Witness Name:
Statement No.:
Exhibits:
Dated:

UK COVID-19 INQUIRY

WITNESS STATEMENT OF DR ANTONY COX

I, Antony Cox, Chief Executive Officer ("CEO") of UK Biocentre Ltd ("UK Biocentre"), will say as follows: -

1. I am a qualified molecular biologist with a bachelor's degree in genetics and a Ph.D. in plant systematics. I was the CEO of UK Biocentre for the duration of the COVID pandemic and confirm that I still hold that position at UK Biocentre.

2. This statement is provided in response to a Rule 9 Request from the UK Covid-19 Public Inquiry ("the Inquiry") made to me as CEO of UK Biocentre and received in September 2024.

3. I am authorised to make this statement on behalf of UK Biocentre as it relates to the Inquiry request. I am making this statement as the CEO of UK Biocentre to support the Module 7 process and examination of the approach to testing, tracing, and isolation adopted during the pandemic.

Introduction

4. This statement sets out the involvement of UK Biocentre in the UK Government COVID-19 National Testing program. It will deal with the setting up and operation of the testing facility at Milton Keynes ("MK"), becoming the first and largest of the so-called "Lighthouse Laboratories". A significant proportion of the UK mass testing capacity was delivered at the UK Biocentre MK site and

formed a key part of the UK Government's response to a Nationwide Testing Strategy Program ("NTP") for COVID-19 as part of Pillar 2 of the NTP. The testing strategy was divided into five principal activities (or "pillars"):

a. Pillar 1: swab testing in Public Health England (PHE) labs and NHS hospitals for those with a clinical need, and health and care workers
b. Pillar 2: swab testing for the wider population, the scope of which was set out in government guidance
c. Pillar 3: serology testing to show if people had antibodies from having had COVID-19
d. Pillar 4: blood and swab testing for national surveillance supported by PHE, the Office for National Statistics (ONS), research, academic, and scientific partners to learn more about the prevalence and spread of the virus and for other testing research purposes, such as the accuracy and ease of use of home testing
e. Pillar 5: build in a short space of time a large UK diagnostics industry, which it lacked, to support its testing requirements

5. UK Biocentre was also asked to support testing of Pillar 4 ONS survey samples, although this was on a much smaller scale than Pillar 2 testing.

6. The NTP was brought into the Government's newly established NHS Test and Trace initiative (TTI) in May 2020, under the leadership of Baroness Dido Harding, and later became the UK Health Security Agency (UKHSA) in April 2021.

Background

7. UK Biocentre's involvement in COVID-19 sample testing started in mid-March 2020 and ended in April 2022. UK Biocentre's remit in the pandemic response was to establish and operate a mass testing facility and ensure its efficient and reliable operation during that time. The facility underwent an almost continuous process of capacity expansion during its operational lifetime, all of which was completed without interruption to the testing service.

Mass Testing Guidance

8. UK Biocentre took direction from the NTP when delivering testing services and responded to Government policy changes as required. While making a very significant contribution to the testing service, we were not at any point responsible either for creating or evaluating the Government's policy of national COVID-19 mass testing.

National Testing Laboratories

9. UK Biocentre was the first large, purpose built, national testing laboratory to be established in the UK, beginning operations in March 2020. As more laboratories were created across the UK, we formed a collaborative network that shared (through regular conference calls, laboratory staff visits, and document exchange) testing knowledge and expertise, training, standards, and ideas. The initial core Lighthouse Laboratories were created at MK (UK Biocentre), Alderly Park (Medicines Discovery Catapult), Glasgow University (partnering with a commercial entity) and AstraZeneca partnered with the University of Cambridge. Further laboratories were added to the network across the UK as the pandemic testing network continued to grow. Further information regarding the Lighthouse Laboratories is detailed later in this document.

10. In April 2022 my role as a Lighthouse Laboratory testing lead ended, and I refocussed my attention as CEO of UK Biocentre. The laboratory network was, after a considerable period of uncertainty about the future of the mass testing program, officially stood down as the worst of the pandemic impacts were brought under control following widespread introduction and uptake of effective vaccination programs. It is important to note that the testing facility at UK Biocentre was fully demobilised by the end of 2021 and is no longer capable of delivering mass testing without once again undergoing significant alteration and redevelopment. I will return to my views on the wisdom of that decision in a later section of this submission.

11. At no point was UK Biocentre compelled to participate in the COVID-19 testing effort. However, given the enormous toll that the pandemic was taking on the

citizens of the UK and overseas, I felt a strong personal and professional duty to ensure that UK Biocentre contributed its facilities and expertise in whatever way it could to service the requirements of the mass testing program.

12. Neither UK Biocentre staff nor I had prior experience of delivering mass testing of the type employed by the NTP during the pandemic response. However, as a biotech company with considerable experience in high throughput processing of human blood, deoxyribonucleic acid ("DNA"), ribonucleic acid ("RNA") and other sample types, the requirements were firmly within the scope of our capabilities. My previous experience in designing and deploying high throughput laboratory processes, the range of staff competence in laboratory processes, and the availability of considerable free space meant that UK Biocentre was well placed to make a meaningful contribution to the mass testing effort.

13. It is important to state that the creation and operation of the testing facility at UK Biocentre took place between March 2020 and April 2022. Much of that time was spent operating under extremely stressful conditions, and there was no precedent for the type of activity we were undertaking. It is natural to reflect upon the actions and decisions that were made during that time. With the benefit of hindsight and our subsequent knowledge of outcomes, the actions and decisions that were made during this time can be questioned, but it is equally important to appreciate the scale of the task being undertaken, the time in which it was required and the awful implications of failing to deliver a functional testing system. These aspects weighed heavily on the executive team at UK Biocentre during those turbulent months.

<u>My Role and Relevant Experience</u>

14. I am the CEO of UK Biocentre Ltd. At the time of the pandemic, I had recently joined the company in that role and had been the CEO for a little over two months before our involvement in the NTP. Prior to this role I had been the Head of Pipelines Development at The Sanger Institute in Cambridge. As such, I had considerable experience in the development of high throughput DNA analysis processes (particularly in DNA sequencing and genotyping). I had

previously been the Head of Production Informatics at the Sanger Institute, and these roles gave me an excellent appreciation of both the laboratory and data processing aspects of developing and delivering very high throughput laboratory processes. I believe that this previous experience, coupled with that of the existing UK Biocentre executive team along with the excellent laboratory facilities, made us extremely well suited to understand the challenges of deploying a very high capacity COVID-19 testing system.

15. Throughout the time UK Biocentre was involved in the NTP, I remained in close contact with the Board of UK Biocentre, who were universally supportive and provided unstinting encouragement.

