Witness Name: Nicola Newman
Statement No.: 1
Exhibits: NN/01, NN/02, NN/03, NN/04, NN/05 and NN/06
Dated: Wednesday 21st May 2025

UK COVID-19 INQUIRY

WITNESS STATEMENT OF Nicola Newman

I, Nicola Newman, Managing Director of Berkshire and Surrey Pathology Services (BSPS), will say as follows: -

1. BSPS is a contractual joint venture between Ashford and St. Peter's Hospitals NHS Foundation Trust; Frimley Health NHS Foundation Trust; Royal Berkshire NHS Foundation Trust; Royal Surrey NHS Foundation Trust; and Surrey and Sussex Healthcare NHS Trust. Frimley Health NHS Foundation Trust acts as the host organisation and legal entity of BSPS.

2. I am employed by Frimley Health NHS Foundation Trust as Managing Director, BSPS. I make this statement for and on behalf of BSPS in response to the request from the UK Covid-19 Inquiry ("the Inquiry"), dated 29 August 2024, under Rule 9 of the Inquiry Rules 2006.

3. This statement provides an explanation of the role and activities of BSPS in the context of the scope of Module 7 of the Inquiry between the 1 January 2020 and 28 June 2022.

4. This statement has five sections, each containing information in relation to the following: -

a. Background to our involvement with the DHSC Test, Trace and Isolate (DHSC TTI) programme.
b. Our DHSC TTI-relevant infrastructure and capacity.
c. Our role within the NHS Test and Trace (NHSTT) organisation as part of its Lighthouse Laboratory Network (LLN).
d. The robustness and efficacy of our testing service.
e. Our views with regards to lessons for the future.

Background

5. BSPS is an established NHS organisation, providing pathology services to primary, secondary, tertiary, regional and national healthcare organisations. We operate from six fully accredited multi-disciplinary laboratories, reporting results from over 56 million tests, serving a population of over 3.7 million people. Over the last twenty-five years, BSPS has successfully combined five NHS pathology services into a single organisation of over 1,500 employees (including more than 500 registered medical and scientific personnel) working to a single clinical governance and quality assurance framework, integrated with all aspects of public healthcare. BSPS is also responsible for regional and national laboratory services, including trace metals, peptide hormones, and bowel and cervical cancer screening for the South and South-East of England. All services are externally accredited by the United Kingdom Accreditation Service (UKAS) to ISO 15189 standards. We are considered by NHS England to be a 'thriving' pathology network, and are often asked to contribute towards national initiatives.

6. Towards the end of July 2020, we understood that NHS 'Test and Trace' (NHSTT), as part of DHSC TTI, were seeking an organisation that could establish a Covid-19 Lighthouse Testing Service (LTS) in the South-East of England capable of processing up to 40,000 samples per day. Given our previous experience in establishing laboratory services, and our understanding of the demands associated with establishing a Covid-19 testing service for the NHS (see further at paragraphs 14 and 15), we proposed our assistance.

7. During August 2020, we worked closely with our partner Trusts to estimate the costs and time associated with the creation of an appropriate laboratory facility. Following a rapid appraisal of options, we suggested converting a vacant space on the second floor of the Healthspace facility at Bracknell. The site had sufficient internal space; good road links; on-site parking; access for large vehicles; and outside areas available for additional temporary storage should any be required.

8. Our proposal was accepted by the DHSC Investment Board late in August 2020, and a project team was formed quickly, tasked with the mobilisation and eventual operation of the BSPS LTS. It was led by Dr Phil Hudson, Programme Director, who reported directly to me on all matters associated. On matters related to the mobilisation of the BSPS LTS, I was accountable to a Covid-19 Lighthouse Laboratory Programme Board. On all other matters, including the subsequent operation of the BSPS LTS, I was accountable to the BSPS Board that was chaired at the time by Neil Dardis, the Chief Executive Officer of Frimley Health NHS Foundation Trust.

9. During the mobilisation and operational phases of the BSPS LTS, we were assisted by specialist resources and guidance from all our partner Trusts, but in particular by the Royal Berkshire NHS Foundation Trust, in whose premises we were located, and who was the employer of the BSPS LTS staff members. We were also supported in our efforts throughout the pandemic by Professor Bryan Charleston and his colleagues at The Pirbright Institute (Pirbright), see further at paragraphs 16 and 25-28.

