Witness Name: Sarah Collins
Statement No.: 1
Exhibits: SC/001 – SC/116
Dated: 03 December 2024

UK COVID-19 INQUIRY

MODULE 5 CORPORATE WITNESS STATEMENT ON BEHALF OF THE UKHSA - COMMERCIAL

SECTION 1. INTRODUCTION

I, **Sarah Collins**, of UK Health Security Agency, 10 South Colonnade, London, E14 5EA, will say as follows:

1.1. This statement is made on behalf of the United Kingdom Health Security Agency ("**UKHSA**") for Module 5 of the UK COVID-19 Inquiry ("**the Inquiry**") which will inquire into the procurement and distribution of key healthcare equipment and supplies. It responds to two requests for evidence dated 28 November 2023 and 19 April 2024 from the Inquiry made under Rule 9 of the Inquiry Rules 2006 ("**the Rule 9 requests**").

1.2. I am the Commercial Director of UKHSA and have held that position since January 2022. My role includes ensuring the organisation has access to the correct commercial arrangements to address current and future health security threats. I am also responsible for our business development function and our vaccines and countermeasures response team.

1.3. I have been a civil servant since 2008, and a senior civil servant since 2014. Between 2008 and 2018 I held various roles at the Department for Transport, including – latterly – Head of Procurement Excellence, Head of Commercial Relationship Management and Interim Group Commercial Director. I am an accredited Senior Commercial Specialist, having passed the SCS2 level assessment through the Government Commercial Organisation ("**GCO**"). In May 2018, I moved to the Cabinet Office, where I held the role of Director of Delivery, Capability and Systems

Performance until September 2020. Thereafter I became Commercial Director of Sourcing and Delivery for NHS Test and Trace ("**NHSTT**"), where I was initially responsible for common goods and services categories (namely Infrastructure, Logistics, Service Centre/Trace, Professional Services, and Digital and Technology). In April 2021 I took on the remaining categories (namely Laboratories, New Testing Technologies and Consumables, Reagents and Equipment), and was responsible for these for the remainder of my time in post. In January 2022, I moved to my current position at UKHSA.

1.4. UKHSA is an executive agency of the Department of Health and Social Care ("**DHSC**") and carries out certain statutory functions on behalf of the Secretary of State for Health and Social Care ("**SSHSC**"). Operational from 1 October 2021, UKHSA's role is to protect the public from both infectious diseases and external hazards such as biological, nuclear, and environmental threats. It brings together expertise from several predecessor organisations including Public Health England ("**PHE**"), NHSTT, the Joint Biosecurity Centre ("**JBC**") and the Vaccine Task Force ("**VTF**").

1.5. This is the twelfth corporate statement which UKHSA has provided to the Inquiry. Professor Dame Jenny Harries, Chief Executive of UKHSA, has provided six corporate statements for Modules 1 to 4. Professor Isabel Oliver, UKHSA's Chief Scientific Officer, has provided two corporate statements for Module 1 and one corporate statement for Module 5 (see below at paragraph 1.8). Professor Susan Hopkins, UKHSA's Chief Medical Advisor, has provided a corporate statement for Module 3. Dr Mary Ramsay provided a corporate statement describing the activity of PHE for Module 4 of the Inquiry.

1.6. This statement has seven further sections as follows:

i. Section 2: Organisational background.
ii. Section 3: Roles in public procurement.
iii. Section 4: Policy-led procurement.
iv. Section 5: Supply Management and Distribution.
v. Section 6: UKHSA's review of contracts awarded.
vi. Section 7: Contract Management and Monitoring.
vii. Section 8: Lessons Learned in respect of UKHSA's commercial function.

1.7. Consistent with the Inquiry's request that statements provided in any module should be free-standing documents, some of the detail set out below repeats information already provided by UKHSA in statements given in earlier modules and published on the Inquiry's website. As requested by the Inquiry, key documents have been exhibited to this statement.

1.8. Taken together the Rule 9 requests ask a substantial number of questions focused on the procurement and distribution activity of UKHSA and its predecessor organisations between January 2020 and 28 June 2022 ("**the Relevant Period**"). During that period the key healthcare equipment and supplies with which UKHSA and its predecessor organisations were concerned were COVID-19 reverse transcriptase quantitative polymerase chain reaction tests ("**PCR**") and lateral flow devices antigen tests ("**LFD**"). A third Rule 9 request for evidence, dated 15 April 2024, more focused on scientific and technical matters, is addressed in a separate statement ("**the Science and Technical Statement**"). To avoid unnecessary duplication and for clarity, insofar as the two requests addressed in this statement raise scientific and technical issues then these are addressed in the Science and Technical statement.

1.9. As UKHSA became operational in October 2021, the Agency itself was only involved towards the end of the Relevant Period in the procurement of PCR and LFD tests. Many senior officers who were most directly involved in the procurement of PCR and LFD tests by predecessor organisations did not transfer to or are no longer engaged/employed by UKHSA. The content of this statement is necessarily reliant on the knowledge of individuals outside UKHSA who were more directly involved in the procurement of PCR and LFD tests prior to October 2021 and contemporaneous documents relevant to the earlier work of predecessor organisations and now in UKHSA's possession.

SECTION 2. ORGANISATIONAL BACKGROUND

A. PHE

2.1. PHE was established as an executive agency of DHSC on 1 April 2013. It primarily covered England, although it had some UK-wide responsibilities, for example international health protection relationships and radiation protection technical expertise. PHE was the only one of UKHSA's predecessor organisations that existed prior to COVID-19.

2.2. The organisation had a broad public health remit beyond health protection activity, which it continued to deliver alongside the COVID-19 response until its health protection functions were formally transferred to UKHSA on 1 October 2021. It was a Category 1 Responder under the Civil Contingencies Act 2004 and, as such, responded to infectious disease, chemical, radiological, and environmental incidents. It also maintained critical national scientific infrastructure and hosted World Health Organization ("**WHO**") Collaborating Centres and Reference Laboratories.

2.3. By reference to the scope of Module 5, the key responsibilities of PHE as set out in its 2018 Framework Agreement were to:

2.3.1. "Fulfil the Secretary of State's duty to protect the public's health from infectious diseases," through "integrated surveillance systems; providing specialist services, such as diagnostic and reference microbiology; developing, translating and exploiting public health science, including developing the application of genomic technologies".

2.3.2. "Improve population health supporting sustainable health and care services," through "promoting the evidence on public health interventions and analysing future demand to help shape future services; ... providing national co-ordination and quality assurance of immunisation and screening programmes, the introduction of new programmes and the extension of existing programmes".

2.3.3. "Ensure the public health system maintains the capability and capacity to tackle today's public health challenges" by "undertaking research and development and working with partners from the public, academic and private sectors to improve the research landscape for public health...providing the professional advice, expertise and public health evidence to support the development of public policies to have the best impact on improving health and reducing health inequalities".

[Exhibit: SC/001 INQ000090327 (M1) (Agreement); Exhibit: SC/002 INQ000090328 (M1) (Annex A); Exhibit: SC/003 INQ000319628 (Annex B); Exhibit: SC/004 INQ000319629 (Annex C); Exhibit: SC/005 INQ000319630 (Annex D)]

2.4. The first remit letter addressed to PHE during the COVID-19 pandemic was dated 29 April 2020 **[Exhibit: SC/006 INQ000090337]**. It stated that PHE should support the COVID-19 response through: "surveillance and modelling to inform action at national

and local level; providing expert advice to DHSC, other Government departments and scientific advisory groups, including national work to support vulnerable groups; clinical diagnostic testing and genome sequencing to inform public health interventions; (and) supporting and delivering evidence-based public health communications and guidance". It also stated that PHE should continue to deliver existing essential activities including ensuring the continuity of its current role in existing vaccine programmes and the supply of countermeasures.

2.5. The senior leadership of PHE over the period relevant to Module 5 is set out in the exhibited organogram **[Exhibit: SC/007 INQ000514408]**. The Accounting Officer for PHE from January 2020 until 31 August 2020 was the Chief Executive, Duncan Selbie. Michael Brodie was appointed as the interim Chief Executive and so Accounting Officer for PHE on 1 September 2020 and remained in post until 30 September 2021.

2.6. PHE was not a regulatory body and did not provide approvals, accreditations or endorsements of any products or laboratories (referred to hereafter as "**lab**", singular, or "**labs**", plural, unless in a quotation or a proper noun), including COVID-19 diagnostic assays or commercial tests to be used in NHS or other labs. It undertook evaluations of diagnostic technologies and commercial products for COVID-19 (addressed in the Science and Technical Statement).

B. NHSTT

2.7. The immediate forerunner to NHSTT was the National Testing Programme ("**NTP**") for the UK, which was set up by and under DHSC in mid-March 2020 and announced publicly on 2 April 2020. Its aim was to offer COVID-19 tests to everyone who needed them through a phased approach, detailed further below.

2.8. NHSTT was initially established as a taskforce reporting to the Prime Minister. It was not clear what the long-term design of the organisation would be. NHSTT was formally established on 28 May 2020 to lead an 'at scale' national testing and tracing service, working with PHE and others. In parallel, in May 2020, JBC was established separately by the Cabinet Office to provide additional and complementary objective analysis and assessment of data and data derived evidence to build on that already in place at a local and regional level across the UK, and to inform local and national decision making in response to COVID-19 outbreaks. After NHSTT's establishment,

the JBC transferred into NHSTT. DHSC had ministerial accountability for the NHSTT programme. Baroness Dido Harding held the role of Executive Chair until 7 May 2021. The Executive Chair reported directly to the Prime Minister ("**No.10**") and the Cabinet Secretary until 2 December 2020. From 3 December 2020 until 7 May 2021, the Executive Chair reported to SSHSC.

2.9. NHSTT was established to carry out "Test, Trace, Contain, and Enable":

2.9.1. Test: increase availability and speed of testing;

2.9.2. Trace: identify any close contacts of anyone testing positive for COVID-19 and alert those most at risk of having the virus of the need to self-isolate;

2.9.3. Contain: identify localised outbreaks and support effective local responses;

2.9.4. Enable: provide information to government to support wider understanding of COVID-19 and explore measures to reduce population viral transmission.

2.10. NHSTT delivered the testing programme, in greater part, on a four nations basis, with the tracing programme developed and managed on a devolved basis, further to a joint agreement between the four Chief Medical Officers ("**CMO**") as to the allocation of testing capacity with scope for additional mutual support beyond that allocation. LFDs were allocated to Devolved Administrations ("**DA**") at the point of procurement based on population shares, for each nation to use based on their policy decisions (explained in Section 5 below).

2.11. Throughout the life of NHSTT the Second Permanent Secretary of DHSC, David Williams, was Accounting Officer for NHSTT and remained Accounting Officer for PCR and LFD contracts until 31 March 2022. NHSTT was subject to DHSC's financial, information and staffing controls.

2.12. The senior leadership changed over time. The leadership in June 2020 is in the exhibited organogram at **[Exhibit: SC/008 INQ000348126]**. The Inquiry will note that some senior leaders had several joint appointments.

C. UKHSA

Establishment

2.13. In August 2020, SSHSC announced that a new national body would be established to bring together the health protection elements of PHE with NHSTT under a single leadership team, initially referred to as the National Institute for Health Protection

("**NIHP**"). NIHP would be a new organisation whose primary focus was to ensure the UK had the best capability to control infectious disease and deal with pandemics or health protection crises. Ministers changed the name to UKHSA.

2.14. The overall transition programme, which also included parts of PHE, was led by Jonathon Marron, Director General of Public Health at DHSC. A transition team was established across PHE and NHSTT to develop the structure of the new organisation.

2.15. On 1 April 2021, Professor Dame Jenny Harries was formally appointed as Chief Executive of UKHSA and Ian Peters was formally appointed as Chair (non-executive). Professor Harries was also Senior Responsible Owner and delegated budget holder for NHSTT from 7 May 2021 for the remainder of 2021 to 2022, but as set out above the DHSC Second Permanent Secretary remained the Accounting Officer for spend on testing contracts.

2.16. From April to October 2021, the component organisations retained their identities, responsibilities, and structures whilst planning for the transition to the new organisation continued. The first remit letter to UKHSA, dated 13 July 2021, set out the priorities for 2021 to 2022, explained the priorities for UKHSA were to "[b]ring together the staff and capabilities of NHSTT and PHE to establish UKHSA as a dynamic and innovative agency that maximises the health security of the country through operational and scientific excellence" and "[b]uild on the legacy of the current response to this pandemic to put in place a resilient and scalable infrastructure that puts the UK in the strongest possible position to protect the public from new and existing threats to health that may emerge, ensuring effective emergency preparedness, resilience and response for health emergencies".

2.17. UKHSA became operational from 1 October 2021, although work continued thereafter to build the structures, systems and processes needed by the new agency. Staff transferred to UKHSA from PHE and NHSTT, which then ceased to be operational although some documentation after October 2021 would still reference PHE and NHSTT as templates, etc, changed.

2.18. From 1 October 2021, the Chief Executive became the Accounting Officer for the former PHE health protection budgets that moved into UKHSA. UKHSA had responsibility for operational decisions to procure and/or deliver testing services that had been overseen by NHSTT.

2.19. UKHSA's Executive Committee ("**ExCo**") was and remains the key decision-making body and it supports the Chief Executive as Accounting Officer. ExCo consists of the Chief Executive as well as other senior UKHSA officials. Its role is to oversee UKHSA's overall performance and delivery, as set out in the Terms of Reference. UKHSA's Advisory Board was recruited in 2021, becoming established in April 2022.

2.20. As of 1 October 2021, UKHSA comprised 11 groups including public health and clinical, science, health protection operations and testing, as well as functions such as finance and commercial. Some elements of testing later transferred into other parts of the organisation, such as Testing Quality and Regulatory which transferred into Science and Public Health. The structure of UKHSA has since changed further.