Other Key Roles at UK Biocentre

16. During the period of the pandemic response the size of the staff at UK Biocentre swelled enormously. Upon joining the company, the staff number stood at 47. At the height of pandemic testing activity this had risen to over 1000. While there was considerable turnover of staff during that very demanding time, all key senior executive roles remained constant. Philip Eeles was the Chief Operating Officer, Nasr Allam was the Chief Finance Officer, and Prof. Peter Weissberg was the Chair of the Board of Directors. These key people formed the core of the executive team and are in large part responsible for successfully delivering the high throughput testing program at UK Biocentre. Much credit must be given to their energy, expertise and countless hours of hard work during that time.

TTI Infrastructure and Capacity

UK Biocentre – background and company purpose

17. UK Biocentre was established by the National Institute of Health Research (NIHR) in 2014 as a subsidiary of UK Biobank. UK Biobank is a national health research project designed to monitor the life-long health of 500,000 40+ year-old UK citizens to investigate the links between genetics, social and environmental factors and lifestyle on their health. UK Biocentre was spun out

of UK Biobank to offer the unique, large-scale blood and other biological sample processing and biobanking technology it had developed to support other UK health research projects in need of such services. UK Biocentre at that time supported a number of Government funded research and clinical trial projects and received modest grant funding from the NIHR. UK Biocentre therefore had a well-established relationship with the NIHR, who were aware of the facility and its capabilities. It is my belief that these factors contributed to UK Biocentre being selected as a Lighthouse Laboratory. It was and remains situated in Milton Keynes, which is geographically centred in the UK and therefore advantageous as a logistical hub for the movement of samples throughout the country.

18. While initially grant funded by the NIHR, the development plan for the business was predicated on UK Biocentre developing a portfolio of services to UK academic and commercial research customers that would allow it to become fully financially independent.

19. Its function was, and remains, to provide large scale, high throughput biobanking, sample processing and testing services to the UK biotech sector. This unique expertise had been developed during the creation of the UK Biobank project and it was viewed as an important asset allowing other large research projects to access efficient sample processing and storage services without having to re-develop their own processing solutions.

20. UK Biocentre therefore had two centres of expertise that proved important in being able to develop and deploy a mess testing operation. First, a detailed understanding of the complexities and challenges of handling biological samples at scale. UK Biocentre has developed much expertise in automation of liquid sample processing. Second, an extensive storage infrastructure for samples, both in manual freezers and in very large, automated cold stores.

21. UK Biocentre is a company limited by shares but operates as a not-for-profit. Accordingly, it reinvests all surplus back into the company and company directors do not receive dividends. At the time of the pandemic, UK Biocentre

was still a subsidiary of UK Biobank, which is a registered charity. UK Biocentre formally became an independent company in 2023.

22. UK Biocentre core business activities involve the receipt, processing and storage of biological samples – mostly blood and blood-derived products. UK Biocentre has a large cold storage infrastructure of -80.C automated freezers with space for more than 30 million individual samples. UK Biocentre therefore also offers long term biobanking services for third parties. Specialising in high throughput projects that would be difficult for normal labs to support, UK Biocentre offers a unique combination of processing and storage capabilities.

UK Biocentre's Involvement with the NTP

23. I was approached directly to set up the testing facility at Milton Keynes. I received a telephone call from Professor Sir John Bell on 19th April 2020 asking whether UK Biocentre could develop laboratory capacity to support a COVID-19 testing facility at Milton Keynes to assist the national pandemic response. It was apparent at this point that Public Health England ("PHE") would not be able to deliver the volume of testing required within their own laboratories, and therefore additional capacity was needed. Although not made explicit, it was clear to me that my role would be to oversee the development, delivery and operation of the testing facility.

24. I considered UK Biocentre to be well placed in terms of its position, facilities and expertise to develop a testing facility. There was no discussion of scale of testing at this point, rather a general sense of urgency to get started.

25. I consulted my executive team because this would place a considerable burden on them if we were to respond to the request. All were agreed this was a vitally important request and one to which we were well suited to respond.

26. I contacted the Chair of the UK Biocentre Board, Professor Peter Weissberg, and a Board meeting was held by telephone on the 19th of March 2020 and the matter was discussed. Despite the financial risks to the company the Board were content for the proposal to continue. Exhibit TC/01 **INQ000587372.**

27. Discussions followed with various government departments including the Cabinet Office (which appeared to be doing much of the initial pandemic response coordination) and the Department of Health and Social Care ("DHSC"). At this point I was briefed by the DHSC on the Pillar structure of the pandemic response, and how UK Biocentre would fit into the structure under Pillar 2 and Pillar 4, providing support for public mass testing, and the ONS national infection survey.

Laboratory and Testing Capacity

28. It was clear from the outset that the size of the effort could only be successful through teamwork and the application of the best expertise available. Although our core experience in high throughput processes was secure, we had not deployed a clinical diagnostic test at scale before, and I was aware of the complexities that this would present. On the 23rd March I contacted Professor Mike Hill, at the University of Oxford, Nuffield Department of Population Health. Professor Hill is an academic colleague and an expert in the design and delivery of clinical trials, and clinical testing processes. I asked Professor Hill to support us as we developed and deployed our testing process – a request to which he readily agreed. Within days Professor Hill and a small team of his expert academic colleagues from Oxford relocated to the MK site to become part of the core team developing the testing system.

29. March 2020 onwards was a time of intense activity at UK Biocentre. There were several streams of work. The first was to develop the physical laboratory space to house the testing process. The second was to implement, test, verify and validate the test assay itself. The third was to establish the contractual and legal arrangements under which the testing would be delivered, and finally we needed to develop a workforce that was both skilled and large enough to support the proposed testing process.

30. The specific COVID-19 test assay to be used had already been identified by PHE (ThermoFisher TaqMan/TaqPath qPCR test). Our role was deploying the test at large scale. UK Biocentre took no part in determining which COVID-19

test was to be deployed in the national testing network. An important part of deploying a diagnostic test to establish that it is a reliable indicator of infection. A formal process of validation and verification is required to determine firstly that the test meets the specification set out by its manufacturer (ThermoFisher PLC) and is free from errors, and second, that the test meets the diagnostic requirements for detecting COVID-19 infection to a specified level of sensitivity.

31. The specific testing capacity had not been agreed at this point, although it was accepted that this may be "hundreds of samples" per day. At this point it was, however, much more important to establish and deliver a working COVID-19 diagnostic test that could be validated for use in the mass testing program.

32. I was aware from media commentary about the sensitivities of testing taking place outside of NHS-managed laboratories and embarked on several visits to NHS virology and testing laboratories to understand the NHS approach to testing, the type of equipment used and the processes for managing test and clinical results data. For example, on the 21st March 2020 I visited the pathology laboratory conducting viral sample testing at Addenbrookes Hospital in Cambridge to discuss their testing process, equipment, space and quality systems. This gave me confidence that UK Biocentre would be able to deploy a testing system that would match NHS standards.