10. Our work on behalf of NHSTT began in September 2020, and completed (on behalf of the United Kingdom Health Security Agency (UKHSA)) in December 2024. Our sole role and involvement on behalf of NHSTT was as a provider of Covid-19 testing services as part of the NHSTT LLN. We had no involvement in any NHSTT policies and strategies developed and deployed throughout the pandemic. We were not involved in designing the structure of the NHSTT system, nor do we know how local infrastructure, resources and expertise were utilised as part of the LLN, or have any knowledge about what organisations

provided advice to the LLN. We had no contact with organisations involved in decision making in the UK and Devolved Administrations, and no role in relation to public compliance. And other than providing indicative costs for the maintenance of a resilience testing service as a contingency measure, we played no part in any decisions associated with the preservation of infrastructure, capacity and research to improve and develop NHSTT schemes for future pandemics.

11. To put it another way, our role on behalf of NHSTT was restricted to mobilising and subsequently operating a Covid-19 LTS capable of receiving and processing tens of thousands of Covid-19 samples each day, every day of the year, for as long as we were required. We were to do so under the governance procedures and policies of BSPS, applying the quality and scientific principles of a long established, fully accredited, 'thriving' NHS pathology organisation.

DHSC TTI-relevant infrastructure and capacity

12. BSPS is a full-service NHS pathology network. As such, we maintain multiple laboratories providing a repertoire of over 1,500 tests used in the diagnosis of disease. For example, we run a rapid response laboratory (RRL) at all six of our partner Trusts' hospitals to inform urgent clinical decision making. We use the RRLs to process samples and provide results to clinicians in less than 60 minutes, albeit for a limited repertoire. We also maintain two cellular pathology laboratories that investigate the presence (or absence) of cancer in over 300,000 solid tumours and liquid biopsies each year. Our molecular pathology laboratory at the Royal Surrey Hospital at Guildford studies molecules within organs, tissues and bodily fluids to diagnose disease, complementing investigations originating in other pathological disciplines. And our blood and infection sciences hub laboratories at the Frimley Park and Wexham Park hospitals process and report over 5,000 tests an hour on average, and over 10,000 an hour at peak times. Finally, our virology laboratory based at St. Peter's Hospital tests over 800,000 samples of suspected viruses annually.

13. We have single clinical, quality and management systems, embedded within the quality, governance and clinical systems of our five partner Trusts. We operate a single laboratory information management system, capable of receiving requests and transmitting results instantaneously at any point within our network of laboratories and clinical requestors. All our services are accredited by the relevant regulatory body. It follows that we are a substantial organisation in the context of public pathology in England, well placed to establish a new laboratory service rapidly.

14. In March 2020, in response to demand from the NHS, we created a 'stand-alone' Covid-19 cell (effectively, a 'pillar 1' laboratory) within the footprint of our molecular pathology laboratory at the Royal Surrey Hospital at Guildford. From it, we were able to provide testing capacity to support the local demand for Covid-19 testing for patients and NHS staff. The laboratory met and maintained DHSC targets for test turn-around times, and we developed a rapid testing workflow to support patient movements throughout our partner Trust hospitals. As pathology incident Director for 'South 5', I regularly attended meetings with the national and regional NHS / Public Health England (PHE) teams, and we worked closely together to optimise the use of scarce equipment, reagents, consumables and controls.

15. To establish our Covid-19 cell, we relied on existing laboratory infrastructure and staff members, supported by additional equipment and colleagues from our public sector partners. No DHSC TTI infrastructure or equipment was used in the BSPS Covid-19 'pillar 1' NHS laboratory throughout the pandemic.

16. To establish the BSPS LTS referred to at paragraph 6 (a 'pillar 2' laboratory), we commenced development of the infrastructure in September 2020; conducted a competitive tender and procured equipment in October 2020; and were validated by NHSTT as being a laboratory capable of providing up to 40,000 Covid-19 tests per day on 14th January 2021. During the eighteen-week mobilisation period, a training facility was established at Pirbright; an inbound logistics facility was acquired and fitted-out at the Sterling Centre in Bracknell; robotic equipment and analysers were procured and commissioned; a sample tracking capability was installed; a workforce was recruited and trained; and measures of quality and

managerial control were established. Progress against our 171-point mobilisation plan [NN/01 – INQ000587443] was monitored weekly by our relationship manager who reported his findings to NHSTT.

