering the Confidante test kit on-line the consumer would self-collect their sample, register on-line and return the sample to the Randox PCR laboratory in the provided, biological-sample-compliant packaging. After processing, the client would have their results sent to them electronically. It was fortuitous that this process modelled that required for the subsequent remote testing during the pandemic.

15. This capability required the biochips, liquid-handling and the analyser systems to run them – resulting in in-house, medical device engineering capabilities including the Evidence Investigator and Evidence Plus systems for PCR analysis. These Evidence systems could be manufactured at scale in order to support pandemic testing.

16. Randox additionally purchased, in the mid 2010's, a secure ex-Ministry of Defence site in Antrim. This forty-five-acre site included some 400,000 square feet of built space - around 200,000 square feet of accommodation and office space and around two hundred thousand square feet in a single large, empty hangar, central to the site. At the onset of the pandemic only around 25% of that hanger had been utilised. Following purchase, the site was rebranded as Randox Science Park.

17. With its growing PCR expertise Randox competed for and was successful in being contracted to the PHE Public Health Microbiology Framework in 2016. In the associated evaluation Randox obtained a score of 98%. Contract award was in July 2016 for 2 years, which was subsequently extended to July 2020. So, at the commencement of the pandemic Randox were already a participant on the PHE Public Health Microbiology Framework.

18. A snapshot of the Randox infrastructure as it was in January 2020 and in January 2022 are set out at the charts on pages 1 - 12 of **Exhibit PF/01 [INQ000513644].** This structure had been developed over thirty-eight years of experience of diagnostic markets and the objective to achieve as much self-reliance as possible. As indicated, prior to the

onset of the pandemic, Randox had a number of assets and capabilities that became relevant to the national requirement once the government had decided that mass testing was going to be its main response to the COVID-19 pandemic:

a. Accredited laboratory facilities with experience of running a PCR testing service;

b. A remote sample collection, sample return and compliant result transmission service;

c. Research scientists with experience of developing coronavirus tests;

d. A proven biochip platform on which to fix those tests;

e. Integral engineering, research and development ('R&D') scientists including Molecular Biology expertise;

f. Diagnostic Quality Assurance and Regulatory expertise;

g. Information Technology and data security ('IT') capabilities;

h. A human resources ('HR') and training team with knowledge of the diagnostic sector;

i. A globally experienced supply-chain operation for sourcing products and raw-materials;

j. Core diagnostic manufacturing capabilities with global accreditations, serving both Randox and third-party requirements;

k. Diagnostically aware management and staff who could be redeployed from their 'business-as-usual' roles as required to meet variable demand;

l. A readily available expansion space for rapid up-scaling of diagnostic operations in the form of 200,000 sq ft of warehousing available for conversion into testing laboratories and associated functions;

m. Expertise in laboratory design necessary for providing a large-scale molecular biology PCR testing facility;

n. Expertise in the operation and programming of liquid handling systems required for reagent formulation during the testing process;

o. Access to proprietary instrumentation in the form of the Randox Investigator and Evidence Plus analysers to perform tests with the ability to manufacture these instruments at a scale necessary to meet pandemic need;

p. Party to Public Health England's Public Health Microbiology Framework from 2016.

At the start of the Pandemic there was no other laboratory in the UK – either public or private – with the depth and range of experience, capabilities or agility of Randox to be able to build PCR testing at speed and at scale.

19. All Randox employees were engaged in support of the TTI programme to one degree or another. Some staff were retrained and allocated to laboratory and associated support and remained there for the duration of the pandemic. Others were trained and surged to the laboratories at times of high demand. In addition, we recruited significant numbers of temporary staff to support the demands of the Pandemic. This approach, which I believe was unique to Randox within the Pillar II laboratories allowed a degree of flexibility and agility to meet demand and maintain the efficient use of personnel. The risk was taken by the conventional business, but as that was also affected by the Pandemic, we could manage with existing staff initially and then with the employment of additional temporary staff. Everyone in the company, including myself, spent time directly supporting laboratory operations as required. The numbers are provided in the Human Resources section of this statement.

20. Randox's first action, directly related to the pandemic threat occurred on Saturday 25 January 2020, when I committed to the development of a COVID-19 test on biochip, based on the Chinese government's release of the Ribonucleic Acid of COVID-19 ('RNA' is akin to the 'genetic fingerprint' of a virus) earlier that month. This was purely on my own initiative. Senior management were contacted that evening and R&D staff were

called into work on Sunday 26 January 2020 to commence assay development. Around 10 February 2020 Randox was satisfied that we had a suitable assay and contact was made with Public Health England (PHE) who were responsible for the evaluation of tests. This evaluation process proceeded inexplicably slowly. Given that we developed an assay from scratch within two weeks and given the seriousness of the Pandemic and the role of the PHE it would not have been unreasonable to expect the validation process to have followed a similar timescale. Following a chaser email on 24 March 2020 we received an email later that day from a senior cabinet office official informing us that, '*while the report has yet to be issued approval by PHE has been confirmed.*' The PHE's email confirming that it found the assay acceptable was received on 25 March 2020 with the undated evaluation attached. A copy of the email dated 25 March 2020 and the evaluation report that was attached to that email are exhibited at pages 13 - 17 of **Exhibit PF/01 [INQ000513644]**.

21. Given the seriousness of the pending pandemic Randox was surprised that PHE did not provide a more timely response. We engaged directly by calls and email and with limited progress decided to ask Mr Owen Paterson – a retained consultant for Randox who was assisting us generate commercial sales leads at the time – to engage with the Secretary of State on the slow progress of the PHE. Mr Paterson did on 18, 25 and 27 February 2020. were subsequently disclosed into the public domain via the DHSC's response to the Humble Address Petition passed on 17 November 2021. The DHSC response was released on 3 February 2022. From the evidence provided to Module 5 of the Inquiry by Lord Bethell on 19 March 2025 regarding the PHE's engagement with the private sector, and Randox in particular, he said that our information was "phenomenally helpful" and of value "to galvanise the system".

Initial Interaction with the TTI Strategy

22. Randox had no part in the UK Government's decision to develop the network of high-throughput facilities dedicated to COVID-19 testing that became known as the Lighthouse Laboratories Network. Nor had Randox any influence on the genesis of the Government's test, trace and isolation strategy. The first interaction that Randox had with the UK Government concerning plans to enable mass testing was an email received at 6:20pm on Monday 16 March 2020 inviting Randox to a meeting at 10 Downing Street at 5:45pm the following day. A Senior Manager of Randox attended. The meeting was

chaired by Secretary of State, Health and Social Care and, when he arrived, by the Prime Minister. The Chief Scientific Advisor, Chief Medical Officer and the Director, Office of Life Sciences were also in attendance as were a number of senior advisors and officials from, amongst others, the PHE and the MRHA.

23. Commercial, and other third-party, attendees included (according to the on-line record of ministerial meetings): Wellcome Trust, Alliance Boots, Roche, Thermofisher, Thriva, 23 and me, Medsci, Altona Diagnostics, Qiagen, Luminec Corp, Amazon, Serco, Brunel University, Babylon Health, TDL Pathology.

24. It appeared at the meeting that the Government had recently fixed on the strategy of mass testing, to be established via a limited number of high-volume sites outside the NHS estate. We understood this decision had been taken because the capacity of the NHS for testing at that time was limited. It was stated at the meeting that the NHS's COVID-19 testing capacity was 2,400 PCR tests per day (t/day) and that if all other NHS PCR testing ceased this could be increased to 10,000 t/day. The national requirement was for the NHS to expand to 25,000 tests per day for their internal use. It was commented upon by an unknown-to-Randox attendee that this was considered to be a really challenging target.

25. In essence, laboratories currently within the NHS estate, which became known as Pillar 1 laboratories, would expand their capacity to support the increased requirements for the NHS's testing of key staff and patients. A group of laboratories outside the NHS estate, which became known as the Pillar 2 laboratories, would build the capacity to meet the government's testing objectives for key services and general population testing as they evolved. Pillar 2 laboratories would provide the foundation of the Government's testing capacity that fed into the overall test, trace and isolation strategy for managing the pandemic. It later became clear that Pillars 3, 4 and 5 would be focussed on antibody testing, surveillance and building national capacity.

26. It was understood by the Randox attendee at the meeting on 17 March 2020 that Roche were to support the NHS Pillar 1 increase its capacity, largely upon current in-place Roche systems, and that Thermofisher were to provide the equipment and consumables for the Pillar 2 network. I was subsequently informed that a Thermofisher instrument, which I believe was called a Quantstudio, was on display at the meeting. Mention was made that the Pillar 2 network would probably need to achieve 100,000 t/day to meet the

national requirement – significantly greater than NHS capability. I was not aware of any documentation at the meeting nor of any subsequent minutes of the meeting and that appears to have been confirmed by the National Audit Office's investigation.

27. At the 17 March 2020 meeting it was unclear whether the planning for mass testing was for England or for all jurisdictions of the UK. Randox were subsequently contacted by the Minister for Health, Northern Ireland in early April 2020 who appeared to have no visibility of the UK government's plan at that time.

28. Also at the meeting on 17 March 2020 it was indicated that the Director, Office of Life Sciences was leading on the concept of Pillar 2 laboratories and passing reference was made to a related meeting arranged for the following day to discuss the concept further, particularly involving Thermofisher. At the conclusion of the meeting on 17 March 2020, the Randox Senior Manager in attendance approached the Director, Office of Life Sciences and asked if he could attend the following day's meeting. Permission was provided by email the following morning.

29. At the 18 March 2020 meeting (also attended by, according to the on-line record of ministerial meetings; Thermofisher, Oxford University, Wellcome Trust, Amazon) the Director, Office of Life Sciences outlined that DHSC wanted partners able to provide an end-to-end service, not just testing. The Randox Senior Manager outlined the Randox end-to-end testing capabilities as developed for STI testing to the Director, Office of Life Sciences and Randox was asked to submit a proposal for high volume, end-to-end testing. The Minister for Life Sciences also briefly attended that meeting, though no discussion took place between the Minister and the Randox Senior Manager.

30. Noting the stated urgency, the Office for Life Sciences initiated a call with Randox on 19 March 2020 in which Randox raised a concern about potential pinch points such as likely equipment shortages, swab supply, Category II cabinets and RNA extraction equipment. We followed up with an email at 14:35 on 20 March 2020 enclosing a ramp up plan which included a comment that support to obtain equipment and consumables might be required to further increase capacity after Week 3 due to global supply chain difficulties (exhibited at pages 18 - 20 of **Exhibit PF/01 [INQ000513644]**. Further confidential contract discussions took place thereafter with DHSC and with myself and Randox's Finance Director representing Randox. The first contract to provide high volume end-to-end testing (to include sample collection kits, a registration portal and result delivery

direct to subjects) from immediate effect was signed on 30 March 2020 – a week after the first lockdown. As a matter of historical fact, all the Randox contracts with the DHSC were the subject of a detailed investigation by the National Audit Office ('NAO') which published a report entitled, 'Investigation into the government's contracts with Randox Laboratory Ltd' that was published on 24 March 2022 ('NAO Report') The NAO Report provides valuable context to Randox's engagement and is therefore exhibited at **PF/02 [INQ000513645]**. We had no awareness of the High Priority Lane (HPL) at the point of negotiating our initial contract and our subsequent understanding is that the HPL evolved after that time. Subsequent negotiations were based on our in-place capability, ability to scale, performance and price and were not through the HPL.

31. At that point Randox pivoted the business from routine working practices to a 24/7 operation, with staff trained and redeployed to support the increased production required to support testing. Operations were initially based on maximising the in-place PCR laboratory infrastructure and capacity. We also engaged with construction companies and built an additional four-lane, high-throughput laboratory on one of our existing sites in County Antrim. This was done without any certainty beyond the first contract or the actual volume of testing that Randox would be required to do.

32. The first contract was due to last 12 weeks and test just under 2.7 million samples, with planned capacity ramping up to 60,000 t/day by 18 May 2020. Critically, Randox included within the contract at Appendix One that their internal capabilities could achieve up to the Week 3 target of 2,800 t/day in week commencing 13 April 2020 (in excess of the entire NHS capacity on 17 March 2020) but that Authority assistance might be required in procurement chains. A copy of Appendix One to the first contract with the DHSC is at pages 21 - 23 of **Exhibit PF/01 [INQ000513644]**. Thereafter, there was a confluence of unprecedented issues that impacted on our ability to build capacity. These were;

    a. Key equipment on order by Randox was placed under government control which delayed its delivery to Randox;
    b. The lack of availability of loan equipment and the serviceability of the equipment which was eventually delivered;
    c. The global spike in demand for consumables in what had been a low volume market impacted availability; and
    d. The imposition of lockdown constricted flights, freight and supply chains;

These factors ultimately made it impossible to deliver the contracted capacity in the defined timescales. Whilst this had some impact initially, the ramp-up of sample availability was slower than anticipated and, overall, capacities were infrequently stretched.

33. The table below sets out the contractual capacity commitments for the first contract:

Week No	Week Commencing	No Tests/Day	No Tests/Week
1	30 March	300	2,100
2	6 April	1,400	9,800
3	13 April	2,800	19,600
4	20 April	5,600	39,200
5	27 April	11,200	78,400
6	4 May	20,000	140,000
7	11May	40,000	280,000
8	18 May	60,000	420,000
9	25 May	60,000	420,000
01	1 June	60,000	420,000
11	12 June	60,000	420,000
12	19 June	60,000	420,000
	Total tests over 12 weeks		**2,669,100**

34. Below are the t/day testing capacities achieved by Randox, by date. We were aware, from at least September 2020, that Randox achieved the highest capacity in the Pillar 2 laboratory network and, in maintaining that position, were the first laboratory to achieve a capacity of 100,000 t/day at the end of December 2020 and 120,000 t/day at the end of January 2021. Only one laboratory ever surpassed that total, and much later in the programme.

Randox Capacity Build Up		
Ser	**Date**	**Daily Capacity Achieved**
1	30 March 2020	500
2	6 April 2020	1,500
3	13 April 2020	2,800
4	20 April 2020	5,000
5	27 April 2020	17,000
6	4 May 2020	10,000
7	27 May 2020	15,000
8	9 June 2020	30,000

9	8 July 2020	35,000
10	30 September 2020	50,000
11	19 October 2020	60,000
12	31 October 2020	70,000
13	11 November 2020	80,000
14	1 December 2020	90,000
15	30 December 2020	100,000
16	28 January 2021	120,000

35. Following the achievement of 120,000 t/day at the end of January 2021 Randox was told not to develop further capacity, as additional laboratories were coming on-line in Great Britain, and from around April 2021, the Randox capacity for TTI was gradually reduced to around 15,000 t/day. Randox were also contracted to provide surge capacity should the rest of the network be unable to cope. That surge capacity was required and, in turn, was provided at very short notice in the summer of 2021 to help deal with the Delta variant and over Christmas and New Year of 2021/22 to help deal with the Omicron variant.

36. I believe that the value Randox provided to the Pillar 2 network, particularly in the first year of the pandemic was indicated by Dame Dr Jenny Harries, Chief Executive, UK Health Security Agency, in her evidence to the Public Accounts Select Committee on 18 May 2022 in which she stated, "*It was the work that Randox did that really got us through the next wave of that pandemic, through that winter* [2020/21]. *It was absolutely critical in the capacity that was provided.*" The Public Accounts Committee ('PAC') published a Report entitled, "Government's contracts with Randox Laboratories Ltd" on 27 July 2022 which is exhibited as a matter of historical record at **Exhibit PF/03 [INQ000513646]**.

37. In total, Randox processed just under 17.5m samples for TTI of which just over 1.04m were positive.

Randox's Responses

38. From the commitment of the first contract, Randox pivoted the company from routine diagnostic operations to provide manufacturing, PCR testing and support functions on a 24/7 basis. Initially, operations were based on in-place infrastructure which was quickly expanded to meet the increasing demand. Utilising the space available at Randox Science Park, Randox built, equipped and staffed four new linear PCR laboratories each with a capacity of 30,000 t/day. Additional space was allocated for the logistical support of the laboratories and to have readily available IT and engineering support as required. Accessioning infrastructure was put in place to provide effective sample acceptance, noting that each sample arrived in multiple layers of packaging. Arrangements were established for high volumes of clinical waste disposal which greatly exceeded that which was routinely required in Northern Ireland.

39. Our scientists and regulatory team ensured processes were compliant with requirements. Our IT team also coordinated the registration, reporting and data sharing requirements with the Network. A senior management team was established to enable 24/7 liaison with the Network as required.

40. Throughout the course of the contracts Randox was focused on continuous improvements and initiatives to refine the service provided. Examples are set out below:

Assay Development Response

(including accreditation and assessment of variants)

Assay Development and Quality Monitoring

41. Using our previous experience of developing coronavirus tests, we developed 2 Biochip assay designs (an initial 10plex extended coronavirus and a 2plex COIVD only kit) and 2 qPCR assay designs. A summary chart of Randox's IVD Assay Development Procedure RRD-1403 is at pages 24 - 26 of **Exhibit PF/01 [INQ000513644]**. Both of these were dual target COVID kits. The concept of the extended coronavirus biochip array was to both identify the COVID-19 virus and to differentiate between patients presenting with similar symptoms but infected with other respiratory pathogens. We did discuss this extended coronavirus capability with DHSC but it was clear that their

requirement was for COVID-19 testing only. Hence the production of the 2plex COVID-19 only kit.