2.21. UKHSA's responsibilities are for England and across the UK on reserved health matters and in partnership with lead agencies in Scotland, Wales and Northern Ireland on devolved issues where relevant. UKHSA also holds UK-wide responsibilities in areas of technical and/or specialist capability and capacity and excepted reserved competence such as specialist radiation capabilities and being the UK's designated national focal point for International Health Regulations. UKHSA has no role in setting budgets for other organisations that the Inquiry has asked about.

2.22. Exhibited here is the current senior leadership organogram: **[Exhibit: SC/009 INQ000348130]**.

Pandemic Preparedness

2.23. UK Government operates a Lead Government Department model for the management of catastrophic risk. DHSC is the lead department for Pandemic Preparedness. DHSC maintains leadership and responsibility across the whole system for the Pandemic Preparedness Portfolio.

2.24. Within this structure, DHSC is responsible for the policy, supply, storage and distribution of pandemic medicines and personal protective equipment ("**PPE**"), as well for the procurement of PPE and ventilators. DHSC is, therefore, better placed to answer questions about stockpiling, distribution, and procurement in relation to PPE and ventilators. UKHSA supports DHSC's lead role on these areas by providing expert clinical advice, including on the requirements and use of PPE, and on vaccine and medicine effectiveness.

2.25. UKHSA procures, stores, and distributes vaccines (for COVID-19 and for national immunisation campaigns) and countermeasures. UKHSA stockpiles medicines and products to enable countermeasures against chemical, biological, radiological and nuclear threats. DHSC is best placed to give evidence on its policies and strategies on the stockpiling of key healthcare equipment and supplies.

2.26. UKHSA has specific responsibilities, and associated programmes of work, for diagnostics, public health measures, surveillance and case and contact management amongst other areas.

2.27. UKHSA has established the Centre for Pandemic Preparedness ("**CPP**") which provides coordination of this work across different specialist teams in UKHSA, works closely with relevant DHSC teams, and feeds into Cabinet Office-led cross-Whitehall work on pandemic preparedness. UKHSA works to help prevent future pandemics, to ensure a faster response where pandemics occur, and to enable any response to a pandemic to be as effective and efficient as possible in reducing the negative impacts of health threats to the UK. The CPP's role is to coordinate this work and to identify gaps in the health protection preparedness and strategic opportunities to enhance our readiness. That coordination extends across the specific topic leadership within UKHSA and enables work with industry, academia, and the international community. CPP also works closely with UKHSA's Commercial Function, the Office for Life Sciences, and DHSC to support market engagement and industry partnerships.

2.28. CPP provides the secretariat for UK contributions to the 100 Days Mission ("**100DM**") (INQ000101061), which focuses on global collaboration with the goal that vaccines in particular but also, diagnostics and therapeutics for a novel virus could be available within 100 days of confirmation of a new pathogen.

SECTION 3. ROLES IN PROCUREMENT

A. Overview

3.1. This section addresses UKHSA and its predecessors' roles in procurement, insofar as it relates to Module 5, generally from June 2009 to present as follows:

3.1.1. PHE:

i. Prior to January 2020; and

ii. from January 2020 until its cessation;

3.1.2. From May 2020, NHSTT; and

3.1.3. From October 2021, UKHSA.

3.2. Prior to 2020, PHE had a relatively limited commercial role in procurement for wider public health matters. PHE's role had, in broad terms, been research, response, and advisory focussed. PHE had procured evidence and surveillance contracts to support its advisory function and provided procurement support for PHE's own corporate and service functions.

3.3. DHSC set up the NTP in early 2020. Whilst PCR testing in hospitals/healthcare settings and public health labs was largely provided by the NHS and PHE respectively, the national population PCR testing provision, including the setting up of Lighthouse Labs, was the responsibility of DHSC in early 2020.

3.4. After September 2020, NHSTT played a significant commercial role in relation to procurement, with delegated authority to approve spending on PCR and LFD tests. Contracts continued to be formally awarded by DHSC.

3.5. The Exhibited PowerPoint shows a sequence of organisation charts for commercial Senior Leadership teams and their team capabilities from June 2020 to June 2022 throughout the period requested **[Exhibit: SC/010 INQ000421930]**. Due to frequency of changes (which is explained further below at paragraphs 4.20 to 4.27), the organograms are based on documents available to UKHSA and may omit some periods of time.

B. PHE

Prior to January 2020

3.6. PHE's involvement in procurement prior to January 2020 is set out in detail in Professor Harries' statement in Module 1 on pandemic preparedness (INQ000148429_0115 - 0130). A summary is provided insofar as it is relevant to the Inquiry's questions in Module 5.

3.7. PHE had a small commercial team at this time. PHE had established the National Microbiology Framework for the procurement of goods relevant to PHE's

microbiology work ("**Previous NMF**"). The value of the framework was sufficient for volumes of supplies in non-emergency times, but not of the requirements for goods and services during the pandemic.

3.8. PHE was commissioned by DHSC to hold a pandemic stockpile for influenza which at this time was the highest rated pandemic risk on the Cabinet Office National Risk Register. PHE carried out the procurement of pandemic stockpile products on behalf of the DAs through a Memorandum of Understanding ("**MoU**") between SSHSC and the Ministers for Scotland, Wales and Northern Ireland **[Exhibit: SC/011 INQ000203654 (Scotland); Exhibit: SC/012 INQ000203656 (Wales); and Exhibit: SC/013 INQ000203653 (NI)]**.

3.9. PHE was responsible for:

3.9.1. confirming DHSC's stated requirements to meet the policy and strategy requirements;

3.9.2. developing the business cases; and

3.9.3. gaining appropriate spending approvals from DHSC Investment Board, Ministers, Cabinet Office and HM Treasury ("**HMT**").

3.10. The Vaccines and Countermeasures Response Team ("**VCR Team**") transferred to PHE from DHSC in 2013. The VCR Team was led by a Deputy Director that reported to Professor Sharon Peacock, who was acting as the Director for the National Infection Service ("**NIS**"), of which VCR was part. The VCR Team was the licence holder and worked with DHSC Commercial and Supply Chain Coordination Limited ("**SCCL**") to source and contract manage, as its agent. In addition to responsibilities for other countermeasures, the VCR Team procured and stockpiled "just-in-case" ("**JIC**") consumables, such as medical consumables, PPE and liquid hygiene products. The volumes as required by DHSC have been provided by that organisation. A table outlining the value of the assets held for the stockpiling provision for PPE from June 2009 to January 2020 is exhibited at **[Exhibit: SC/014 INQ000101065]**.

3.11. There were consumables in the stockpile which were used in testing and were for generic use (such as pipette tips, test tubes, ethanol, viral transfer media). The volumes required to meet the large-scale demand COVID-19 needed to be procured in addition because of the numbers of people that needed to be tested for COVID-19 infection.

Role from 1 January 2020

Stockpiles: PPE

3.12. In order to receive products associated with a "just-in time" ("**JIT**") contract, PHE gave formal notice to the supplier/s that the products were required, commonly referred to as 'activating' the contract. On 31 January 2020, the VCR Team activated JIT contracts for PPE to supplement the JIC stockpiled PPE, in line with the contracts that were in place. The contracts were with both domestic and international suppliers and/or manufacturers. The contracting authority was SCCL. PHE was the business owner and contracted with SCCL to provide PHE with procurement and contract management services for logistics and Pandemic Influenza Preparedness Policy ("**PIPP**") consumables. The JIT contracts activated by PHE were for FFP3 respirators and safety glasses.

Testing

3.13. PHE's wider role included research, clinical diagnosis and guidance development. Therefore, in relation to procurement, this included the early initial development of a COVID-19 diagnostic assay which was subsequently rolled out to other labs and formed the basis for development of commercial testing products and services, expanded on in the Science and Technical Statement.

3.14. Professor Harries' statement to the Inquiry in Module 2 dated 22 August 2023 (INQ000251906_0097) states at paragraphs 430 – 431:

> "Together with the NHS and DCMOs, PHE developed a prioritisation of COVID-19 testing based on clinical and epidemiological need. The prioritisation groups were reviewed and agreed by the DCMOs, PHE Medical Director, PHE NIS Director, PHE Incident Director, NHSE Medical Director and NHSE Strategic Incident Director. The document dated 11 March 2020 (INQ000087299) was sent from the PHE [Incident Director] to testing laboratories with information on DHSC, NHS and PHE agreement to prioritise testing capacity in the following order:
>
> a. Group 1 (test first): Patients requiring critical care for the management of pneumonia, acute respiratory distress syndrome (ARDS) or influenza-like illness (ILI), or where an alternative indication of severe illness had been provided, for example severe pneumonia or ARDS;
>
> b. Group 2: All other patients requiring admission to hospital for management of pneumonia, ARDS or ILI;

c. Group 3: Clusters of disease in residential or care settings e.g. long-term care facilities, prisons, boarding schools;

d. Group 4: Community patients meeting the case definition and not requiring admission to hospital – those over 60 years old or with risk factors for severe disease (recognising that this is challenging). It was agreed that over 60s should be prioritised over other risk factors;

e. Group 5: Community patients meeting the case definition and not requiring admission to hospital – those under 60 years old and with no risk factors for complication;

f. Group 6 (test last): Contacts of cases.

Following this, on 12 March 2020 at the Tripartite Senior Clinician's Group chaired by the CMO, the consensus view was that PHE should publish the top three priority groups to share with the health and care system. The message on how PHE, together with NHS England and DHSC will prioritise testing for those most at risk of severe illness from the virus was published on 14 March 2020".

3.15. In order to facilitate the detection of COVID-19, a large-scale testing system was likely to be needed, which is explained in more detail below in Section 4. There was no nationwide large-scale testing capacity nor service infrastructure for mass population testing in early 2020. PHE's remit had not previously (and did not at that time) extend to establishing or maintaining large-scale testing capacity and infrastructure. PHE's limited lab capacity was utilised predominantly to process PCR tests for its specialist work and to support the NHS.

3.16. As of 1 March 2020, PHE could process up to 2,100 PCR tests per day (i.e. collected, delivered to lab, and processed by lab). The volume of PCR tests that could be processed would depend on a number of other variables including the collection and delivery of samples to the labs, the type of machine, and the staff available to run PCR tests (which would be subject to factors such as illness). I have been asked how many machines were available. The answer will depend on the particular day in question but in any event does not assist in terms of how many PCR tests could be processed a day. Different machines have different processing abilities in terms of number and turnover. Additionally, the maximum number of tests that can be processed with a particular machine will be dependent on the availability of the consumables for the type of PCR test, the staff available to operate the supply chain and in the lab itself, and any ad hoc day-to-day issues that may be expected with any machinery.

3.17. Following a meeting at No.10 that took place on the evening of 15 March 2020, PHE's role was understood to focus on increasing testing capacity for the specific provision of up to 15,000 PCR tests per day, evaluation of prospective tests, and on surveillance work, which eventually came to be under Pillars 1 (increasing PCR testing for the NHS) and 4 (surveillance testing) **[Exhibit: SC/015 INQ000055915]**.

3.18. By the end of March 2020, PHE and the NHS – in partnership with a commercial PCR testing provider – were together able to process up to 10,000 PCR tests per day.

3.19. Scientists from PHE and NHS England ("**NHSE**"), along with external scientists, were involved in the Technical Validation Group ("**TVG**"), described further in the Science and Technical Statement.

3.20. From 15 August 2020, PHE Porton Down assisted with the evaluation of LFD antigen tests, dealt with in the Scientific and Technical Statement.

Procurement

3.21. A member of the PHE procurement team started work in Summer 2020 on the development of the revised National Microbiology Framework ("**Microbiology Framework**") with the Prior Information Notice being published on 5 June 2020 **[Exhibit: SC/016 INQ000514410]**.

3.22. PHE established the new Microbiology Framework in March 2021 and the framework went live in May 2021 **[Exhibit: SC/017 INQ000514411]**. The process is described further below.

C. NHSTT

28 May 2020 to August 2020

3.23. NHSTT sat within DHSC, supported by DHSC's commercial function. Contracts were authorised by and awarded on behalf of DHSC. DHSC's commercial team had been supported by additional personnel from the Government Commercial Function ("**GCF**") who undertook procurement of goods and services in response to the COVID-19 pandemic. The DHSC commercial team that procured testing technologies ("**Testing Commercial Team**") was led by officials from the Cabinet Office Complex

Transactions Team ("**COCTT**") and included commercial staff from other government departments and external contractors and consultants.

3.24. The Testing Operations team ("**Testing Ops**") was part of the NTP and subsequently subsumed into NHSTT. Testing Ops was responsible for the operational aspects of procurement and delivery of the testing service. It managed the end-to-end operations of testing. It managed volumes of testing supplies, directed on technical requirements for kitting of PCR sample collection kits, and steered on the volumes of tests needed, to align with policy direction set by the UK Government.

From August 2020

3.25. NHSTT's Commercial Function was established in August 2020 ("**NHSTT Commercial**"). NHSTT Commercial became responsible for the procurement of testing technologies in line with UK Government policy decisions, with delegated spending approvals. The Testing Commercial Team, along with the commercial team focussed on contracts to support NHSTT's "Trace" responsibilities (dealt with in Module 7), were brought into NHSTT Commercial, but remained focussed on the procurement of tests and the wrap-around testing service infrastructure.

3.26. NHSTT Commercial inherited responsibility for contracts to supply PCR and LFD antibody tests that had already been awarded prior to August 2020, including those from the NTP; LFD antigen tests were still in developmental stages. NHSTT continued with its work building an end-to-end contact tracing service (which included the procurement of other services aside from PCR and LFD tests, which will be dealt with further in Module 7).