33. It is important to note that at this point no formal contract was in place between DHSC and UK Biocentre to support the work being undertaken. However, the UK Biocentre Board was content to proceed "at risk" for a period until these matters could be settled. The estimated cost of building and other modifications was £3.3M and UK Biocentre therefore accepted that it was incurring significant costs and financial risk by undertaking the work without a formal contract in place to ensure those costs would be met by the Government.

34. By mid-April 2020, a summary quotation for provision of testing services was submitted to the DHSC. This detailed the costs for building conversion and laboratory changes needed, and the per-test charges, set out in volume tiers ranging from 5000 to 100,000 tests per week. We also requested, and received,

a letter of indemnity from the DHSC to cover any UK Biocentre liabilities that might arise as a result of delivering testing services.

35. UK Biocentre made a very modest margin on the testing service, and we operated an "open book" accounting process with the DHSC to ensure there was complete transparency in our financial dealings with the Department. I believe this contributed to the excellent cooperative working relationship we developed with the Department.

36. We also requested and received a formal letter of permission from the DHSC (owners of the UK Biocentre building) to modify the building to suit increased volume of testing.

37. At this point I was made aware by the DHSC that Deloitte would be assisting them in developing the national testing framework. Shortly afterwards a small team of Deloitte personnel arrived on site and were quickly integrated into our operational team. They provided the core communication with the DHSC, relaying requirements and establishing plans, timelines and capacity objectives. This small team of professionals were of enormous support to UK Biocentre, and I can only speak of them in the highest terms.

Lighthouse Laboratory Network

Overview

38. By the 21st March 2020 I was contacted by phone by Professor Christopher Malloy, CEO of the Alderley Park Medicines Discovery Catapult, who was then acting as a network coordinating leader for the mass testing network. He made me aware of three other labs which were being rapidly mobilized like UK Biocentre, and that we were to be allied under the moniker of the "Lighthouse Laboratories". The name referred to the light generated during the detection phase of the assay used to test for the presence of the viral genetic signatures in samples. The decision to develop a de-centralized network of testing laboratories was appropriate for the situation. A more centralized approach

replying on a single very large testing facility would both have overlooked the large pool of available nationwide experience and expertise and concentrated the risk of failing to develop a high-capacity testing service at speed. On the other hand, creating a highly diffuse network of much smaller facilities would risk fragmentation of standards and consistency of testing procedures. This approach would also increase the overhead of operating the system and the speed with which it could adapt to new requirements. The Lighthouse network represented, in my view, a sensible compromise between these two positions.

39. On the 1st August 2020 Professor Dame Anna Dominiczak was appointed as the new testing network coordinator for Pillar 2, succeeding Professor Christopher Malloy.

Partnerships and Cooperation

40. The other laboratories were to be geographically spread in Cambridge, Manchester and Glasgow. We were to coordinate as a network of high-capacity laboratories, working to the same operating process, and delivering the same standardised test, and with whom we could share expertise and knowledge. In time, more laboratories would join the network. Regular telephone calls were set up between the heads of the laboratories and other key network individuals, usually chaired by the network coordinator and supported by the Deloitte team. The key topics of discussion were the evolving requirements of the testing network, as driven by government testing policy, updates on progress in development of labs and deployment of testing assays, delivery plans and targets were laid out, coordinated and reported on. Other important topics included how to improve process efficiency and productivity, evaluation of new technology and equipment that could potentially benefit the network, safety procedures for both patients and testing personnel and the requirements for diagnostic quality standards. Over the course of the pandemic this conference call expanded to include the heads of other testing laboratories, DHSC, supporting teams from commercial suppliers and NHS and clinical experts.

UK Biocentre's role

41. Despite a search for supporting documentary resources, there appeared to be very little, or indeed no, information available from either previous epidemics or desktop exercises that could support the implementation of a test infrastructure at the national scale. Although I became aware of an influenza pandemic simulation conducted by the Government in 2016 called "Cygnus", I could find no report or summary of outcomes. UK Biocentre focused heavily on the implementation of the local testing process and deliberately did not become involved in the design of the testing system at a higher level. It was apparent that much work was being conducted to construct a national system and I did not feel that contributing to that effort was the best use of UK Biocentre's experience and expertise. I viewed the most important role of UK Biocentre as developing and delivering a high-quality testing service suitable to support the demands of the national requirement. In that respect we did not need to become involved in the operation or specification of the systems at any higher level. In addition UK Biocentre took no role in relation to pharmaceutical support and acted only in a diagnostic support capacity.

42. Prior to the pandemic, I had no knowledge of whether a mass testing infrastructure existed, apart from that which was routinely operated in hospital pathology and public health laboratories. I was aware that much of this capacity was outsourced to private providers.

Specifications and Requirements of the Test

43. UK Biocentre was not party to any decision made about the specific type of test to be implemented for COVID-19. The specification and requirements for the test were communicated to us by DHSC and we took our role to be designing a process that delivered the test at very high capacity and to a high-quality level.

The Testing Process

44. The test assay had been decided upon by PHE and was itself not complex. This simplified considerably the way in which we approached its design. Our role was to build and deploy a laboratory process that allowed the assay to be performed to the necessary quality standards, but at extremely high capacity.

The expertise of UK Biocentre in designing and operating large scale laboratory processes was the key experience that we brought to this deployment.

45. While delivering test assays in batches of tens, or hundreds, is commonplace across UK laboratories, very different skills and expertise are required to successfully operate a process that routinely delivers hundreds of thousands of tests.

46. The test assay was to be deployed in a consistent manner across all Lighthouse Laboratories, with necessary modifications to accommodate local conditions such as building layout etc. The process was broken down into several discrete steps which were supported by teams of operators specifically trained to deliver each part of the process:

    a. Sample receipt. Samples were delivered in large batches throughout the day and night. The size and cadence of deliveries changed as the mass testing system evolved.
    b. Samples were removed from their protective cardboard delivery boxes leaving them sealed in plastic bags.
    c. All samples were labelled only with an anonymised number and corresponding barcode. No personal information was included with the sample. A typical sample kit, as delivered, was in a small cardboard box, suitable to go through an average letterbox. Inside was a sealed plastic bag containing a sample tube. Each tube contained a small volume of liquid (viral transport medium, "VTM") and the swab from which a nasal or buccal scrape had been taken. It is important to note that the samples were potentially infectious at this stage and therefore needed to be handled with necessary caution.
    d. During the pandemic, very many different collection tube types were employed. Samples were therefore collated by tube type to allow more efficient batch processing in the laboratory.
    e. Samples were passed to the laboratory in batches of 95 samples. Standard laboratory labware supports a batch size of 96, allowing the addition of a negative control sample to the batch – an important quality control factor.