42. We maintained records of the kits' performance, validation and accreditation. Each COVID assay developed by Randox underwent verification of their design, which included assessment of analytical sensitivity and analytical specificity. Analytical sensitivity ensured all known SARS-CoV-2 strains were successfully detected at the limit of detection of the assay. Analytical specificity ensured that no significant cross-reactivity with non-targets was observed which, in turn might have caused false positive results.

43. These tests were based upon target genes that rarely change (known as conserved regions) to minimise the risk of the test failing as the virus evolved and new variants developed. These kits were registered for use by either PHE initially or later with the MHRA. As such, we were responsible for monitoring the design of the kits and reporting our findings with evidence to MHRA.

44. Use of Internal Quality Control (IQC) materials is essential to enable the laboratory to monitor the quality of their testing processes. Our COVID-19 laboratories used four IQC samples in each analytical run, a positive and negative extraction control and a positive and negative PCR control. The positive controls contained certified reference material of SARS CoV-2. The function of the positive controls was to demonstrate that both the extraction and PCR processes had been completed correctly and successfully identified the known Covid sample. The negative controls were deionised water. The function of the negative controls was to demonstrate that there was no contamination present within the analytical run that could result in incorrect results being released. All 4 of these controls had to pass in order for the run to be considered successful and the results released as valid. A single IQC failure within an analytical run was considered a fail, results were considered invalid, and the samples were subject to retesting to obtain a valid result.

45. With regard to the re-running of samples. If one of the extraction controls failed, then the samples were repeated from the extraction stage. If one of the PCR controls failed, then the samples were repeated from the PCR stage. Our process also included a human control for each sample to verify that extraction of each sample was successful. If any individual sample had human control fail the sample would again be repeated from the

extraction stage. Such samples were subjected to a maximum of 3 tests before resampling was requested.

46. Any QC failures were responded to in real time to identify any emerging issues within the test process that might indicate a larger validity issue. Randox had a quality management system ('QMS') in place to address such issues with the appropriate procedures formally stated. The QMS is audited annually as part of the UKAS accreditation process.

47. In addition to the routine testing of IQC material, our laboratories also used External Quality Assurance (EQA) schemes to provide independent oversight of our quality. Also referred to as Proficiency Testing (PT), EQA schemes involve the testing of blind sample material the results of which were reported back to the EQA provider who reviewed them to determine the accuracy of results being produced. EQA offers a measure of performance that can be compared to other laboratories conducting the same type of testing and provides insight into the overall efficacy of the test method being used. Throughout the pandemic, in our COVID-19 laboratories, a pass rate of 100% was maintained across all sites and test methods.

48. With regard to any laboratory non-conformances, there were robust procedures in place for handling such events relating to COVID 19 samples. The COVID 19 testing process was incorporated into our existing Quality Management System (QMS) which was used for all our accredited testing, meaning it was fully compliant with ISO standards. This included all aspects of testing from receipt and accessioning through to analysis and reporting and the support systems for non-conforming work management and internal audit processes.

49. Any examples of non-conforming work were handled in line with our quality management system processes. This included a full investigation into the root cause of the error that caused the non-conformance and implementation of appropriate corrective/preventative actions to address this root cause. There was also an effectiveness check conducted into any corrective actions implemented to ensure that these had sufficiently addressed the source of the non-conformance.

50. Upon identification of an adverse or potentially adverse event relating to the validity of a result, repeat analysis was conducted. Where applicable, the result had to be verified with a 2/3 rule being applied in the event of a discrepancy between results. This meant that 2 out of 3 results must agree in order for this to be considered a valid result.

51. In the event that an incorrect result was released there were also processes in place to ensure that all relevant bodies were notified of the issue, root cause and corrective actions. This included representatives from PHE/UKHSA and DHSC. The DHSC would then notify the subject and confirm with the laboratory once this had been done at which point the updated report would be released by the laboratory. Overall, there were twenty four TTI incidents reported during the Pandemic that involved 154 samples for which corrective results were issued (i.e. one in every 113,600). Our improved processes and automation reduced the risk of incidences over time. This percentage error rate was 0.00088%. It is difficult to find comparative statistics, however, a Report published by the US National Institute of Health in 2013 entitled, "The Measurement of Errors in Clinical Laboratories" stated that laboratory errors had a reported frequency of between 0.012% and 0.6% of all test results.

Accreditation

52. At the beginning of the pandemic Randox Clinical Laboratory Services ('RCLS') were an ISO17025 accredited lab for clinical chemistry testing for a range of biochemistry and molecular tests, including a PCR based molecular assay for STI testing. This test method was based on the same principle as the initial Covid-19 test used within Randox using their proprietary biochip technology and was onboarded under the same Quality Management System (QMS) as the accredited testing.

53. RCLS commenced Covid-19 testing for TTI at the end of March 2020 using the Randox SARS-COV-2 biochip test approved by PHE. The testing was conducted by RCLS staff who conducted the accredited testing process. As more staff were drafted in from Randox Laboratories to assist, only those with relevant experience in molecular techniques were selected and then trained. Training included multiple shadowed and observed runs to ensure the correct processes were observed.

54. We developed two separate qPCR versions of the PCR kit which were verified and manufactured under ISO 13485. These tests were subject to stringent verification testing to CE marked comparator assays and ultimately were granted CE marked status as well as being registered with the MHRA. The second test was granted stand-alone DHSC validation which was not required for the first test by virtue of a change in the regulations applied by DHSC. The tests met all the regulatory requirements to be included on the DHSC approved products list.

55. An extension to scope application was submitted to UKAS to include the Covid testing on our ISO 17025 scope in December 2020.

56. This was carried out as a remote review of documentation followed by an on-site assessment of the RCLS facility in Antrim in May 2021 due to an overwhelming demand on UKAS causing delays in progression of accreditations. After this assessment RCLS were recommended for a grant of accreditation for the Covid testing; this was formally awarded in October 2021.

57. Once the ISO17025 accreditation was granted extension to scope applications were submitted in September/October 2021 to transition from ISO17025 to ISO15189. Again, due to the delays within the UKAS organisation these were not assessed until March and April 2022. These processes and locations were assessed and RCLS were recommended for ISO15189 accreditation. This was formally granted in August 2022.

58. In May 2021 we submitted an application for next generation sequencing of SARS CoV-2 variants for the surveillance of variants and mutations of the virus. This project was assessed in December 2021 and recommended for accreditation. This was formally granted in April 2022.

Assessment of variants

59. It became clear from a relatively early stage in the pandemic that variants or mutations were a major concern in assessing disease transmission, infectivity, detectability, vaccine resistance and severity of illness/prognosis. Gaining a better understanding of the mutation process may remain important to understand the mechanisms of long-term symptoms/long-COVID. Randox understood the significant importance of variant

identification, with such information being essential for disease surveillance and public health action.

60. When developing PCR tests for COVID-19 it was essential for Randox's R&D Team to target genes that rarely change (known as conserved regions) to prevent the test failing as the virus evolved and new variants developed.

61. The Randox COVID-19 arrays and qPCR assays had been designed to target two different regions of SARS-CoV-2: a highly conserved pan-SARS-CoV target (E gene) in combination with a SARS-CoV-2-specific target (ORF1ab) to mitigate the risk of viral mutations impacting the test performance. However, routine monitoring of viral mutations in publicly available databases was required to evaluate the impact of new virus variants on test performance.

62. Throughout the use of the assay, SARS-CoV-2 genomic sequences, including emerging SARS-CoV-2 variants, were reviewed to determine their impact on the performance of the kit (procedure RRD-3654). Sequenced data from SARS-CoV-2 isolates collected within the UK were analysed against the oligonucleotides (short chain genetic probes used for testing) contained in the Randox COVID testing kits using in-silico analysis (computational models). Additionally, Variants Under Investigation ('VUI') and Variants of Concern ('VOC'), when first identified, were also analysed against the kits. Where available, sequenced VUI/VOCs were acquired and tested using the kit to provide an additional confirmation of acceptable assay performance. Where confirmed VUI/VOC were not available, synthetic RNA sequences homologous to the VUI/VOC sequences in question were synthesised and tested at the limit of detection of the assay. This identified potential mismatches between the kit oligonucleotides and any SARS-CoV-2 sequences encountered during routine screening and ensured acceptable performance of the assay during use. Reports were generated containing the in-silico analysis and the results of any "wet" testing; these were then submitted to MHRA for their review. All VUI/ VOC's tested using in silico analysis or wet testing would have been detected by our test.

63. Randox's R&D team performed computer simulation analysis every two weeks on samples that had been sequenced in the UK. The team also performed the same analysis on new variants when these appeared globally. This continual analysis allowed Randox to confirm that there would be no issues when our PCR test encountered strains or new variants should or when they arrived in the UK. Randox backed this evidence up with

wet/lab testing of new variants (synthetically synthesised or using a sample confirmed to have a newly identified variant) to test for proof of kit performance.

64. Variants were shown to be a real moving target. As variants emerged we were informed by the government of the those of concern and undertook analysis as required.

65. To assist with the sequencing effort, in early 2021, Randox implemented an automated process to collect and remove all positive samples for variant analysis/sequencing. A list of positive samples was pulled every six hours allowing us to rapidly pick out all positive samples from a 96-well plate using automated liquid handlers (a process known and referred to as 'Cherry-Picking'). At the time, these cherry-picked, positive samples from across Northern Ireland and Mainland UK were packaged and sent daily to Queens University Belfast (QUB) or the Sanger Institute respectively for sequencing as quickly as possible.

66. Randox took the initiative to invest its own resources into high throughput sequencing instruments and bespoke facilities to expand its (and the UK's) capacity for COVID-19 sequencing. By April 2021 the Randox COVID-19 Sequencing Department was operating 24/7 to ISO17025 standards and was capable of sequencing more than 1,500 samples/day whilst adhering to 120-hour turn-around times.

67. In line with other Pillar 2 laboratories, Randox also completed qPCR reflex testing for the following four variants - E484K, K417T, K417N & P681R - using the Thermofisher (Applied Biosciences) Taqman mutation qPCR kit ran on the Quantstudios (a PCR analyser). Due to the sensitivity of this test kit, only samples that had initially tested strongly positive were reflexed for further analysis. The extracted samples were reanalysed using the Thermofisher mutation kit and the results were returned to the program to allow for additional surveillance of the Covid-19 virus. This would not offer the same level of analysis as sequencing, which is capable of identifying all mutations across the COVID-19 genome and tracking how the virus was evolving over time, but would allow for identification of main variants 'at a glance'. From April 2021 Randox reflex-tested over 200,000 positive TTI samples to check for variants.

68. Randox also used its private sequencing facilities to test samples used to support international travel and processed approximately 56,000 private positive samples from

April 2021 for that purpose, with results sent to UKHSA. Randox had excess sequencing capacity to check for variants which was offered to the TTI network; we understood that national sequencing capacity was limited, and laboratories were struggling to meet turnaround times and experiencing backlogs. Randox's offer was made via the TTI Laboratory Director's network. The offer was not taken up by any of those in the network. We do not know why.

Engineering Response

69. Examples of engineering innovation within the Randox laboratories include:

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

b. Developing robotic solutions to automate many of the more labour-intensive parts of the process was essential to meet the ever-increasing sample testing demand. As an example, to make the accessioning of samples prior to analysis more efficient two automated box cutters were developed to handle the tens of thousands of boxed sample tubes processed daily.

c. To avoid a bottleneck on sample arrival into the laboratory, an automated decontamination tunnel was developed. Sample racks were fed along a conveyor through a mist of disinfectant and by the time they reached the end, the exterior of the tubes were virus free, dry and ready for sorting prior to entering the laboratory for testing.

d. Gantry robots were programmed to pick up each sample and scan a barcode that logged the sample on the Laboratory Management Information System ('LIMS') that determined its age. The samples were then deposited in corresponding racks on the other side of the unit based on the time left to prioritise sample processing. This helped Randox achieve a void rate better than the rest of the National Testing Program laboratories.

e. The Extraction Automated Sample Transfer (EAST) instrument helped reduce process risk through a fully automated system for extracting RNA from the

sample. This also freed up staff for other roles by removing the need for two staff in a biosafety cabinet unscrewing sample caps and pipetting samples with reagent into deep well plates. This system was designed by Randox engineers to improve on the contamination risks posed by other available sample-handling systems.

f. Digital tracking software developed by the IT team meant samples were scanned and tracked individually or collectively through each stage process. This meant samples could be tracked accurately through the complete process. It also allowed the Operations Team to monitor each stage of the process, identify potential bottlenecks, and redirect samples to other testing lanes to maintain the constant flow of samples. We were unaware of any other TTI laboratory having a similar process. We were collaborative and ideas were generally shared through the laboratory Directors' network. However, we did not have visibility of which ideas were adopted, and which ideas were not, by other laboratories.

g. By July 2021 Randox had developed the Randox Cube – a fully deployable robotic testing laboratory conducting COVID-19 PCR testing. Randox designed a compact testing line utilising a series of robots and liquid handling systems to handle and process samples taking them through the extraction, amplification and detection stages of the PCR test. The modular design of the Cube meant it could be moved almost anywhere and be operational within weeks. The fully robotic system reduced manual input, error and risk to the process, and could be more flexibility deployed thanks to the less operational space required. Four Cubes were installed and fully operational in Great Britain within five weeks of initiation at Warrington and Dunstable and had the potential to contribute significantly to the overall testing capacity, with an additional 48,000 PCR t/day. Whilst subsequently used by private testing, this innovation made laboratories more accessible within Great Britain and reduced the related logistics requirements. Our Cube labs remained in use for the duration of the Pandemic.

h. Designing the script for, and delivery of, a robotic sample handling unit that allowed samples presented in standard PCR 96 sample plates to be screened for positive samples and for those positive samples to be automatically

transferred to a 'positive only' sample plate for more detailed variant analysis. This process, known as 'cherry picking', removed the risk of human error and accelerated the identification of new variants. Using this technology Randox were amongst the early adopters in the application of in-laboratory reflex testing to screen for variants within positive samples.

Human Resource Response

70. Over the relevant period, Randox staffing levels increased from 1,360 in February 2020 to 3,298 in December 2021. The recruitment and training of sufficient numbers of staff in the teeth of the pandemic was a substantial challenge and posed a significant risk.

71. Randox established assessment centres where the HR team in tandem with Randox scientists and manufacturing created an end-to-end assessment procedure for the recruitment of candidates and determination of where the successful candidates should be placed within the business.

72. The assessment centres were able to process cohorts of 18-21 candidates at a time. A tri-partite interview process was designed that started with a preliminary one-to-one interview based on the candidate's CV and their responses to some competency questions. There followed a critical reasoning assessment and then an 'attention to detail' assessment that focused on a candidate's ability to check for errors in a process. The attending interviewing managers would then discuss the results of each candidate and determine which would be offered roles and where they were suitable to be placed.

73. At the same time as Randox ramped up its advertising and recruitment processes, it also broke down a number of the processes in the laboratory to specific modules and successful candidates were offered specific roles that were aligned with the different modules of the end-to-end testing process. This reduced the training time for candidates. Previously, a laboratory analyst at Randox would be trained in the many and various roles that are required for working in the laboratory environment. In the pandemic, however, there was a sufficient volume of testing required that allowed employees to focus on just one or a very few elements of the testing process, which in turn, increased the quality and efficiency of those employees in their roles.

74. All candidates were required to complete three layers of training successfully before being taken on as Randox laboratory staff. These layers of training were designed by the Randox HR team. The first of these layers involved an understanding and the technical skills associated with pipette use. Second, there was an accuracy and precision test and finally a consistency assessment. Randox established a dedicated team of trainers deployed to complete the 2–4-day training of the scientific processes required. The structure of the training was a mixture of theory-based learning and hands on practical sessions to increase the efficacy of the training and to cover different learning styles.

75. In addition to the onboarding training Randox ensured that all new employees had continuous competency training to maintain standards in the laboratories and ensure best practice throughout.

76. Set out below is a table to show Randox staffing levels between January 2020 and June 2022:

As of end of	Total Staff Numbers	Core Staff	Short-term Temporary Contracts	Agency Workers
Jan-20	1360	1360	0	0
Feb-20	1360	1360	0	0
Mar-20	1365	1365	0	0
Apr-20	1387	1374	13	0
May-20	1567	1492	75	0
Jun-20	1608	1507	101	0
Jul-20	1662	1542	120	0
Aug-20	1792	1620	172	0
Sep-20	1940	1741	199	0
Oct-20	2071	1760	311	0
Nov-20	2240	1810	430	0

Dec-20	2239	1859	380	0
Jan-21	2321	1902	419	0
Feb-21	2256	1913	343	0
Mar-21	2204	1922	282	0
Apr-21	2100	1892	208	0
May-21	2213	1924	280	9
Jun-21	2400	1961	349	90
Jul-21	2745	2078	404	264
Aug-21	2965	2164	346	455
Sep-21	3111	2235	282	594
Oct-21	3102	2306	276	520
Nov-21	3086	2377	227	482
Dec-21	3298	2402	301	594
Jan-22	3198	2432	227	539
Feb-22	3112	2402	193	517
Mar-22	2939	2359	154	426
Apr-22	2674	2152	237	285
May-22	2570	2129	201	240
Jun-22	2514	2214	139	161

77. The table above covers Randox staff numbers during the pandemic – supporting conventional business, TTI and private COVID-19 testing. The total number of new starts processed during this period was 5,532. Testing for TTI was conducted at our laboratories at Randox Science Park where the majority of laboratory staff were 'core' staff with greater career stability. Additional staff were also required for semi-skilled or manual tasks such as sample accessioning and operating the packing lines (for sample collection kits), where there

was a higher degree of staff turnover. This was to be expected given the nature of agency work and the short-term contracts offered due to the lack of certainty over the duration of the testing requirement. We also found that many applicants who sought employment during the pandemic were looking for short term stop-gaps. No member of staff was released to a role without successfully completing the appropriate training. Staff were recruited from a wide range of scientific and non-scientific backgrounds. We trained them and only selected those who passed the competency tests that we developed.