17. Our efforts to mobilise the BSPS LTS were successful. At its peak in December 2021, our laboratory processed and reported over 52,000 samples in a day. We provided 24/7 genotyping of positive samples, reporting detail of variants on up to 6,000 samples per day. In total, over 9 million samples were processed, using products and services from multiple local and global suppliers. We recruited a workforce of over 500 scientists, medical technical officers, logistics and support staff, and routinely exceeded all our performance targets.

18. To note, throughout the pandemic, our 'pillar 1' laboratory (hospital setting) and 'pillar 2' (community setting) Lighthouse laboratory (part of the LLN) were kept geographically, operationally, managerially and technologically separate, except for the routine exchange of samples to cross-check testing processes and results. The BSPS LTS had no involvement in 'pillar 3' (antibody testing) or 'pillar 4' (surveillance testing) activities.

Our role in the Lighthouse Laboratory Network

19. The BSPS LTS was commissioned by NHSTT to add capacity to the existing LLN. The chronology of our involvement is set out at paragraphs 6-8 and 16. We had no role in the establishment or development of the LLN, and did not provide any expertise or resources to it. Neither did we play any role in the leadership, management or operations of the LLN, other than that of a contracted provider of laboratory capacity to it. Explicitly, we were not responsible for any key decisions and / or policies associated with the LLN, and had no role in the design and development of the national testing regime (including modelling; capacity planning; provision of scientific advice; cost and value for money, or the development of any policies and strategies associated). We cannot, therefore, offer an opinion to the inquiry about any of these matters.

20. Neither did we work with UK Government Departments to develop the LLN. We provided no advice in support of any Government strategies with respect to

DHSC TTI, and received no oversight, input or scrutiny from UK Government Departments during our involvement. We were not involved with DHSC TTI in April 2020 when the 100,000 tests per day target was set, and so have no opinion about how the target may have influenced capacity, or whether it was feasible. Likewise, we played no role in relation to the development of testing for variants, asymptomatic testing or pharmaceutical and diagnostic support, and are unaware of systems established to understand the effectiveness of the testing regime in reducing the transmission of Covid-19. We have no knowledge of the extent that previous pandemics, the approach in other countries, and previous pandemic exercises were considered in the development of the LLN. Finally, we have no knowledge of how other LLN laboratories collaborated with existing NHS or PHE / UKHSA laboratories, or what data was shared with other public sector bodies.

21. We did, however, have considerable and regular contact with the LLN throughout our work on behalf of NHSTT. For example, during the mobilisation phase of the BSPS LTS (September 2020 to January 2021), we met daily with NHSTT to discuss progress against the plan agreed. As our infrastructure approached completion, we were invited to observe regular national testing 'situation report' meetings that provided invaluable context of our place in the national effort, and what was required of us. When our LTS became operational, we received daily feedback on our performance relative to targets and to other laboratories in the LLN. We participated in monthly LLN quality meetings [NN/02 – INQ000587445] and in weekly LLN Laboratory Director meetings throughout our operational period.

22. Our initial commitment to NHSTT was to provide a testing service capable of testing up to 40,000 samples per day. During 2021, with the procurement of additional equipment and recruitment of supplementary staff members, we were able to raise our daily capacity to test Covid-19 samples to 60,000 per day, as well as developing a capability to conduct additional tests on positive samples to identify the variant of the pathogen.

23. As stated previously at paragraphs 19 and 20, we had no involvement in the establishment or development of the LLN, and therefore have no direct knowledge of any of its public or private sector partners, or how closely they worked with DHSC TTI or NHSTT. We are not aware of how the LLN communicated and worked with local councils and health authorities. We do not know how local public sector organisations cooperated with the LLN, DHSC TTI or NHSTT, and as such, have no view about the impact of centralisation of testing, or any opinion about what difference a more decentralised approach would have made. Finally, we are unaware of how the LLN complied with health protection regulations relating to notifiable disease.

24. We also have no knowledge of how the UK Government, DHSC TTI, NHSTT or LLN considered the impact of the pandemic on individuals and groups with protected characteristics, albeit we are aware that DHSC TTI had formed a 'Satellites & Vulnerable Communities team' before our involvement in September 2020. With respect to BSPS, each sample that arrived at our LTS contained no personal identifier except for a bar code that differentiated the sample from all others. Therefore, we had no access to data or information that could link a sample and its test result to an individual and their clinical and demographic characteristics.