3.27. UKHSA has provided the Inquiry with organograms reflecting the organisational changes in NHSTT Commercial **[Exhibit: SC/018 INQ000421924; Exhibit: SC/019 INQ000383562; Exhibit: SC/020 INQ000383563; Exhibit: SC/021 INQ000383572]**.

3.28. In March 2021, NHSTT established the Dynamic Purchasing System ("**DPS**") which provided a route to market for LFD antigen test suppliers with early development commenced October 2020. The process is described further below. The length of time to set up a DPS will be determined primarily by the estimated total value of the contract and complexity of the requirement. Typically, large UK-wide frameworks or DPS with a high value over £20m would take between 6 to 12 months to set up, but that is predicated on the basis that the market for the products likely to be sought is

established. Throughout 2020, testing technologies were being created. It was only from the date that the first LFD tests were validated for use that work could begin on a DPS to include LFDs in scope. The DPS was live until 6 July 2022.

D. UKHSA

3.29. When UKHSA became operational in October 2021, NHSTT Commercial transferred to the UKHSA Commercial Team ("**UKHSA Commercial**"). From October 2021, UKHSA became responsible for managing contracts awarded prior to its establishment and for further procurement of PCR and LFD tests, as well as the functions of PHE that had been involved in the technical evaluation and advice in respect of COVID-19 tests.

3.30. After June 2022, UKHSA started work to revert to business as usual by updating and transforming commercial practice as the "Living with COVID" approach was implemented, beginning with introducing new spend controls and thresholds to align UKHSA with the rest of government. In April 2023, operational and financial responsibility for PCR testing in NHS acute settings for diagnostic purposes transferred from UKHSA to NHSE **[Exhibit: SC/022 INQ000527709]**. In October 2023, NHSE took over operational and financial responsibility for LFD testing in hospital settings **[Exhibit: SC/023 INQ000527705]**. This extended, in November 2023, to COVID-19 LFD testing to any member of the public eligible for COVID-19 treatments, as defined by the National Institute for Health and Care Excellence, whether at home in community settings, residents in care or other high-risk settings **[Exhibit: SC/024 INQ000527704]**.

3.31. An organogram of the UKHSA Commercial team is exhibited at **[Exhibit: SC/025 INQ000421937]**.

E. Products and Services Procured

3.32. Procurement work in respect of COVID-19 testing services goes beyond key healthcare related equipment and supplies, which is the focus of Module 5. It is not solely a procurement and test allocation process. The work involved the procurement of an end-to-end public service with, over time, more and more complex purposes. Accordingly, the procurement of PCR and LFD tests was intertwined with the wider

test, trace and isolate strategies, that UKHSA understands will be dealt with by the Inquiry in Module 7.

3.33. The types of diagnostic technologies and tests are detailed in the Science and Technical Statement. From a commercial perspective, at the outset of the COVID-19 pandemic (i.e. January to April 2020 in respect of COVID-19 PCR tests and through to Winter 2020 in respect of COVID-19 LFD antigen test), the marketplace did not exist for many of the COVID-19-specific diagnostic technologies that the UK is now familiar with, because no COVID-19-specific tests had been developed before COVID-19 existed. The procurement focus was on working with third parties to create products (for example a COVID-19 specific LFD antigen test) and markets that had not been conceived before Summer 2020.

3.34. In addition, because testing is an end-to-end service (see **[Exhibit: SC/026 INQ000527707; Exhibit: SC/027 INQ000514391]**), rather than a single product like PPE, once the tests were procured they needed to be integrated into a testing service with an ongoing operational function.

3.35. Over the Relevant Period, NHSTT, PHE and later UKHSA were responsible for the procurement of:

For PCR Tests

3.35.1. PCR sampling collection kits, including swabs, tubes, waste disposal bags;

3.35.2. PCR consumables (the plastics used to carry out PCR reactions through the thermal cycler) and reagents;

3.35.3. Transport for the PCR test kit components to be received ("**inbounding**"), distributing compiled PCR tests, and services to collect used PCR test kits and deliver to labs for processing;

3.35.4. Warehousing to store PCR test components and compiled kits;

3.35.5. Kitting services, for individuals to manually compile PCR testing kits;

3.35.6. Identifying and mobilising 1,056 testing sites including mobile testing vans (sites for sample collection) for individuals to attend for tests;

3.35.7. Arranging mobile lab vans;

3.35.8. Lab Capacity (including the Lighthouse Labs);

3.35.9. Digital services to allow booking of physical site test slots by the public and ordering systems for sample collection kits by organisations and individuals;

For other tests

3.35.10. LFD antigen tests;

3.35.11. LFD antibody tests;

3.35.12. LAMP Testing Solutions including new testing technologies (all referenced above);

3.35.13. Transport for inbounding and distributing other tests;

3.35.14. Pharmacy Collect Services;

For all tests functions

3.35.15. The externally contracted Genomic Sequencing, used to monitor new and emerging variants of concern (as an additionality to the PHE capacity, where the activity was predominantly not delivered internally within PHE/UKHSA);

3.35.16. Digital services to allow for: the collection of key data allowing linkage of test results to individuals; return of test results to individuals; including linking into GP records; developing contact tracing notification and systems and also fulfilling the formal notification of infectious disease requirements to the relevant bodies; support systems for people accessing the digital infrastructure; supporting accessibility to testing for those that could not access these systems;

3.35.17. Systems to report issues with sample collection kits and/or other tests, and quality management systems.

3.36. The procurement of testing supplies and goods had complex supply chain requirements, as follows:

3.36.1. The timeframe for sample degradation, after which the sample would be redundant, limited transport options;

3.36.2. Some reagents required cold-chain transport and storage;

3.36.3. There was competing global demand for reagents, e.g. ethanol used in testing, but also used in sanitising products where demand increased;

3.36.4. Variation across testing protocols e.g. some labs had a bill of materials (a list of materials and components required to manufacture a product) consisting of approximately 60 items which varied over time as infection control processes were developed;

3.36.5. Labs needed qualified personnel, such as lab technicians;

3.36.6. Technical specifications - as the scientific specifications became available for PCR and LFD testing kits, demand for the products increased, creating

global competition for products. Even swabs had tight technical specifications;

3.36.7. Technical compatibility - There was an added challenge of matching specific materials to the different machines available. Most of the high-tech testing platforms are 'closed', meaning that PCR consumables and reagents could only be supplied by the same manufacturer as the machine. The trend across the NHS, prior to the pandemic, had been to opt for PCR equipment that was brand specific. The NHS used large global suppliers mainly, which resulted in limited supply options because only the specific reagents and consumables were compatible for use with the specific PCR machines.

3.37. Supply production capacity was impacted by different approaches to managing COVID-19 in different countries at different times: lockdowns were taking place globally; production facilities were closing in China and other countries; and there was reduced availability and accessibility of raw materials. The global demand for supplies and equipment substantially outstripped supply and capacity. The global shortage of materials threatened the ability to run the PCR end-to-end testing process at full capacity, because there was a shortage of the reagents needed. Such competition for materials had not occurred in respect of any other testing goods or services prior to the COVID-19 pandemic.

SECTION 4. POLICY-LED PROCUREMENT

A. Introduction

4.1. The role of “commercial” is an enabling one, i.e. to facilitate the procurement process and contracts needed to deliver on the UK Government's policy decisions and requirements. COVID-19 policy decisions shaped the procurement of testing technologies during the pandemic. PHE/NHSTT/UKHSA were not responsible for the policy decisions, though each organisation may have provided advice or made recommendations to those responsible for such decisions. Where appropriate PHE provided scientific evidence to the Scientific Advisory Group for Emergencies ("**SAGE**"). In May 2020, UK Government established two formal Cabinet sub-committees: COVID Operations ("**COVID-O**") to deliver the Government's policy and operational response and COVID Strategy ("**COVID-S**") to oversee the UK Government's response.

4.2. The Commercial Team Lead for the Testing Commercial Team from the Cabinet Office's Complex Transactions Team ("**COCTT Commercial Team Lead**") contributed to discussions on developments in testing technologies. These contributions included information from their discussions with suppliers and scientists. The COCTT Commercial Team Lead did not have a decision-making role. No.10 and DHSC are better able to assist on core decision making.

Pillar testing and use cases

4.3. On 2 April 2020, UK Government announced the establishment of the five testing "Pillars":

4.3.1. Pillar 1: Scaling up NHS swab testing for those with a medical need and, where possible, the most critical key workers (PCR testing, utilising PHE and NHS labs);

4.3.2. Pillar 2: Mass-swab testing for critical key workers in the NHS, social care, and other sectors (PCR testing), and their families, which was important as households with a symptomatic individual were at higher risk of developing secondary cases and all required to self-isolate, and a negative result allowed NHS workers to also return to work;

4.3.3. Pillar 3: Mass-antibody testing to help determine if people had immunity to the COVID-19;

4.3.4. Pillar 4: Surveillance testing to learn more about the disease, infection transmission and pathogen characteristics; and

4.3.5. Pillar 5: Spearheading a diagnostics national effort to build a mass-testing capacity at a completely new scale.

4.4. Each Pillar had a Senior Responsible Officer. The Pillars were set up in such a way that supply for Pillar 1 ought not to be affected by the other pillars. DHSC, and later NHSTT, also procured PCR tests, reagents and specialist equipment on behalf of the NHS for Pillar 1 testing, described below. Whilst testing within hospitals and healthcare settings was delivered by the NHSE, PHE did provide some support where requirements for testing interfaced between community and healthcare settings.

4.5. The intended uses of different testing strategies ("**use cases**") changed over the Relevant Period by reference to what was known about COVID-19, the viability of the testing technologies, and whether sectors/industries could benefit from large-scale testing.

4.6. Use cases during the COVID-19 pandemic focussed on:

4.6.1. Testing to care: to inform appropriate clinical management and patient care pathways. When PCR testing capacity was limited, testing to care was prioritised whilst rapid scaling-up continued. This work fell under Pillar 1.

4.6.2. Testing to treat: testing to support clinical triage to enable potentially eligible individuals at higher risk of severe outcomes to access treatments as early as possible. Overall, the aim was to reduce morbidity and mortality from COVID-19 by providing timely access to clinically appropriate treatments.

4.6.3. Testing to isolate (controlling outbreaks): to control outbreaks in specific settings such as critical worker settings, schools, factories and residential settings.

4.6.4. Testing to isolate (controlling major waves): to attenuate transmission in the community to target and support isolation of cases and control COVID-19 waves. This same approach was explored in some pilot evaluation programmes described below.

4.6.5. Testing to protect/prevent: asymptomatic testing to ascertain whether an individual was COVID-19 negative before entering an environment with individuals at higher risk, to limit exposure and protecting any contacts. The approach was often used as an adjunct to mitigate risks e.g. testing visitors to prevent potential isolation of care home residents.

4.6.6. Testing to survey: to determine parameters, such as the incidence and prevalence, of COVID-19 and its variants as they developed, to support decisions on relevant interventions, to identify communities at risk and to support development of new tests and interventions.

4.6.7. Testing to evaluate: for trials assessing the effectiveness of COVID-19 interventions notably including delivery of robust outcome evidence for vaccine trials and therapeutics.

4.6.8. Testing to release: to ensure that individuals who would otherwise be required to self-isolate (either those who had previously tested positive or were close contacts of a positive case) were testing negative before 'release' from isolation.

4.6.9. Testing to enable: an approach used later in the pandemic to reduce the risks to the community associated with increased public interaction, such as testing before public events.

4.7. The Inquiry has asked about mass testing. In the Relevant Period, mass testing can be understood in differing ways: mass testing of different communities; mass testing

of specific regions; and whole country mass testing in a short space of time. The types of mass testing was discussed in March 2020, using LFD-type technology.

4.8. The Inquiry has asked UKHSA whether there were delays in providing PCR sample collection kits and LFDs to the care sector from January 2020 to summer 2020. The answer depends on the use case.

4.9. In respect of PCR sample collection kits, testing of suspected outbreaks in care homes took place from the beginning of the pandemic. However, the testing, that eventually came under Pillar 1, prioritised NHS key workers. Pillar 2's focus on NHS key workers and their families was aimed at maintaining the availability of NHS key workers, so they would only be required to self-isolate, when evidentially necessary rather than based purely on the key worker or their household member's symptoms alone.

4.10. Early in the pandemic PCR testing capacity was the main limitation on rolling out testing, including asymptomatic testing, and was the reason that building of a large scale, high throughput PCR testing infrastructure was considered necessary. To build a large capacity diagnostic industry to process the PCR tests needed took time, even when working at accelerated speed.

4.11. Validated LFD antigen or antibody tests for COVID-19 did not exist in the early days of the pandemic (i.e. from January 2020 to June 2020); no COVID-19 LFD tests could be provided until the LFD tests had been developed, identified, validated, and procured.

Policy Changes

4.12. Government policy on testing developed rapidly over the period January 2020 until the end of June 2022, in response to:

4.12.1. The evolving understanding and scientific evidence in respect of the COVID-19 virus itself and its anticipated epidemiological trajectory;

4.12.2. The economic and social impact of social measures implemented by the UK Government to mitigate the spread of COVID-19 infection; and

4.12.3. The development of pharmaceutical and non-pharmaceutical interventions to mitigate the spread of COVID-19 infection.

4.13. Inevitably perhaps, these factors, and consideration of them, evoked differences of political opinion about the appropriate policy decision, where there had been no comparable global emergency of the scale of COVID-19 in modern times. Similarly, scientific opinion and understanding of COVID-19 evolved over time, especially in respect of testing technologies and whether a particular intervention would be practically possible and/or effective, when many COVID-19 testing products were novel and evaluation evidence was consequently not available.

4.14. UK Government had a much greater than usual procurement risk appetite to securing tests to mitigate the human and economic cost of the pandemic and lockdowns. UK Government instructed the Testing Commercial Team, and later NHSTT, to investigate any tests that might work and procure as many of them as fast as possible, once validated (with an exception dealt with below). This approach led to the UK being able to deploy effective LFD antigen tests at scale sooner than most other countries.

