Witness Name: Professor Dame Anna Dominiczak OBE DBE

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Exhibits: AD1/01 – AD1/12

Dated: 4 June 2025

UK COVID-19 PUBLIC INQUIRY

MODULE 7

WITNESS STATEMENT OF PROFESSOR DAME ANNA DOMINICZAK

I, **PROFESSOR DAME ANNA DOMINICZAK**, will say as follows:

SECTION 1. INTRODUCTION

1.1 I make this statement in response to the request sent to me by the UK COVID-19 Inquiry ("**the Inquiry**") dated 4 April 2025 ("**Rule 9 Request**") for Module 7 which concerns the approach to testing, tracing and isolation adopted during the COVID-19 pandemic ("**the pandemic**") in England, Wales, Scotland and Northern Ireland from January 2020 until February 2022 ("**the Relevant Period**"). This is the first witness statement I have provided to the Inquiry.

1.2 The Rule 9 Request raises questions concerning my role and involvement in the testing programme that comprised part of the UK's response to the pandemic.

SECTION 2. BACKGROUND AND INTRODUCTION TO THE LIGHTHOUSE LABORATORIES

2.1 I am currently the Regius Professor of Medicine at the University of Glasgow, a post I have held since September 2009, and have been the Chief Scientist (Health) for the Scottish Government since July 2022. I am also a doctor

registered with the General Medical Council ("**GMC**"), with 30 years of experience in medicine and biomedical research, including laboratories.

2.2 I first obtained my Doctor of Medicine Honours from the Medical School in Gdansk, Poland in 1978 and my Doctor of Medicine from the University of Glasgow in 1989. I became a member of the Royal College of Physicians (UK) in 1986, a Fellow of the Royal College of Physicians and Surgeons (Glasgow) in 1995, and then a Fellow of the Royal Colleges of Physicians (Edinburgh and London) in 2017. I received an OBE for services to medicine in 2005 and a DBE for services to cardiovascular and medical sciences in 2016.

2.3 During the pandemic, the Government's strategy for scaling up testing capacity involved implementing five 'Pillars', as described in the UK Government's strategy document, published on 4 April 2020 **[Exhibit AD1/01 - INQ000106325]**. These Pillars were described as follows:

2.3.1 Pillar 1: scaling up NHS Polymerase Chain Reaction ("**PCR**") testing for those with a medical need and, where possible, the most critical key workers. Pillar 1 utilised both Public Health England ("**PHE**") and NHS laboratories.

2.3.2 Pillar 2: mass-swab PCR testing for critical key workers in the NHS, social care, and other sectors. Pillar 2 grew exponentially, dealing with in excess of one million tests during the Omicron wave. Laboratories that later became known as the Lighthouse Laboratories formed part of Pillar 2.

2.3.3 Pillar 3: mass-antibody testing to help determine if people have immunity to coronavirus. Pillar 3 primarily made use of lateral flow device antigen tests ("**LFDs**").

2.3.4 Pillar 4: surveillance testing to learn more about COVID-19 and help develop new tests and treatments.

2.3.5 Pillar 5: spearheading a Diagnostics National Effort to build a mass-testing capacity at a completely new scale.

2.4 From mid-March 2020, I led development of the laboratory at the Queen Elizabeth University Hospital in Glasgow ("**the Glasgow laboratory**"), which functioned as a COVID-19 laboratory for Scotland outside the NHS. Following a July 2020 visit to the Glasgow laboratory by Alex Cooper, the Director of Mass Testing at NHS Test & Trace ("**NHSTT**"), Department of Health and Social Care ("**DHSC**") officials became aware of my success in establishing the Glasgow laboratory and developing its testing capacity, along with my unique experience in both medicine and laboratories. I was then asked to join DHSC as Director of Laboratories from 17 August 2020 through a Secondment Agreement between the University of Glasgow and DHSC. Although my secondment was originally intended to last until August 2021, it was later extended until 31 March 2022, and then to 30 September 2022. However, I decided to leave my post as Director of Laboratories at the end of June 2022 in order to commence my position as Chief Scientist (Health) for the Scottish Government on 1 July 2022. Directly before my secondment to DHSC, I was the Vice-Principal and Head of the College of Medical, Veterinary and Life Sciences at the University of Glasgow.

2.5 On 9 April 2020, the then-Secretary of State for Health and Social Care ("**SSHSC**") launched the first of a group of DHSC-funded laboratories that sat outside the NHS (hereafter referred to as **"the Lighthouse Laboratories"**), which became my primary responsibility. When I became the Director of Laboratories at DHSC, I replaced Professor Chris Molloy, who was then leading on Pillar 2 laboratories.