f. Bags containing samples were visually checked for leaks or tube damage. Intact samples were removed from their plastic bags in Biosafety Level 2 (BSL2) controlled environment cabinets. BSL2 equipment is used for clinical, diagnostic and other work with moderate-risk agents that are present in the community and associated with humans. Hepatitis B, HIV, salmonella, and Toxoplasma are examples of microorganisms assigned to this containment level. BSL2 is employed when work is done with human-derived blood, body fluids, tissues, or cells where the presence of an infectious agent may be unknown.
g. This was a very important step where safety of the operator was a primary concern. The carrier fluid (VTM) in the sample collection tubes did not inactivate the virus and therefore cabinets were needed to protect the operators from potential infection. Although the tubes were not opened at this point, potential contamination of the outside of the tube with infectious material could not be ruled out.
h. While in the cabinets, sealed sample tubes were transferred to racks. Racks were transferred securely to the deck of an automated liquid handling robot that was itself in a controlled environment cabinet and the caps removed. Swabs remained in the tubes since their presence did not generally prevent automated liquid transfer.
i. The robot added a strong denaturing reagent that inactivated any virus that may be present and released genetic material into solution by rupturing the walls of any virus particles or cellular material that may be present.
j. Inactivated (and therefore now safe) samples were transferred to a second robot which automated the extraction of genetic material from the samples.
k. A portion of the extracted genetic material was combined with the assay reagents and a small aliquot then transferred to specialized assay test plates.
l. Assay plates were then placed in an instrument called a “thermal cycler” which performed the assay and transferred the assay output results data to a central location where it was subjected to automated data analysis.
m. Any test results that could not be determined unequivocally by automated analysis software, and therefore needed expert human assessment, were flagged for review by a Biomedical Scientist.

n. Electronic test results, linked to the original sample number/barcode were transferred in batches to the central TTI system via secure, encrypted network connection.

47. The testing process was laid out in the laboratory in a "production line" fashion with samples progressing through the stages of testing as they moved physically from one end of the laboratory to another. Much of the success of the process at large scale is linked to the physical layout since it is a very important factor in efficient flow of samples through the process. Much thought was given to capacity of the various stages of processing since bottlenecks at any point, whether due to people or equipment, could vastly reduce the overall throughput of the entire process.

48. The environment in which qPCR is performed is very sensitive to contamination with airborne or other genetic material. For this reason, the actual assay process was performed in rooms dedicated for the purpose. Samples only flowed one way into this area and the air pressure in these rooms was raised slightly with respect to other areas to prevent the ingress of potentially contaminated air. Operators in these rooms wore different coloured laboratory coats to alert staff to contamination risks.

Expansion of the Testing Process – Robustness and Efficacy

49. As the testing process grew rapidly in scale, there would be a requirement for more laboratory equipment to perform the tests. The test employed was a quantitative real-time polymerase chain reaction ("qRT-PCR") assay. The result depended on the amount of assay target amplified from the source samples over a given number of successive amplification cycles. This technique has been a basis for quantitative testing for many years and is both reliable and robust. The instruments that perform these tests are a familiar sight in many molecular biology labs although most rarely have more than one or two instruments.

50. It was clear that we would need dozens, and eventually more than a hundred, of these instruments to deliver the required capacity. In addition, there were a number of different models and manufacturers that were common throughout

UK laboratories. We alerted the NTP to these requirements and a discussion between the network coordinator, heads of the Lighthouse Laboratories and logistics experts from Pillar 2 was had about how best to use any instruments that could become available. It was decided that individual laboratories would focus on using a particular make and model of qPCR instrument. This would simplify the design of the testing and data interpretation process by operating a homogeneous instrument base and a single set of labware and reagents. It also simplified the training process for operators.

51. As the size and throughput of the testing process grew, this type of detailed, highly pragmatic design decision had a significant beneficial influence on the overall efficiency of the entire testing process.

52. The Government responded to the requirement by the NTP for more instruments capable of doing qRT-PCR by purchasing what stocks were available from UK suppliers, and by requisitioning suitable instruments from laboratories across the UK. Requisitioned equipment began arriving in MK shortly after from universities and a range of research institutes and organisations. It was not clear at this point whether equipment would be returned after the period of pandemic reuse or replaced like-for-like by the Government at some stage in the future.

53. We carefully inventoried the equipment we received and maintained detailed lists that we shared with the DHSC. The instruments arrived in a variety of conditions that ranged from almost brand-new to clearly very heavily used. Each was assessed for its general utility and used accordingly.

54. Given that these instruments were to be used to deliver a clinical diagnostic test it was very important that the instruments were functioning correctly and were accurately calibrated. The manufacturers of instruments responded to our requests for assistance by sending field service engineers to service and repair the instruments. Over the course of the pandemic these engineers were to become permanently stationed across the various Lighthouse Laboratories. The primary requirement for additional instruments related to qPCR

instruments, and liquid handling robots, although many other sundry items were received and used.

Getting Testing Operational

55. Our general strategy to get testing operational was to first deploy a fully manual process, operated by very experienced laboratory technicians. This would qualify the assay and help us to learn lessons about handling samples efficiently. As we developed a detailed understanding of how the process performed, we would identify the key stages where automation was necessary to support high-throughput and deploy laboratory robots to automate the precise liquid handling requirements needed on these stages.

56. The first diagnostic COVID-19 tests were performed at UK Biocentre in MK on the 26th March 2020, just one week after the initial call to action. Thirty-nine samples were analysed, showing a ~13% positive rate. While this was a significant achievement in terms of time to get testing up and running, the capacity was clearly far below what would be needed. Indeed, at this time it was not clear what the actual testing capacity requirement was to be. UK Biocentre did not take part in any discussions regarding the policy of mass testing.

57. The testing process implemented was manual and involved laboratory staff opening and processing samples, and their packaging, by hand. A large team of skilled staff (many of them volunteers from the UK academic sector at this time) were required to deliver just a few dozen tests each day. By the 10th April 2020 the number of samples being delivered each day had risen to ~400 and intense planning was underway to introduce an automated process that would convert the current manual process to one supported by automation. It was clear from the very start that automation was the only route to mass testing and that a manual implementation was only ever a means to deliver low volumes of tests, at speed.

58. One lesson learned early was that the process generated a very large amount of waste material. Much of this was cardboard and plastic packaging and moving and disposing of it was onerous. In addition, the inner sample package could potentially be contaminated with infectious material and therefore needed to be disposed via a clinical waste route. This problem was solved by increasing our clinical waste provider contract and installing cardboard and plastic baling machines in the warehouse. At the height of the pandemic, we were producing 8 tons of waste material (clinical and non-clinical) each day.