4.15. The uncertainty around the longevity of each policy, that UK Government deemed necessary to combat the pandemic, restricted ability to forecast, plan procurement of tests and testing capacity.

Procurement structure and approach

Availability and qualifications of commercial personnel

4.16. As part of the GCF, the GCO, that sits within the Cabinet Office, was established in 2015 to recruit, retain, and develop senior commercial personnel to operate in departments across government. It provides commercial specialists with centralised commercial accreditation for civil servants, targeted development and access to a network of commercial leaders.

4.17. GCO commercial specialists become accredited through the GCO Accreditation and Development Centre ("**ADC**"), which assesses leadership, technical and commercial acumen, skills and experience. All GCO employees must be accredited through the ADC. All Government departments have been transitioning into the GCO since its inception, and for senior staff G7 and above in commercial roles to be accredited. GCO staff are then measured against the commercial competency framework on an annual basis. The Cabinet Office is best placed to give the Inquiry further information as to the organisational structure of GCO.

4.18. In the Relevant Period, senior commercial staff across the civil service, including those that were seconded to support the procurement of testing technologies as described further below, were largely members of the GCO and employed on GCO terms and conditions. The Cabinet Office is best placed to give the Inquiry further information as to the organisational structure of GCO.

4.19. UKHSA was and remains a member of the GCF. UKHSA's senior commercial staff (G7 and above) are largely members of the GCO.

Team capacity and staffing

4.20. Emergency procurement of key medical devices/equipment and wrap around services, at the scale and urgency that the COVID-19 pandemic demanded, required a workforce incomparable in size to that which existed in non-emergency times. This procurement took place in the context of widespread global competition and uncertainty around if and when a vaccine may be developed and available for widespread deployment. There was a lot of work to do, at speed, and with a finite number of civil servants with public procurement expertise working within central government, the detail of which is dealt with, by reference to time periods, below.

4.21. UKHSA understands that, in March 2020, DHSC's existing commercial team had been mostly allocated to non-testing products and services' procurements. UKHSA understands that the Cabinet Office provided additional commercial resources to support DHSC. From 18 March 2020, COCTT, which worked as a governmental internal commercial consultancy, had been deployed to the DHSC Commercial teams.

4.22. 15 people from COCTT were deployed to assist with procurement of COVID-19 tests and testing services. The GCO also deployed civil servants from other departments and fixed-term contractors to support DHSC's commercial team to procure testing products. The core of the Testing Commercial Team consisted of 25 to 30 civil servants from March to August 2020 and had procurement responsibility for testing across all five pillars.

4.23. Nevertheless, the speed and volume of work could not be undertaken without more personnel. Additional delivery support was also provided by NHS Supply Chain, which supports NHSE to support, deliver, and supply healthcare products and services. Contractors and consultants had to be brought in to assist with

procurement, delivering on the contracts and managing the supply chain. UKHSA understands that some external commercial contractors and consultants were already working with DHSC when COCTT and GCO personnel arrived. Contractors and consultants, who were recruited from consultancies and the private sector, were trained and supported by civil servants and provided guidance, but still needed time to adapt to the rigorous requirements of public procurement. Consultants and contractors from the private sector were not permitted to sign contracts.

4.24. Resourcing shifted on a daily basis. As set out in **[Exhibit: SC/010 above]**, between June 2020 and September 2020, the headcount for NHSTT Commercial was 221 people with one third (73) being civil servants. Resource peaked between April 2021 and March 2022 at the full-time equivalent of 378 people.

4.25. The difficulties in rapidly increasing the numbers of staff needed to undertake procurement work during the pandemic made working conditions extremely challenging.

4.26. An 'all hands on deck' approach was taken by staff working on the testing programme, as in other parts of the public sector's response to the pandemic. 16-hour+ days were not uncommon. The urgency and unpredictability of the pandemic's course meant that staff were unable to take leave for many months, despite senior civil servants encouraging teams to take breaks. Nevertheless, there was strong camaraderie across everyone involved, driven by the imperative to deliver on ministerial promises made to the public, including their own families, and to mitigate the effect of the pandemic.

4.27. NHSTT faced challenges in recruitment across the organisation. Competition across the civil service for skilled commercial staff was fierce, as - in NHSTT's understanding - other departments were also experiencing an increase in their commercial activity (as well as other COVID-19 related activity). NHSTT struggled to compete for senior civil servants that had commercial experience, with its unpredictable term, as no one knew how long the response would be needed but considered that the pandemic would end at some point. Further, in or around June and July 2020, some departments who had loaned commercial staff to DHSC requested their return which impacted the resourcing of testing procurement work.

4.28. New joining civil servants (whether from other departments or recruited) and contractors were inducted, as described below, in the procurement processes in place to procure LFD and PCR tests and associated services with the aim of consistency in procurement practice during the pandemic.

Procurement Legal Framework

4.29. Public procurement is undertaken in accordance with the Public Contract Regulations 2015 ("**the Regulations**"). As far as UKHSA has been able to confirm, all contracts for tests and testing services were awarded in accordance with the Regulations, which is dealt with below in Sections 4 and 6.

4.30. Where feasible, regulation 12(7) provides scope to collaborate with the wider public sector. Procurement procedures are outlined in regulation 26. Routes to market include competitive tenders, multi-supplier frameworks (regulation 33), or using a DPS (regulation 34). A supplier will have undergone evaluation in order to be named on a framework agreement under regulation 33. Framework contracts may be awarded after a mini-competition, or directly, dependent on the rules dictated by specific framework agreements.

4.31. There are some circumstances in which neither a framework procurement nor a competitive tender is possible. Regulation 32 makes provision for compliant awards without competitive tender for:

4.31.1. Technical reasons, for example where there is a sole supplier;

4.31.2. Where an economic operator has exclusive proprietary rights or has an exclusive licence; or

4.31.3. Extreme urgency caused by unforeseeable events.

4.32. The flexibility provided by regulation 32 has particular utility in the technical area of public health, where the UK requires access to niche products and must keep pace with innovation, for example when specialised lab equipment and vaccines are needed (where there may be only one global supplier).

4.33. In addition to the Regulations, the following guidance and policies are applicable through the Relevant Period (this list is not exhaustive): HMT's guidance, Managing Public Money (May 2012); the Cabinet Office's Code of Practice; HMT's Green Book (which was updated many times during the pandemic); the Outsourcing Playbook (later superseded by the Sourcing Playbook); PHE's procurement policy &

operational framework (until it was superseded) **[Exhibit: SC/028 INQ000383523]**; the GCF, Guide to using the Social Value Model; Procurement Policy Notices ("**PPN**") such as: PPN 01/19 "*Applying Exclusions in Public Procurement, Managing Conflicts of Interest and Whistleblowing*" (now, PPN 04/21), PPN 01/20 issued on 18 March 2020 "*Responding to COVID-19 Information Note*", PPN 02/20 "*Supplier relief due to coronavirus*", PPN 04/20 "*Recovery and Transition from COVID-19*", PPN 10/20 "*Public Procurement after the transition period ends 31 December 2020*", PPN 01/21 "*Procurement in an Emergency*", PPN 08/21 "*Taking account of a bidder's approach to payment in the procurement of major government contracts*." UKHSA has its own procurement policy **[Exhibit: SC/029 INQ000421923]**.

4.34. UKHSA understands that, where feasible, the Testing Commercial Team used existing frameworks, which included but was not limited to the following:

4.34.1. NHS Supply Chain frameworks including those within the existing Category Tower structure - these were for more basic consumables.

4.34.2. PHE Microbiology Framework - if the Framework could not be used, the Testing Commercial Team used the framework to identify potential suppliers that had already been verified.

4.34.3. Crown Commercial Services frameworks - for more general common goods and services, such as rental of vans or facilities management for a large and diverse network of testing sites.

4.34.4. London Universities Purchasing Consortium frameworks.

4.35. The limitations of these existing frameworks, the demand for lab capacity, and speed at which lab capacity and equipment / consumables was needed, drove the use of regulation 32 awards, because:

4.35.1. The capped values set for frameworks were at risk of being breached from single high-value contracts awarded, which would essentially render the framework redundant.

4.35.2. New suppliers are not allowed to be added during the lifetime of the framework, unlike a DPS. The Procurement Act 2023 will change this restriction going forward.

4.36. In the first six months of the pandemic, the Testing Commercial Team made extensive use of regulation 32, as can be seen from the contracts awarded in this period, because the UK needed to secure supplies, often rapidly, to move quickly as the pandemic spread and infection numbers rose and to meet targets set by UK

Government, in circumstances where competition was almost non-existent due to limited suppliers and global demand for suppliers. All available PCR testing capacity was predominantly contracted and utilised by the NHSE and PHE for Pillar 1. The Testing Commercial Team had difficulty procuring PCR machines in circumstances where global demand for specialised PCR testing equipment significantly outstripped supply.

4.37. Contracts for PCR and LFD tests that were awarded under regulation 32 are subject to the same evaluation processes and technical validation. To make a direct award pursuant to regulation 32 an assessment of the criteria under regulation 32 is required. Any amendments to the standard contract terms and conditions were subject to review by lawyers, either by DHSC lawyers (focussed on the testing programme), the NHSTT legal team or through the Government Legal Department (together, "**Legal**"). The intention was to draft and award regulation 32 contracts for the minimum possible duration to cover the period required until there would be time to initiate a non-emergency procurement process under the Regulations. The plan had been to reduce the use of regulation 32 through the Relevant Period **[Exhibit: SC/030 INQ000527691]**.

4.38. UKHSA has been informed that the Testing Commercial Team would mirror the terms from the PHE Microbiology Framework (prior to March 2021) where it was appropriate, though it had not been able to call-off from the framework.

4.39. UKHSA has been informed that the Testing Commercial Team that they provided written justifications for contracts awarded (submissions went to Ministers and the accounting officer and business justifications to the Cabinet Office and HMT depending on the threshold). From September 2020, NHSTT's governance framework required that the justification for direct awards was recorded within the completed business justification templates for each individual contract to be evaluated **[Exhibit: SC/031 INQ000527690]**.

4.40. Advance payments were used towards the beginning of the pandemic to secure manufacturing capacity, and research and development into novel testing technologies, with a small number of suppliers with the expertise to rapidly develop testing equipment. Other advance payments were made where companies could demonstrate a significant working capital requirement for them to complete testing product development, production and delivery. The use of advance payments for

these purposes had the support of Ministers, the Cabinet Office and HMT, and UKHSA understands that the Testing Commercial Team accepted terms where suppliers required advance payments to secure order volumes but DHSC/COCTT will be better placed to address the details.

4.41. The DPS and the Microbiology Framework were established in Spring 2021. Setting up a new framework or DPS is a lengthy process. Typically, large UK-wide frameworks or DPS with a high value over £20m would take between 6 to 12 months to set up, but that is predicated on the basis that the market for the products likely to be sought is established.

4.42. Generally, the process for a new regulation 33 framework requires: gathering information on product specifications and requirements (which requires input from UK Government commercial and product teams and, in the case of testing products, input is also required from science and technical teams) and designing lots with that information; drafting the tender documentation; processing the receipt of bids by suppliers to be appointed to a framework; evaluating the suppliers putting themselves forward and appointing suppliers to the framework. The process is time and labour intensive. It is dependent on several teams and/or departments or other public authorities (depending on the type of framework), as well as third party suppliers who may bid to be appointed to a new framework. A framework of the size of the Microbiology Framework requires Cabinet Office, and in some cases HMT, approval. In normal, non-emergency times, the establishment of a framework of the size of the Microbiology Framework can take approximately 12 months.

4.43. The Microbiology Framework needed a significantly higher value threshold and broader category coverage (to include products/services specific to COVID-19) than required pre-pandemic. As a result of the testing volumes needed during the COVID-19 pandemic, the award of a single contract could have exceeded the maximum value of the previous NMF, rendering it redundant as a compliant route for the procurement of testing technologies. The revised framework increased the maximum value from £120 million to £840 million. PHE worked with NHSTT on the specification for the lab lot in the Microbiology Framework.

4.44. Similarly, the length of time to set up a DPS will be determined primarily by the estimated total value of the contract and complexity of the requirement. A DPS of the size that was established in March 2021 for LFD antigen tests would typically take

six to twelve months to establish, in circumstances where the products sought already existed in the market. Throughout 2020, testing technologies were being created. One of the challenges encountered in development of the DPS was the need to include the general requirements for LFD tests. When work began on the DPS for LFDs in October 2020, the LFD products were still being developed and evaluated. The DPS could not be established if LFD tests, and the associated suppliers, had not passed technical evaluations, because the objective was to include viable devices in the DPS. It was only from the date that the first LFD tests were validated for use that work could begin on a DPS to include LFDs in scope. The DPS was live until 6 July 2022.

4.45. The DPS and the Microbiology Framework were established in Spring 2021. Accordingly, both were established faster than a DPS and/or a framework agreement would be established in non-emergency times despite the uncertainty around the testing technologies that would be available to be procured in 2020. NHSTT and subsequently UKHSA were able to systematically reduce the use of regulation 32 awards and advance payments as the market for COVID-19 testing technologies became more established. Advance payments (classed as pre-payments) are not a common occurrence within UKHSA.

Spending controls

4.46. Before the pandemic, UK Government contracts (including those managed and/or awarded by PHE and DHSC) valued at £10 million and above required approval by the Cabinet Office. The Cabinet Office and HMT spending control limit during the pandemic was £150 million **[Exhibit: SC/032 INQ000473893; Exhibit: SC/033 INQ000527687; Exhibit: SC/034 INQ000527698]**.