IT Response

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

    a. The team launched the first version of the COVID-19 kit registration portal on 20 March 2020, within 48 hours of an internal request and in anticipation of private need and the potential to service any public need. During the early stages of the pandemic, Randox refined the initial version of the kit registration portal, enabling customers to register their samples and gather the necessary information for sending results reports to individuals. Additionally, Randox implemented a results delivery system to automatically send PDF reports to individuals based on their registration details. Randox briefly partnered with UKFast for hosting while its IT Team custom-built a new application and migrated all services to Microsoft. Randox's software was configured to store data within Microsoft's UK data centres, utilising data encryption and firewall protection provided by Microsoft's suite of services. This allowed customers to register their test kit online and to assist the UK Government with contact tracing. Randox was instructed by Deloitte as to what information to collect at the point of kit registration. On 24 March 2020, for example, Deloitte instructed us to synchronize the data fields in our collection with the data that the NHS collected via its portal. By 30 March 2020 we had developed a second iteration of our portal with the guidance of Deloitte. Although we were reporting results directly to individuals we only began sharing those results with NHS Digital ('NHS D') once a data sharing agreement was in place from around 30 April 2020. From then we began to transfer all the data collected up to that date and from then we sent our data on a daily basis to NHS D via a CSV file. All the data that we provided was at the behest of Deloitte and was for the purpose of

contact tracing such as name, address, postcode, NHS number, National Insurance number, date of birth and contact telephone number. Once we provided the data to NHS D that body was responsible for integrating it with the contact tracing system.

b. The IT team reconfigured the Laboratory Information Management System in only two weeks, developing a full end-to-end process that never failed despite the huge increase in tests. As Randox scaled up to process higher volumes, the move from more manual processes, the integration of internal systems and then merging with the TTI Programme's systems caused complexity in the transfer and management of data, particularly in the first four months. That complexity was resolved for Randox by NHS D taking responsibility for the data that it collected from us and who it subsequently sent that data to. Randox had no part in that decision making and simply took its instructions from Deloitte.

c. Randox managed its kit registration and the result delivery process until July 2020, covering approximately 490,000 tests, taking pressure from the TTI Network whilst those systems were developed and refined. Our understanding is that our kit registration system ran in parallel to that used by the other laboratories in the TTI Network. The kit registration systems were merged from 1 July 2020.

d. In April 2020, the IT team launched the first version of the Randox sample accessioning platform to manage the sample receipt and formal chain of custody process. This allowed for scanning of samples and automatically updating their information onto the Laboratory Information Management System. By reaching back to identify the sample collection time Randox was able to develop a traffic-light system to identify the period of time between sample donation and expiry and prioritised samples into the laboratory on a green-amber-red basis. In other words, rather than processing samples based on the order in which they were received by Randox (i.e. 'first in, first out') our system, on receipt of the sample, analysed the sample donation time and date in order to prioritise the testing of samples based on proximity to expiry. This traffic-light system allowed Randox to improve the integrity of testing by prioritising samples close to expiry and reducing the number of time-related voided samples. This went some way to addressing the problem that we were

receiving samples from across the country with varying transit times that may have been taken several days prior to receipt. The sample accessioning platform was subject to constant improvement processes and a number of iterations followed to support the changes in service requirements. For example, we introduced a live sample tracker dashboard that enabled us to track the time that each batch of samples was taking in the testing process and included a sample priority indicator, based on age of the sample, and a coloured timer for testing to simplify the process for laboratory managers. All these served to reduce turnaround times. We ensured that the Network was aware of the developments and benefits in case they could be applied more generally. For instance, we participated in a regular IT Leadership Forum meeting where we demonstrated the refinements to our traffic-light system to those attending and offered to provide the other attendees with access to their own version of our system within two weeks of the meeting. The offer was not taken up.

e. The paperless Laboratory Information Management Application (LIMA) was custom developed in-house by the Randox IT team to manage the end-to-end sample workflow process from receipt of sample to the transfer of results to NHS D. The system tracked hundreds of quality related data points as samples moved through the testing process. These systems ensured complete traceability of all samples entering the lab, providing detailed information on sample status and visibility throughout the testing process (including equipment used, kits used, lab technician, etc.). A key function was to enhance quality processes and reduce manual data entry and decision-making, while also incorporating additional checks throughout the testing process. This improved both quality and sample turnaround times and enabled detailed tracking and management of information and assets. The system digitised the entire end-to-end process. LIMA was an internal system for Randox's laboratories and was never integrated into the TTI system. However, the results of the testing system were shared with NHS D.

79. Information security was a fundamental tenet of the Randox IT response. From July 2020, all sample information processed by Randox was received without any personal identifying information ('PII') – Randox only received the sample, the donation date and time and URN. For the limited number of samples Randox processed prior to July 2020,

we held customer registration details as defined by the TTI Network. These were subsequently transferred to the Programme directly and anonymised for future traceability and audit. Hosting the various innovations referred to above on the Microsoft Azure cloud services platform allowed Randox to manage and secure all the relevant data using the following technologies:

a. All data was stored within Microsoft Azure UK data centres.

b. All the data was encrypted at rest within the database and report storage areas.

c. All the data was encrypted while in transit using the industry standard encryption-in-transit-protocol (i.e. data transfers from registration portal to database and from Randox to the programme).

d. Microsoft Azure Front Door (encompassing its web application firewalls) provided sufficiently fast, reliable, and secure access between all external systems / end consumers and Randox's hosted applications.

e. Randox also used Microsoft's Azure database specific firewall which provided an additional layer of security to control access to the underlying database.

f. Randox also utilised Microsoft Azure's automated data backups for both the SQL Server database and Report Storage areas. Backups were automatically taken and stored in a geo-redundant Microsoft location in the UK.

Randox's data sharing with the Network

80. It was evident from the outset that modelling, data and scientific advice would be very influential in Governmental decision making and, by extension and over time, the development of the Network. Otherwise, however, Randox, had no visibility of the influence of data, modelling and scientific advice in the development of the TTI Network infrastructure.

81. Randox shared both raw data and statistical analysis based on the samples that we had processed. Up to 48-times a day our sample result information was transferred to NHS

D electronically. Separate to this we provided a daily synopsis of the sample results to a client relationship manager nominated by DHSC to manage the contract with Randox. As a general rule, throughout the pandemic, day-to-day communications to and from the testing network were processed through the client relationship managers. Randox developed a daily reporting format for sharing its synopsis with the Network which went to the client relationship managers for onward transmission to the TTI network. These reports developed over time and included:

a. daily and cumulative numbers of samples processed;

b. positive and negative numbers;

c. number of samples awaiting processing;

d. total samples processed against capacity and the hours of capacity utilised;

e. the number of samples voided by Randox at accessioning on arrival as unfit to process, with the reasons for voiding;

f. the number of samples voided during in-laboratory process, with the reasons for voiding;

g. the number of data results uploads to National Pathology Exchange (NPEx); and

h. the age profile of the samples for testing on accessioning.

In addition to the daily reports, we also provided a monthly summary. Examples of the daily reports are at pages 27-39 of **Exhibit PF/01 [INQ000513644]** and an example of the monthly summary is at pages 40- 53 of **Exhibit PF/01 [INQ000513644].**

82. The transmission of the report would be routinely followed by a daily call to discuss outstanding issues, any information requirements to or from Randox, and projections for the following days. Randox provided daily data sets to the TTI network, but had no visibility on how it was used to support the development of the TTI response.

83. Randox's daily KPI statistics were directly shared during our calls with our client relationship manager, who then presented the data on our behalf to the TTI Programme. We discussed any issues that may have arisen in the previous 24 hours and any anticipated issues in the next 72 hours. The issues ranged from transport concerns, accuracy and volatility of sample volumes received and predictions for sample volumes anticipated. The frequency of these meetings meant that they went unminuted by Randox. These statistics evolved regularly and were discussed in depth during each daily meeting.

84. With regard to raw data sharing, once an appropriate data sharing method had been established in April 2020, Randox began the sharing of results data with NHS D. The data sharing method initially involved Randox uploading a daily CSV file via an Amazon Web Service (AWS) secure S3 bucket, which then progressed to hourly and then every half-hour. Subsequently results were sent via API integration. This process for sharing our results data continued throughout Randox's programme-related sample testing.

85. By January 2021, NHS D instructed us that it was ready to receive Randox's full history data set. NHSD had already received all of this data but as the Data Controller, NHS D wanted to do a complete data reconciliation process before Randox removed the data from its systems. As the data processor Randox had no need to retain the information. In February 2021 NHS D confirmed receipt and instructed us to delete all our records. Thereafter, Randox retained no personal data.

Effectiveness of Response

86. Noting 38 years of previous global diagnostic experience and the pre-pandemic investment to develop and sustain a wide range of directly relevant diagnostic capabilities, the overall effectiveness of Randox's response can be assessed from the paragraphs below.

87. Capacity increased from 300 t/day to 120,000 t/day within 10 months. We understand this highest capacity figure is twelve times the maximum NHS PCR capacity at the start-point. Randox's development of capacity led the Pillar 2 network, at least from September 2020 onward. Randox sustained its capacity at 120,000 t/day and thereafter

dropped and varied that capacity in line with demand from the TTI programme. We surmised at the time that the TTI programme was bringing additional laboratories online and was therefore less reliant on Randox's capacity at a national level.

88. An external assessment of Randox was commissioned by DHSC and produced by Newton Consultants in June 2020. Newton commented that, '*work to optimise the manual handling processes already achieves cycle times as fast as the speed targeted in other labs.*' Overall, as stated by the second permanent secretary DHSC, to the Public Accounts Committee during oral evidence into government contracts with Randox Laboratories Limited on 18 May 2022, Newton, '*placed Randox at the top end of performance in terms of its testing provision on a number of different metrics.*' The section of the report prepared by Newton Consultants for DHSC that was subsequently provided to Randox is included at pages 54-74 of **Exhibit PF/01 [INQ000513644]**.

89. An external review commissioned by Randox from consultants OCO Global commented that Randox went from processing 96 samples in 12 hours just prior to at the start of the pandemic, to being able to process 5,000 samples in one hour by the end of January 2021, 10 months later. To put this into context, between September 2020 and January 2021 Randox increased sample processing by 233% with only a 50% increase in laboratory operations staff. A copy of the OCO Global Report is set out at **Exhibit PF/04 [INQ000513647]**.

90. Overall void rates ran at approximately 15% below the network average. The NAO report entitled, "Investigation into the government's contracts with Randox Laboratories Ltd" states as a matter of historical fact at Paragraph 3.8 on Page 43 that, "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" (**Exhibit PF/02 [INQ000513645]**. Had the void rates achieved by Randox been replicated across the Pillar 2 network, an additional 490,000 subjects would have received a valid result first time and avoided the need for repeat testing.

91. In addressing laboratory efficiency, Randox strove to balance optimising in-laboratory turnaround time with reducing the number of voided tests. At times these two requirements produced a tension as the requirement to minimise voids would mean that some samples with good stability periods remaining would be held in a refrigerated

processing area prior to commitment to the laboratory – extending the in-laboratory turnaround time. However, this resulted in a higher number of subject results being processed and delivered. With the optimisation of our process, Randox was able to achieve the following in-laboratory turnaround times as illustrated by the chart at pages 75 - 76 of **Exhibit PF/01 [INQ000513644].** This chart superimposes monthly in-laboratory turnaround times upon monthly testing volumes for ease of reference. Illustratively, the in-laboratory turnaround times at six monthly intervals is set out below to demonstrate the trend:

a. August 2020 – 32.74 hours
b. February 2021 – 9.31 hours
c. August 2021 – 9.54 hours
d. February 2022 – 6.62 hours

92. Randox was also faced with significant volume sample surges for the Delta variant in June/July 2021 and the Omicron variant in December 2021/January 2022. In June/July 2021, Randox processed 1.3m samples with an average in-laboratory turnaround time over this period of 17.35 hours. In December 2021/January 2022, (particularly over Christmas and New Year) in dealing with the Omicron variant, Randox was faced with significant laboratory overloading. Over these two months Randox processed 1.4m samples with an average in-laboratory turnaround time of 15.07 hours. Whilst daily in-laboratory turnaround times will have shown greater variability, the monthly figures are more reliable for general trends.

93. In conclusion, during the period of the pandemic Randox constantly strove for improvement through process, technical and management innovation. The impact of Randox's initiatives is evidenced by:

a. the increase in capacity from 500 t/day to 120,000 t/day within 10 months,

b. void rates remaining 15% below the network average; and

c. average in-laboratory turnaround times (with the exception of the Delta and Omicron variant surges) reducing from 33 hours in August 2020 to just over 6.62 hours in February 2022 whilst all the while dealing with very high levels of sample volatility.

94. Set out below are the dates at which Randox reported its millionth test numbers:

1 million	11 August 2020
2 million	10 September 2020
3 million	1 October 2020
4 million	19 October 2020
5 million	8 November 2020
6 million	28 November 2020
7 million	17 December 2020
8 million	2 January 2021
9 million	19 January 2021
10 million	11 February 2021
11 million	10 March 2021
12 million	9 April 2021
13 million	12 May 2021
14 million	19 July 2021
15 million	18 September 2021
16 million	14 December 2021
17 million	10 January 2022

95. It is noteworthy that from the Spring of 2021, when Randox was maximising its efficiency at high volume, TTI markedly reduced its reliance upon Randox. It was understood from the daily calls that we had with the TTI programme that this was due to additional laboratory capacity coming onstream in Great Britain. By way of example, the daily projection charts that accompanied these calls over 2021 started to list other laboratories such as 'NP', 'BB', 'NC', 'SW', 'HSL' and others. We were not privy to the decision making regarding which laboratories were assigned testing volumes. In our view, the TTI programme did not take full advantage of the efficiencies to be gained by the use of Randox's expanded capacity from that time.

UK Government's oversight and scrutiny of Randox

96. At the onset of Randox's first contract oversight and scrutiny were, at least initially, largely conducted remotely due to lockdown and physical travel restrictions. The widescale use of Microsoft Teams, Zoom, conference calls and other electronic communications provided sufficient channels to service the high volumes of liaison, coordination and passage of information required.

97. From the outset Randox provided datasets of laboratory activities to inform the TTI programme – samples processed, positives, negatives, presumed positives and samples in process. KPIs were subsequently established in Randox's second contract and additional data was provided to cover percentage utilisation, in-lab voids, accessioning voids, age of swab on accessioning, numbers accessioned and frequency of data uploads. These KPIs were reported upon daily. The daily report format varied over time and examples are provided to show how they evolved after KPIs were established. See pages 27 - 39 of **Exhibit PF/01 [INQ000513644].**

98. In contractual terms, regarding oversight and scrutiny, it is a matter of historical fact that the NAO's Report stated that, "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." (Paragraph 17 on Page 10). That omission has been the subject of some criticism. Whilst I understand related concerns, I would make the following two points. First, Randox provided daily information that supported the development of the subsequent KPIs sought by DHSC. Second, when any two parties are engaged in an unprecedented and complex project, at speed, and assuming both parties are making best endeavours, there may be merit in letting the project bed-in before assessing the most appropriate, formal KPIs. Otherwise, there is a risk that ill-advised or ill-informed KPIs may adversely affect the conduct of operations as supplier activity will thereafter be orientated to the service of those KPIs. From July 2020 and with each subsequent contract, KPIs were included. Examples of those in the form of the KPIs included in the 30 September 2020 contract and the KPIs within the framework contract covering 2021/2022 are exhibited at pages 77 - 81 of **Exhibit PF/01 [INQ000513644].**

99. The established programme KPIs from 1 July 2020 required 80% of test site samples to be reported to individuals within 24 hours from sample collection and 60% of samples from care homes to be reported to individuals within 48 hours of sample collection. These KPIs were outside the control of Randox as we had no influence over the sample collection or logistic processes. We saw our role as maximising laboratory throughput whilst reducing in-laboratory turn-around-time (TAT) as much as possible.

100. A routine daily pathway for Randox to engage with the TTI Network was established through a Client Relationship Manager ('CRM') portal staffed by Deloitte/DHSC personnel. As a general rule, routine requests to and from the TTI Network were processed through this portal. A daily report on laboratory performance provided via the CRM portal was the core communication vehicle for contributions to national level statistics and for the regular review and assessment of Randox's performance. CRMs were working remotely and were generally in post for around three months. They tended to make a single visit each to see our laboratory facilities.