2.6 By way of chronology, the Lighthouse Laboratories were established as follows:

2.6.1 In April 2020, the Milton Keynes laboratory, being the first of the Lighthouse Laboratories, was launched by the SSHSC on 9 April 2020. This was followed by the Alderley Park laboratory and the Glasgow laboratory, in the same month;

2.6.2 In October 2020, the Newport laboratory was opened;

2.6.3 In March 2021, the Newcastle, Brants Bridge and Plymouth laboratories were launched; and

2.6.4 In June 2021, the Rosalind Franklin Laboratory was opened.

2.7 My initial focus at the beginning of my post as the Director of Laboratories was on the first three laboratories in Milton Keynes, Alderley Park and Glasgow. The number of Lighthouse Laboratories in active operation varied at different times during the pandemic. By Winter 2021/2022, there were 11 Lighthouse Laboratories in operation: this not only included the laboratories mentioned above, but also the Randox laboratories in Northern Ireland, and the Health Services Laboratory ("**HSL**") in London **[Exhibit AD1/02 - INQ000610049]**. Despite sitting outside the NHS, the Lighthouse Laboratories collaborated with the NHS laboratories and shared learning with them. However, the Lighthouse Laboratories collaborated very little with PHE.

2.8 Of particular note is the Rosalind Franklin Laboratory (initially known as "Project Jupiter" and also known as the "Mega-Lab"), which was a purpose-built high-output laboratory dedicated to COVID-19 testing. This included features to maximise efficiency, flexibility and resilience such as separate, aseptic laboratory lanes which could carry out different functions at the same time. Other features of the laboratory can be seen in the following slide-deck **[Exhibit AD1/03 – INQ000610048]**. The Rosalind Franklin Laboratory was built and become operational at record pace: the first PCR test samples were processed in June 2021, just six months after building work began in December 2020. Notably, building a laboratory of this scale typically takes 2-3 years.

2.9 The Rosalind Franklin Laboratory contributed significantly to testing in the winter of 2021/22, helping to protect the public from the impact of the Omicron variant.

2.10 The Lighthouse Laboratories were developed with the support of academic and private sector partners in the diagnostic industry, as well as laboratory experts. Due to the diversity in size and structure of each Lighthouse Laboratory, I would refrain from labelling the Lighthouse Laboratories as one monolithic 'network'. Community testing was facilitated by the setting up of regional and mobile testing sites, whilst tests were located and tracked, and results communicated, via the creation of a digital infrastructure.

2.11 Laboratory experts were either from academic or industry backgrounds. The sites themselves were not set up by us; we just conducted the testing. Within the Test, Trace and Isolate ("**TTI**") infrastructure, colleagues procured the samples, following which my team decided which laboratories received each sample.

2.12 For the avoidance of doubt, my team was not involved in the actual collection of samples itself - other specialist teams from NHSTT directed by other individuals were responsible for this, as outlined in the Testing Senior Leadership Team organogram on page 7 of this slide pack **[Exhibit AD1/04 - INQ000563805].**

2.13 As Director of Laboratories, I worked with a plethora of talented individuals and organisations in respect of the testing programme, which included but were not limited to the following:

2.13.1 Baroness Dido Harding – Executive Chair of NHSTT;

2.13.2 Professor Chris Molloy – founding Director of the Pillar 2 Laboratories;

2.13.3 Alex Cooper – Director of Mass Testing at NHSTT;

2.13.4 Professor Dame Jenny Harries – Chief Executive of UK Health Security Agency ("**UKHSA**") from 24 March 2021;

2.13.5 Deloitte LLP, including Philip Coleman, a senior partner who developed logistics and comprised part of the team building the Rosalind Franklin Laboratory in Leamington Spa;

2.13.6 Professor Dame Sue Hill – Chief Scientific Officer for NHS England;

2.13.7 Christine McLaughlin – Head of Test and Protect in the Scottish Government; and

2.13.8 Mike Coupe – appointed under Baroness Harding as Testing Director of NHSTT in September 2020.

SECTION 3. TESTING INFRASTRUCTURE AND CAPACITY

3.1 In March 2020, the TTI infrastructure in the UK was insufficient to meet testing demand. We had never in history conducted large-scale infectious disease testing, later known as 'mass testing', as was necessitated by the demand during the pandemic. As such, the Lighthouse Laboratories were developed to address

this insufficiency. It was essential to change from small-scale 'cottage laboratories', which processed a few hundred tests, to the much larger factory-like laboratories.

3.2 As I have mentioned in paragraph 2.5 above, the Lighthouse Laboratories existed outside of normal NHS activity; whilst not completely private, they fused academia, the public sector (NHS) and industry, creating a 'triple helix' collaboration. This model describes interactions between academia, industry and the public sector to drive economic and social development, emphasising the importance of collaboration and knowledge sharing between these three sectors to foster innovation.