4.47. UKHSA understands that contracts awarded between January 2020 to August 2020 exceeded the spend controls framework (at the time the threshold was £10 million), but understands that DHSC, the Cabinet Office, HMT, and/or Ministers were aware of the value of contracts awarded, including by use of submissions to Ministers. Ministers were aware of this arrangement as a necessary and temporary expedient measure. Bulk retrospective lists of contracts were submitted to the Cabinet Office. This did not constitute approval by them. Ministers were aware of this arrangement as a necessary and temporary expedient measure.

4.48. NHSTT was given increased spending controls delegation from HMT to expedite its work **[Exhibit: SC/035 INQ000514384; Exhibit: SC/036 INQ000527696]**. DHSC Finance officials, the DHSC Commercial Assurance Team, and Cabinet Office representatives, as well as representatives from the DAs, were involved with the NHSTT Investment Board.

4.49. With the creation of UKHSA, a strengthened organisational governance framework was implemented and through governance reforms the organisation more formally transitioned to business-as-usual operations (i.e. Living with Covid arrangements) from January 2022, detailed further below. This included reverting to the standard spending controls delegations that apply across UK Government from 1 July 2022 and adopting DHSC Controls Assurance protocol.

4.50. The Inquiry has asked about total spend on tests and testing services in the Relevant Period. The table below sets out budget allocations and expenditure from the UK COVID-19 Budget for national testing and tracing for the period from 1 January 2020 to 28 June 2022, by financial year:

Contracting Authority	**Financial Year**	**Total Resource Funding for COVID-19[1]**	**Actual Spend PCR testing**	**Actual Spend LFD testing**	**Total Actual Spend[2]**
DHSC From end May 2020: DHSC (NHSTT)	2020/21	£20,369 million	£5,249 million	£5,622 million	£11,070 million
DHSC (NHSTT) From 10/21: UKHSA	2021/22	£15,651 million	£6,554 million	£8,101 million	£15,154 million
UKHSA	2022/23 (Q1 – Apr-Jul)	£882 million	£230 million	£195 million	£425 million
	TOTAL:	£36,902 million	£12,034 million	£13,918 million	£26,649 million

[1] Not exclusively tests and testing services.
[2] Not exclusively tests and testing services.

Suspicious / Fraudulent activity

4.51. The Inquiry has confirmed that it defines 'suspicious' and 'fraudulent activity' as:

4.51.1. "Suspicious" - any concerns of criminal deception intended to result in financial or personal gain.

4.51.2. "fraudulent" - behaviour/conduct/proposals that has resulted in a criminal conviction or civil findings of fraud in respect of the referenced behaviour/conduct/proposals.

4.52. PHE: Prior to January 2020, PHE worked closely with the DHSC Anti-Fraud Unit and Government Internal Audit Agency ("**GIAA**") who managed any investigations for PHE. PHE's framework agreement with DHSC required it to safeguard against fraud in line with HMT Guidance. This included keeping records of any fraud in the form of an annual report and notifying DHSC of any unusual or major incidents as soon as possible. PHE received fraud alerts from the DHSC Anti-Fraud Unit, which provided information and updates on priority areas for counter fraud action, and these were circulated within the organisation. PHE's approach to fraud risk was also developed via regular reporting to the Audit and Risk Committee.

4.53. In 2017, PHE conducted a high-level fraud risk assessment. DHSC guidance entitled "Fraud-proofing policies: A guide for policy makers" **[Exhibit: SC/037 INQ000514415]** assisted this assessment. These assessments were to take place annually. Any risks rated as "high/red" were to be added to the tactical risk register of the particular directorate/s within PHE. All other risks were managed within the directorate and reviewed during the following year's assessment. This assessment process identified 13 key fraud risk areas, which were included on a directorate fraud risk register. Civil Service Learning training on countering fraud, bribery and corruption was made mandatory for all PHE staff.

4.54. GIAA conducted a review at the end of 2017 of PHE's fraud risk assessment process and published a report in January 2018, which awarded PHE a rating of "Moderate". The report recognised good progress PHE had made in promoting awareness of risk, fraud and bribery across the organisation, training on fraud, bribery and theft and the introduction of a fraud risk assessment process. GIAA recommended a review be undertaken of PHE's current policies to be completed and all staff notified of the updated policies.

4.55. In consultation with the DHSC Anti-Fraud Unit, PHE's policies were reviewed and updated. PHE issued a new 'Countering Fraud and Theft Policy' in September 2019 **[Exhibit: SC/038 INQ000514389]**, along with Countering Fraud Procedure, Countering Bribery and Corruption Policy and Procedure, and Countering Theft Procedure. UKHSA does not have access to final versions of PHE's other policies relating to fraud.

4.56. NHSTT: DHSC was the contracting authority for all NHSTT contracts, NHSTT therefore relied on DHSC policies in relation to Fraud Prevention Measures (in addition to PPNs). In January 2021, NHSTT launched a Commercial Workflow & Toolkit, which contained links to the DHSC policies under which NHSTT operated (including in relation to Conflicts of Interest and Financial Due Diligence) and contained guidance on supplier due diligence (see below at paragraph 4.177).

4.57. UKHSA: In July 2021, prior to the formal establishment of UKHSA, an assurance assessment was carried out to improve PHE's standards and practices to counter fraud risks as PHE moved through the transition period to establish UKHSA **[Exhibit: SC/039 INQ000514390]**. UKHSA has a policy "Emergency Procurement Procedures", which is based on the February 2021 PPN 01/21 "Procurement in an Emergency" and highlights the risk of poor practice due to procurement at speed and how to address those issues, such as retrospective due diligence checks, as well as a lack of documentation around key procurement decisions, including how conflicts of interest are identified and managed.

4.58. PCR and LFD tests that were procured needed to perform within specific sensitivity and specificity parameters and so technical validation processes were designed to ensure all products used were fit for purpose (addressed in the Science and Technical Statement). UKHSA understands that the Testing Commercial Team requested information from prospective suppliers to evaluate an offered testing product and/or service before progressing the offer, as set out below. When the Testing Commercial Team received offers that, on their face, seemed unrealistic or otherwise lacked substance, the offer was discounted. In the early days of the pandemic, where some offers which were outliers in terms of design or assay target antigen did appear to be realistic, they were referred for technical evaluation, but the evaluation process revealed poor performance, such as the LFD antibody tests (see below). UKHSA understands that the commercial approach for referring a product for technical

validation was tightened to reduce testing of "proof of concept" or developmental LFDs.

4.59. To the best of its knowledge, UKHSA is not aware of any previous or ongoing UK-based criminal investigations of fraud in respect of PCR or LFD testing contracts awarded by predecessor organisations or subsequently by UKHSA itself. UKHSA's Anti-Fraud team confirmed that UKHSA has supported other departments and the NHS counter fraud teams with their enquiries, but UKHSA is not aware of the detail of the issues/proceedings that have underpinned those enquiries.

4.60. DHSC Fraud Investigations Unit have confirmed that they did not carry out any investigations on behalf of NHSTT or UKHSA.

Declarations of interest

4.61. The Cabinet Office and GCO operate a Commercial Declarations of Interest Policy. As part of the recruitment process, GCO commercial staff must register any potential or actual conflicts of interests. There is also an obligation to disclose a conflict of interest if it arises post recruitment and during employment. The GCO would be best placed to provide an accurate register of any declarations made for those staff seconded or contracted to testing services procurement. DHSC also had a Code of Business Conduct Policy and Procedure (including guidance on how to manage conflicts of interest) and had its own "Managing Conflicts of Interests in Procurement" policy. UKHSA has not exhibited these to limit duplication but can provide copies if necessary.

4.62. NHSTT relied on DHSC's policy on conflicts of interest. NHSTT also followed DHSC policy in respect of the evaluation of tenders, which required that evaluation panel members declare any conflicts of interest to the procurement team, which would be addressed at a moderation meeting. Conflicted panel members could be excluded from further activity on the procurement **[Exhibit: SC/040 INQ000514413; Exhibit: SC/041 INQ000514412]**.

4.63. Since October 2021, UKHSA has a published policy document of its own on "Conflict of Interest", which has been updated **[Exhibit: SC/042 INQ000421929]**. UKHSA has also published guidance on "How to Disclose Conflicts of Interest" **[Exhibit: SC/043 INQ000514392]** and "Managing conflicts of interest in commercial activities" **[Exhibit: SC/044 INQ000514394]**. UKHSA Commercial requires team officials to

complete conflict of interest declarations as part of its recruitment processes **[Exhibit: SC/045 INQ000514409]**. Officials are obliged to declare actual or possible conflicts of interest that arise during their employment.

4.64. Lists of ministerial declarations are published on gov.uk. UKHSA has not identified any evidence to suggest UKHSA or its predecessors were sighted on the DHSC "controls pack" for ministers.

Publication

4.65. All contracts for PCR and LFD tests were processed for publishing on Contracts Finder, though not always within the stipulated time period in the first six months of the pandemic, as set out in the High Court's decision in *R (Good Law Project Ltd) v SSHSC* [2021] EWHC 346 (Admin), as far as UKHSA understands.

4.66. From March 2020 to Summer 2020, the Testing Commercial Team prioritised sourcing and contracting work, meeting testing demand and policy objectives. Urgent demands on the team resulted in a backlog of contracts being submitted for publication on Contracts Finder. The COCTT Commercial Team Lead recruited a contractor in June 2020 to clear the backlog, with publication of notices on Contracts Finder completed by the end of 2020.

B. January 2020 to end May 2020

UK Government Policy and Context

4.67. In March 2020, the policy objective was to increase daily testing capacity to 100,000 PCR tests by the end of April 2020. On 18 March 2020, DHSC set up NTP to rapidly increase testing capacity and meet the testing targets set by the Prime Minister.

4.68. Additionally, the UK Government strategy was to procure LFD antibody tests to be distributed to the general population for home use. The Prime Minister called on companies to work with the government to rapidly develop antibody tests, as well as an aim to develop a point-of-care test.

4.69. The policy aspiration was that, if rapid antibody tests could detect immunity and individuals could test themselves, it could potentially ease or determine the kinds of non-pharmaceutical interventions needed to be implemented by the UK Government.

4.70. The global demand for antibody tests was extremely high and other countries were buying unvalidated antibody tests in very high volumes. The concern expressed by SSHSC, Lord Bethell, and Ministers was that the UK would not be able to secure an appropriate volume of LFD antibody tests (as opposed to LFD antigen tests) as available supply would have been purchased by other countries. These concerns were discussed in meetings attended by the COCTT Commercial Team Lead on 19, 20 and 21 March 2020. SSHSC indicated that the UK needed to start securing antibody tests as a priority because global demand could be a barrier to obtaining sufficient quantities for the UK.

4.71. At this point, no LFD antibody tests had been provided by suppliers through DHSC for PHE to validate. Initially, SSHSC instructed the Testing Commercial Team to procure a large number of antibody tests in parallel with the activity of validating those tests, but the validation process could take up to 2 weeks (not including the time to receive sample tests). More critically, many suppliers refused to even send samples without a substantial volume commitment. The Testing Commercial Team had been told by suppliers that demand was so high that they did not have time to send samples. As a result, SSHSC approved the purchase of tests which had not been validated.

4.72. Once procured and received, these LFD antibody tests were sent to PHE Porton Down to be validated. The validation results confirmed that none of the LFD antibody tests purchased met the standard required (see the Science and Technical Statement). The results meant that the tests could not be used as intended, though some tests were retained for surveillance studies. The DHSC/COCTT Testing Commercial Team negotiated a refund in respect of a research contract.

4.73. In early April 2020, the "call to arms" was repeated, seeking antibody tests, PCR reagents, Point of Care ("**PoC**") testing mechanisms and requesting assistance from the industry **[Exhibit: SC/046 INQ000514407]**.

4.74. On 2 April 2020, DHSC published its strategy "Scaling up our testing programmes" **[Exhibit: SC/047 INQ000514385]**, announcing the commitment to reach 100,000 PCR tests a day across all Pillars by the end of April 2020, with 25,000 tests a day committed to Pillar 1, and targets to reach 250,000 tests per day eventually (without a date announced). At the time the strategy was published, 10,000 PCR tests were being processed each day. The strategy explained its focus was on PCR tests and

antibody tests, the latter of which fell under Pillar 3. DHSC announced its commitment to mass testing.

4.75. The plan also referred to UK Government partnerships with private companies to create a "mass testing infrastructure in the UK through the creation of a network of new labs and testing sites across the UK." The labs included in this network came to be known as the Lighthouse Labs, described below.

4.76. On 15 April 2020, the government announced that PCR testing would be offered to all symptomatic care residents; all patients discharged from hospital before going into care homes; and all symptomatic social care staff.

4.77. On 23 April 2020, PCR testing was extended to essential workers, who could from this date book a PCR test on GOV.UK.

4.78. On 28 April 2020, DHSC published a press release that PCR testing would be available to: "everyone in England aged 65 and over with coronavirus symptoms… along with symptomatic members of their household"; "[s]ymptomatic workers who are unable to work from home also eligible for testing"; and "all asymptomatic NHS and social care staff and care home residents".

4.79. On 6 May 2020 the UK Government published its COVID-19 Recovery Strategy.

4.80. On 13 May 2020, DHSC confirmed the roll out of a programme of whole care home PCR testing in England, in phases starting with care homes whose primary clients were older people or those with dementia.

4.81. On 18 May 2020, DHSC published a press release that anyone with symptoms of COVID-19 would be eligible to receive a PCR test (separate to the whole care home PCR testing offer), as well as a target of increasing daily PCR testing capacity to 200,000 a day by the end of May 2020.