25. We are, however, able to comment about the value of partnership working from our local perspective of mobilising and maintaining the BSPS LTS. Throughout the development of our service, we were able to form good and deep working relationships with, for example, WSP, the project managers responsible for the refurbishment of the Healthspace building; Deloitte, who provided our relationship manager for the mobilisation period; and Thermo Fisher, the eventual suppliers of testing equipment and reagents. Notwithstanding our almost universally positive experience with over 120 suppliers to the BSPS LTS, the collaboration with local public sector organisations in general, and Pirbright in particular, was key to our success.

26. Pirbright is a world leading centre of excellence in research and surveillance of virus diseases of livestock and viruses that spread from animals to humans. Its vision is to apply scientific research to prevent and control viral diseases,

protecting animal and human health and the economy. The organisation employs around 450 staff, research students and visiting scientists, and maintains a national capability to prevent and control viral diseases of livestock. As an example, it manages ten reference laboratories that work on behalf of national and international organisations such as the Department for Environment, Food and Rural Affairs, and the World Organisation for Animal Health.

27. We started to work substantively with Pirbright in early April 2020 as we established our 'pillar 1' NHS testing capability. Pirbright loaned us equipment and reagents at a time of national shortage, and also provided colleagues to draft procedures for their use. For several weeks, our NHS workforce was supplemented by Pirbright volunteers, and they worked with us to develop 'home brew' extraction kits to circumvent global supply chain difficulties with reagents for PCR testing. But it was in the mobilisation of the LTS in September 2020 that relationships built previously started to come to the fore.

28. In September 2020, as described at paragraph 8, a BSPS LTS project team was formed. As part of the mobilisation process, we established multiple workstreams concerned with, for example, operations; clinical; IT; finance; estates and facilities; HR and training. Colleagues from Pirbright were embedded in many of the working groups. We were able to learn from Pirbright's experience of rapidly establishing laboratories in Africa in response to outbreaks of disease, and also to jointly establish a training and contingency facility for the LTS at the Pirbright facilities in Surrey. Throughout the period of mobilisation, and for some months beyond, we were extremely grateful that whenever we asked, Pirbright made its best efforts to help.

29. We are also indebted to the Animal and Plant Health Agency; the Universities of Surrey and Reading; and the Ministry of Defence for the assistance they provided BSPS throughout the pandemic. Building on many years of collaborative working and long-held personal relationships, we were offered, for example, scientific advice, equipment, and support with recruitment. Our overall response, and in particular, the establishment of our 'pillar 1' capability, was all the better because of it.

The robustness and efficacy of our testing service

30. Our initial contract required us to provide a testing service that '*shall comply with ISO 15189 standards for medical laboratories'*. It is not possible to be accredited by UKAS to ISO 15189 until sufficient evidence of the adherence of any laboratory to its stated policies and processes can be gathered, and until embedded practices can be demonstrated. As such, we relied on the general policies and procedures of our fully accredited Quality Management System (QMS), adapted for the demands of the LTS, to assure the quality of our testing to both NHSTT and our partner Trusts. We have no knowledge other than that contained in the UKHSA January 2023 'Testing Times' document [NN/03 – INQ000496317] of the approach of the LLN to other Lighthouse laboratories, or to the role that the NHS and PHE / UKHSA had in the LLN.

31. As part of the mobilisation plan and prior to us being approved to join the LLN, we needed to demonstrate to NHSTT that our LTS processes and instruments were capable of producing consistent results. As such, we had to successfully demonstrate compliance at an audit to a NHSTT checklist [NN/04 – INQ000587444]. The checklist contained 34 sections that included, for example, having a QMS in place that operated according to ISO 15189; having records of training and competence for all operational staff; and having standard operating procedures for all elements of sample handling and testing. We passed the NHSTT audit on 14th January 2021. And, when suitable and sufficient evidence had been gathered, we applied for UKAS assessment to ISO 15189 and were subsequently accredited. Section 3.2 of the UKHSA January 2023 'Testing Times' document [NN/03 – INQ000496317] accurately reflects our understanding and experience of the quality policies and controls across the LLN.

32. In compliance with our BSPS QMS (an extract of which is at NN/05 [NN/05 – INQ000587441]), we routinely gathered and reported data from the BSPS LTS associated with the quality and accuracy of our testing, including internal quality controls; the speed of delivering results; the meeting of demand for tests in a timely manner; the competence of staff; staff turnover, and many other operational performance indicators. We routinely reviewed performance of the BSPS LTS against contractual key performance indicators (at NN/06 [NN/06 –

INQ000587442]) with NHSTT. And, at times of high network demand, we would twice daily discuss sample receipt; operational workflow; sample positivity; staff and equipment availability with the NHSTT Laboratory Directorate.