3.3 Working with the private sector was essential to achieving this goal. Some of the laboratories, for example Randox in Northern Ireland, were rooted entirely in the private sector, whilst others required a collaborative effort involving universities, the NHS, and the private sector to develop the desired capacity. An example of the latter is the Glasgow laboratory.

3.4 Whether based in the private or public sector, or a mixture of both, the technology developed in all cases was underpinned by collaborations with organisations within the diagnostic industry. We collaborated mostly with ThermoFisher Scientific, but also with a host of other diagnostic companies. ThermoFisher was essential to our efforts: based next door to the Glasgow laboratory, the ThermoFisher Scottish Laboratory shared skilled staff and reagents with us, which resulted in the development of a truly constructive collaboration.

3.5 Furthermore, I was involved, along with other Government bodies such as HM Treasury, in the purchasing of automated liquid handling machines for several of the Lighthouse Laboratories from Hamilton Robotics on behalf of the UK Government.

3.6 At the start of the pandemic, as already stated, laboratory capacity to test for viral infectious diseases was inadequate to meet demand. The testing of viruses was very different to bacteriological testing, which was done on a much larger scale.

This is because viruses had no specific treatments and viral screen results would have turnaround times of weeks rather than hours or days. As a consequence, virology laboratories were typically quite small and undeveloped at the time. However, in contrast to this, the UK's virology research sector was well advanced. The quality of the UK's medical research sector, funded by the Medical Research Council ("**MRC**"), is widely regarded as one of the UK's core strengths in its pandemic response.

3.7 Equally, at the beginning of the pandemic, NHS laboratories did not employ a high level of technology and did not have robotics and automation which would enable efficiencies in testing. Throughout the pandemic, NHS laboratories acquired new equipment, in some cases learning from and duplicating what the Lighthouse Laboratories were doing. This led to the use of tests that produced immediate results: starting with machines at patients' bedsides upon arrival in the hospital, and later the development of LFDs using rapid diagnostic assays. This process did not happen in isolation but was rather the product of consistent collaboration between laboratories and colleagues in industry, academia and Government.

SECTION 4. LIGHTHOUSE LABORATORIES NETWORK

Infrastructure and capacity

4.1 As the Director of Laboratories, my line manager was Alex Cooper, the Director of Mass Testing at NHSTT. Under Alex Cooper, and later Mike Coupe and Mark Hewlett, I led a small central team which mostly comprised colleagues from Deloitte. Although the majority of the employees recruited by the Lighthouse Laboratories already had a laboratory background, we did not recruit them ourselves as each laboratory recruited their own staff.

4.2 My central team were based within DHSC, alongside the rest of the TTI team, and contributed to TTI reports which were discussed at daily morning stand-ups. My team and I worked closely with directors and staff in all the Lighthouse Laboratories, holding meetings at least weekly, if not more frequently.

4.3 Every night, a number of samples directed to each laboratory was monitored and their results were assessed in the morning. The work was highly intensive. and these procedures were operational 24 hours a day, 7 days a week.

4.4 As well as capacity, a major key performance indicator ("**KPI**") for all UK laboratories was turnaround times. If a sample was taken and the person subsequently found to be infectious, the result would need to be transmitted as soon as possible to avoid the subject meeting with and infecting other people. Therefore, it was imperative to successfully divide samples across the whole of the UK, to enable a turnaround time of less than 48 hours. During the first wave, the demand was such that we were unable to provide such a short turnaround time.

4.5 I worked with organisations such as the NHS, the Cabinet Office, No. 10 officials and occasionally the Scientific Advisory Group for Emergencies ("**SAGE**"), which provided the Lighthouse Laboratories modelling predictions.

4.6 Data and modelling were used daily throughout the development of the Lighthouse Laboratories infrastructure. We also received helpful assistance from both Deloitte and SAGE. We used this data to match capacity to meet the demand necessitated by each consecutive wave of the pandemic. As a leading consultancy, Deloitte was particularly good at such modelling, forecasting how much capacity would be needed for the laboratories in the foreseeable future. This modelling was supplemented by the more formal modelling conducted and provided by SAGE's Scientific Pandemic Influenza Group on Modelling, Operational sub-group ("**SPI-M-O**").

4.7 The quality of available data had improved by the end of 2020 alongside the progression of the pandemic. Specifically, we developed a more comprehensive understanding of different waves of COVID-19 and the variants of the virus that emerged throughout the pandemic.

4.8 Further, another helpful example of data and modelling was the use of Post Test Performance Reports which portrayed the utilisation and positivity rate across

the laboratories, with notable performance outliers mentioned and trends illustrated – by way of example, I refer to the Post Test Performance Reports dated 5 October 2021 and 7 October 2021 **[Exhibit AD1/05 - INQ000610042] [Exhibit AD1/05a - INQ000610043].**

4.9 Regarding the processes and systems that were put in place for collation and sharing of data, in late 2020 and early 2021, regular end-of-day reports on all data were started to ensure we had visibility over changing demands – for Pillar 1, NHS laboratories in England joined these sessions at some point in 2021. Cumulative data was reported regularly to Ministers. Although these systems were in place, I am unable to comment on the efficacy of these systems.