101. Remote meetings were conducted at least daily: initially morning and afternoon and ad hoc as required, seven days per week. Randox established a relationship management team comprising at least five senior managers who attended these meetings and acted as the key liaison between DHSC and the internal departments within Randox. This team remained in situ for the duration of the testing programme. The team was available for meetings in the evenings and over the weekend as needed. In addition, a high volume of ad hoc telephone calls were handled particularly in the early days and periods of rapid capacity ramp up and high testing demand.

102. A weekly meeting of Network Laboratory Directors chaired by the Director of Laboratories, evolved as a vehicle for the update and coordination of initiatives across laboratories which Randox greatly valued. The purpose of this meeting was to review performance, discuss issues, understand impacts from other parts of the programme on testing, be informed of policy changes and impacts - for example, testing capacity ramp up/down; Forecast volumes; genotyping; sequencing. In addition, there were ad hoc meetings and telephone calls as needed.

103. Several times a week the head of the TTI testing network chaired a Teams/Zoom call for a wide range of attendees covering operational performance, trends, policy issues and projections which was highly useful to support our overall situational awareness.

Examples of the summaries that Randox was able to extract from these regular briefings for internal distribution and discussion are at pages 82 - 88 of **Exhibit PF/01 [INQ000513644].**

104. In June 2020 Newton Consultants, who were commissioned by DHSC, conducted a week-long assessment of the Randox laboratories and produced a detailed report for DHSC (see pages 54 - 74 of **Exhibit PF/01 [INQ000513644]**). Two key observations in the report were; '*Culture on site is open, all staff are passionate about delivering the tests and improving processes*', and '*Work to optimise the manual handling processes already achieves cycle times as fast as the speeds targeted in other labs'.*

105. Site visits were obviously limited by lockdown and associated risks. However, on 25 June 2020, Randox hosted a visit of the Pillar II SRO and its Chief of Staff, DHSC Staff and senior staff from Deloitte Consulting. We received a feedback email from the Pillar II SRO on 26 June 2020 (see page 89 - 90 of **Exhibit PF/01 [INQ000513644]**). Then on 8 October 2020, Randox hosted the Executive Chair NHS Test and Trace, the Director of Laboratories, the Chief Operating Officer and the Deputy Director, Operations, TTI Covid-19 Testing Programme. We received a feedback email to that visit from the Director of Laboratories on 14 October 2020 (see page 91 of **Exhibit PF/01 [INQ000513644]).** On 21 October 2020 we also received feedback from the Executive Chair NHS Test and Trace (see pages 92 of **Exhibit PF/01 [INQ000513644]**).

106. There were other forms of oversight and scrutiny of Randox by the TTI programme during the pandemic. At the operational level there were, at a higher frequency initially, routine meetings with TTI subject matter leads into various aspects of service provision. By way of examples these included a clinical group reviewing the threshold of positive and negative results (the CT threshold value most appropriate to the assay); consideration of Randox's 'presumptive positive' category (a *partial positive* in a two-gene test i.e. where one gene was positive and one gene was negative. Randox initially reported these as presumptive positives. However, after discussion, they were subsequently reported as positives for the avoidance of doubt); stability of samples for reporting (reviewing the period of time after a sample had been taken for which a valid result could be given); sample re-run procedures (the procedures and frequency of sample re-runs where a valid result is not achieved on the first run); redesigning of sample packaging (to improve the user experience) and so on. At the technical level there

was the considerable IT to IT engagement referred to above regarding the integration of Randox's reporting into the national system via NPEx.

107. Discussions were also held with the CRM on how the quality of samples provided to Randox might be improved, to avoid accessioning voids, and so on. The requirement for such meetings reduced somewhat as processes were established and improved but lines of contact were maintained.

108. We would comment that throughout the pandemic we were never provided with an overview of the TTI infrastructure – and were largely unaware of the structure beyond the gateway controlled by the customer relationship manager. The consequence of working blind within the programme was that the sharing of ideas and process refinement was impeded. The development of the programme required a far more agile forum for exchanging ideas and developing a culture that valued initiative. A small but revealing example was our repeated request for an overview of the structure of the programme that went ignored. For example, if we had been aware of the organisation responsible for the efficient sample flow into the laboratories we could have reached out and worked with them to initiate improvements. In addition, a more focused technical innovation hub would have served the programme well. This may have existed but we were not aware of it and were unable to reach out. Whilst we were directed to operational areas of responsibility when needed and personal visits did instigate some short-term benefit, the lack of structural awareness did curtail greater engagement.

Centralisation of the National Testing Programme and TTI

109. As a provider of largely centralised testing it was not clear that the Government had any option but to establish a largely centralised testing network.

110. As previously stated, the NHS testing capacity for COVID-19 PCR testing on 17 March 2020 was 2,400 t/day. If all other PCR testing was stopped within the NHS, then 10,000 t/day was possible but involved risk. It was also stated that a target had been set for NHS testing of 25,000 t/day and that was considered a stretch target and very challenging. At the same briefing it was stated that a likely initial requirement for mass testing was 100,000 t/day. This was well beyond the NHS's capacity, and it was clear that

Government had decided that a testing infrastructure had to be established outside the NHS estate.

111. The question then arises whether the testing model could or should have been decentralised, or focussed upon a few high-volume sites? Noting the dominance of the NHS in the UK, with laboratory testing provided free to all at the point of use, the nation is not fertile ground for an expansive number of alternative laboratory providers. However, that limited number of laboratories could perhaps have provided the foundation upon which a more decentralised laboratory testing network may have been based.

112. Randox understand that DHSC did put out a call to arms for testing providers in late March/early April 2020. See DHSC Press Release dated 8 April 2020, "Industry responds to call to arms to build British diagnostics industry at scale". (see pages 94 - 100 of **Exhibit PF/01 [INQ000513644]**). Randox are unsure of the response. However, to offer to support the TTI testing provision at that time did involve considerable challenge – supply chains and services were faltering, any participating laboratory would be required to greatly scale up their PCR capacity and move to 24/7 services, greatly impacting their in-place business model and a lockdown was in place. Randox decided we would step forward from the very outset – we are unsure how other laboratories responded.

113. Whilst TTI settled initially on five Pillar 2 laboratories, Randox understand that other laboratories did subsequently step forward later and joined the network. Randox understand the network became increasingly more decentralised over time, with eventually around 20 laboratories within the Pillar 2 network in 2021.

114. Considering the volume of testing required by the Network, the potential scale of decentralisation is an important issue. Given that the complete NHS PCR capacity pre-COVID-19 was assessed at around 10,000 samples per day it is unlikely that any other laboratory would have had a capacity of more than a few hundred tests per day. The ability to scale-up significantly and integrate with TTI processes and procedures would be a major consideration for any participant. We would comment that scaling-up is not a straightforward exercise.

115. It is not therefore clear to Randox that the Pillar 2 testing network could have achieved a great deal more decentralisation given the demands and circumstances at the point when key decisions were being made. Had a wider network been quickly available it is

possible a more localised logistics structure could potentially have reduced turnaround times at the likely cost of much greater coordination and resource demands to support and ensure the effective output of a wider network.

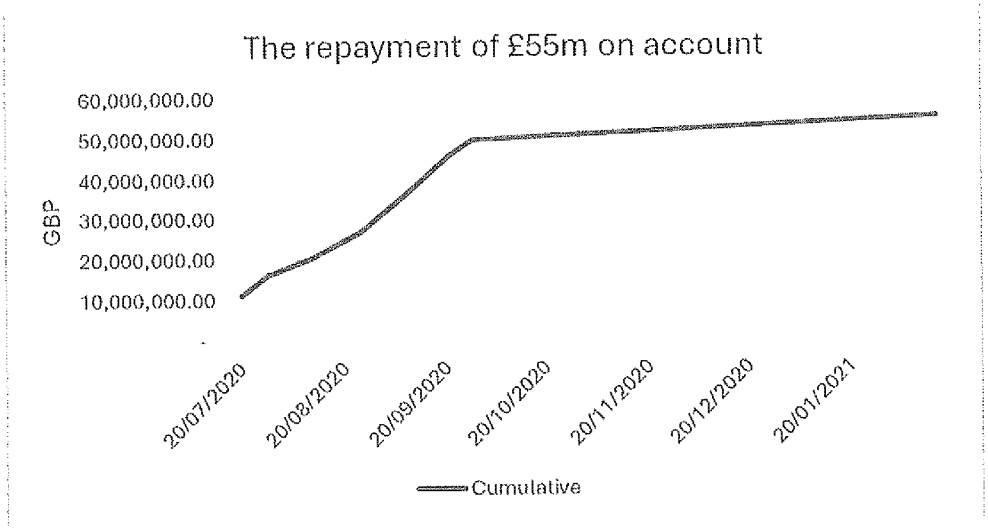
116. The use of Randox's deployable Cube laboratories could have assisted with establishing a decentralised laboratory network for TTI, although these were not available until July 2021. Four testing Cubes were deployed to Warrington and Dunstable and in the event were largely utilised to support private testing.

Contracts, Costings, Profitability and Value For Money

117. Ultimately Randox, and its strategic partner Qnostics Ltd, were awarded 22 testing associated contracts. It is a matter of public record that 13 were awarded under Public Contracts Regulations 2015, under Section 32(2)(c), or under extensions to those contracts, or as Regulation 72 modifications of those contracts. Section 32(2)(c) refers to 'use of the negotiated procedure without prior publication'. Nine contracts were awarded from a competitive framework. The total value of these contracts was £776.9m, of which £770m was for COVID-19 testing services and £6.9m for testing related goods. Randox ultimately invoiced just under £469.5m (ex VAT) for the testing services rendered. Randox also invoiced £2.89m for testing goods and Qnostics Ltd invoiced £2.85m for testing goods. A detailed breakdown of these contracts was set out at Figures 3 and 4 at Pages 22-26 of the NAO report entitled, "Investigation into the government's contracts with Randox Laboratories Ltd" and I refer to these for context, and to record the details as a matter of historical fact, (see **Exhibit PF/02 [INQ000513645]**).

118. Committing to the first contract, Randox was granted a payment on account from DHSC of £55m. As a matter of context and historical fact, the NAO Report states at Paragraph 2.9 on Page 10 that, "*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,*" (see **Exhibit PF/02 [INQ000513645]**). These monies enabled the company to ramp up at speed and build laboratories, recruit and train staff, purchase equipment and consumables. However, this transferred considerable risk to Randox. The duration and volume of the testing under the contract was not guaranteed. Indeed, in his evidence to Module 5 (Procurement) on 19 March 2025 Lord Bethell indicated that at this

early stage it was still considered possible that antibody testing might be a key focus for DHSC, identifying those with immunity and possibly reducing the PCR testing requirement. Therefore, if the anticipated volume of testing was ultimately not required, Randox faced having to pay back monies that had already been committed. The payment on account was largely paid back by the end of the first contract and settled in full by January 2021.This is shown by the graph below:



119. Set out below is a table for the price per test charged by Randox by date.

Date effective	Contracted Price point	Comments
Mar 20 - Sep 20	I&S	This price includes I&S for each sample collection kit. Swab and testing price separated after further negotiation summer 20
Sep 20 - 23 Dec 20		Reduction in price reflecting economies of scale and labs now set up
24-31 Dec 20		
Jan - Feb 21		
1-14 Mar 21		
15-31 Mar 21		
Apr - May 21		
1 Jun - 12 Dec 21		

Dec 21 - Jan 22	I&S	
Dec 21 - Jan 22		Tiered pricing introduced meaning more per test charged when certain thresholds were met, this was part of the surge capacity agreement
Dec 21 - Jan 22		
Dec 21 - Jan 22		
14 Jan - 31 Mar 22		Back to pricing prior to surge agreement
Apr - Jun 22		Increase in price to reflect lower numbers so less economies of scale

120. As can be seen from the table above, the price was highest in the first contract with a cost to DHSC of I&S per sample processed and I&S per sample collection kit. This price was established for the first contract at risk as initially there was no guarantee of the numbers of samples to be processed. There was also no guarantee of any future contract and as such, the initial cost had to cover the costs of scaling up and building the appropriate infrastructure.

121. Thereafter, it can be seen that Randox was able to drive down cost once the infrastructure costs had been covered, efficiency initiatives had been implemented and economies of scale realised. The chart at page 75 - 76 of **Exhibit PF/01 [INQ000513644]** superimposes the sample volumes on turnaround times and illustrates that in early 2021 Randox had achieved low turnaround times whilst processing high volumes of samples, all whilst void rates remained at 15% below the network average. At that time, the Network became less reliant on the samples being processed by Randox as other laboratories came on stream. My sense is that the TTI programme did not fully realise or benefit from the efficiencies that Randox achieved through 2021. I accept, however, that the efficiency of the other laboratories in the Network would need to be analysed to validate my belief. It was for the TTI Network to determine whether the logistical costs of shipping samples to Randox's laboratories was outweighed by the costs of onboarding additional laboratory capacity elsewhere.

122. With regard to the initial pricing, the NAO Report into Randox recorded as a matter of historical fact that, *"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."* (Paragraph 2.11 on Page 32 of **Exhibit PF/02 [INQ000513645]**). In light of the fact that Randox provided an end-to-end service, it is possible that we were the cheapest of the four services compared by the UKHSA.

123. There was no specific price for voids that was set by DHSC for the first contract. Thereafter, the price for processing voids from September 2020 to May 2021 was progressively reduced from **I&S** to **I&S** Thereafter, voids were processed without charge.

124. I am aware that much comment has been made on the profits generated by Randox through the TTI contracts. The income from the TTI contracts was processed through the accounts of Randox Laboratories Limited. In particular, the PAC reported that Randox reported a profit in the year to 30 June 2021 which was 100x greater than the profit for the eighteen months to 30 June 2020. (See **Exhibit PF/03 [INQ000513646]**). The PAC published its conclusion after a superficial reading of the Randox Laboratories accounts without seeking the necessary context and depth of understanding from Randox. Had the PAC bothered to contact Randox prior to publication we would have highlighted the need to take into account the published exceptional losses and increase in turnover. A more detailed consideration of the published accounts for Randox Laboratories for the year ending 30 June 2021 shows that the gross profit margin (excluding exceptional items) for 30 June 2021 was 52% as opposed to 47.7% for the previous eighteen-month period. The operating profit margin for the year ending 30 June 2021 (excluding exceptional items) was 47.1% as opposed to 27.8% for the previous eighteen-month period. The actual relative increase in operating profits from 2019/20 to 2020/21 is 69.4%. This analysis provides a different perspective to the 10,000% profit increase claimed by the PAC.

125. A review of gross profit margins of the Randox Laboratories Limited accounts from 2014 to 2022 shows the following gross margins in the financial years ending:

Dec	Dec	Dec	Dec	Dec	June	June	June

2014	2015	2016	2017	2018	2020	2021	2022
48.2%	52.4%	47.0%	52.3%	46.8%	47.7%	52.0%	23.4%

It can be seen that the Gross profit margins during the Covid years to June 2021 were very much in line with previous years (in a range from 46.2% to 52.4%). However, the quantum of gross profits in the Covid years will have risen as a result of the significant volume of increased sales. Operating profits will have increased during the pandemic as a number of the overheads will have remained fixed whilst other overheads such as staffing and disposal costs will have increased. Randox also had to take account of risk and the uncertainty of how the pandemic would develop over the following months. By way of example, the lead time for the consumables required for testing was frequently greater than the government notification for testing and our contract renewals. As such, Randox had to commit to high volumes of consumables without assurance that they would be required. These consumables also had a defined shelf-life making their utility time-sensitive. As of November 2024, Randox is still holding significant levels of COVID stock that is having to be written off. In addition, surge commitments required us to maintain fixed base costs without any commitment as to their use.

126. Our higher profits, in particular to the year 2021, can be attributed solely to significantly higher testing volumes. These volumes were dictated by the DHSC noting that in the June 2020-June 2021 period other laboratories lagged in their development of capacity.

127. The risk Randox had taken can be seen in the drop off in gross profit in 2022. There was an overall reduction in testing volumes in that period but with the requirement to maintain the fixed cost base for short notice surges in testing. The overall loss subsequentially reported in the financial year to 30 June 2023 is due, at least in part, to the time and cost of scaling down after the pandemic.

128. Randox's initial price has been shown to be favourable with comparative pricing in mid-2020 and once the initial set-up costs had been covered, Randox reduced pricing by 55% to achieve the lowest price of I&S We believe that this would compare favourably with other Pillar 2 laboratories provided that all costs of service are taken into account.

129. I am aware of comment made by Lord Agnew (DHSC Update, Statement made on 3rd February, UIN HCWS586, Humble Address, Randox Contracts, Page 40) prior to the extension to our first contract that, 'I am very worried about pricing. Given the huge

volumes we are paying dramatically over the odds'. We understand from other correspondence that an internal memo had been distributed with DHSC comparing the full cost of the Randox end-to-end service with the cost of reagents, only, in other laboratories. Any such comparison was incomplete, inaccurate, unreliable and misleading.

130. Randox achieved remarkable efficiency within a short space of time and as indicated previously, TTI did not avail itself of those efficiencies which would have reduced Randox's gross and operating profit margins over time.