33. With respect to the quality and accuracy of our testing processes, we conducted both internal quality control (IQC) and external quality assurance (EQA). With respect to IQC, we included positive and negative controls on every sample 'plate' to assure ourselves there had been no contamination or adverse events during sample processing. And with respect to EQA, as we commenced operations at our LTS service, we routinely 'cross-checked' our results with our 'pillar 1' laboratory (referred to at paragraphs 14, 15 and 18) and vice versa. Soon afterwards, we joined the Quality Control for Molecular Diagnostics EQA scheme to monitor our performance.

Lessons for the future

34. We have not commissioned or taken part in any internal or external 'lessons learned' exercises associated with our LTS, and we have no views about what could or should have been done differently with respect to the Government's decision to use private sector suppliers to support the testing infrastructure and capacity. As stated previously at paragraphs 10 and 11, we had no involvement in the establishment or development of DHSC TTI or NHSTT, and cannot therefore comment about any lessons learned. We do, however, have three observations from the perspective of a provider of testing services to NHSTT that may be helpful for future preparedness.

35. Our first observation is the value of local partnerships and individual relationships. As Covid-19 struck the UK in March 2020, we were able to call upon the support, equipment and advice of multiple local public sector organisations who we had worked alongside previously. Because we had already built trust between organisations and key individuals, we were able to ask for and receive help as if we were all one organisation serving a common purpose. Without the support and commitment of resources from elsewhere, our LTS mobilisation project would have been at greater risk of delay, and very definitely, of sub-optimal decision making. Our point is that efforts made

previously to develop local relationships enabled us to overcome challenges more rapidly than would otherwise have been the case, and enabled us to build our LTS from 'the bottom up'.

36. Our second observation is about the retention of capacity and capability to scale PCR testing rapidly for a future pandemic. Until May 2024, we had been under contract to provide a resilience testing capability to UKHSA capable of processing up to 30,000 'pathogen-X' samples per day within 30 days. The contract required us to maintain space, equipment and a small senior team as contingency should a future pandemic strike the UK. At the end of 2024, all of our resources (space, equipment and people) associated with the LTS have been dismantled and / or reassigned. Our point is not to criticise decisions made by UKHSA about how best to use scarce resources to provide contingency for a future pandemic, but simply to reflect that at the end of 2024, nothing tangible from the BSPS LTS remains.

37. Our final observation is about the legacy of the national testing programme and our small part in it. At the start of the pandemic, as the provider of NHS pathology services to our five partner Trusts, we were able to 'keep the front door' of our hospitals open by developing a Covid-19 testing service with sufficient capacity and resilience to satisfy demand. Expanding our 'pillar 1' service to satisfy the demand from our local community, given the space, equipment and staff we and our partners had available at the time, was not an option. However, being considered competent by others to mobilise and run an LTS meant we could contribute directly to the national effort, and in doing so, contribute to the health of the local population we serve. So, the legacy of our involvement in DHSC TTI is embedded in the health of our local population.

38. Finally, a word about our staff, and the impact of their time at the BSPS LTS on their future careers. BSPS has, for many years, been approved by the Institute of Biomedical Scientists as a training provider for the registration of biomedical scientists with the Health and Care Professions Council (HCPC). We were able to establish a training pathway at the LTS that led eventually to some of our staff members achieving HCPC registration and subsequently, securing scientific roles elsewhere in BSPS and in the wider NHS. Some of our senior scientific staff, in

part due their experiences with us during the pandemic, were able to secure positions at NHS England and UKHSA.

39. All our staff gained extensive understanding of working at a high-capacity, high-throughput UKAS accredited molecular diagnostic testing facility under the governance of a 'thriving' NHS pathology network. This provided them with demonstrable experience of, for example, scientific experiment planning, design, implementation and review; inventory, workforce, supply chain and infrastructure administration; training and competency assessment, and of working in an organisation subject to public sector governance and ethics. Hopefully, this experience will serve them well throughout their continuing careers.

40. Reflecting on our involvement with DHSC TTI and NHSTT as we prepared this witness statement, our overriding memory is of a highly complex project to mobilise and subsequently run our LTS. Although we knew little of the activities taking place outside the organisational boundaries of the LLN, our overall impression is one of having played a small part in a vital national effort, and we remain pleased to have been considered competent to do so.

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 , for and on behalf of BSPS.

Dated: Wednesday 21st May 2025