4.10 There was a relatively fixed capacity in NHS England laboratories in Pillar 1. In contrast, the UK-wide Lighthouse Laboratories in Pillar 2 were able to continue expanding capacity. Although the Lighthouse Laboratories were located across all four nations, we worked as one. The factory-like laboratories in Pillar 2 were built to be scalable to meet a surge in demand: at the height of the Omicron wave, by which time the Rosalind Franklin Laboratory was in operation, testing across the Lighthouse Laboratories well exceeded one million tests per day.

4.11 Although we requested that NHS laboratories in Pillar 1 increase testing, they simply could not do so due to their capacity limitations. Further, funding was available to Pillar 2 laboratories to buy robotics and automation equipment, which assisted the large Pillar 2 laboratories in increasing their capacity. Pillar 2 laboratories were built to facilitate speed, capacity and automation, which was not the case for the smaller NHS laboratories. For example, at the Glasgow laboratory, there were systems in place which would allow the laboratory to simply occupy additional floors in the building to increase testing capacity if required. At the start of 2022, the Glasgow laboratory occupied the entire building.

4.12 From my occasional attendance at SAGE meetings and through my work as a scientist more generally, I was aware that SAGE collected data relating to learnings from previous infectious diseases, endemics, pandemic in the UK (e.g.

Severe Acute Respiratory Syndrome ("**SARS**"), Middle East Respiratory Syndrome ("**MERS**"), Swine Flu), as well as the approaches in other countries. However, the work of SAGE in relation to this was not something with which I was directly engaged in.

4.13 On the issue of testing capacity, I was still in Glasgow at the time of the Government setting its 100,000 tests per day target in April 2020 and so I did not have any involvement in reaching this figure. Nevertheless, this target did help to increase laboratory capacity and paved the way for future increases that were facilitated by robotics and automation.

4.14 I would also like to note that we were not solely focused on increasing testing capacity, but also downsizing when necessary to provide value for money when demand was lower. As well as peaks in demand (such as during the Omicron wave in late 2021, which necessitated the processing of 1 million tests per day), we also experienced significant troughs (such as in March 2021, requiring just thousands of tests to be processed per day).

4.15 In relation to the internal communication channels that were in place between the different Lighthouse Laboratories:

4.15.1 A meeting was held and attended by all laboratory directors on a weekly basis, some of which were also attended by senior clinical virologists who were responsible for advising the larger laboratories;

4.15.2 In conjunction with the weekly meeting, separate meetings with individual laboratories were held regularly to discuss various operational matters, including capacity and turnaround times; and

4.15.3 Following the receipt of testing results, we received a daily report that was presented to everyone at 8am each morning.

4.16 Additionally, I personally visited most of the laboratories myself if there was anything that needed addressing, even during lockdowns. This included the Glasgow laboratory, which I originally led, Milton Keynes, Alderley Park, Cambridge and the Randox laboratory in Northern Ireland.

4.17 As I have already mentioned, each Lighthouse Laboratory was responsible for their own staff recruitment. Although my central team was initially sourced from Deloitte in 2020, we were later permitted to recruit staff through regular job advertisements and the standard DHSC human resourcing processes. At the beginning, there was very little time to proffer formal advertisements for jobs. Instead, we relied on our networks to recruit highly recommended individuals (such as our Quality Control expert, Colin Seller) who had senior experience in building laboratories, drawing from our military and consultancy networks.

4.18 Alongside the Deloitte team members, we also benefitted from military expertise, which was instrumental in the early stages of the development of the Lighthouse Laboratories. On the one hand, we had then-serving members of the UK Armed Forces come in to assist with the testing effort. On the other hand, we were fortunate to have colleagues in the NHSTT team itself with prior military experience, with Alex Cooper being a notable example.

4.19 The AstraZeneca headquarters also provided experienced experts in automation and the setting up of laboratories. In addition, colleagues from other Government departments, such as the Ministry of Defence, provided assistance when needed.

4.20 On the issue of staff turnover, we did indeed lose some of our fantastic high-quality staff involved with testing in the Lighthouse Laboratories as we emerged out of the pandemic in 2022. This was because many of these individuals were experienced academics. For example, I recall we had PhD students and post-doctoral researchers with biomedical laboratory knowledge and experience conducting testing in the Glasgow laboratory: this was also the case in other Lighthouse Laboratories. Once life began to return to normal, these individuals understandably returned to their studies. In any event, we had a very different workforce by then.