131. Randox is unable to comment on the value for money of its service in comparison to the provision of other laboratories in the Pillar 2 Network without access to the necessary data, which we do not hold. However, in the opening statement of Module 5 (Procurement), Counsel to the Inquiry stated that £12 billion had been provided by the Government for PCR testing. Randox received £470 million of those funds for testing, just under 4%, and conducted around 12% of the PCR testing for Pillar 2. Whilst Randox was not responsible for sample collection kits after the first contract, or logistics, those details may provide a useful indication of value for money provided by Randox. Furthermore, at Pages 4 and 67-71 of the study by OCO Global that Randox commissioned (see **Exhibit PF/04 [INQ000513647])** it was estimated, based on OCO Global's modelling on the Central Projection, that Randox's contribution to the TTI programme averted 3,136 deaths, 14,100 extra hospitalisations and boosted the UK's GDP by £6.48 billion. Noting the £470 million investment that may also provide a useful indication of an overall return on investment.

Additional Context

132. The general trend of the pandemic, from a Randox perspective, was starting with low throughput, largely manual systems and gradually transferring to higher throughput, more automated systems, seeking continuous optimisation and efficiency.

133. At the outset a significant increase in output had to be achieved from a small initial global supply base, at that time scaled to supply only pre-pandemic needs. When TTI was initiated, suppliers had to greatly increase production at a time when workforces were constrained by lockdown and global supply chains were hampered by travel

restrictions and, potentially, national self-interest. Randox's internal capabilities were a considerable strength during that initial period and thereafter.

134. Randox initiated testing for TTI immediately upon signing the first contract on 30 March 2020 and reported our last sample results on 21 June 2022.

135. Randox was involved in 22 testing associated contracts, of which thirteen were awarded under use of the negotiated procedure without prior publication, or Regulation 70 modifications thereof. Nine were awarded from a competitive framework. In the associated contract negotiations Randox did not engage with Ministers; all negotiation was conducted through officials.

136. Randox's engagement with Ministers, as reported within the NAO investigation into the government's contracts with Randox Laboratories Ltd., published on 22 March 2022, has attracted some highly speculative and inaccurate media and political comment, particularly as DHSC failed to keep a record in six of the eight reported meetings. On two of these occasions Randox engaged with a Minister, with officials in attendance, to discuss Randox related operational matters, outside of contract negotiations. The other unrecorded meetings all had multiple other suppliers and civil servants in attendance and Randox did not meet privately with Ministers. For the record I have covered these matters in more detail at Annex A of this statement.

137. Throughout the pandemic Randox were solely a provider of high-volume testing capacity within the Testing limb of TTI and had no function or responsibility within the Trace or Isolate limbs. Within the Testing limb, Randox did not set or advise on strategy or policy. Input was generally limited to the provision of data and offering advice and technical capabilities to help improve efficiency within the Testing limb.

138. When Randox agreed its first contract with the DHSC on 30 March 2020 it joined the Pillar 2 testing laboratory network that included four lighthouse laboratories that were to be established at Milton Keynes, Cambridge, Alderley Park, Cheshire and Glasgow. Randox was different from the other laboratories who were set up from scratch. Alternatively, we had 38 years of global diagnostic experience, a developed COVID-19 PCR assay, previous experience in the development, registration and deployment of accredited PCR tests, in-place quality assured laboratory facilities, an active, direct-to-consumer, end-to-end PCR service at low scale (for STIs) including remote sample

collection and registration, along with experience of the associated logistics, a secure on-line reporting system, an active global supply chain and a diagnostically aware and trained workforce.

139. The other sites were all facing similar challenges in establishing initial capability and then ramping up. The Randox focus from the outset was more geared toward ramp-up but doing so in the face of lockdown and restricted global supply chains. Our needs and the level of support we required, did vary from those of the other Pillar 2 laboratories, and relationships developed accordingly. The four Pillar 2 laboratories that were developed from scratch had common issues and required greater support from DHSC and consequently developed a close working relationship. As a result of our in-place capabilities Randox was one level detached from that engagement.

140. Given that Randox was, in the first instance, seeking to increase capacity in a number of weeks to 60,000 t/day – six times the complete pre-pandemic capacity of the NHS, we knew there were likely to be pinch-points in accessing key equipment and consumables. This became particularly acute in the face of a national lockdown, restrictions to supply chains and the global demand for the same equipment and consumables soaring. At the on-set of the pandemic DHSC stepped in to control the flow of key equipment from suppliers to laboratories, including those ordered by Randox. In anticipation of such constraints, it was included within the contract that support from the Authority may be required after Week 3; up to which point we could meet capacity targets from internal resources. Our subsequent and entirely appropriate engagement to access loan equipment, at that time lying unused in universities and R&D centres, attracted much ill-informed media and political comment. For the record I have addressed this matter further at Annex B of this statement.

141. In terms of operational logistics, samples to be processed were transported to Randox from Great Britain, via the TTI logistic network, arriving by ferry and truck initially and also by aircraft to the adjacent Belfast International Airport. Randox understood that we processed largely care home samples, and some home samples, but were blind to point of origin of samples. Samples were also transferred from Testing Centres and Care Homes in Northern Ireland. The inconsistent and variable flow of samples into the laboratory was a constant source of frustration with very high volatility impacting upon laboratory efficiency. Despite regular engagement this matter of sample volume volatility into Randox's laboratories was never satisfactorily resolved. The graph below shows the

rate of accessioning into our laboratories – whilst there will be a lag between delivery and accessioning depending on delivery volumes, the graph below illustrates the degree of volatility with which Randox had to contend.

Randox TTI Accessioning Count – July 2020 to June 2021

142. To illustrate the impact within reporting data, note that laboratory daily returns to DHSC covered midnight to midnight and assume circumstance when the laboratory was operating at a capacity of 120,000 tests per day (or 5,000 per hour), with a turnaround time (TAT) of 9 hours. Due to logistic flow it was common for our laboratories to run out of samples on a Monday evening. Assume then 60,000 samples arrive at 0001 on Tuesday and 60,000 samples arrive at midday – the daily capacity allocation of 120,000. When Randox start to process the first batch of 60,000 samples, the first results would be released after the 9 hour TAT at 0900 and the last at 2100. The first samples from the second batch would be accessioned at noon and first results released by 2100 – with 15,000 results released in the 3 hours to midnight. In these circumstances, the daily statistics would show Randox receiving 120,000 samples by midday on Tuesday and reporting 75,000 samples on Tuesday.

143. It was all too common thereafter, and throughout the pandemic, for central staff to assume there must be an issue in the laboratory. In fact, the laboratory was operating very efficiently, the drop in output was purely due to inefficient logistic flow.

144. In order to support laboratories to plan ahead, the network did establish a sample projection service which would start a number of days before the delivery date and be refined closer to the delivery date. Whilst this was broadly helpful, we found that there were also high levels of variation between projections and what was actually delivered – at times this could be 50% or more and did not particularly support staffing projections. This often resulted in the short notice mobilisation of staff to meet higher unpredicted demand. Despite this becoming a significant issue, our staff showed high levels of responsiveness throughout the pandemic, although toward the end of the second year, the lack of predictability made it very difficult to staff appropriately. This was particularly noteworthy during the Omicron surge over Christmas and New Year of 2021/22. At that time, having increased capacity to 80,000 t/day, Randox received 138,000 samples on 30 December and 130,000 samples on 31 December. Throughout the Pandemic more should have been done to both smooth sample flow and improve volume predictions. For example, a programme should have been developed to equalise care home testing across a seven-day period and harmonise logistics to equalise delivery to the laboratories. Where that was not possible, greater efforts should have been made to fill the troughs in supply to the laboratories from other sources. This would have ensured equitable distribution of samples across all the laboratories in the Network. There was also a considerable discrepancy between the predictions for samples to be received and the actuality. DHSC needed to improve the tools for anticipating the likely volume of samples which could then have been passed to the laboratories on a daily basis so they could anticipate and provide a more efficient service.

145. Given the erratic flow of samples and surge requirements, there were occasions where some laboratories were faced with excess demand that they could not cope with efficiently. In these circumstances, the DHSC instigated a process whereby samples were shipped from an over-committed laboratory to one with spare capacity. This enabled samples to be processed but did increase turnaround times. Randox both received samples from other laboratories and sent samples to other laboratories on different occasions. The cross-referral system worked relatively effectively when required.

146. One impact of the ad hoc nature of the commencement of mass testing, and the shortage of consumables, was that multiple types of sample tubes were utilised across the network – with varying heights, diameters and caps. This complicated the drive for automation which relies, to a large extent, upon standardization. Whilst the

circumstances of any future pandemic and consumable availability will be unknown, greater focus on the scope for 'key consumable standardisation' from the outset will support automation and efficiency thereafter. That does not mean moving toward a single supplier, but that early consumable specifications could be provided to wider supplier networks.

147. Regarding void rates, Randox reported two types of voids. First, accessioning voids where the sample was voided on arrival at the laboratory as unfit to process. This could be for a variety of reasons of which the two most common were the age of the sample (where the sample had exceeded its stability period at the point of accessioning) and leakage from the sample tube. The second type of void was an in-lab void. Again, these were caused by a variety of reasons such as insufficient volume or sample integrity fail, both of which were caused by external factors to Randox. Other in-lab voids included extraction fails due to technical issues. For context and as a matter of historical fact, the NAO Report into Randox noted that, "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" (see at Page 43, Paragraph 3.8 of **Exhibit PF/02 [INQ000513645]).**

148. Whilst Randox reported accessioning voids, Randox was not the cause of the voiding which resulted from issues with the sample collection and logistic chain. It was commonly misunderstood that the voids reported by Randox were caused by Randox which was not the case. However, Randox did take responsibility for the processing and costs of disposal of all the voided samples. The vast majority of voided samples were the responsibility of the sample collection and logistic chain.

149. In parallel with the provision of testing to the TTI Network, Randox also provided private COVID-19 testing. The private testing was at a very low volume throughout 2020 and in early 2021. The volume of private testing picked up from March 2021 which coincided with the introduction of testing before and after international travel. The increase in private testing also coincided with additional TTI laboratories in Great Britain coming onstream and the TTI Network's reliance on Randox reducing markedly (other than when there were surges.) From July 2021, Randox deployed four cube laboratories to Warrington and Dunstable. The Randox approach to testing private and TTI samples is outlined at Annex D of this statement.

150. The initial Randox contract required Randox to manufacture and supply sample collection kits, which were dispatched to DHSC designated hub sites for onward distribution to individuals. Randox also had to provide an on-line registration portal for individuals receiving Randox sample collection kits, and following the return and processing of samples, to send the results direct to individuals, as well as to DHSC. The requirement for Randox to supply sample collection kits was paused in July 2020 following questions regarding the sterility of supplied swabs, pending a PHE investigation. Whilst repacking was undertaken the requirement to supply sample collection kits was not subsequently reinstated. For the record I have provided further details on this issue at Annex C of this statement. The responsibility for transmitting results direct to individuals was also transferred to DHSC in July 2020 once their system was established and transfer enabled. Thereafter all Randox results were directly uploaded to the DHSC National Pathology Exchange (NPEx) system for onward transmission to individuals.

151. From early 2021 Randox made the decision to invest in equipment and staff to develop an in-house genetic sequencing capability in order to identify COVID-19 variants. By April 2021 we were satisfied that this capability was operating to ISO 17025 standards, though the formal accreditation process was much slower to respond. This capability was offered to, but not utilised by TTI. We found that disappointing noting the limited capacity at Queen's University Belfast and the Sangar Institute to which we were directed to send samples; we understood back-logs at these locations were common.

152. Randox had extensive experience and R&D capabilities to support diagnostic operations of Randox and these were available to the network, should they require them. By way of some limited examples of activity of benefit: we understand the Randox-developed-model of mass PCR testing laboratories was instrumental in the design used at the Rosalind Franklin laboratories. Following the visit to Randox by the Executive Chair of Test and Trace and the Director of Laboratories on 8 October 2020, the Director of Laboratories asked us if we could host follow up visits to showcase our structures, processes and automation to inform other laboratory development. That follow up email was received by Randox at 22:11 on 14 October 2021 (see pages 101 - 103 of **Exhibit PF/01 [INQ000513644]).** The Randox accessioning model with automated sample age testing and laboratory prioritisation was promoted to the network – this process was at least partially responsible for the lower void rates achieved at Randox. Randox staff were

active in the development and use of automated 'cherry-picking' (the centralisation of positive samples from multiple sample plates), reflex testing and the development and use of the sequencing technology necessary to assess variants. Randox also played a role in the assessment of pooled testing and developed reporting data methodologies to improve TTI visibility of laboratory performance with the sub-sets of information available. We also felt, at times, that we were providing an unpaid consultancy service – advising those drafted into the network at short notice as client relationship managers and so on, who had no experience of laboratory operations.

153. We also found it necessary when discussing testing capacity claims more broadly within the TTI programme to stress the difference between daily theoretical and operational capacity. At its simplest theoretical capacity might be calculated by multiplying the hourly capacity of key equipment by 24. Operational capacity, on the other hand, must take into account staffing levels and work rates, demand, consumables, training and skill levels, process bottlenecks, equipment maintenance and downtime, disposal process and so on. Operational capacity – which reflects true laboratory potential output - would vary on a daily basis and needed to be constantly monitored. Any tendency within the TTI network to rely upon on more theoretical figures across laboratories would inevitably stress the system during short notice surges.

154. Randox played no role in in assessing the equality impact of testing on different categories of people across the UK or in assessing or redressing issues of public compliance.

Randox - Key decision makers, structure and capacity in respect of TTI

155. As Managing Director of Randox, I led the strategic direction of the project, guided contract negotiations, maintained oversight and prioritisation of planning, delivery, operations and process optimisation.

156. Our Finance Director led contract negotiations and financial management.

157. Our Chief Scientist assessed and monitored the technical effectiveness of the testing and processes, liaised with me and coordinated on matters of wider programme technical

coherence. He also monitored and addressed the impact of COVID-19 variants on testing and directed and prioritised our research and development resources.

158. Our Laboratory Operations Director led and controlled the day-to-day laboratory and support operations and oversaw the delivery of efficiency/optimisation initiatives.

159. Our Network Laboratory Directors Liaison Manager was responsible for liaison and coordination laboratory directors across the network and attendance at laboratory directors meetings.

160. Our Head of Engineering coordinated the engineering effort and delivery of automation/robotics initiatives and supported the Operations Director.

161. Our Chief Information Officer developed and oversaw all the information technology support, including internal requirements to structure and optimise the operational processes required to scale up the delivery. He was also responsible for the integration of our software systems with the wider TTI programme IT systems.

162. Our Manufacturing Manager was responsible for the planning and delivery of internally manufactured product to enable and support operations.

163. Our Regulatory Affairs Manager was responsible for maintaining, coordinating and delivering compliance with all laboratory regulatory and accreditation requirements.

164. Our DHSC Communications Group Manager was responsible for coordinating general and routine communications with DHSC, generally via the CRM portal.

Observations and Conclusions

165. It is worthy of note that whilst the building of capacity was initially very challenging, by no later than September 2020 Randox, as a private supplier, had achieved the largest laboratory testing throughput in the national network. Randox's capacity continued to lead the network well beyond January 2021 by which point Randox had achieved capacity of 120,000 t/day – Randox were then advised that further capacity would not be

required. Only one other laboratory eventually surpassed Randox's highest capacity, but much later.

An intrinsic PCR testing capability

166. A key observation from the COVID-19 experience is that the UK would have benefited from a larger initial, intrinsic PCR testing capability, enabling the nation to respond in a timely manner to the initial testing demands of this pandemic. Larger volume testing capacity, provided earlier, would have provided much better intelligence on the progress of the disease within the UK and provided policy makers with key data with which to inform decision making. Capacity of course needs both testing infrastructure and a suitable assay.

167. We understand that Government committed to implement mass testing within the UK, around mid-March 2020. We were also advised in early April that an initial capability requirement was set to achieve 100,000 PCR t/day by the end of April 2020. This was to be achieved in a limited number of high-volume testing sites to be developed from scratch outside the NHS estate. Randox played no role in establishing that construct or target.

168. From information provided to us verbally at the meeting on 17 March 2020 we understand that the NHS's PCR capacity pre-pandemic was in the region of 10,000 t/day. And, within 4 weeks of initiating mass testing the Government wished to achieve an initial PCR testing capacity 10 times greater than that NHS testing, in new, undeveloped testing facilities outside the NHS estate. That this target was set whilst implementing a national lockdown and during unprecedented disruption to global supply chains, restricting access to required equipment and consumables, indicates the scale of the challenge.

169. To its considerable credit we understand that the Pillar 2 network eventually developed a testing capacity of around 1,000,000 t/day in late January 2022. Randox were advised that we would not be required to provide additional capacity having achieved 120,000 t/day at the end of January 2021. We also understand that Randox were the largest volume provider of PCR testing to TTI from at least September 2020, and well into 2021.

170. A key issue to address is how the nation might maintain a scalable laboratory testing capability for a pandemic - with an entirely unknown source - that is both responsive and multiple times higher than the routine national requirement – and how to maintain and engage the staff and resources required in the potentially lengthy period prior to any subsequent pandemic?