Procurement Response

4.82. The targets to scale PCR testing from up to 4,500 tests a day to 200,000 tests a day from 2 April 2020 to the end of May 2020 required the creation of large-scale diagnostic capability. This included developing testing kits, manufacturing testing kits and components, increasing lab capacity to process PCR sample collection kits,

staffing for labs, logistics to accommodate the volume of tests that would need to be received, delivered, and sent for processing, and processing high volumes of test results. Alongside the establishment of Lighthouse Labs, the infrastructure and logistics required to allow the public to access a PCR test, and for the transfer of samples to labs, was procured. This included establishing drive-through test centres, local walk-in centres, mobile testing units and the assembly and delivery of home test kits, warehousing and the safe transfer of samples via various logistics providers to labs for processing. Infection prevention and control and protocols, to mitigate the potential spread of infection, due to attending testing sites were required.

4.83. The range of goods and services required to establish a large-scale testing system was very substantial (see above at paragraph 3.35). There was no established market for manufacturing and/or supplying LFD tests (whether antigen or antibody), nor a COVID-19 specific PCR market that could meet the scale required. It was anticipated that there would be offers to supply tests from companies that had not manufactured or supplied COVID-19 specific PCR and/or LFD tests before, as was the case with other COVID-19 testing products that were required and utilised during the pandemic.

4.84. PCR and LFD tests that were procured needed to perform within specific sensitivity and specificity parameters and so technical validation processes were designed to ensure all products used were fit for purpose (addressed in the Science and Technical Statement). UKHSA understands that the Testing Commercial Team requested information from prospective suppliers to evaluate an offered testing product and/or service before progressing the offer, as set out below. When the Testing Commercial Team received offers that, on their face, seemed unrealistic or otherwise lacked substance, the offer was discounted. In the early days of the pandemic, where some offers which were outliers in terms of design or assay target antigen did appear to be realistic, they were referred for technical evaluation, but the evaluation process revealed poor performance, such as the LFD antibody tests (see below). UKHSA understands that the commercial approach for referring a product for technical validation was tightened to reduce testing of "proof of concept" or developmental LFDs.

4.85. Often potential suppliers would put themselves forward to assist. In early April 2020, there were offers of capacity from small labs, although the volumes were not sufficient to provide large scale operations at pace. A decision was made by DHSC to focus

attention on offers of substantial volumes, prioritising offers of support for consumables and/or lab space, to provide additional testing capacity of 20,000 PCR tests per day or more and building capacity by the Lighthouse Labs. Lighthouse Labs were higher throughput diagnostic testing facilities purposefully created to process COVID-19 samples that were contracted by the Testing Commercial Team with input from PHE specialists and other specialist stakeholders.

4.86. The Testing Commercial Team worked with existing partner labs and partners setting up new labs, including construction of the Rosalind Franklin Laboratory. This included providing equipment, reagents and consumables for labs; developing new testing technologies; building contact tracing capability through call centres, setting up testing sites and facilities management including the staff needed to operate these; and scaling logistics.

4.87. At the outset of the pandemic, there was limited market information against which to benchmark the price offered by suppliers for COVID-19 PCR testing in the quantities needed prior to the award of the first contracts, because (i) COVID-19 specific PCR tests had been created in early 2020 and (ii) in respect of generic consumables used in PCR testing, PCR testing prior to the pandemic was small scale. The methods used to benchmark pricing were to compare price information between suppliers and/or to consider existing frameworks for generic consumables. The frameworks assisted the Testing Commercial Team to recognise whether offers were unjustifiably overpriced, though market dynamics affected pricing. Despite the pressure of timescales and global competition for suppliers, UKHSA understands that the Testing Commercial Team negotiated down prices when confronted with unreasonably high offers; the reductions achieved would have been dependent on the contract in question. The Testing Commercial Team comprised civil servants with commercial experience including those from the COCTT, which has already been described above.

4.88. In April 2020, the Testing Commercial Team started to look for alternative testing technologies for COVID-19. Consideration of different testing methodologies included focus on LFD antigen tests, as an alternative to PCR testing, which is dealt with in UKHSA's M5 Scientific and Technical Statement.

Procurement Process

4.89. NHS Supply Chain was involved in procuring vials and swabs for clinical diagnostic COVID-19 PCR testing and COVID-19 PCR testing of critical key workers until March 2020.

4.90. Between January 2020 and the end of May 2020, DHSC was formally responsible for the commercial procurement work of testing services and, for the reasons set out above, the procurement was recorded across several other government department systems. Prior to June 2020, documentation was shared between the Cabinet Office and DHSC on a document platform that UKHSA does not have access to. Accordingly, DHSC and the Cabinet Office are better placed to assist with dates of meetings and the rationale underpinning the decisions taken on specific contracts that the Inquiry has asked about. UKHSA has limited direct knowledge of the procurement process that was operated as set out here.

4.91. In March 2020, DHSC set up a "COVID Testing Triage" inbox to streamline the offers being received. UKHSA is unable to provide a detailed explanation of the origin of this mailbox, as it had been set up before COCTT officials started working with DHSC and the Testing Commercial Team was established.

4.92. UKHSA understands that the Testing Commercial Team checked the FIND website (https://www.finddx.org/covid-19/) on a regular basis to view the list of emerging COVID-19 tests.

4.93. On 8 April 2020, a webinar was organised by one of the industry operators for life sciences, the Bioindustry Association, which was attended by representatives from 500 UK businesses, the COCTT Commercial Team Lead and Lord Bethell, and presented by SSHSC. The purpose of the webinar was to engage industry who may have been able to offer supplies for COVID-19 testing. Any business who wanted to be on the webinar could register to attend. These webinars took place approximately every 2 weeks and continued to be introduced by SSHSC, to keep them high profile. They continued for approximately six weeks, and stopped because the Testing Commercial Team became inundated with offers to triage.

4.94. The Testing Commercial Team launched an online portal to invite suppliers to come forward with proposals. Suppliers completed and submitted online forms, detailing what they could supply.

4.95. The Testing Commercial Team also used the suppliers named in framework agreements, referenced above at paragraph 4.34, as a starting point to proactively contact suppliers. In early April 2020, the COCTT Commercial Team Lead proactively contacted OptiGene, who produced LAMP-related devices, after it was publicised that OptiGene were using LAMP to rapidly triage people presenting with COVID-19 symptoms at A&E departments in Hampshire. The scientists working in those A&E departments had links to the University of Southampton. As one of the policy objectives involved exploration of testing solutions, DHSC funded an expanded pilot in Hampshire ('lab in a van' testing at care homes and GP hubs) and the saliva testing pilot of asymptomatic people in Southampton, after being approached by the University of Southampton ("**Southampton Pilot**").

4.96. From April 2020, DHSC expanded the dedicated shared email mailboxes to capture supplier offers for testing capacity and to manage supplier communications. They were:

4.96.1. "COVID Testing triage"

4.96.2. "COVID19 Offer Triage"

4.96.3. "COVID Testing Priority Contacts"

4.96.4. "COVID19 Innovations".

4.97. UKHSA's review ("**UKHSA 2022 Review**"), dealt with in more detail below, noted that the high volume of process changes led to inconsistencies in the ways in which the mailboxes were being used and the ways in which suppliers were communicated with. Multiple mailboxes were in use over the same period with a lack of clarity on the delineation between them.

4.98. Suppliers could:

4.98.1. Send an offer directly to "COVID Testing Triage" mailbox and "COVID19 Offer Triage" mailbox;

4.98.2. Be referred from public sector bodies (such as MHRA; NHS; PHE) sent to the "COVID Testing Triage" mailbox, "COVID Testing Priority Contacts" mailbox, and "COVID19 Offer Triage" mailbox.

4.98.3. Be referred by senior individuals in the UK Government (e.g. Ministers, their special advisers, other parliamentarians, or other public figures) to "COVID Testing Priority Contacts". In some cases, initial contact was made by the

senior individuals and then entered through the inboxes established to manage offers of support with testing.

4.99. UKHSA 2022 Review reported that DHSC operated a tagging system, whereby some offers received through these inboxes were designated "VIP", "Fast Track" or "Priority", sometimes appearing to refer to a referral from a senior individual in the UK Government and/or where there was an immediate shortage of a particular product or service. The use of these terms and/or the intention of the tagging was not clear or consistent. It was difficult for the UKHSA 2022 Review to confirm with certainty how many contracts that were awarded had been tagged with "VIP", "Fast Track", or "Priority" at some point in the consideration of the particular supplier and/or offer, and as such UKHSA would not be able to confirm all suppliers that had been tagged as such. Paragraphs 4.1877 - 4.188 below explains the reason why it is not possible to determine this information and exhibits the review conducted. UKHSA has provided the list – as far as it has been able to discern it – as an exhibit, but as explained there may be inaccuracies.

4.100. There was no separate "High Priority Lane" through which contracts were awarded, as far as UKHSA has been able to determine. Being tagged as “VIP”, “Fast Track”, or “Priority” did not route a supplier to a different/separate procurement process.

4.101. UKHSA understands now that the designations were used to coordinate offers by: referring to the origin of the referral; denoting offers in areas of potential "bottleneck" or shortage; flagging for the Testing Commercial Team that they needed to communicate the outcome of an offer to the referrer; escalating supplier complaints; and reducing the likelihood of suppliers sending repeated communications through their referrers. Suppliers were not aware of the tagging system at the time, as far as UKHSA has been able to determine.

4.102. All testing products, including those where offers were initially flagged by officials as "VIP", "Fast Track", or "Priority", went through the same commercial appraisal and evaluation before contract award, as described elsewhere in this statement. All supplier offers were required to undergo the same technical validation processes for PCR tests to ensure efficacy of use, explained in the Science and Technical Statement. Contracts awarded pursuant to regulation 32 required the offered product to pass technical evaluation.

4.103. The Testing Commercial Team would verify an offer by researching suppliers on the internet, checking whether the offer was from a supplier on an existing framework (if the supplier had come forward themselves), and requesting additional product information e.g. data sheets that would detail ISO accreditations.

4.104. Commercial contract negotiation often involves refinement of terms and conditions specific to the goods or products. Legal would support drafting on complex contracts and/or review any amendments to the standard terms.

4.105. The evaluation of offers is set out in **[Exhibit: SC/048 INQ000383569]**.

4.106. Approval was required from DHSC officials under the remit of the Second Permanent Secretary of DHSC. The Testing Commercial Team prepared the contract overview, summarised the process followed, justification for the proposed contract, and approvals received, for DHSC Officials to consider. DHSC Officials signed the contracts.

4.107. The PHE procurement approvals process is set out in **[Exhibit: SC/049 INQ000383525]**.

C. End May 2020 to August 2020

UK Government Policy and Context

4.108. The launch of NHSTT resulted in procurement activity to increase PCR testing capacity.

4.109. The Prime Minister tasked NHSTT with delivering testing capacity of 325,000 PCR tests daily by the end of July 2020. Targets set later included: processing 485,000 PCR tests daily by the end September 2020, and 500,000 tests daily by the end of October 2020, across all Pillars.

4.110. On 8 June 2020, DHSC announced the further phase of the whole care home testing offer in England to all care homes. On 3 July 2020, regular repeat asymptomatic PCR testing commenced for all adults over 65 and dementia patients in care homes.

4.111. On 29 June 2020, UK Government placed Leicester in a local lockdown. To further enhance support to populations in local lockdowns, NHSTT explored mobile testing

options to reach communities less able or willing to attend testing sites. Increasing population surge testing capability enhanced NHSTT's ability to identify and contain outbreaks.

4.112. On 17 July 2020, the Prime Minister announced the target of increasing testing capacity to 500,000 PCR tests per day.

4.113. In or around July 2020, following the initial results of the Southampton Pilot which demonstrated lower sensitivity rapid tests could identify COVID-19 positive individuals who were asymptomatic, No.10 began to consider a similar application on an all-citizen basis.

4.114. Special Advisors at No.10 were also in contact with researchers who had published a paper advocating testing using lower sensitivity tests but at more frequent intervals. In August 2020, various scientists and special advisors became interested in the idea that mass testing of the whole population at least twice over a one-to-two week period and isolating everyone who was positive would eradicate the virus such that further lockdowns would not be necessary. This is dealt with further below, but was the beginnings of the "Operation Moonshot" idea. At this stage there were no validated, affordable at-home self-tests. LFD antigen tests were being developed. The UK Government directed NHSTT and the Testing Commercial Team to further explore more portable means of testing.

4.115. SAGE provided advice to UK Government and had a specific Task and Finish Group to consider mass testing. SAGE is best placed to assist on the professionals who were involved and contributed to advice provided. SAGE published a consensus statement on mass testing on 31 August 2020. PHE contributed to the SAGE consensus statement **[Exhibit: SC/050 INQ000421918]**.

4.116. On 3 August 2020, the UK Government announced that 450,000 new rapid LamPORE tests would be made available to care homes, which sat alongside PCR testing in NHS and Lighthouse Labs, with millions more tests to be rolled out later in the year.

4.117. In August 2020, the SSHSC had announced the creation of NIHP (which later became UKHSA).

Procurement Response

4.118. The task set for NHSTT to be delivered in the timelines promised by the UK Government, insofar as relevant to Module 5, necessitated an even larger national network of PCR testing infrastructure across the UK, as all symptomatic individuals over the age of five across the UK would be eligible for testing.

4.119. The increased PCR testing targets required the Testing Commercial Team to again scale PCR testing capacity on short timescales to meet the targets promised **[Exhibit: SC/051 INQ000501913]**.

4.120. From June 2020, the Testing Commercial Team awarded contracts for additional lab PCR testing capacity and the Lighthouse Lab network expanded with several new sites around the country.

4.121. By the summer of 2020, the NHSTT working with the Testing Commercial Team had considered then available testing methods, including LFD, LAMP, LamPORE test, which could be delivered outside labs, and identified new products that would allow for greater capacity for testing.