4.21 On 11 January 2022, UK Government announced it was no longer recommended for people testing positive with LFDs to book themselves a confirmatory PCR test. Naturally, the lower the demand for tests is, the more expensive each test

becomes. If the laboratory sits idle and is only required to process a few tests a day, the costs of each singular test is astronomical, resulting in very low value for money for taxpayers.

4.22 Accordingly, the Lighthouse Laboratories were closed after the pandemic. However, my team and I provided detailed plans for the preservation of residual laboratory capacity.

4.23 The plans to retain residual capacity mostly related to the Rosalind Franklin Laboratory, which was the last to close. As I had returned to the University and accepted the role of Chief Scientific Advisor to the Scottish Government on Health by this time, another team ultimately handled the final stage of the Rosalind Franklin Laboratory closure.

4.24 There was extensive discussion regarding the ways to preserve the use of the Rosalind Franklin Laboratory for pandemic preparedness, alongside ways to utilise the laboratory for other purposes when extensive COVID-19 testing would no longer be required. From the outset, the site was designed to be flexibly utilised for a range of biological processes and methodologies beyond the pandemic. I participated in several discussions relating to preserving the operation of the laboratories and we produced various versions of a proposed course of action. A broad overview of future uses of the laboratory can be seen at slide 8 of the following exhibit **[Exhibit AD1/03 - INQ000610048]**.

4.25 In summary, these were:

4.25.1 Biosecurity and surveillance;

4.25.2 Diagnostic testing (for example, screening for diseases such as familial hypercholesterolemia);

4.25.3 Research and development; and

4.25.4 Commercial propositions, especially public/private partnerships with the Life Sciences industry.

4.26 It was envisaged that academia, the public sector (NHS) and industry would have key roles in the legacy of this site, known as the 'triple helix' model of innovation.

Options on the long-term future use of the Rosalind Franklin Laboratory were explored with the NHS, other Government bodies, local universities and many potential third parties in the commercial sector. Ultimately, no parties came forward to take over the lease for the site. Given the high cost of maintaining the site, it ceased to operate in January 2023, UKHSA exited the site's lease early, and its residual capacity was not utilised.

4.27 The closure of the Rosalind Franklin Laboratory was the subject of the House of Common's Science, Innovation and Technology Select Committee on 24 January 2024, at which I provided evidence **[Exhibit AD1/06 - INQ000511372]**.

4.28 Despite its closure, the Rosalind Franklin Laboratory provides the blueprint for surging testing capacity in any future pandemic.

Testing Technologies

4.29 The testing regime that was in place across the Lighthouse Laboratories was as well organised as was feasible in a pandemic environment that was constantly changing. My colleagues and I worked tirelessly round-the-clock to facilitate collaboration across all UK laboratories and to guarantee continual improvement in the Lighthouse Laboratories' capacity, automation, quality control and turnaround times.

4.30 For clarity, and as the Inquiry is aware, SARS-CoV-2 is the actual virus that is tested for, and COVID-19 is the disease that is caused by the SARS-CoV-2 virus.

4.31 The testing technology that was used at the Lighthouse Laboratories was the same as all other laboratories – it was the PCR, which is widely regarded as the 'gold standard' in detecting the SARS-CoV-2 virus. Although some NHS laboratories may have used slightly different test kits, the PCR testing technology was fundamentally the same across both the Lighthouse Laboratories and other laboratories that conducted testing for SARS-CoV-2.

4.32 The testing regime developed as the pandemic progressed, and technology became available:

4.32.1 From mid-March 2020, my team and I worked with the ThermoFisher reagents in the Glasgow laboratory. At that stage, the first three laboratories involved in SARS-CoV-2 testing relied on commercial test kits. The NHS began to develop capacity to process higher volumes of PCR tests after the first commercial PCR test kits became available.

4.32.2 From April 2020 onwards, there was 'triple helix' collaboration between the public sector, academia and industry to increase testing capacity.

4.32.3 Throughout 2020 and 2021, the Lighthouse Laboratories grew with the use of robotics and automation, which in turn provided better value for money. As alluded to in paragraph 4.14 above, the difficulty was that the capacity was never right – there would either be 'too little' capacity or 'too much' capacity, depending on the prevalence of SARS-CoV-2 in the community. However, when infectiousness significantly increased with the emergence of the 'Kent variant' in September 2020, the scope to increase testing capacity became essential.

4.33 Baroness Harding, the Executive Chair of NHSTT and later, Professor Harries, the Chief Executive of UKHSA, were responsible for the development of the policies and strategies surrounding the testing regime. Professor Harries was announced as the Chief Executive of UKHSA on 24 March 2021. Baroness Harding left her role as Executive Chair on 7 May 2021 and UKHSA became operational on 1 October 2021: as the Inquiry is aware, UKHSA incorporated elements of both PHE and NHSTT.