171. Whilst the public health sector may provide core capabilities, the impact of training and exercising surge staff away from other day-to-day responsibilities, and maintaining infrastructure and personnel for that purpose, is likely to impact directly on other public health functions. At times of fiscal tautness pressures are likely to be applied to such insurance capabilities and experience would indicate that resources and facilities are likely to be tasked with multiple responsibilities over time.

172. In the event of a challenging business case to sustain public sector assets for this purpose, we would offer that the private diagnostic sector – which incorporates assay development capabilities, laboratories with active quality processes, IT, engineering and global supply chain networks - has the potential to respond rapidly if engaged to retain resources to be maintained for that specific purpose – which could be regularly exercised (including sample processing and reporting) with staff flexed from routine private sector diagnostic employment (at risk to the private sector) as required. Proposing a 'warm capacity capability' rather than relying upon more dormant 'sleeping' or 'cold' advanced supply contracts.

173. Having built-up amongst the largest PCR laboratories in Europe, and in the absence of involvement in any longer-term planning, Randox have now largely decommissioned laboratory capacity with no plans in place for reestablishment The Randox assay development capability is retained, as are the regulatory, engineering, IT, logistic support and global supply chain expertise necessary to support a pandemic response.

Consideration to Strengthen the UK's Diagnostic Industry

174. Throughout the pandemic the UK was very heavily reliant upon overseas providers of PCR equipment and consumables. Whilst this ultimately worked, we might be mindful of three possible implications in any future pandemic. First, the UK could be placed as a lower priority for supply should nations prioritise their own internal need for testing; second, at the very moment an increase of supplies is required global supply chains are

likely to be restricting and, third, the majority of the financial benefit from any national resources expended on testing resources goes overseas.

175. The problem of supply was evident at the start of the pandemic, particularly with a marked shortage of essential PCR extraction systems. There was no UK manufacturer for this equipment and systems were removed from universities and R&D centres to try and build initial Pillar 2 capacity. This was far from satisfactory.

176. Randox were initially an exception to the supply rule in that we had developed a Randox COVID-19 PCR test by 10 February 2020, on our patented biochip technology. Testing was provided on our 'Evidence Investigator' system (a PCR biochip based system to enable the analysis of samples of COVID-19) with support from a bespoke 'Evidence Plus' system for larger capacity. We subsequently commenced manufacture of our own additional consumables as well.

177. The problem of supply could of course be addressed by stock piling equipment and consumables from overseas suppliers for use in the event of a pandemic. That may prove problematic as required stocks are likely to markedly exceed routine usage needs and consumable stabilities will create wastage. Stockpiled equipment is likely to need maintenance and regular software updates.

178. We would recommend that consideration be given to strengthening the UK's internal diagnostic capabilities to build self-reliance and improved responsiveness in the event of a subsequent pandemic. Such an internal capability would also be well placed to support UK health initiatives and grow exports.

Laboratory Efficiency – Sample In-flow

179. In our experience the one singular step that could be taken to improve laboratory performance and efficiency would be for the supporting logistic process to maintain a consistent, accurately predicted, flow of samples into laboratories for processing. In Randox's experience this was very rarely achieved, with supply often producing a stuttering, 'stop, start, stop' effect on laboratory processes, frustrating both staff and reducing efficiency and output.

180. By way of example a laboratory capacity of 120,000 t/day means the laboratory is optimised to process 5,000 samples per hour – if supply stops for 6 hours, sample capacity of 30,000 t/day is lost and cannot be regained. Similarly, if 30,000 samples are dropped-off at a site it will be 6 hours before the final samples are accessioned to begin processing which impacts on turnaround time – assuming the samples were predicted to arrive, and staff had been rostered.

181. The information provided has detailed the inconsistency and high volatility of the sample volumes provided to Randox throughout the pandemic - the associated problems were frequently reported via the DHSC Client Relationship Manager but to little avail. As a consequence, the volatility in receipt of samples and their projections did not substantially improve throughout the Pandemic.

182. Randox are not in a position to comment on the reasons for sample supply volatility but had been advised, for example, that testing in care homes was generally much reduced during weekends, producing variable mid-week peaks and extended turnaround times. It may also be the case that the efficiency of logistic processes were prioritised over the efficiency of laboratory performance. It is likely much more could have been done to smooth out the flow from care homes for example, or to utilise the available 'trough' capacity by allocating samples from other sources.

183. In anticipation of a future pandemic, and to avoid hindering laboratory efficiency, we would recommend that a study be undertaken to identify processes and procedures to improve the predictability and relative consistency of the flow of samples into processing laboratories. As mentioned above, this should be combined with consideration of timely standardisation, to assist automation'.

Commercial Consultants and Whole System Management

184. We are aware that, faced with the scale of the mass testing programme, Government officials at DHSC engaged a single consultancy company to assist. That consultancy company was given whole system responsibilities i.e. was responsible for organising the sample flow from collection sites to laboratories (referred to for this point as the 'tactical level') and also to support operational planning and policy development at DHSC

(referred to for this point as the 'operational level'). We assumed that this approach this had the advantage of whole system visibility and offered some related efficiencies.

185. However, we believe this approach also has potential disadvantages in that when we, the tactical laboratory level, raised issues regarding the efficiency of the tactical flow of samples to the operational level, we were raising those issues with consultants from the same consultancy company - who were also responsible for that tactical flow. We were never sure how our complaints were processed but, whilst this is a difficult problem, the smooth and consistent flow of samples to our laboratory was never achieved. This left our laboratory, which was outside the consultancy envelope, to deal with the issues of inconsistent flow and carry the resultant inefficiency into our reporting data.

186. Whilst we wouldn't wish to claim any ulterior motives this approach had the systemic potential for the commercial and presentational interests of the consultants becoming a factor whilst dealing with whole system issues. There may be merit in the separation of consultancy support at the tactical and operational level for TTI benefit from the associated creative tension.

187. We were also aware of a plan within DHSC to provide consultants with DHSC email addresses whilst working on pandemic support. This may have had the effect of creating the impression of a singular team – we can only say we found it useful if we knew whether we were dealing with a commercial consultant or a DHSC staff member. We were impressed by the quality and standards of the Civil Servants that we dealt with who brought a breadth and experience and understood what was required. The consultants, in contrast, perhaps because of the limits of their retainer or instructions, adopted a narrower, less-open view.

188. We would recommend that a review of commercial consultancy support to pandemic operations consider the separation of commercial responsibilities at the tactical and operational levels.

189. We would also comment that the consultants with whom we engaged and who were responsible for running the TTI programme lacked knowledge and understanding of laboratory processes. This risked misreporting and consequential inefficiencies. By way of example, it was necessary to educate each new client relationship manager on the realities of laboratory processes which took up valuable time and resources. We also

never felt that the issue of volatility of sample supply to laboratories was ever fully understood, let alone addressed. We would recommend in any subsequent pandemic that a programme of training and awareness to support efficiency within laboratory operations be provided to the relevant staff prior to their assuming an operational role.

Lack of Knowledge of the Test, Trace and Isolate Infrastructure

190. Randox acted as a testing services provider from 30 March 2020 and processed our final test for the TTI programme on 21 June 2022. In that time Randox processed just under 17.5m samples for the TTI programme.

191. During Randox's time as a testing provider access to DHSC was through a client relationship manager, who acted as a gate guardian to the wider testing infrastructure – passing questions on, bringing answers back and generally restricting access through the gate. Client relationship managers were changed frequently with some associated disruption to processes.

192. However, Randox were never once provided with an organic chart of the wider testing infrastructure – despite requests – and we lacked understanding of the structure within which we were operating. Whilst set-piece engagement took place for specific and directed purposes, the lack of understanding of the wider structure had a detrimental, 'end of the line effect' and hampered our flexible engagement with the wider ecosystem to raise initiatives and so on. If this approach was reflected throughout the system, there would have been a detrimental impact on both culture and system development.

193. Whilst we suspect the TTI structures were in a state of some flux, much more could have been done to ensure a system-wide understanding of the pandemic infrastructure – to promote increased effectiveness.

Political Discourse

194. We would wish to make note of our experience of political discourse during the pandemic. We fully accept that when contracts are awarded by Government, particularly in exceptional circumstances using 'negotiated procedure without prior publication' procedures, then those contracts should be open to wider and political scrutiny. We would have hoped that that scrutiny would have been inclusive and objective. We were

concerned by a series of political events where objectivity appeared to be lacking. I do not believe that there was any other organisation – private or public – that could have provided the end-to-end testing solution that Randox provided at speed and at scale.

195. In February 2021 we became aware that the then Shadow Chancellor for the Duchy of Lancaster had, through verbal comment and social media posts, and without a proper understanding of the circumstances, been critical of Randox's performance and questioning whether we had received the government contracts on merit. We wrote to the Shadow Chancellor for the Duchy of Lancaster on 12 February 2021 (see pages 104 - 108 of **Exhibit PF/01 [INQ000513644]**) to correct the reported assertions in some detail and invite her to visit Randox for herself. The letter was copied to the then Leader of the Opposition and the invitation to visit was extended to him also. Neither individual acknowledged nor replied to our letter or invitation.

196. Subsequently, the official opposition tabled a Humble Address, which was debated in Parliament on 17 November 2021. The Humble Address asked for all communications related to the COVID-19 contracts awarded to Randox Laboratories to and from: Ministers or former Minsters of the Crown; Special Advisors of such Ministers or Members or former Members of Parliament,

197. In the associated debate on Randox COVID contracts, under parliamentary privilege, members of the official opposition and the Scottish Nationalist Party (SNP) used the words 'corrupt' or 'corruption' on twenty-nine occasions. None of these accusations were directed at Randox and many were related to wider government activity. Nevertheless, these accusations were made during a specific debate on Randox COVID-19 contracts and, by implication, Randox were tainted by association with the allegation of corruption. One might have assumed that, whilst the claims were made under parliamentary privilege, the official opposition and SNP had firm evidence on which to base such claims.

198. Following the release of the documentation requested by the Humble Address, and a subsequent NAO investigation, the NAO concluded, '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' (see Page 13, Paragraph 23 of the Report at **Exhibit PF/02 [INQ000513645]**). This quote is included for context and as a matter of historical fact of the NAO's finding. This

conclusion sits in stark contrast to accusations made by opposition parties during the Humble Address debate.

199. Subsequently the Public Accounts Committee (PAC) conducted an investigation into the 'Government's contracts with Randox Laboratories Ltd' and published their Report on 27 July 2022. The first of the PAC's conclusions was that, "Woefully inadequate record-keeping by the Department makes it impossible to have confidence that all its contracts with Randox were awarded properly." In addition to the indirect criticism of Randox there was also a direct criticism in the PAC's press release to accompany its report which stated, "... Randox struggled to deliver the expected level of testing capacity: yet the Government still awarded Randox a contract extension worth £328 million seven months later, again without competition." It is important to note that despite both the direct and indirect criticism of Randox contained within the PAC's Report and press release, it did not engage with or seek any evidence from Randox. Randox only became aware of the content of the PAC Report immediately prior to publication and subsequently wrote to the PAC in detail to highlight inaccuracies within the Report. The Chair of the PAC declared the matter closed on 20 October 2022, a position Randox are on record as rejecting.

200. The PAC's conduct in producing its Report was disappointing and, in my opinion, procedurally unfair. It resulted in the publication of inaccuracies and misinformation that do not serve the public interest. I note from Lord Bethell's evidence to Module 5 of the Inquiry on 19 March 2025 that he characterised the treatment of Randox at the time as 'highly politically motivated' and that we were 'demonised'. I agree.

201. Either way, whilst reacting to a government request to respond to a national crisis Randox found the tone and nature of the political debate on the Randox contracts, conducted under parliamentary privilege, to be febrile, to lack objectivity and to be woefully inaccurate. The genesis of that inaccuracy appeared to be a deliberate mischaracterisation of Randox's relationship with the Right Honourable Mr Owen Paterson. Mr Paterson was engaged as a consultant by Randox from 1 August 2015 to 5 November 2021. The basis of the consultancy agreement was that Mr Paterson would provide strategic advice on potentially relevant markets and customers that we might approach to grow the business and to act as an Ambassador for Randox, both nationally and internationally. Where Mr Paterson suggested potential commercial business partners or territories that we might explore, he would seek to arrange and attend

introductory meetings on our behalf. At such meetings, Mr Paterson would explain Randox's capabilities at a broad, strategic level. If invited to do so, Randox's technical and sales teams would then follow up with more detailed meetings to explore the viability of a mutually beneficial commercial relationship. Randox entered into the agreement with Mr Paterson because its senior management had been impressed with the enthusiasm and commitment that he had demonstrated, first as Shadow and then as Secretary of State, for Northern Ireland. In those roles, Mr Paterson had demonstrated a sincere interest in the business and support of the diagnostic technologies that Randox was developing. Beyond the strategic level engagement, Mr Paterson played no role in any subsequent, more detailed discussions. More specifically, when it came to the Pandemic, Mr Paterson played no role in the identification, negotiation or securing of testing contracts with the Department of Health and Social Care. We understand from the evidence that Mr Paterson provided to the Parliamentary Commissioner for Standards that he requested and received advice from the Office of the Advisory Committee on Business Appointments (ACOBA) prior to assuming his role with Randox and declared his interest in the Register of Members' financial interests. Mr Paterson's evidence was entirely consistent with what he had told us when he became a consultant to Randox. From our perspective this was a transparent arrangement and we understand that Mr Paterson's connection with Randox, insofar as he addressed Ministers and Officials on occasions during the emergency of the Pandemic, was understood. Lord Bethell's evidence to Module 5 of the Inquiry on 19th March 2025 would support that understanding.

202. The Randox position is supported by:

a. The NAO's report which did not identify any evidence that the government's contracts with Randox were awarded improperly.

b. Evidence provided by Shona Dunn, 2nd Permanent Under Secretary, Department of Health and Social Care to the Public Accounts Committee on 18 May 2022 who stated in evidence, 'I don't believe (Mr Smith) from any of the documentation I have seen that Randox gained any benefit from their direct engagement via Mr Paterson or any other route with anyone'.

c. Letter from Rt Hon Matt Hancock MP to Dame Meg Hillier, Chair of the Public Accounts Committee, dated 20 May 2022. Mr Hancock, Secretary of State for

the Department of Health and Social Care (SoS DHSC) at the time of the outbreak stated, "*Not to work with Randox would have been ridiculous – going into the pandemic they were the largest testing provider onshore in the UK. It is important to understand the context: we were not attempting to select between competing providers as might be normal – we were trying to buy as much testing capacity as possible to keep the public safe. These were extraordinary times.*" (See pages 109 - 112 of **Exhibit PF/01 [INQ000513644]**).

203. Randox accepts that Mr Paterson did engage with SoS DHSC in attempting to secure positive COVID-19 sputum samples necessary to confirm assay validation and in pressing for PHE to expedite their assay validation programme more quickly. We understand Mr Paterson assessed that these actions were in line with his obligations as a Member of Parliament. There was no indication of Government testing contracts at that time and the threat to the population was growing.

204. Randox did not benefit from those communications – positive COVID-19 sputum samples were not provided by DHSC to Randox for assay validation and we do not believe the assessment of the Randox assay was accelerated by PHE due to these communications. I believe Randox were selected for PHE assessment on a technical basis because in a briefing note to SoS DHSC on 1 March 2020 regarding PHE's approach it states that Randox had been prioritised for testing as a result of, 'on-going horizon scanning for instruments that look promising'. The note also stresses PHE's aim to be fair to all commercial companies (see Ref 16, Page 26 of the Humble Address documents at page 113 - 114 of **Exhibit PF/01 [INQ000513644]**). A Cabinet Office official notified Randox of PHE approval late on 24 March 2020. By this time it was in the interests of both DHSC and Randox for the assessment to be completed as there was insufficient national testing capacity and significant pressure to imminently increase the volume of testing.

205. The point at which Randox engaged with a potential DHSC contact only occurred following an invitation to attend the meeting on mass testing held at No 10 Downing Street on 17 March 2020. We did not receive any minutes of this meeting. A contract was subsequently signed on 30 March 2020. Mr Paterson has advised Randox that he had no prior knowledge of that 17 March 2020 meeting and was ill with COVID-19 at the time. It bears repetition that Mr Paterson played no role in identifying, negotiating or securing that initial contract or further contracts.

206. Subsequently Mr Paterson did contact the SoS DHSC to provide him with an update after visiting Randox on 17 September and again on 24 October 2020 and, having identified himself as a paid consultant in each case, did promote Randox's then current and future capabilities and suggested a visit and discussion on longer term strategy. At that point Randox were the highest capacity Pillar 2 laboratory nationally, at 60,000 t/day by 19 October – and would double that capacity to 120,000 t/day in just over 3 months to address the Winter of 2020/21. There had been no ministerial visit since the commencement of testing.

207. Mr Paterson's suggestions did not result in any ministerial engagement; there were no Ministerial visits to Randox and no Ministerial discussions on longer term strategy. Indeed the published record of ministerial meetings covering the period from September 2020 to the end of June 2021 shows no ministerial engagement with Randox, less two multi-company calls with Lord Bethell on 29th April 2021 and 11 May 2021, covering completely different issues. Those two meetings are covered in more detail at Annex A.