Setting up a new Laboratory

59. In parallel, we had been working on plans to fit out a much larger automated testing laboratory capable of supporting tens of thousands of tests each day. UK Biocentre was fortunate in having sufficient unused free space to allow the rapid reconfiguration of the facility. I am convinced that, after having numerous discussions on the subject with other laboratory leads, both during and after the pandemic, the availability of configurable space was a critical factor in our successful deployment of mass testing.

60. The new laboratory, with a nominal capacity of 100,000 samples/day, represented the culmination of our plan to rapidly deliver a high-capacity testing laboratory that was automated, and which would be able to flexibly respond to the evolving needs of the pandemic. For this to be successful a wide range of additional activities needed to happen. A contingent of the 5th Regiment Royal Logistical Core was allocated to us under Government sponsored Military Aid to Civilian Authorities ("MACA") and overhauled our Goods Inward and warehouse, making it suitable for the much higher flow of reagent deliveries and materials through the facility. In conjunction with the Deloitte team, they installed an Enterprise Resource Planning ("ERP") software system that served to manage warehouse stock levels and ordering. This was critical to ensure that we did not run out of key reagent of labware items or supporting materials such as personal protective equipment ("PPE") and cleaning products.

61. Given the increase in workforce that would be necessary to support the laboratory operation, more general facilities were required, and a canteen area and additional toilets were installed. External semi-rigid temporary structures

were placed in the car park adjoining the main building to serve as delivery and marshalling points for the larger volumes of tests to be brought in each day by lorry.

62. An entire team was dedicated to managing deliveries, opening outer packaging, sorting samples by tube type and assembling them in batches suitable to be passed to the laboratory for processing. We came to learn that this was a critical activity in efficient processing. If the laboratory could not be "fed" properly the productivity of the facility could suffer. It was also a logistically challenging activity as it generated large volumes of waste, involved numerous movements of samples in specific batches both inside and outside of the building. Temporary structures were essential to protect staff and samples from the elements during this important early phase of sample testing.

IT Infrastructure

63. The UK Biocentre IT infrastructure was also upgraded to support the much larger computer network needed for testing data management. With hundreds of new staff in the building it was clear that wired and wireless networks needed upgrading and the routing and server infrastructure improved to cope with the rate and volume of traffic.

64. Concerns were raised at this time about the potential for malicious attacks on our computer systems. Indeed, our own cyber security monitoring informed us that our networks were being challenged hundreds of times each day. Given these concerns and the importance of our operation to the NTP, we were put in touch with "Scott C." in early May 2020 at the National Cyber Security Centre (NCSC) by Deloitte and NHS Digital. Following a visit by NCSC individuals to evaluate our facilities, the decision was taken by the UK Biocentre executive team to route the UK Biocentre network traffic through their network security system. With this in place we would be better protected and be alerted of any malicious activity.

Building Modifications

65. A very extensive program of building modifications was needed during the pandemic to make the building suitable for high throughput operations. UK Biocentre had an existing relationship with a company of builders who originally worked on the construction of the UK Biocentre building. They therefore already had a very detailed knowledge of the building infrastructure. They were commissioned to deliver the new laboratory fit out and additional works needed around the facility. They worked cooperatively with Philip Eeles, UK Biocentre COO, to rapidly translate plans to reality. Time pressures did not permit the orthodox construction planning and review process, and a system of daily walks around the site served to develop and review our overall building plan. This proved to be very successful and the new laboratory, dubbed "The Megalab" was fitted out and commissioned rapidly and began operations on the 9th April 2020.

Workforce

66. As the testing operation transitioned to the new laboratory facilities we began to increase the workforce. As academic volunteers began to return to their homes and families, we began an intensive program of recruitment and training of new staff to meet the testing demand. This was especially important as the decision was made to move to 7 days a week, 24 hours a day operation.

67. The UK Biocentre Human Resources team worked with recruitment agencies provided by the DHSC and developed a batched recruitment procedure whereby groups of new staff could be inducted, trained and deployed to the lab in waves. **TC/02, TC/03, TC/04, TC/05.** This allowed us to rapidly increase the workforce but at the same time maintain full control of training and competency of the workforce.

TC/02 - INQ000587373, TC/03 - INQ000587778, TC/04 - INQ000587374, TC/05 - INQ000587375.

68. From the summer of 2020 we were taking in 40 new laboratory technicians per week. This was the limit where we could accept and deliver effective induction and training. For many this was their first experience of laboratory work, many of whom were deployed on night shifts - an additional new work experience for most. We built a team of recruitment specialists that worked directly with the

government assigned recruitment agencies, specialist trainers and welfare experts.

69. Our workforce steadily expanded from its original number of 45 to nearly 1100 staff, working in four shift teams, thereby enabling continuous laboratory operations.

Overview of Testing Procedures by the NHS

70. Quality of testing procedures and confidence in the outcome of testing was paramount. This had been a key focus from the outset and UK Biocentre had worked closely with the office of Professor Dame Sue Hill, the Chief Scientific Officer (CSO) for NHS England. NHS officials conducted formal site inspections of all lighthouse laboratories which included a review of sample processing pathways and operating procedures. UK Biocentre was inspected on the 28th March 2020 with Glasgow and Alderley Park following later in April. Exhibit **TC/07 - INQ000587779, TC/08 - INQ000587368.**

71. I was acutely aware that commentary in the popular press and in social media at that time was suggesting that testing was tantamount to privatisation of the NHS. I therefore made considerable efforts to ensure that our colleagues from the Office of the Chief Scientific Officer for NHS England were involved and invited to the site to review our activities. Maintaining public confidence in the quality of mass testing was paramount. In my opinion, this was broadly achieved.

72. There was never any question of the activities at UK Biocentre (or other Lighthouse Laboratories) replacing the work of NHS laboratories. The intention was to augment the available capacity with a specific test, delivered to the same high quality demanded of NHS facilities.

73. By the middle of 2020 the MK operation was the largest testing operation in the UK by some degree. As such we hosted numerous visits from Government, research and healthcare organisations who were interested in our large-scale approach to testing deployment.

Interaction with UK Government

74. A 4pm teleconference organised by the network coordinator, supported by the Deloitte team, took place each weekday with representatives of the DHSC, laboratory heads, clinical advisors to the network and Test and Trace management was put in place and these served as an excellent channel for communicating strategy, plans and objectives. For example, the call routinely reviewed the previous days testing volumes, error rates, operational capacity issues and reviewed any technical issues with the testing process. Forecasts of testing volume requirements in different parts of the UK were also communicated. It also provided a means for expert administrators and scientists to meet and debate the best approaches and methods for future activities. Debate was often brisk, but always professional.

75. In general, the focus for conversation was on daily laboratory performance, issues that needed escalation, communication of new testing policy decisions and for coordinating the deployment of testing capacity.