4.34 Baroness Harding was supported by her senior leadership team who were responsible for the development of policies and strategies around the testing regime. Advisors from the NHS, Cabinet Office and No. 10 also assisted Baroness Harding and her team with the practical development of the testing regime.

4.35 It is my understanding that SAGE was primarily responsible for considering lessons learnt from previous infectious diseases, endemics and pandemics in the UK, and approaches in other countries. I was not aware of any use of learning from previous pandemic exercises in my role.

4.36 My primary responsibility was developing and directing the operation of the Lighthouse Laboratories. Although on a personal level as a Professor of Medicine I was absolutely concerned about wider public health implications, I was not directly engaged with this in my specific role as the Director of Laboratories. As such, SAGE, PHE, NHSTT and later UKHSA, among other organisations, are better placed to provide observations on these concerns.

4.37 Regarding the advisory system that was in place to inform the development of the testing regime, between August 2020 and approximately mid-2021, there were weekly meetings on scientific matters. No. 10 officials organised these meetings and I attended them alongside Professor Chris Whitty, the Chief Medical Officer ("**CMO**"), Sir Patrick Vallance, the Government Chief Scientific Adviser ("**GCSA**"), and many other senior clinicians and officials. As expected, the testing regime was frequently discussed during these advisory meetings.

4.38 Very significant consideration was given to the development of testing for different variants. Once the exact sequencing was shared from the Sanger Centre, it was clear that the SARS-CoV-2 virus had started mutating.

4.39 As sequencing takes a substantial time to process, we worked with experts to develop fast PCR tests – this effort was led by both the laboratories in Glasgow and Alderley Park. Although I am of the view that these fast PCR tests should ideally have been used earlier, it allowed for the 2–3-week turnaround time to be shortened to 48 hours.

4.40 Regarding asymptomatic testing, this was initially done through laboratory PCR tests, but from September 2020 this was conducted with LFDs, which can be administered by patients themselves and do not require laboratories at all. It is worth noting that PCR tests processed through laboratories have always

constituted the 'gold standard' of testing due to their superior sensitivity and accuracy.

SECTION 5. INEQUALITIES AND VULNERABILITY CONSIDERATIONS

5.1 Regarding inequalities and vulnerability considerations, I can confirm that the Lighthouse Laboratories actively considered the impact of policy decisions on vulnerable groups throughout its decision-making processes.

5.2 One specific example, within my recollection, was that the Lighthouse Laboratories worked with NHSTT to ensure that there was an effort to reach vulnerable immigrant communities in Leicester and the East Midlands. NHSTT colleagues from Alex Cooper's team, during the more severe COVID-19 waves, visited Leicester and worked with Leicester City Council after being made aware that senior citizens and various ethnic minorities did not get tested. This was amid early recognition of increased COVID-19 risks for individuals from ethnic minority backgrounds – evidence from the Joint Biosecurity Centre in 2020 has consistently shown higher rates of infection among individuals of Pakistani and Indian backgrounds, along with other non-white ethnic minority groups **[Exhibit AD1/07– INQ000592560] [Exhibit AD1/07a - INQ000592557].**

5.3 However, due to privacy obligations and our position outside the NHS, the Lighthouse Laboratories themselves did not hold any personal data, such as names and ethnicities, in relation to the tests that the laboratories processed. Instead, the Lighthouse Laboratories utilised anonymised sample numbers, placing being limitations on the measures that the Lighthouse Laboratories could take to mitigate the disproportionate impact of the pandemic on vulnerable groups. Once the Lighthouse Laboratories finalised their testing of a particular sample, the results would be pushed through the NHSTT application – it was only after this stage that the personal data in relation to a sample processed through the Lighthouse Laboratories could be analysed. By then, this information was outside the purview of the Lighthouse Laboratories. Unlike the vaccination effort, in which it was indeed possible to focus vaccine sites on vulnerable groups, such as senior citizens and ethnic minorities, the lack of information

available to the Lighthouse Laboratories meant that this was something we simply could not do.

5.4 As I have mentioned in paragraph 4.36 above, I was not directly involved with the detailed consideration of wider public health implications, including epidemiological inequalities in my role as the Director of Laboratories. I reiterate, however, that I was certainly concerned about these issues on a personal level. Other organisations are better placed to assist the Inquiry with its investigations on this issue.

SECTION 6. INTEGRATION AND COOPERATION WITH LOCAL INFRASTRUCTURE

6.1 The Lighthouse Laboratories used a mixture of local infrastructure and resources from universities, the NHS, as well as the medical technology industry and other private diagnostic facilities, all of which were essential to the functioning of the Lighthouse Laboratories as a whole.

6.2 One such example of the Lighthouse Laboratories benefiting from local infrastructure is when universities lent their laboratory equipment, including PCR machines and flow hoods, to individual Laboratories. Further, early on in the pandemic, all the protective clothing used in the laboratories was obtained from the NHS. We also worked with various smaller laboratories, some of which were located in Northern England and throughout London.