208. That development of Randox's capacity was critical to the nation's winter response, was evidenced by Professor Dame Jenny Harries CE of UKHSA, to the Public Accounts Committee on 18 May 2022 where she stated, "*It was the work that Randox did that really got us through the next wave of that pandemic, through that winter* [2020/21]. *It was absolutely critical in the capacity that was provided.*"

209. We again understand Mr Paterson, in light of the national situation and the exceptional circumstances of the time, assessed that these actions were in line with his obligations as a Member of Parliament and the public interest.

210. Mr Paterson played a peripheral role only in Randox's COVID-19 response and was kept scrupulously detached from any aspect of contract identification, negotiation or securing. It is clear that his communications to Ministers show no active engagement with the contracts. In the Humble Address submission, Ref 34, in a Whatsapp I believe to be to the SoS DHSC, Mr Paterson confirms that he knows, 'absolutely nothing about the contract'.

211. Whilst we realise that the nature of UK political discourse is outside the remit of the Inquiry, we wish to record the significant damage that was suffered to Randox's reputation as a consequence of our involvement in supporting the TTI programme. The seed of the attack on our reputation was the perception of a lack of transparency in the negotiation of the contracts that Randox was awarded. With hindsight, we would have welcomed far greater transparency and would suggest that any similar circumstances in the future should trigger a mechanism for greater transparency in all aspects of the process in order to achieve greater political unity of purpose. It would be regrettable if businesses and other organisations were dissuaded from stepping up to support the government's needs in the future for fear of the collateral damage they might suffer. This risk was recognised by both Mr Hancock and Lord Bethell in their evidence to Module 5 of the Inquiry in 19 Match 2025.

212. As it was, Randox's reputation suffered significant damage in the febrile political atmosphere and, in our view, the wayward use of parliamentary privilege.

Legacy

213. Whilst not directly engaged with any next-pandemic preparedness post COVID-19, Randox remain committed to strengthening the UK's diagnostic infrastructure. Randox remain active, within the UK, in diagnostic assay development, analyser system engineering development, associated supporting R&D, diagnostic IT systems, diagnostic manufacture, global distribution of manufactured diagnostic products and global supply chain management for inward goods.

214. Randox have invested heavily in biochip development and engineering and in both comprehensive diagnostic testing infrastructure and processes to promote prevention within healthcare, directly to the consumer. Access is via a network of UK Randox Health clinics.

215. We have observed from both our clinics and the pandemic more generally that the UK's population adapted and responded positively to periodic testing. I believe that experience could and should be used to encourage a far greater proportion of the population to undergo more regular diagnostic testing and that, over the short, medium and long term, it has the potential to substantially improve early diagnosis and prevention

and, by extension, allow more people to live better for longer and improve national productivity.

216. Randox retain the capability to support a future UK pandemic response, should that be requested.

Additional Information

217. Whilst the matters above address those questions covered under the Rule 9 Request made to Randox on 29 August 2024, there are a number of other related issues in respect of how and when we became engaged with the TTI Network that I would like to address within this statement. It has been a matter of public comment, some of which has been misleading, that Randox participated in a number of ministerial meetings that were not recorded by the DHSC, required loan equipment to fulfil contractual obligations and withdrew sample collections kits through the first contract. Randox also coordinated private testing with its contractual commitments to the Network and all these issues are addressed at Annexes A, B, C and D of this statement for the Inquiry's consideration.

Conclusion

218. In conclusion, at the outset, Randox was the only UK laboratory with the breadth of expertise, experience, agility and capability to deliver molecular testing from end-to-end at speed and at scale. Thereafter, we built upon our experience and pre-pandemic investment across a very wide range of diagnostic capabilities to deliver COVID-19 PCR testing at scale and speed.

Statement of Truth

219. I believe that the facts stated in this witness statement are true. I understand that proceedings may be brought against anyone who makes, or causes to be made, a false statement in a document verified by a statement of truth without an honest belief of its truth.

Signed: Personal Data

Dated: 30/04/25

List of Annexes:

ANNEX A – Ministerial Meetings

ANNEX B – Loan Equipment

ANNEX C – Withdrawal of Sample Collection Kits

ANNEX D - The Randox approach to testing private and TTI samples

ANNEX A - MINISTERIAL MEETINGS

220. The NAO Report identified as a matter of historical fact that there were eight cases of 'Ministerial meetings on testing with Randox Laboratories Ltd'. For context, the NAO Report provides details of those meetings at Figure 8 on Page 39 of **Exhibit PF/02 [INQ000513645]**. In six of those cases cited by the NAO, the Government was not able to provide a record of the discussion. Clearly the paucity of Government record keeping is a matter for Government. Whilst this matter has been raised by the NAO, and subsequently by the Public Accounts Committee, neither party requested Randox to provide an account of those meetings. I believe there is a general misunderstanding about the nature and purpose of these meetings. For the record:

a. **First meeting unrecorded by DHSC - 17 March 2020**. Roundtable on mass testing for COVID-19. Prime Minister's office. This meeting, chaired by the Prime Minister and SoS DHSC, was attended by senior officials across a range of departments. Including CMO, CSO, senior officials from PHE and MHRA, and Director, Office of Life Sciences. The meeting was also attended by multiple other commercial and private entities. From the record of ministerial meetings by: Wellcome Trust, Alliance Boots, Roche, Thermofisher, Thriva, 23 and me, Medsci, Altona Diagnostics, Randox, Qiagen, Luminec Corp, Amazon, Serco, Brunel University, Babylon Health, TDL Pathology. The meeting outlined Government plans and needs in addressing mass testing for COVID-19. Randox did not have any private engagement with ministers in the period before, during or after this meeting.

b. **Second meeting unrecorded by DHSC - 18 March 2020.** Meeting to discuss COVID-19 Testing capacity, Department of Health and Social Care. Randox were invited to this meeting having approached the Director Office of Life Sciences on 17 March. From the record of ministerial meetings this meeting was attended by: Cabinet Office, Thermofisher, Randox, Oxford University, Wellcome Trust, Amazon. The meeting was to discuss how mass testing might be delivered. The meeting was briefly attended by the Minister for Life Sciences. There was no private engagement between Randox and the Minister.

c. **Third meeting unrecorded by DHSC - 13 May 2020**. Telephone call between the Department and Randox, to discuss Randox's backlog in processing tests. Attended by the Minister for Life Sciences and civil servants. This meeting took place after Randox's first contract and was an operational discussion covering Randox's testing output. It was appropriate that direct communications were engaged.

d. **Fourth meeting unrecorded by DHSC - 7 August 2020**. Online meeting between the Department and Randox, to discuss the potential recall of Randox test kits on safety grounds. Attended by the Minister for Life Sciences and civil servants. This meeting again took place after Randox's first contract and was an operational discussion covering the potential withdrawal of Randox's sample collection kits. It was appropriate that direct communications were engaged.

e. **Fifth meeting unrecorded by DHSC -29 April 2021**. Meeting to discuss laboratory testing provision for international arrivals. Attended by the Minister for Life Sciences Randox, other suppliers and organisations. This meeting was conducted by telephone conference call and was also attended, according to the ministerial record of meetings, by: Acculab Diagnostics, Eurofins Scientific, Honeyman Group, iGenomix, Somerset Foundation Trust, LinksBio Ltd, Covance / Labcorp Drug Development, Salient Bio, Nationwide Pathology, Dante Labs, TDL Pathology, Cignpost Diagnostics, Luxelife care, Biograd Diagnostics, Nkaarco Diagnostics, Anglia DNA, MDNA Life Sciences, Minton, Treharne & Davis Ltd, Pura Diagnostics, Source Bioscience, Prenetics, Epistem Ltd, 2030 Labs Ltd, Camclin Labs, HMR London, Oncologica, Novacyt, Imperial College London, Viapath, Accendo Lab Ltd, Oxsed, St George's Hospital, NL Clinic, Randox, Circular 1 Health, Nonacus Ltd, Association of British Healthtech Industries, Excalibur Health, Concept, YourGene Health. Randox did not engage privately with the Minister.

f. **Sixth meeting unrecorded by DHSC - 11 May 2021**. Meeting to discuss upcoming legislation to validate COVID-19 tests on the market. Attended by the Minister for Life Sciences, Randox, other suppliers and organisations. This meeting was conducted by telephone conference call and was attended, according to the ministerial record of meetings, by: Abbott, ABHI, Agile Life Sciences, Biopanda Reagents, i-Abra Ltd, BS Partnership Ltd, Roche, Confederation of British Industry CBI, Global Health Committee, Lloyds Pharmacy, Make UK, McKesson UK, BMA, National Pharmacy Association, Randox, Royal Pharmaceutical Society, British In Vitro Diagnostic Association BIVDA, Thermofisher Scientific, UKAS Una Health Ltd, University of Sussex Science Policy Research Unit, UR Care, Lloyds pharmacy Online Doctor. Randox did not engage privately with the Minister.

NAO Report - Meetings with Ministers for which there is a Government Record

221. Two additional meetings took place, for which the Government has produced records:

a. **Meeting with DHSC record - 8 April 2020**. Meet of COVID-19 Testing Taskforce. SOS DHSC, Minister for Life Sciences, Randox, other suppliers and organisations, civil servants. Randox attended by telephone to discuss issues with service delivery, after the first Randox contract. The meeting was attended, according to the ministerial record of meetings, by: Catapult, Amazon, Wellcome Trust, Oxford University, Queen Mary University, Astrazeneca, Roche, Thermofisher, GlaxoSmithKline, Synconaltd, Walgreens Boots Alliance, Andrew Feldman Associates (Lord Feldman), Defra, Office for Life Sciences, Scottish Government, Welsh Government, Northern Ireland Government. The record of this call as is provided by DHSC. In particular, MD Randox raised the issues of difficulty accessing RNA extraction systems/kits to accelerate testing at this time, noting the difficulty with global supply chains and that systems were unused in universities. This led to the call on 9 Apr 20. Randox did not engage privately with the Minister.

b. **Meeting with DHSC record - 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, the MP for North Shropshire (paid consultant to Randox), civil servants.

Appendix B of this statement sets out the Randox position on the loan equipment and provides detail on what was borrowed.

222. The record of the 9 April 2020 call was provided by DHSC to the NAO. The Ministerial meeting was as a direct result of comments that I made on a call with the Minister of 8 April 2020. At the time of this call the Randox testing contract had been in place since 30th March and Randox had maximised the capacity of in-house RNA extraction equipment. The contract had anticipated this matter, in the event that global supply chains were unable to deliver key equipment due to pandemic pressures, DHSC had allowed for equipment and consumable support to Randox, from the third week of the contract.

223. At this time Randox had additional RNA extraction systems and other equipment on order but were faced with global shortages. In addition, noting the critical nature of RNA extraction systems, DHSC were controlling the supplies from international manufacturers to laboratories within the UK.

224. Randox had previously engaged with unknown officials on or around the 4-7 April 2020 regarding access to unused equipment within universities (which were closed at that time) but were not satisfied by the speed of response. Randox does not have minutes of those calls. Consequently, I escalated the matter to Ministerial level in a group call on 8 April 2020 with the Secretary of State for Health in order to seek a timely resolution. The result of that escalation was a further call on the 9 April 2020 with the Minister for Life Sciences and his team which is referred to earlier in this Annex. The outcome of that call was some momentum was put behind the provision of the loan equipment.

225. In early April 2020 testing and lockdowns were the only control measure available to government to keep the economy and society functioning. On 8 April 2020 the number of Covid reported deaths in the UK was 1,461 and on 9 April 1,375 – unknown at the time this was the Wave 1 peak.

226. The Randox position is that utilising every asset to press for loan equipment in April 2020 to go beyond our Week 3 capacity, noting:

a. Unprecedented global shortages of PCR materials,

b. Increasing deaths,

c. Increasing requirement for testing,

d. Delayed delivery of equipment orders (extraction systems controlled by DHSC),

And

e. our contract terms

The PCR equipment lay unused in closed universities and R&D centres. Seeking to access this equipment was practically, contractually and morally, the right thing to do. Further detail on the equipment provided is set out in Annex B of this statement.

ANNEX B – Loan Equipment

227. Prior to entering into the first contract, Randox anticipated that it would need DHSC support to access additional equipment to meet its targets for week three onwards. Consequently, Randox was in discussion with the government within a week of signing its first contract on 30 March 2020 to access additional equipment to increase testing capacity. This has been misunderstood as an inability by Randox to meet its contractual obligations.

228. Prior to the onset of Covid-19, PCR testing within the UK was conducted in very small numbers. To illustrate that point the entire NHS capacity for Covid-19 PCR testing on 17 March 2020, six days after a global pandemic was declared by the WHO, was 2,400 tests per day. At that time no testing site in the UK was capable of processing more than minimal numbers of PCR tests. Unprecedented scaling would be required to reach the volumes of tests per day required within the new Pillar 2 (external to NHS) laboratory network – to reach a network total of 100,000 PCR tests per day within 30 days and subsequently up to 120,000 t/per day at Randox's laboratories alone.

229. Furthermore, scaling in the UK was required at a time of exponential increases in global demand for the specialist equipment and consumables required for PCR testing – at the very time when global supply chains were closing down due to the pandemic.

230. Randox recognised these unprecedented demands and in negotiations with DHSC for the first contract, stated that Randox could reach the targeted Week three capacity from within their own resources. Randox would additionally scour their global supply chains for the required equipment and consumables, to go beyond the Week three capacity. However, noting the growing pressure on global supply chains, Randox stated that government assistance may be required to build capacity beyond Week three. This was reflected within the first Randox/DHSC contract, Appendix 1: '*Supply Issues: Raw Materials: Contractor anticipates that it will be able to cover supplies of raw materials, including reagents, until the end of week three from the contract commencement date. Authority support may be required in procurement chains thereafter (including access to third party systems outside contractor control as indicated in presentation sent to OLS)* (See pages 21 - 23 of **Exhibit PF/01 [INQ000513644]**)

231. In addition, on the call with the Office for Life Sciences on 19 March 2020, Randox referred to pinch points in the supply of swabs, tubes, Category II cabinets and the supply of other equipment and related consumables that would be required.

232. In early April 2020 DHSC recognised the critical shortage of key PCR equipment for the Pillar 2 laboratory network and initiated a process, which Randox actively supported, of identifying unused PCR equipment in universities and R&D centres – which were then closed. The 4 government-based Pillar 2 laboratories (Milton Keynes, Alderley Park, Cambridge and Glasgow) were heavily reliant on this loan equipment, much more so than Randox which was operating from previously established private facilities, albeit at relatively low capacity. DHSC utilised MoD resources to identify and deliver the loan equipment from their original sites to all specified Pillar 2 laboratories.

233. At the end of the first week of April 2020 it was clear to Randox that global supply chains for PCR equipment were indeed very heavily stressed. DHSC was controlling the supply of key equipment from suppliers. Once internal capacity had been maximised (in Week 3) the only way to increase capacity was by access to unused loan equipment from universities and similar facilities. The need for such support was anticipated within the contract. Despite raising the issue of access to loan equipment with DHSC officials the response was very slow, verging on ponderous.

234. This matter was raised as an issue by me during a multi-agency/commercial organisations Testing Taskforce call with SoS DHSC and Minister for Life Sciences on 8 April 2020. The specific issue of the loan to Randox of available but unused RNA extraction systems, which were critical to the testing process, was deferred by DHSC to a call on the following day. With the passage of time I do not remember the details of the call on 9 April 2020 and did not take a record. However, I note in the NAO investigation into Randox contracts (See Page 39 Figure 8 of **Exhibit PF/02 [INQ000513645]**) that a record of this meeting was acknowledged by the NAO. The NAO records that Minister for Life Sciences, Randox, MP for North Shropshire (paid consultant to Randox) [i.e. Mr Owen Paterson] and civil servants were all in attendance. I was not provided with a copy of that record by anyone. However, a DHSC Update entitled, "Statement made on 3 February 2022, Statement UIN HCWS586" (Reference 7, Page 13) was released to

Parliament by the DHSC as a result of a Humble Address Motion of the House of Commons passed on 17 November 2021. That Motion requested access to communications between Ministers, Special Advisors or Members (or former members) of the House regarding Randox COVID-19 contracts. It included an email which I exhibit at pages 115 - 117 of **Exhibit PF/01 [INQ000513644]**. Whilst I cannot be certain, I believe it is likely from the content of this email that it served as the record of the call on 9 April 2020 notwithstanding the fact that it is dated 26 November 2020 (at 12:23). From what I believe to be the record of the call it appears to have been more straightforward than I anticipated. From that record, I cannot see that Mr Paterson provided any advice on that call and I cannot recall him providing any advice subsequently.

235. At the time of that call, testing contracts were already in place and 'testing' and 'lockdowns' were the only control measures available to government to keep the economy and society functioning. On 8 April 2020 the number of Covid reported deaths in the UK was 1,461 and on 9 April 1,375 – unknown at the time this was the Wave one peak.

236. Following the call on 9 April 2020 the then Minister for Life Sciences initiated contact with several universities to request equipment loans for Pillar 2 laboratories, including Randox.

237. By way of illustration – by the time Randox received four working loan RNA extraction systems on 17 April we had twenty-six extraction systems on order. At that time, as such equipment was considered to be a vital national asset, the supply of extraction systems from international manufacturers to laboratories was strictly controlled by the DHSC. Randox ultimately ordered an additional one hundred and six RNA extraction systems of which ninety-nine were delivered.