4.122. In July 2020, the COCTT Commercial Team Lead obtained a list of global suppliers who could supply or were in the process of developing testing technologies likely to be suitable for mass testing from scientists specialising in mass testing at the ffeller Foundation in New York. This consisted mostly of suppliers of LFDs, LAMP and similar PoC devices. The Testing Commercial Team contacted suppliers on the list provided to identify suitable tests and suppliers.

4.123. In late Summer 2020, NHSTT Commercial was established, which absorbed the Testing Commercial Team.

Procurement Process

4.124. Suppliers continued to be able to make offers through the routes available described above. The Testing Commercial Team ran workshops on the approach to commercial work undertaken **[Exhibit: SC/052 INQ000527695]**.

4.125. An online testing methods sourcing platform was also launched (https://testingmethods.crowdcity.com/), seeking new and novel solutions to help increase COVID-19 testing methodologies, supplies and capacity across the UK.

This platform was a partnership between DHSC, the UK Bioindustry Association, British In Vitro Diagnostics Association and the Royal College of Pathologists. It was intended as a method of industry engagement and triaging. UKHSA understands the platform allowed DHSC to consider credible testing product offers which could be passed forward to be part of more formal supplier engagement and those proposals that required substantial further work.

4.126. On 31 August 2020, NHSTT set up a Manufacturing Industry Coalition (sometimes referred to as DMIC or MIC), which was a forum used to proactively seek guidance and identify blockers and enablers in the scale-up to mass testing. The intention was to bring together suppliers of the different components/stages in the creation of LFD tests and create a manufacturing and consumer design process that assisted with scaling mass testing. UKHSA understands that MIC may have also been working with the NHSTT Innovations team by looking at new ways of testing that were still at a concept stage. If a product offer was at concept stage, the offeror was referred to the NHSTT Innovations team. Some of the concepts considered did result in contracts awarded. The group ceased in November 2020.

4.127. The evaluation of offers is set out in **[Exhibit: SC/049 INQ000383525; Exhibit: SC/048 INQ000383569; Exhibit: SC/053 INQ000421926; Exhibit: SC/054 INQ000501915; Exhibit: SC/055 INQ000501914]** as far as UKHSA had been able to determine in January 2022.

4.128. The spend controls and approvals process is set out in **[Exhibit: SC/056 INQ000421467]**.

D. September 2020 to March 2021

UK Government Policy and Context

4.129. In September 2020, after schools reopened, the UK experienced a second wave of increasing infection, resulting in further lockdowns across the UK.

4.130. It was anticipated that the winter would create a dual challenge of managing flu and COVID-19 and the UK Government wanted to avoid a second lockdown. NHSTT was therefore asked to expand PCR testing beyond the target 500,000 tests per day by the end of October 2020.

4.131. The Prime Minister and his advisors were interested in mass asymptomatic testing of the whole population in a short period of time, similar to a proposal being considered in Slovakia. This is what the Prime Minister referred to as "Operation Moonshot."

4.132. NHSTT had recommended a testing programme that eventually came to be the Universal Testing Offer in April 2021, i.e. making testing available to the wider population, as opposed to whole population, near simultaneous (within a short space of time), testing.

4.133. The Prime Minister decided to proceed with the announcement of Operation Moonshot on 9 September 2020.

4.134. UKHSA understands that No.10 directed NHSTT to procure the volume of tests required for whole population testing, particularly as concerns over supplies had been raised. NHSTT was tasked with procuring enough LFDs and other types of rapid tests, and building the associated systems and processes, to be able to ultimately test the whole population. UKHSA understands that NHSTT leadership met with the PM weekly, to review progress and consider the detail of various approaches. Initially, a budget of £500 million was agreed and then the funding available was extended to £2.9 billion. This funding was approved by HMT.

4.135. Whilst negotiations were underway to scale up the purchasing of LFD tests, NHSTT became aware that the WHO intended to formally endorse the use of LFD tests to respond to COVID-19, which had the potential to increase the global demand for LFD antigen technology and would potentially result in greater difficulties in the UK securing supply. The WHO issued its interim guidance on 11 September 2020. In anticipation of increased global demand for LFD tests following the WHO's endorsement, a request came directly from No.10 to secure 250 million LFD tests.

4.136. NHSTT was encouraged to build UK capability to make LFD tests to reduce reliance on the global supply chain, after technical evaluation indicated that LFDs were a viable technology (dealt with in the Science and Technical Statement). A UK-based manufacturing programme had the potential to mitigate delay associated with solely relying on overseas manufacturers **[Exhibit: SC/057 INQ000527693; Exhibit: SC/058 INQ000527694]**.

4.137. On 16 October 2020, the Prime Minister announced that LFDs would be made available to Directors of Public Health in England for them to direct and deliver asymptomatic mass testing in line with local priorities. The Prime Minister also announced that the UK would be trialling new COVID-19 tests (including LAMP tests).

4.138. In early November, the focus shifted from a whole population testing model to a regional approach; namely testing the entire population of specific regions based on tier status. The Cabinet Office prepared a proposal, which was submitted to COVID-O on 21 November 2020, to offer a community testing programme to everyone over 11 years old in the high prevalence areas of the North East, North West and Yorkshire and the Humber. The Cabinet Office are better placed to assist with the rationale behind the proposal and its submission to COVID-O.

4.139. In its Winter Plan published on 23 November 2020, the UK Government announced what came to be known as the Community Testing Programme ("**CTP**"), which was developed and overseen by DHSC. The CTP offered the facility for local authorities with high COVID-19 prevalence to identify asymptomatic individuals within their own communities through the provision of free asymptomatic testing, using rapid response LFDs. The Winter Plan also included a plan for the use of testing using LFDs for care home residents and staff. This was rolled out on 23 December 2020, when the UK Government announced the start of twice-weekly LFD testing for care home staff and followed the announcement on 1 December 2020 that families could visit care home residents if they had a negative LFD test.

4.140. Throughout December 2020, the epidemiological picture continued to evolve rapidly, leading to most local authorities moving into Tier 3 or 4 restrictions. On 12 December 2020, community testing was rolled out to 67 Tier 3 areas.

4.141. Over the Christmas period in 2020 and the first few days of January 2021, the country saw a substantial rise in COVID-19 case numbers. Viruses will often mutate over time, but the frequency and chronicity cannot easily be predicted. The risk was that existing countermeasures, such as vaccines and antivirals, may become less effective. Three new variants causing COVID-19 emerged in close proximity to the winter peak of 2020: Alpha, Beta and Gamma. Alpha was considered by PHE to transmit more easily, though PHE anticipated that new vaccines being developed would be effective for variants.

4.142. On 15 December 2020, the UK Government announced that LFD tests would be deployed in secondary schools and further education colleges.

4.143. On 4 January 2021, the Prime Minister announced a national lockdown commencing on 6 January 2021. On 6 January 2021, the CTP was extended to all English local authorities and Ministers decided that the programme would run to at least the end of March 2021.

4.144. On 22 February 2021, the Prime Minister announced a roadmap for the UK to emerge out of its third lockdown and for the economy to reopen. Central to this was the scaling up of asymptomatic testing using LFDs and a significant switch to LFD self-testing.

4.145. In March 2021, as the country emerged from lockdown, secondary schools and colleges were advised to commence testing for all pupils using LFDs.

Pilot Programmes

4.146. Between November 2020 and July 2021, a number of testing evaluation pilots took place in a range of settings and were carried out for different purposes. Settings were chosen for mass testing for differing reasons: high prevalence rates (Liverpool); protecting key workers in a particular setting (the NHS); or to keep particular institutions open (schools and colleges). Pilot studies for assessing testing practicality and effectiveness were just one sub-set of the pilot programmes run by NHSTT with additional key evaluation and modelling support from PHE, academia and others. Other pilots focused on supporting people to self-isolate or on how to reach people who had tested positive for COVID-19 more quickly. Evaluation outputs of the testing programme, as a whole, were subject to further oversight from the Testing Initiatives Evaluation Board. A comprehensive list of reports can be found online.

4.147. The testing pilots included:

4.147.1. Liverpool: December 2020;

4.147.2. Higher education institutions: winter 2020;

4.147.3. NHS repeat asymptomatic testing: November 2020 onwards;

4.147.4. NHS Daily Contact Testing: January - February 2021;

4.147.5. Secondary schools and further education colleges: spring 2021.

4.148. The LFDs used in the mass testing pilots had passed PHE Porton Down Phase 3 evaluation (see the Science and Technical Statement).

Higher education institutions ("**HEI**")

4.149. In November 2020, just before the HEI winter break, the COVID-19 infection survey consistently showed that positivity rates were highest amongst teenagers and young adults. There was a perceived risk that university students travelling home for the winter break (estimated to number around 370,000) could transmit infection to their relatives, including those who could be vulnerable. The Innova LFD was used for the HEI pilot. At this time, regulatory approval for the self-test use of LFDs was in progress so use of assisted testing procedures on sites was the only option. Individuals who tested positive were advised to undertake a PCR test (known as a confirmatory PCR), and they and their close contacts were required to self-isolate for 10 days as per UK Government guidelines at the time. If the confirmatory PCR test was positive, they had to continue their self-isolation for the full 10-day period.

Liverpool

4.150. On 3 November 2020, DHSC announced a pilot scheme of whole city testing in Liverpool. The City of Liverpool was selected as it had the highest prevalence of COVID-19 in England in the preceding weeks. This was implemented from 6 November 2020, as a national lockdown started, in a partnership between NHSTT, Liverpool City Council, NHS Liverpool Clinical Commissioning Group, Cheshire & Merseyside Health & Care Partnership and the University of Liverpool. The Innova LFD test was used for the Liverpool Pilot. At that stage, Innova was the only LFD provider whose test had been validated by PHE Porton Down and where the supplier could produce a sufficient volume of tests at speed. During the pilot, those who had returned a positive LFD were asked to undertake a confirmatory PCR.

NHS Repeat Asymptomatic Testing

4.151. This pilot involved asymptomatic patient-facing healthcare workers using LFDs, self-testing at home twice per week. The pilot used the Innova LFD Test, which on 11 September 2020 was the first LFD test to pass phase 3(a) validation at PHE Porton Down. The MHRA then on 22 December 2020 granted an "Exceptional Use Authorisation" ("**EUA**") following an application from DHSC. Tests were supplied in boxes of 25 Innova LFD tests. In January 2021, testing was extended to some non-frontline managerial and administrative staff. Those who tested positive were asked to self-isolate in accordance with the applicable government guidance and to take a confirmatory PCR test.

NHS Daily Contact Testing Pilot

4.152. The pilot involved four acute hospital trusts and one ambulance trust. Daily Contact Testing was used in this pilot as an alternative to immediate self-isolation for healthcare workers, who had been identified as a close (high risk) contact of someone who had tested positive for COVID-19. Once identified as a contact, staff members tested themselves at home using an LFD each day for seven days. If the result of their test was negative, they could continue to work as usual. Innova LFDs were used in this pilot. NHS staff involved had access to PCR testing for asymptomatic staff.

Secondary Schools and Colleges Pilot

4.153. Mass asymptomatic testing was implemented after schools and further education colleges reopened in March 2021 following national lockdown. Asymptomatic pupils initially took their tests at specific locations, where they self-swabbed under supervision and a trained staff member conducted the test and read the result. Tests were repeated on site for pupils ideally at a three-to-five-day interval, and for staff twice-weekly self-tests at home. After two weeks, pupils moved to home-based self-testing when the levels of self-test stock available allowed. The pilot deployed LFDs from a number of different suppliers. For assisted testing, Orient Gene and Innova; and for self-testing: COVID-19 Self-Test from Innova, Acon, and Orient Gene (self-test). Positive tests at an asymptomatic test site did not initially require a confirmatory PCR test, but from 31 March 2021 a confirmatory PCR test was required. Positive LFD tests taken at home required a confirmatory PCR test.

<u>Procurement Response</u>

4.154. To be able to test the whole population, as Operation Moonshot envisaged, NHSTT needed not just to procure huge volumes of tests but also to build an even larger storage and distribution network to enable all citizens to access tests, and a digital platform to process the results to evaluate the effectiveness of all-citizen testing.

4.155. PCR testing was not realistic for whole population asymptomatic testing envisaged under Operation Moonshot because of the need for lab processing, the relatively high costs and high resource needs (testing sites and lab technicians), the turnaround time, and the fact that PCR testing was sensitive to viral fragments long after infection had resolved, which meant that the test would show a positive in circumstances where a person was not infectious (and so not necessarily a risk to their contacts). LFDs offered the possibility of returning results in 15 to 30 minutes and being able to be used in the home. They did not require the infrastructure of a lab, which could

reduce the cost of each test. LFD tests offered the potential to be mobilised quickly across many sites, so increasing overall population accessibility to testing.

4.156. As set out in the Science and Technical Statement, LFD tests generally have lower sensitivity than PCR but, with an LFD of sufficient quality available at scale and used appropriately, the LFD test could be reliable and accurate at detecting those most likely to be infectious and therefore to enable mass routine asymptomatic testing.

4.157. NHSTT were tasked with taking forward the Prime Minister's decision to progress mass whole population testing. From August 2020 onwards, the Prime Minister ordered NHSTT to expand testing capacity as much and as fast as possible. The decision not to proceed with "Operation Moonshot" meant that the procurement work in anticipation of it was redirected to the CTP.

4.158. The UK Government's instruction to build UK LFD testing capability prompted NHSTT Commercial to further use advance payments where appropriate to the pandemic response and in line with HMT requirements.

4.159. NHSTT started developing the UK Make team in September 2020 due to the cost, timing and volatility of global manufacturing and logistics, which risked supply and increased the costs of LFD tests that had the potential to be saved for the volume of rapid tests that the UK appeared likely to need. The UK Make programme was set up in October 2020 and aimed at delivering the capacity and capability to produce UK LFD tests for COVID-19 at volumes of greater than 2 million tests per day.