6.3 In relation to the channels of communication that existed between local infrastructure and the centralised Lighthouse Laboratories (as detailed in paragraph 4.2), all laboratory directors met with the central team at least weekly during the Relevant Period. Samples were taken and coded, after which they were sent in batches to the laboratories for processing. Towards the end of the afternoon each day, our central team would decide how many samples would be sent to each laboratory. As the local NHS laboratories did not have spare capacity, there would have been minimal communication and co-operation

between the local NHS laboratories and the centralised Lighthouse Laboratories at this stage in the operation.

6.4 The benefits of the centralised Lighthouse Laboratories over a more localised alternative model included:

6.4.1 Increased testing capacity, as a result of a targeted network of laboratories with similar procedures specialising in COVID-19 samples only;

6.4.2 Straightforward allocation of samples to specific laboratories for maximum efficiency and quicker turnaround times; and

6.4.3 Stability to procure equipment in bulk, such as robots, reagents and consumables, thereby allowing better value for money.

SECTION 7. DECISION MAKING

7.1 I played a key role in the decision-making process behind the building of the Rosalind Franklin Laboratory in Leamington Spa. As a Senior Responsible Officer ("**SRO**") for development, I assisted both with planning strategy and with the presentation of the proposal to the NHSTT Senior Team and the relevant Ministers.

7.2 Having reflected on the decision-making process, I do not believe that these decisions could have been made differently, especially considering the unprecedented and urgent nature of the pandemic.

7.3 I would like to emphasise that the Rosalind Franklin Laboratory was a key decision, for the following reasons:

7.3.1 Following the emergence of more contagious variants of the SARS-CoV-2 virus and, after the 100,000 per day target, we needed to process in excess of 500,000 tests per day by 2021;

7.3.2 With the existing infrastructure at the time, we could not promise to process even more tests per day. Existing laboratories, such as the

Glasgow laboratory, were not purpose-built as laboratories, and we needed the sequencing and detection of the SARS-CoV-2 virus to be perfect;

7.3.3 In contrast, the Rosalind Franklin Laboratory was designed to produce high throughput from its establishment, and had a purpose-built and flexible structure inside an existing industrial space; and

7.3.4 After the Rosalind Franklin Laboratory was built, we were able to increase testing capacity to an excess of 1 million tests per day.

SECTION 8. ROBUSTNESS AND EFFICACY

8.1 In December 2020, SARS-CoV-2 testing activities were exempted from requiring full accreditation[1] meaning that the Lighthouse Laboratories initially did not require full accreditation from the United Kingdom Accreditation Service ("**UKAS**").

8.2 I would like to clarify that I was not directly involved with the laboratory accreditation process, and I am not an expert on this subject. This was delegated to a quality control team consisting of experts from the NHS, who assisted us with laboratory accreditation-related issues from the beginning. Throughout the entire pandemic, this team would visit each laboratory during its early development stage to conduct an exceptional truncated version of accreditation-related quality checks, such as safety matters, and our Lighthouse Laboratories team would not start sending samples to a laboratory before this NHS team verified that everything was up to the requisite standard. A link to sending samples for regular quality control checks was also provided.

8.3 In 2021, all laboratories commenced the full accreditation process with UKAS, and I understand that most of the Lighthouse Laboratories received full accreditation by 2022.

[1] As per The Health and Social Care Act 2008 (Regulated Activities) (Amendment) (Coronavirus) (No. 2) Regulations 2020.

8.4 The first known incident at the private Immensa laboratory in Wolverhampton was raised by Public Health Wales on 11 March 2021 over the validity of Immensa's laboratory results. Specifically, the reporting of a higher rate of positive results for asymptomatic care home screening, compared to all other labs. The use of the Immensa laboratory was immediately suspended upon notification of such concerns. An investigation into this was undertaken by Professor Dame Sue Hill's team, who were responsible for ensuring the validity of laboratory results. During my tenure, I appointed Colin Seller, who held UK board responsibilities for manufacturing across Pfizer Group UK, to provide his supply chain and manufacturing expertise, particularly in relation to quality assurance. He assisted UKHSA in its Serious Untoward Incident ("**SUI**") investigation of this incident.

8.5 The investigation found that Immensa had followed their diagnostic standard operating procedure and that the results were in accordance with the relevant instructions for use. I reported these findings to Public Health Wales accordingly **[Exhibit AD1/08 – INQ000610041]**.

8.6 On 12 October 2021, UKHSA was notified of new concerns over the PCR test results at Immensa, specifically that negative confirmatory PCR tests were reported following positive LFD results. This was a concern given PCR tests are far more sensitive than LFDs and can therefore detect lower concentrations of the virus. This incident was notably distinct from the earlier March incident where, conversely, a higher rate of positive PCR results than anticipated were reported.