238. In total Randox received one hundred and eighty-five items of equipment on loan, of which sixty-two were used (including four working RNA extraction systems). The bulk (82%) of loaned equipment was returned by the end of August 2020, with the remainder returned by mid November 2020 (less two low-value, faulty vortex mixers which were sent for disposal). For the avoidance of doubt, the loan equipment was only borrowed until the equipment that Randox had ordered was delivered. The sixty pieces of borrowed

equipment that were utilised and returned comprised four PCR extraction systems, one 'Evidence Investigator', four plate centrifuges, twenty-one vortex mixers, seventeen safety cabinets, nine freezers that went down to -20c and four freezers that went down to -80c, it was noteworthy that much of the loaned equipment required considerable servicing. The servicing of the loaned equipment was undertaken by a variety of third part suppliers and paid for by Randox.

239. Randox conducted subsequent analysis of the sample throughput of the 4 loan RNA extraction systems, which were the loan systems most in demand within the laboratory process. That analysis showed that whilst the equipment was very important at the time, less than 0.5% of the overall samples processed by Randox for the TTI Programme were processed on loan RNA extraction systems.

240. Appearing before the Public Accounts Committee on Wednesday 18 May 2022 to review the NAO investigation into Government contracts with Randox, Dame Dr Jenny Harries/Shona Dunn (CE UKHSA/2nd PUS DHSC), confirmed that loaning equipment to Randox at the early stages was anticipated, was covered by contract, and was common across all testing providers at that time.

Annex C – Withdrawal of Sample Collection Kits

241. Randox's initial contract for COVID-19 testing with DHSC, from 30 March 2020, differed from other Pillar 2 laboratories in that Randox, as part of an end-to-end testing service, were additionally contracted to provide:

    a. Sample collection kits, for the collection and return of samples to Randox's laboratories for analysis, and

    b. Provision of IT systems to register samples and return results to individuals.

242. From late March 2020 global supply chains faced significant pandemic related turbulence whilst, simultaneously, there was world-wide unprecedented demand for PCR consumables. International borders were closing and a number of PCR consumable suppliers faced temporary closure. In some cases, government-imposed restrictions on the export of PCR consumables were threatened, to restrict products for internal national use. International travel was effectively halted.

243. In these circumstances and in line with contract requirements Randox utilised our global supply network to source consumables for 2.7 million sample collection kits for use within the TTI testing programme, including:

    a. Collection tubes containing liquid transport media,

    b. Nasal and throat swab for specimen collection, and

    c. Packaging materials conforming to the specifications of UN3373.

244. Randox had previously sourced collection tubes containing liquid transport media and swabs for its private business from an established European manufacturer. However, faced with global turbulence that supplier was unable to support significantly larger volume demands, as required by the DHSC contract.

245. Randox therefore sought to secure alternative PCR consumable supplies.

The Supplier - Compliance and Swab Assessment

246. Using its global supply chain network Randox identified the Supplier as one of a number of potential suppliers of PCR tubes containing liquid transport media and swabs.

247. The Supplier's product was a sealed package comprising one capped tube containing liquid transport media and one swab, which was considered as potentially suitable.

248. The Supplier's product information sheet stated the item:

a. Was mainly composed of swab and/or cup, tube and sample storage liquid.

b. Was CE Marked.

c. Complied with European In Vitro Diagnostic Medical Devices Directive 98/79/EC, to classification Annex III/General IVD.

d. Unit packs displayed a sterile symbol showing method of sterilisation.

e. The Supplier advised separately that the swab was Ethylene Oxide (EO) sterilised.

249. The Supplier also produced a Declaration of Conformity to Directive 98/79/EC of Medical Devices for the collection tube and liquid transport media.

250. The Supplier confirmed their ability to supply the required product at high volume; commercial arrangements were processed through a third party. The supporting certification for the Supplier as an ISO 9001 and ISO 13485 accredited manufacturer of medical devices was provided by the third party.

251. In March/April 2020, travel to undertake an audit of suppliers was not possible in the face of increasing lockdowns and travel restrictions. As part of due diligence, Randox ordered samples the Supplier and completed laboratory validation of the tubes and swabs. The Randox validation covered the stability of sample in the liquid transport media and detectability of the virus, both of which were satisfactory.

252. Laboratories do not routinely submit swabs purchased from accredited manufacturers, with sterility marking, for sterility analysis.

253. At that point Randox believed that the manufacturer's accreditations, Certification of Conformity, manufacturer's Technical Information Sheet, CE marking with sterility symbol and Randox's internal validation of product performance were sufficient for use of the product within the TTI testing programme. The Supplier was selected for supply as other potential suppliers had issues with capacity of supply and/or performance.

254. Randox prepared the sample collection kits for DHSC accordingly, 'Randox COVID-19 Home Testing Kit', Catalogue Number: EV4429.

255. In early July 2020 the third party also confirmed that the Supplier's product to Randox had also been provided to users in Switzerland, Germany, Spain, Italy, Portugal, Serbia, Turkey and for countries in SE Asia, amongst others.

DHSC Mass Testing – Network Review

256. In June 2020 the TTI Programme sought to increase the flexibility within the national laboratory network and to assess the compatibility of a wide variety of consumables across multiple laboratory workflows.

257. As part of that work, MHRA subsequently confirmed that a nasal or throat swab for specimen collection was regulated as a medical device (directive 93/42/EEC as amended by 2007/42/EEC). If it was sterile, it became a Class I medical device, which required additional oversight from a Notified Body. If the manufacturer met the required standards, the Notified Body issued a certificate to the manufacturer to that end. PHE

have subsequently stated that the Pillar 2 specification for swabs required them to be sterile, but that specification had not previously been provided to Randox. During the investigation we subsequently sought a definition of sterility from PHE. Our request went unanswered.

258. In light of this clarification Randox approached the Supplier, through a third party, for the Notified Body certification regarding sterilisation. That certification was not forthcoming from the Supplier. Randox informed MHRA on 10 July 2020.

259. Randox do believe there may have been wider misunderstanding on the classification of swabs as Class I medical devices. On 23 July 2020 MHRA found it necessary to publish related clarification on the Gov.UK website. The clarification was as follows:

a. Evidence of registration and declaration of conformity are documents of regulatory validity and may be requested from the manufacturer or the EU Authorised Representative.
b. For Class I medical devices, the manufacturer of the medical device must issue a Declaration of Conformity to Directive 93/42/EEC and must register their Class I medical device with an EU Competent Authority for medical devices. For non-EU manufacturers, an EU-based Authorised Representative must be appointed and will undertake the registration on their behalf. There is no CE Certificate for a Class I medical device unless that device is supplied sterile or has a measuring function.
c. Information on the requirements for Class I medical devices:
d. For Class I medical devices which are supplied sterile or have a measuring function and for all other Classes of medical devices the manufacturer must obtain a CE certificate from a Notified Body designated under the Medical Device Directive. This must be done in addition to the registration and declaration of conformity. A list of designated Notified Bodies is available on the European Commission website.
e. Valid CE certificates will be issued by one of the organisations listed and will have been issued from within the EU.

Testing within the Northern Ireland Regional Public Health Laboratory

260. Following the initial MHRA confirmation of the sterility requirement and the inability of the Supplier to produce appropriate Notified Body certification, DHSC/Deloitte directed that Randox should provide the Supplier sample swabs to the regional public health laboratory in Belfast to assess their sterility. Sample swabs were delivered late afternoon of 10 July 2020, and ninety-nine swabs were cultured over the period 10 -13 July 2020. This initial testing indicated that a high proportion of the sample swabs were not sterile. Following a subsequent follow-up from Randox it was determined that this laboratory did not have UKAS or ISO accreditation for sterility testing, nor was sterility testing part of their routine function. The laboratory also indicated to PHE that some of the organisms identified could have been environmental from the 'broth' (a microbiology term for a liquid growth medium used to cultivate microorganisms). This was clearly not a good setting to assess sterility and Randox questioned the validity of the results.

Decision to Pause use of and Quarantine Randox Sample Collection Kits

261. Based on the results from the Northern Ireland regional public health laboratory, the decision was made to pause the use of Randox sample collection kits within the TTI programme. On 16 July 2020 the Secretary of State, DHSC, the Rt Hon Matt Hancock MP advised the House of Commons that the use of Randox swabs had been suspended. The Secretary of State added that there was no evidence of any harm, that test results were not affected and that there would be no impact on access to testing.

262. DHSC provided direction to sites in possession of Randox sample collection kits to both pause using them and to place unused kits in quarantine. Randox had no visibility of the deployment of kits to user sites, beyond dispatching them to centralised logistic hubs.

263. Secretary of State for DHSC stated that there was no impact on access to testing. Randox had no visibility of the supply of alternative sample collection kits.

DHSC engagement with a private sterility testing company - STERIS

264. Following the DHSC ordered pause, and the understanding that the Northern Ireland laboratory did not have UKAS or ISO accreditation for sterility testing, nor was sterility testing part of their routine function, DHSC engaged with a private company, STERIS, to conduct further accredited sterility testing.

265. STERIS were commissioned on 23 July 2020 to undertake UKAS and ISO accredited sterility testing and bacteriostasis and fungistasis testing on a wider sample of Randox provisioned swabs (n=300).

266. STERIS were not accredited to perform microbial identification tests.

267. Randox understand that Steris were to assess a number of swabs in use within the TTI. Randox requested the results of testing of other swabs from the TTI Network suppliers, but none were ever provided.

Decision to Recall Randox Sample Collection Kits

268. On 7 August 2020, MHRA instructed Randox to recall, 'Randox COVID-19 Home Testing Kit', Catalogue Number: EV4429 from NHS Test and Trace testing settings. Randox did so at its own expense.

269. MHRA stated that this decision was been taken as a precautionary measure to prevent any further use of the quarantined Randox sample collection kits. Randox understand that instruction was provided as testing sites were not being wholly compliant with the DHSC instruction to pause use and quarantine those kits.

270. On 7 August 2020 Randox senior management also had a call with the Minister for Life Sciences, accompanied by civil servants to discuss the recall of the sample collection kits on safety grounds. On that call Randox were advised that the Steris swab sterility testing had not been completed at that time but that the initial (seven day) readout from Steris was that further investigation was needed.

STERIS Sterility Testing Assessment

271. The Steris analysis concluded, based on fourteen-day incubation for sterility testing and five days incubation for bacteriostasis and fungistasis testing, that the majority of the swabs were non-sterile.

272. Randox are unsure of how the fourteen day and five-day incubation periods that were utilised reflected the risk within the operational use of the swabs. Randox have requested clarification from PHE, without response.

273. The organisms identified by Steris were normally environmental or commensal in nature and are not normally associated with clinically significant infections in healthy individuals. However, as there could be some risk to immunocompromised patients and those with lines, prosthetics and penetrating injuries mainly in hospital settings, PHE undertook a detailed analysis to assess if there was any resultant harm.

Subsequent PHE Analysis (as reported to Randox)

274. PHE undertook a detailed assessment of laboratory surveillance data of positive specimens (i.e. for non-COVID infections) reported to the Second-Generation Surveillance System (SGSS) and statistical weekly exceedances in laboratory reports to SGSS. This included analysis of

    a. Weekly numbers of specimens in 2020, five-year (2015-2019) mean overall and 2019 for organisms identified on Randox swab testing by i) all specimen types and ii) blood specimens only (England).

    b. SGSS weekly exceedance reports, comparing data loaded into SGSS for an identified week and data from the corresponding week and three weeks either side for the last five years.

    c. Cross matching: number and proportion of SGSS reports (all specimen types and blood specimens only) of contaminant organisms linked to patients who had a Randox versus Non-Randox swab for COVID-19 testing, April-July 2020.

d. Weekly numbers of specimens in 2020, five-year (2015-2019) mean overall and 2019 for organisms associated with hospital outbreaks reported to PHE HCAI by i) all specimen types and ii) blood specimens only (England)

e. Cross matching: number and proportion of SGSS reports (all specimen types and blood specimens only) of hospital outbreak organisms linked to patients who had a Randox versus Non-Randox swab for COVID-19 testing, April-July 2020.

f. Demographic characteristics of patients and tests done using Randox COVID-19 swabbing kits.

Key Findings of PHE Analysis (as reported by PHE to Randox)

275. From engagement with PHE, Randox understand the following conclusions from the analysis contained in the draft Final Report (**exhibited PF/05 [INQ000513648]**):

a. PHE assessed the risk of harm to public health from non-sterile Randox Covid-19 sampling kits to be very low.

b. PHE did not identify any actual or potential harm that required public health action in those who had a Randox sampling kit.

c. The proportion of outbreak reported micro-organisms in Randox swabbed patients was very low (<1.5%) and much lower than in non-Randox swabbed patients.

d. There was unlikely to be an impact on molecular test specificity, sensitivity and performance due to contaminated swabs, and any loss of sensitivity should be detected through the controls for inhibition.

e. The organisms identified were normally environmental or commensal in nature.

f. Dry swab simulation indicates that it is likely there is a very low level of transfer of organisms from a Randox swab to the nasal and throat mucosa.

276. Overall, any contamination of the Randox swabs was environmental or commensal in nature. I would comment that any swab, once opened, is exposed to such risks. It would appear from the PHE Report that the risk to patients was greater from non-Randox swabs than from from Randox. We asked to see data from swabs used as quality assurance in the process and the results of other commercial swabs but none were provided.

Supply of Sample Collection Kits to DHSC

277. The Randox contract with DHSC stipulated that Randox would provide bulk sample collection kits to nominated DHSC logistic hubs, from which the kits would be dispatched to testing locations as required by DHSC. Randox did not have visibility of the individual testing locations where the sample collection kits were to be utilised.

278. When the recall was initiated Randox had supplied 1,541,480 million sample collection kits to DHSC logistic depots. As of 25 July 2020, it was assessed that;

a. 1,541,480 sample collection kits had been deployed to logistic depots for onward shipping.

b. 648,850 kits had been registered.

c. 583,870 samples had been processed within Pillar 2 laboratories, approximately 14% of sample collection kits used at that point (PHE assessed this represented ~400,000 unique individuals).

Recall Process

279. Randox initiated the recall of sample collection kits to DHSC, from 7 August 2020 and worked in close liaison with DHSC to assist with their recall from end users and logistic depots. DHSC were responsible for all communications to end users and logistic depots.

280. Randox sent a final report on the recall to MHRA on 19 February 2021, Under Field Safety Corrective Action Reference Number, 2020/008/010/601/004, reporting in conclusion: '*There is only one customer: the Department of Health & Social Care. The FSN (Field Safety Notice) was issued on Friday 7 August 2020. Receipt was confirmed*

on Friday 7 August 2020. We worked with the appropriate logistics team to return the EV4229 kits to Randox Laboratories Ltd. In total Randox shipped 1 514 480 kits, 575 670 kits have been returned to Randox unused, 493 337 kits were returned used and testing was conducted at Randox and 155 513 were returned used to our partner laboratories and testing was conducted. Complete.'

Subsequent Discussions with DHSC and Actions to Re-Kit

281. Randox offered to re-kit all the withdrawn kits using a swab of DHSC choice. This was agreed. However, DHSC did not subsequently call for these kits.

Review/After Actions by Randox to Avoid Re-occurrence.

282. Randox understand the swab was Ethylene Oxide EO sterilised by the Supplier but was then placed in a combination pack with a collection tube with liquid transport media. The seal on the packaging was inconsistent. These factors compromised swab sterility.

283. Following this incident, Randox sourced alternative swabs that met the sterility requirements as clarified by MHRA.

ANNEX D - The Randox approach to testing private and TTI samples.

284. Randox regularly reviewed testing capacities for the TTI Network and private testing, wishing to optimise the availability for both.

285. It is important to note that whilst Randox had stated capacities available to the TTI Network, Randox was not paid to hold capacity, but were paid by the number of samples processed.

286. Daily sample projections from the TTI Network very rarely approached capacity. This enabled Randox to moderate its actual capacity through staffing levels on a day-to-day basis.

287. Whilst up to four individual laboratory lines could be operating at any one time at the Randox Science Park, efficiency ruled against dedicated public and private laboratory lines as capacity would go unused on the lower demand line (either private or TTI), when that capacity could have been used to support the higher demand lines (either private or TTI).

288. Randox operated an advanced accessioning system and prioritised samples to meet required Turnaround Times (TATs), processing them to the laboratories accordingly. The TTI and private samples were therefore processed simultaneously in the laboratory lines, with meeting the required TAT as the determining factor in priority.

289. By receiving daily sample projections from the TTI Network and from sales figures, Randox was able to govern operational/actual capacity to meet the total required sample numbers within the required TATs.

290. In practice, the TTI sample processing benefitted most from this approach, gaining access to greater operational capacity on a daily basis to assist TATs, whilst allowing improvements to the overall efficiency of the laboratories.

291. From July 2021, when the volume of private samples started to increase, Randox deployed four Cube system laboratories, two each to Warrington and Dunstable. Total capacity ~48,000 t/day. The Cubes largely dealt with private samples from Great Britain

and reduced the requirement to send private samples to the Randox Science Park in Northern Ireland – providing greater real and potential capacity to the TTI Network. Had the demand from the Network been there, Randox could have increased capacity to 168,000 t/day.