76. The head of the testing network had oversight of daily activities and ensured there was scrutiny of the testing processes. This was an important part of the daily 4pm calls. Based on the fluctuating national demand for testing volumes, Lighthouse laboratories would negotiate a commitment to deliver specific testing capacity and be accountable for providing it. This system was flexible and could respond to changing national needs or to fluctuations in individual laboratory capacity. For example, COVID infection outbreaks in laboratory staff would on occasions cause laboratories to reduce their daily testing capacity. This capacity could, by agreement, be redistributed among other laboratories until the situation was resolved. In general, the volume of test kits delivered daily to individual labs would be matched to their capacity to deliver tests. Turnaround of tests within 24 hours was a very important performance indicator for each laboratory and laboratory heads were held to account on daily 4pm conference calls for missed capacity or performance targets. Allocating the volume of tests to individual labs was done centrally by the program and was (apparently) difficult to change at short notice. It was therefore important for

laboratories to honour their capacity commitments to avoid delays in returning test results.

77. Test results were created and uploaded in batches every hour to the central data clearing system operated by NHS Digital. Test results were communicated from this central system to individuals. Individual laboratories never directly communicated test results.

78. The question of daily, national testing capacity was a regular topic of conversation. In conversations with successive heads of the Test and Trace program I discussed the forward need for testing capacity. It was my view that the DHSC was being too conservative in its forward capacity estimates. I felt it would be better to decide to build greater capacity than incrementally increase it over a longer interval. In the absence of a vaccine at that point, our best defence against further increase in infection rates was in regular testing, contact tracing and isolation. I remember clearly offering my opinion to successive heads of the NTP that the current ambition for testing was too low and that if infection levels rose then sudden increases in requirement for testing could not be matched by equally rapid deployment of laboratory capacity. I felt that we needed to "get ahead" of the requirement, think boldly, and commission sufficient capacity that would anticipate the increase in demand for testing as infection numbers continued to rise. I was aware of the risk in this approach – capacity is expensive to procure - and should as far as possible be matched to demand. However, smaller, step increases in capacity provision would not keep pace with demand and burden testing facilities with a continuous cycle of capacity upgrades. I received no clear explanation for the conservative approach to building capacity although I remember suggesting to Alex Cooper, the then head of the TTI program that a cumulative capacity of one million tests per day should be considered. I believe this suggestion was received in good faith and contributed to subsequent decisions on increasing the capacity for testing.

Difficulties Experienced at UK Biocentre

79. Numerous difficulties arose during the scaling of the testing operation. These ranged from the mundane to the esoteric. In general, the problems related to

either consumables or workforce. Of particular concern was the contents (e.g. tube type and dimensions, reagent type and volume, swab type) of the test kits. Numerous debates were had across the testing network over the reagents to be included in home testing kits. For example, whether inactivating reagents should be included in home test kits. Apart from the logistical issues of acquiring sufficient reagents there were concerns that the reagents were not suitable for unsupervised home use, particularly on minors. However, such reagents would mean that infectious virus would not be present within the sample transport and delivery chain and would considerably simplify the laboratory testing process. In the end, this was not implemented and infectious samples continued to be delivered to all testing laboratories.

80. Another important and impactful difficulty related to the numerous different types of plastic tubes used in sample kits. This situation was apparently driven by acute shortages in raw plastic, with manufacturing supply chains at home and abroad being stretched to capacity by unprecedented global demand. The UK Biocentre lab had assumed the responsibility for testing and validating all new sample tube types ahead of their deployment in the testing process. By the end of the pandemic, we had validated many dozens of different tube types. The lack of a consistent tube format considerably complicated the laboratory operation. Since most liquid sample transfers were done by automated liquid handling robots, these had to be individually updated and validated for each tube type to ensure they worked correctly and reliably.

81. In addition, the complex mixture of tube types arriving at the lab meant that resources were needed to identify, sort, collate and process the different sample tube types efficiently through automated platforms. At one point the main processing line had subtly different processing routes for tubes of different dimensions.

82. A project was commissioned by the NTP to design and manufacture a single sample tube at scale, and for the entire mass testing program. Although it got to a late design stage and a specification was agreed, it was not progressed. I never discovered the reason for this.

83. A considerable problem arose in dealing with COVID-19 infections in the laboratory and support function workforce. Testing laboratories were dismayed and angered in the first year of the epidemic when they were denied access to test kits because they were not considered to be "front line" activities. While great efforts were taken to isolate laboratories teams physically in "bubbles", outbreaks were inevitable, and at times severe. During the Autumn of 2020 as the new, more infectious "Kent Variant" emerged approximately one third of the UK Biocentre capacity was unavailable because laboratory teams had been reduced by infection and/or isolation.

84. I remain of the view that this was a fundamental failure by the program to not recognise and appreciate the importance of the relatively small number of people who were supporting a vital service in managing the pandemic response.

85. When test kits became available in June 2020 for Lighthouse Laboratories, a program of routine testing was implemented which resulted in much more effective management of infectious outbreaks.

86. Equipment and more generally consumable shortages were frequent. The international market for such things was heavily oversubscribed and it was necessary at times to reduce capacity when consumables were limiting. A particular example relates to the shortage of sterile robot pipette tips over the Christmas period of 2021. Manufacturers had promised supplies that they clearly were not able to deliver and caused considerable impact on capacity plans at that particular time of need. These episodes served to highlight our reliance on overseas manufacturing and supply chains, and lack of sovereign capacity in many areas.

Ensuring Health and Safety

87. The safe handling of potentially infectious COVID-19 samples was understandably viewed with paramount importance. It will be evident that the concentration of potentially infectious material was probably higher within the confines of UK Biocentre's facility than at any other location in the UK.

Everybody was acutely aware of the need to handle samples with care and attention.

88. Regulations were issued in May 2020, and updated in April 2021, along with appropriate guidance that were specific to the management of COVID-19. PHE and the Health and Safety Executive ("HSE") issued a document titled *"COVID-19: Safe handling and processing of samples in laboratories"* that we took as the standard against which we would assess the suitability and compliance of our procedures and that controls were in place to ensure we met the guidance. Exhibit **TC/09 - INQ000606911.** With these measures in place, we were able to satisfy HSE inspections (for example on the 17th of March 2021), who were content with our approach.

89. We worked closely with the HSE to develop our processes and procedures that both protected our people and supported a high throughput processing system. Risk assessments were undertaken to ensure that the approaches we adopted were both appropriate and sufficient.

90. I am proud of the fact that no member of staff working at UK Biocentre during the pandemic was found to have been infected with COVID-19 as a result of their receipt, handling or processing of patient samples.