8.7 As was the case in March, the use of the Immensa lab immediately ceased and an investigation was urgently carried out by Professor Dame Sue Hill's team. I invited Paul Klapper, an expert virologist at the University of Manchester, to assist with this review **[Exhibit AD1/09 – INQ000610044]**. The team's investigation ultimately endorsed Immensa's initial findings, which determined that the immediate cause of the misreporting of PCR test results was the incorrect setting of the threshold levels for reporting positive/negative results by their laboratory staff. It was estimated that approximately 43,000 results (10% of

total testing undertaken by Immensa between 2 September and 2 October 2021) were incorrectly reported as negative when they may have been positive.

8.8 Professor Harries additionally commissioned an investigation under the SUI procedure, to which I provided evidence. I would like to refer the Inquiry to UKHSA's *Final report of the Serious Untoward Incident investigation into the misreporting of PCR test results by the Immensa Health Clinic Limited*, which was published in November 2022 **[Exhibit AD1/10 - INQ000513642].** This document provides a detailed overview of the failings reported, what was known at the relevant time, when issues were identified, and steps taken.

8.9 Following this incident, a monitoring dashboard was developed for easy comparison of all Lighthouse Laboratory positive results on a day-to-day basis to identify any outliers and take action early where necessary. This development is outlined in the following documents **[Exhibit AD1/11 – INQ000610045] [Exhibit AD1/11a – INQ000610046]**.

SECTION 9. LESSONS FOR THE FUTURE

9.1 In my view, the use of the Lighthouse Laboratories supplemented and benefitted the UK's response to testing within the pandemic. I refer to Chapter 6 of the *Technical report on the COVID-19 pandemic in the UK* regarding testing ("**Technical Report**") **[Exhibit AD1/12 - INQ000203933]**, which provides a useful analysis of how testing was approached during the pandemic and reflections for the future.

9.2 As I have previously noted at paragraph 3.2, I do not regard the Lighthouse Laboratories as exclusively 'private' organisations - for example, the Newcastle laboratory was NHS-based, and the Glasgow laboratory was run by the University of Glasgow.

9.3 In accordance with what I have mentioned throughout this statement, I strongly support 'triple helix' collaboration between the public sector, academia and industry in any future pandemic response. Although this was valuable during the

pandemic, such collaboration could still be improved. I would like to repeat the following observations at page 206 of the Technical Report, with which I agree:

> *Collaboration was essential to testing delivery – between government, the NHS, public health agencies, industry and academia, through the exchange of staff, equipment, knowledge, skills, data sharing and interoperable systems. It was a significant challenge, particularly during the first wave when multiple organisations were having to act outside their usual remit, an unprecedented volume of samples and data had to be gathered, stored and shared, and there were multiple competing demands on resources. There was widespread sharing of staff between universities and the cross-UK laboratory network, but interoperability has not yet been achieved – the UKHSA Rosalyn Franklin laboratory, for example, is not interoperable with NHS testing laboratories, and sample tracking and results sharing has had to be retrofitted rather than done using shared interoperable systems across laboratories. Having agreements and sleeping protocols for sharing information, equipment, samples and staff across the sector (including with private sector suppliers) is an important step to avoid this in the future, but realistically the move to scale up any testing system in such a short time will likely meet similar challenges in the future.*

9.4 I also believe that the Government response to testing in the event of a future pandemic should certainly include considerations relating to data, technology, automation and robotics. However, despite their importance, I also recognise the difficulty in scaling their use to help millions in a pandemic setting, in line with the situation that the UK faced during the Relevant Period.

9.5 The legacy of the testing programme used during the pandemic is a blueprint to be used during future pandemics. However, the lack of a residual infrastructure may create bottlenecks for testing in the future if not remedied. I would like to reiterate the following point from page 207 of the Technical Report, which I concur with (emphasis added):

Reflections and advice for a future CMO or GCSA

Point 1

...

Limitations in testing capacity and an end-to-end system to effectively use the output of testing were initially a major constraint. The magnitude and speed of scale-up required in the testing system for COVID-19 was unprecedented.

The major efforts required to expand testing capacity highlighted the importance of building testing systems that maintain some form of contingency response, or at least retain some expertise on how to surge in the event of a new variant or an entirely new pandemic. The diagnostics industry should be included in planning as they may be a key partner (for example, in providing rapid surge capacity).

9.6 If another viral pandemic unfolds in the UK, we will again need large high-throughput factory-like laboratories similar to that of the Lighthouse Laboratories and, in particular, the Rosalind Franklin Laboratory. Attention needs to be directed to building a national diagnostic system with contingency capacity in 'peacetime' – otherwise, we will not be able to sufficiently respond again for the next viral pandemic in 'wartime'.

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: 4 June 2025