Variant testing and the emergence of the "Kent" Variant

91. The qRT-PCR test assay employed by the mass testing program relied on the simultaneous detection of three distinct regions of the viral genetic material to generate a confident positive. My background and interest in informatics meant that I followed the details of the testing process with great interest. I noticed an increasing trend for one of the three genetic regions of the test to fail (the other two still working correctly). This was a source of concern as it potentially weakened the power of the test to confidently identify a positive sample. I raised this concern on a call with the network in late December 2020 and further examination of this phenomenon led to the identification of a new strain of the virus that was genetically distinct in a small way that coincidentally caused the test assay to fail for one of its three assay elements, but also with increased

infectious potential. This new and more infectious version of the virus became known as the "Kent" variant (relating to the geographical region where it was first identified) and triggered interest in the monitoring and identification of new viral strains.

92. In parallel, I contacted colleagues at The Sanger Institute (Dr. Jeffrey Barratt, John Sillitoe) to enquire whether they would be able to sequence the RNA of the virus to confirm any genetic difference. From these early interactions developed the wider viral sequencing program that routinely monitored the genetic evolution of the virus during the course of the pandemic and was responsible for identifying a series of new genetic variants that ebbed and flowed within the UK population and abroad over the following years.

93. In the later part of the pandemic, mass testing period additional specific tests were created to assess the specific strain of positive samples.

94. Following the establishment of the TTI program after the first few months of the pandemic, all policy and decision making regarding the operation of the test system was made centrally by the TTI executive. Where it was felt appropriate, the laboratories in the network were consulted as to the impact of various decisions. Labs were asked at various times about their ability to change their testing capacity, evaluate new technologies, and so forth. UK Biocentre adopted a pragmatic approach where all improvements would be reviewed for their potential benefits where there was organizational bandwidth to do so, and where the potential benefit was proportionate to the short-term impact of implementing the change.

Quality and Validation of the Testing Process

95. From the outset it was expected that Lighthouse Laboratories would deliver testing at a quality standard suitable for clinical diagnostics. This involved the accreditation of the testing to the international standard ISO15198 (*Medical laboratories — Requirements for quality and competence)*. This was very important to ensure high confidence in the testing process, especially as this was operated outside of the NHS laboratory environment.

96. Our Clinical Director, Dr Malur Sudhanva of Kings College Hospital (London) and Professor Mike Hill of NDPH (Oxford) were instrumental in guiding UK Biocentre through the complex and detailed process of constructing an accredited workflow, and then getting it accredited. Accreditation is the formal process by which an independent audit is conducted to establish that a process conforms to the formal requirements of the standard.

97. Part of this accreditation process involved running tests on samples provided by external laboratories to ensure there was concordance between our process and other providers. Since the tests were diagnostic in nature, the quality standard demands that the results are reviewed for suitability before being released. This was done by a team of Biomedical Scientists who were responsible for reviewing and maintaining the quality and integrity of the testing process. Given the number of tests being performed, it was to prove impossible for each test to be individually reviewed. We therefore used test analysis software provided by Ugentec Software to automate the evaluation of the tests. This was a machine learning system that was trained on a batch of control data, which was then used to evaluate real test results. As more data from the testing process was collected, it was used to create improved training sets, thereby improving the accuracy of the software over time. The test results that were unequivocally positive or negative were automatically reported since these represented a very small risk of being interpreted incorrectly. All results that could not be evaluated unequivocally by the software system were flagged for manual review by the team of Biomedical Scientists. The test evaluation software was used across all main Lighthouse Laboratories to ensure consistency of test results.

98. To further ensure consistency across the network of laboratories, batches of anonymised samples were swapped at intervals between labs and tested for concordance. This was an important part of accepting all new laboratories into the network.

99. All laboratory activity was tracked by a software system called a Laboratory Information Management System ("LIMS"). All labware was barcoded and as

labware containing samples or their derivative components moved through the analysis process, the labware barcodes were scanned to provide a consistent and comprehensive record of activity. This ensured that all samples were tracked in detail on their journey through the testing process and all steps could be reviewed if required.

100. UK Biocentre already operated an on-premise LIMS software system called BiobankPro from the commercial company Azenta Life Sciences. Given our existing familiarity with the system, it was natural for UK Biocentre to use this system to support the testing process. The size and throughput of the testing operation however dictated that this system could not be hosted at UK Biocentre. DHSC secured a cloud-hosted instance of an updated version of the software called LIMFINITY to support testing at UK Biocentre. This software was deployed on a set of virtual servers in the cloud. This system was also used at a number of other Lighthouse Laboratories.

Technology Evaluation and Process Improvement

101. As the pandemic rolled into 2021 the demand for increased testing capacity was ever-present. We therefore regularly reviewed our own processes seeking opportunities to improve efficiency, reduce turnaround time, reduce costs, or reduce complexity for operators.

Improving efficiency

102. Over this time, we introduced many small but often significant improvements. We reviewed daily operational performance data in detail to identify bottlenecks in our process and then focus improvement activities at these areas. Some changes were seemingly simple but proved complex in practice. An example serves to illustrate this point. All sample tubes arrived in an airtight sealed plastic bag. It had to be assumed that the sample was contaminated and therefore an infection risk. Indeed, at the height of the pandemic we know that the majority of samples we processed were positive for COVID-19 virus. Operators, wearing two pairs of gloves, removed the tubes from the plastic bags

but this operation had to be performed in a cabinet for safety reasons. Removal of tubes from bags was a big process bottleneck. While the use of open blades would have greatly speeded up the process, they could not be used due to the risk of cuts to gloved hands and while handling potentially infectious materials. Contaminated packaging had to be disposed of safely, and leaked or damaged tubes were a daily occurrence. Over time, we developed patterns of work and even our own home-designed tools for opening the plastic bags safely and at speed. Attention to the details of these mundane but crucial steps was key to improving overall process efficiency.

Evaluating new equipment

103. During the design and particularly during the operation of the testing system, we received numerous requests for us to evaluate new equipment, software systems and reagents. The manufacturers claimed many of them would offer higher performance, faster operation, high levels of automation etc. For example, we evaluated the "Hydrocel" instrument to conduct high volume, rapid end-point PCR reaction which could potentially accelerate testing. There was also a myriad of alternative test assays on offer from numerous manufacturers.

104. Where possible we would evaluate these reagents and technologies, many of them coming with elaborate claims of improvement. This usually involved receiving, installing and validating either a new piece of equipment or reagent kit. After this was complete a concordance test would be performed to assess the performance of the new process compared to current standards. Depending on the complexity of the changes needed, this could prove to be a time-consuming diversion from our core testing effort, and it was important to evaluate potential benefits of new equipment/reagents before this was embarked upon. It must be understood that making changes to a very high throughput system is complex and introduces considerable risk. When processing between 80,000 and 100,000 tests in each 24-hour period, the risk of compromising the testing system frequently overrode the defined benefits of adopting a new piece of equipment that delivered a marginal or modest gain.

105. Our unwillingness to adopt specific new technologies sometimes led to significant frustration for their advocates, some of whom took to campaigns of public criticism and accusations of poor management. Exhibit **TC/10 - INQ000587370.** . This was unfortunate since the complexities underpinning the decisions are almost impossible to set out to an audience not expert in the field, and it consumed a good deal of time and effort to manage.

106. It must be always remembered that the main testing process had to be maintained at all times. There was very limited development capacity available, therefore, within the daily operation to introduce significant changes to equipment, alongside the necessary modifications to tracking and reporting systems, and followed by an extensive qualification and validation process.

The development and introduction of "End-point PCR" (ePCR)

107. One significant exception to this development was the development and introduction of "End-point PCR" (ePCR) at UK Biocentre as an alternative approach to delivering the COVID-19 assay. This method was somewhat similar to the quantitative PCR method already in use, but considerably simplified. While qPCR assays are monitored for their amplification profile over the duration of the assay period (approximately one hour), epPCR delivers a result only at the conclusion of the amplification period – a binary "yes/no" result indicating that detection of COVID-19 genetic material has or has not taken place. There is no quantitative component associated with the result. The ePCR method therefore trades the amount of information generated by the assay with speed and complexity.

108. In and of itself, this would not be enough to recommend its use and, indeed, up to this point ePCR had not been used in any accredited human diagnostic test. However, we were made aware by NHS colleagues (**Name Redacted** Chief Executive, Eastern AHSN, Angela Douglas, Deputy Chief Scientific Officer, Office of the Chief Scientific Officer, **Name Redacted** Global NGS Business Unit Manager Genomics, LGC) of an instrument made by the commercial company LGC (formerly the Laboratory of the Government Chemist) for performing ePCR assays at huge scale. This instrument was targeted at the agricultural sector –

principally for screening seeds in very high numbers for advantageous breeding markers. We discussed an evaluation of the instrument using an ePCR assay for COVID-19. Over the last quarter of 2020 a detailed evaluation of the instrument was performed at UK Biocentre. It was decided after testing that while qPCR remained the "gold standard" for assays (because it delivers real time dynamic data on the course of the amplification), the ePCR system was sufficiently robust to warrant its use in COVID-19 testing and could offer significantly increased testing capacity.

109. A series of validation experiments resulted in the approval by the Medicines and Healthcare products Regulatory Authority approving use of the instrument and its assay protocol for human COVID-19 diagnostic use. I received a letter from the MHRA granting the Authorisation of Special Use for the LGC end point PCR system on 21st December 2020. **TC/11 - INQ000587371.**

110. By the time the production ePCR platform had been developed, commissioned, deployed and a series of reliability issues resolved in late 2021, the pandemic was beginning to decline and demand for testing was falling.

111. The coordinator of the testing network and other laboratory heads had come to the decision that the ePCR system would not be used generally throughout the network although it was in use at UK Biocentre for nearly a year. This decision was reached after considering the cost, space and training requirements that a wider deployment throughout the testing network would entail. The NHS subsequently decided to buy several ePCR instruments for use after the pandemic, and these were routed to a new laboratory being commissioned in Royal Leamington Spa, and which subsequently became the Rosalind Franklin Laboratory.

Lessons Learned

112. In this section I set out my personal views of the key points that can be taken from our experience of delivering the mass testing operation at UK Biocentre. I

do not attempt to speak for others at UK Biocentre, or for other laboratories in the testing network.

a. It was apparent from an early stage that there was no plan that existed, or indeed one which could be adapted, to guide the delivery of a mass testing program. We were therefore working "from scratch". In addition, there was no reserved infrastructure (space, equipment, etc.,) available with which to set up a new system. The system that was created relied on a large number of organisations offering their facilities for use over an extended period.

b. Pandemic response, and the success of the mass testing program, arguably depended to a large degree on the decision by numerous individuals to step forward and offer their expertise, time and experience. It is not clear to me how many would do that again and therefore it would be a dangerous assumption to rely on a similar response occurring during a future pandemic.

c. A critical factor in the successful, rapid deployment of mass testing was the availability of laboratory space suitable for rapid reconfiguration. In many subsequent conversations with COVID-19 testing facility managers I was told of the acute difficulties other organisations had in identifying suitable space for large scale operations. Availability of space was a significant factor in UK Biocentre's ability to respond successfully.

d. The willingness of all involved in the testing network to collaborate constructively was one of the most important factors in overall success. It is a testament to the attitude of all "pulling together" in a crisis that not only distinguished our efforts but maintained momentum and built relationships and friendships that will be long-lasting.

e. The size and immediacy of the requirement meant that many members of staff were thrust into roles and took on responsibilities that would not normally have been theirs. As such, many rapidly gained experience and skills that ordinarily might have taken years to develop. While not all will

thrive in such a selective environment, I am confident that the pandemic experience has given many people, especially numerous junior laboratory staff, an accelerated experience that will serve them well in their careers. We have rapidly created the next generation of experienced research technicians.

f. While Government departments were supportive and worked very collaboratively with UK Biocentre, I was frustrated at times by the lack of scientific background by some senior administrators, and especially by the speed at which individuals moves in and out of roles. If felt at times that we were continuously educating Government administrators about how testing technology and laboratory operations work. As we achieved a good level of understanding that made interactions more efficient, a new cadre of individuals would rotate into the positions, and we would have to begin all over again. While not a disastrous situation, this undoubtedly slowed down our ability to act at some points.

g. Lack of early access to tests for staff reduced our ability to manage outbreaks among the workforce. At time this led to significant reduction in our overall testing capacity. In future, laboratory staff and their supporting teams should be considered "front line" workers in the pandemic response.

h. Supply chain issues hampered laboratory operations at many points. Such shortages served to highlight the fragility of global supply chains when subject to intense competition and the lack of sovereign manufacturing capacity for fundamentally important consumables and equipment.

i. The testing network has been fully demobilised and little, if anything, remains of the infrastructure constructed over the two years of the pandemic. UK Biocentre's facility has been completely converted back to normal use.

Mass Testing in the event of another Pandemic

113. Undoubtedly the most important lesson to be learned in my view is that we should have been better prepared for the challenge that came. Nowhere was this more obvious than in the lack of national infrastructure to manage the crisis. We should learn from that experience. Having rapidly built a national test and trace system that arguably served the nation very well in a crisis, it should be maintained in a manner such that it can be rapidly brought back to use.

114. Space should be identified as being suitable for use in the next pandemic and provision made for its rapid mobilisation in the event of a crisis. This could be done my requesting proposals from commercial companies or government agencies prepared to allocate suitable, flexible high quality laboratory space in times of pandemic-related need in exchange for a very modest retainer.

115. There will be an inevitable trade-off between the cost in developing from-scratch a network capable of responding to a need at national scale, and the long-term cost of maintaining the quiescent foundations of such a network, possibly for a long period of time, before it is needed. These are policy questions of risk management and preparedness for Government at the national scale.

Statement of Truth

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: 16 June 2025