4.160. Due to the rapid speed and changing view of the UK Government's decision-making process within a fast moving epidemiological and technological context, a full competitive procurement procedure under the Regulations had not been undertaken in August and September 2020. The majority of offered LFD tests evaluated at PHE Porton Down failed at Phase 2 or 3 of the technical evaluation (see the Science and Technical Statement). Following the first technical validation of LFD tests, the plans were to purchase 40 million LFD tests from the small number of suppliers whose product had passed the technical evaluation at PHE Porton Down.

4.161. Given the limited number of suppliers that had passed technical evaluation, NHSTT needed to contract with all of them to obtain the volume of tests promised by the UK Government. The policy commitment required tests to be available in a matter of

weeks and a 15-to-35-day cycle, as required by the regulation 27 or 28 procedure, would have created unnecessary delay, where an open competition would have been fruitless (because only LFD tests that had been validated would be procured). Direct awards were therefore necessary.

4.162. After Operation Moonshot was announced and when it was anticipated the WHO would issue guidance recommending the use of LFD tests in early September 2020, negotiations were concluding with Innova, Tanner Pharma, Abbott Panbio (for LFD tests) and OptiGene (for Direct-LAMP) for contracts that could accommodate the higher volume of tests. Only Abbott Panbio, Innova, and Tanner Pharma's LFD tests had passed the technical evaluation stages. At this time the LFD tests available had regulatory approval for assisted (professional) use only.

4.163. As mentioned above, Innova's LFD test was the first test to pass phase 3(a) validation at PHE Porton Down on 11 September 2020. To expedite appropriate regulatory approvals, DHSC assumed responsibility to be the 'legal manufacturer' when applying to the MHRA for EUA for the Innova self-test, explained in the Science and Technical Statement. On 22 December 2020, the NHS-branded Innova product was granted an EUA for self-test for six months.

4.164. On 31 October 2020, the UK's lab PCR testing capacity reached the UK Government's target of processing 500,000 tests per day.

4.165. From November 2020 onwards, discussions began in NHSTT on plans to build two large high throughput labs termed "mega-labs", and to use e-PCR technology to provide a total of 600,000 high-sensitivity e-PCR tests per day at a significantly lower cost than private labs. This was announced on 16 November 2020.

4.166. The emergence of three new variants of COVID-19 in quick succession (and the impact thereof), combined with rising infection rates, the potential for new testing technologies that may not require lab capacity, and the first deployment of the COVID-19 vaccine made the demand forecast for tests volatile.

4.167. The policy decision by UK Government on 15 December 2020 to test school children when they returned to school in January 2021 led to emergency procurement of additional LFD tests which were to be sent to schools in readiness for the start of term and extensive work to facilitate deliveries to school. This work was no longer

required for the January 2021 school start as a result of the announcement on 4 January 2021 of the national lockdown to commence on 6 January 2021. The tests stayed in schools and further education colleges until these establishments re-opened.

4.168. On 17 December 2020, NHSTT submitted advice to the SSHSC to continue with the Rosalind Franklin lab but pause the proposed high throughput lab in Scotland until there was a clearer view on demand projections through to the end of 2021 **[Exhibit: SC/059 INQ000223455]**.

4.169. NHSTT launched an accelerated open tender for LFDs in January 2021 **[Exhibit: SC/060 INQ000421932]**, to limit the potential gap in supply **[Exhibit: SC/061 INQ000527688]**.

4.170. By February 2021, 15 million LFD tests were deployed for use each week. In the context of the rollout of the vaccine programme and the expansion of LFD testing, which was more cost-effective per test than PCR testing, NHSTT began the process of consolidating and decommissioning the PCR lab network. The consolidation process involved a combination of terminating contracts on surge capacity and decommissioning some labs.

4.171. NHSTT sent a submission to the SSHSC on 4 February 2021 with advice to review and retain PCR lab testing capacity to process a maximum of 750,000 test per day (across the lab network), in line with the reduction in PCR testing demand after the winter 2020/21 increased capacity **[Exhibit: SC/062 INQ000223459]**.

4.172. The Prime Minister's announcement on 22 February 2021 of the roadmap outlined increased national reliance on self-testing, which led to the decision not to place orders for assisted LFD tests (which could only be administered at testing sites) and a direct award to Innova (with DHSC remaining the legal manufacturer of the Innova self-tests), to guarantee sufficient LFD stock until delivery in April 2021 of stock procured through the DPS.

4.173. As explained above, the DPS had been in development since early October 2020 and was established in March 2021.

Procurement Process

4.174. The policy decision to move towards mass testing took place against the backdrop of other challenges to procurement, while NHSTT was growing exponentially and establishing its commercial function in-house, with the challenges to recruitment that have already been mentioned. Scaling up the organisation with new contractors and consultants made knowledge transfer and upskilling challenging. NHSTT Commercial ran an induction programme for new joiners **[Exhibit: SC/055 INQ000501914; Exhibit: SC/063 INQ000383497; Exhibit: SC/064 INQ000514398]**.

4.175. In September 2020, DHSC commissioned and made available a portal on GOV.UK that allowed suppliers to submit details of their COVID-19 diagnostic devices. While the portal was for all COVID-19 diagnostics devices, LFD tests made up the majority of the supplier submissions.

4.176. The process is summarised in slide decks prepared by NHSTT contemporaneously. The slides are exhibited and show the process developed for contractors and new joiners in NHSTT as the organisation's commercial function expanded, to ensure a consistent approach by all consultants, contractors and civil service staff and address the turnaround of staff **[Exhibit: SC/065 INQ0000383520; Exhibit: SC/066 INQ000501912; Exhibit: SC/067 INQ000501910; Exhibit: SC/068 INQ000421928; Exhibit: SC/069 INQ000383495; Exhibit: SC/070 INQ000421927; Exhibit: SC/071 INQ000501916; Exhibit: SC/072 INQ000421921; Exhibit: SC/073 INQ000383545; Exhibit: SC/074 INQ000383504; Exhibit: SC/075 INQ000501919; Exhibit: SC/063 INQ000383497]**.

4.177. NHSTT developed and launched a single end to end commercial process and toolkit called "T&T Commercial Process & Toolkit" **[Exhibit: SC/076 INQ000527706; Exhibit: SC/077 INQ000421722; Exhibit: SC/078 INQ000514403 and Exhibit: SC/079 INQ000514388]**, with process discovery workshops starting in October 2020, and the initial Commercial toolkit being delivered in January 2021. The evaluation of offers is set out in **[Exhibit: SC/048 INQ000383569]** as far as UKHSA has been able to determine.

4.178. Prior to the public announcement of Operation Moonshot, all suppliers that offered to supply LFD tests had been referred to PHE Porton Down for technical evaluation. All other tests offered (including from those suppliers the Inquiry has asked about) failed, at a time when tests were needed quickly.

4.179. In respect of LFD tests, before the establishment of the DPS, clauses reviewed by Legal were included in the contract to allow for termination if the LFD test failed to obtain validation or accreditation requirements.

4.180. Ministerial submissions were provided in respect of all LFD procurements (save for those under the £150 million delegation limit permitted at the time, which did not require a submission) and had to be approved and followed by a business justification, according to the NHSTT Commercial processes (exhibited above). Further approval from DHSC Finance, Cabinet Office Controls and HMT was then needed **[see Exhibit: SC/031 above]**.

4.181. The scale up of the UK Make programme is described in **[Exhibit: SC/080 INQ000507380]**.

Contracts Awarded

4.182. In response to the policy commitment for mass asymptomatic testing (including for Operation Moonshot) from early September 2020, eight contracts were awarded for the procurement of LFD tests, pursuant to regulation 32.

4.183. The following contracts were awarded, to meet need across the UK, on:

4.183.1. 11 September 2020 to Abbott Panbio. This first contract was for the purchase of Abbot Panbio COVID-19 LFD tests. The contract provided for an initial order of 1,000,000 units with the option, exercisable at DHSC's discretion, to purchase up to 10,000,000 further units. The contract also provided for ancillary transportation and logistics for the devices. The contract was conditional on the test passing the PHE Porton Down evaluation, which it did.

4.183.2. 17 September 2020 to Innova. This first contract was for the purchase of 18,000,000 units of Innova COVID-19 LFD tests, including ancillary transportation and logistics for the LFDs. These were "Professional Use" tests (where a clinician/ trained professional takes the swab) in packs of 25, though later the "Professional Use" requirement was updated with the EUA.

4.183.3. 22 September 2020 to OptiGene. The contract was for various DIRECT LAMP-related devices which included Genie HT machines and accessories and DIRECT RT-LAMP assays.

4.183.4. 5 October 2020 to Tanner Pharma. This first contract was for 2,000,000 LFD tests and ancillary logistics services.

4.183.5. 8 October 2020 to Abbott Panbio. This second contract was to provide for 15,000,000 Abbot Panbio COVID-19 LFD tests and related logistics services, with an option to purchase an additional 15,000,000 tests.

4.183.6. 9 October 2020 to Tanner Pharma. This second contract was 37,500,000 LFD tests and related logistics services.

4.183.7. 20 October 2020 to Biodot, as part of the UK Make Programme. This first contract was for manufacturing equipment to make LFD tests including: four RR120 Reel to Reel Depositors and two LM9000 Laminators, which was based on an advance payment.

4.183.8. 20 October 2020 to Biodot, as part of the UK Make Programme. This second contract was for further manufacturing equipment to make LFD tests including further RR120 Reel to Reel Depositors and LM9000 Laminators.

4.183.9. 3 December 2020 to SureScreen, as part of the UK Make Programme. Further contracts were signed with SureScreen on 22 December 2020 and 24 December 2020. Its LFD test was validated in January 2021.

4.184. Direct awards were used for the OptiGene contract because its solution was the only validated DIRECT-LAMP assay available (saliva and swab). OptiGene was the only manufacturer of equipment specifically optimised for DIRECT-LAMP, at a lower cost than standard PCR equipment **[Exhibit: SC/081 INQ000527686; Exhibit: SC/082 INQ000527692]**.

4.185. Biodot was under pressure of global demand. If an order had not been placed, there was a risk that NHSTT would not have been able to secure the equipment from Biodot as such equipment may not have been available at a later point. It was understood there was a long lead time for them to manufacture and supply more equipment, which would have led to delays in supporting the initiative to manufacture LFDs in the UK **[Exhibit: SC/083 INQ000527699]**.

4.186. On 15 January 2021, NHSTT closed the accelerated open tender to supplier bids (see above at paragraph 4.169). A small number of suppliers were successful in this initial accelerated procurement exercise **[Exhibit: SC/084 INQ000527703]**. Multiple call-offs (individual contracts) were made with the successful bidders.

4.187. As set out above, UKHSA undertook the UKHSA 2022 Review **[Exhibit: SC/085 INQ000383567, Exhibit: SC/048 INQ000383569; Exhibit: SC/086 INQ000383570]**. Its findings are summarised as follows.

4.188. 360 contracts were awarded to 158 suppliers. 50 of those suppliers entered the process by a "priority" or equivalent route (i.e. associated to a "VIP", "fast-track" or equivalent key word; in correspondence with a minister; or through correspondence in the priority contacts mailbox), and the supplier's route is specified in the review. 50 suppliers did not come through the "priority" or equivalent route. 58 suppliers were not corresponded with through the mailboxes mentioned, though, as explained previously, correspondence may have taken place through the inboxes of civil servants who were seconded to the Testing Commercial Team, that UKHSA did not have access to at the time the UKHSA 2022 Review took place.

4.189. The review noted "[a]ll suppliers went through a scientific validation process which involved a network of expert stakeholders. This provided rigour to ensure no products were progressed that did not meet the required specification. To meet challenging time pressures, the scientific validation processes could be managed in parallel to supplier engagement and initial commercial discussion."

4.190. The UKHSA 2022 Review confirmed that the proportion of suppliers awarded a contract out of the total offers provided to the aforementioned inboxes (upwards of 2,000 offers) were as follows:

4.190.1. "COVID Testing triage" - 5.4%

4.190.2. "COVID Testing Priority Contacts" - 16%

4.190.3. "COVID19 Innovations" - 7.3%.

E. April 2021 to 28 June 2022

UK Government Policy and Context

4.191. Infection rates started to fall as the vaccination programme was rolled out, which resulted in fewer symptomatic people requiring PCR tests.

4.192. On 5 April 2021, the SSHSC formally announced the Universal Testing Offer, twice weekly rapid testing available to everyone in England from 9 April 2021 through:

4.192.1. A home ordering service, which allowed people to order LFD tests online to be delivered to their home.

4.192.2. Workplace testing programmes, on-site or at home.

4.192.3. Community testing, offered by all local authorities.

4.192.4. Collection at a local PCR test site during specific test collection time windows.

4.192.5. Testing at schools and colleges.

4.192.6. 'Pharmacy Collect', which allowed people aged over 18 without symptoms to visit a participating local pharmacy and collect a box of 7 rapid tests to use twice a week at home.

4.193. The Universal Testing Offer stated that by "making rapid tests available to everyone, more cases will be detected, breaking chains of transmission and saving lives" as "[r]apid testing detects cases quickly, meaning positive cases can isolate immediately".

4.194. The Inquiry has asked about UKHSA's awareness of an article published in the British Medical Journal ("**BMJ**") on 28 April 2021. This cites a newspaper report that the MHRA had authorised Innova LFD self-tests for which DHSC was the legal manufacturer ("**DHSC/Innova 3/7 LFD self-tests**" - as explained further in the Science and Technical Statement) to be used to find infectious people so they could self-isolate, not for "test to enable" (though the distinction is not described in the BMJ article itself). The news article further raised a separate issue around how negative results could be interpreted by test users as testing to enable. NHSTT was aware that (i) the authorisation for the DHSC/Innova 3/7 LFD self-tests did not extend to Testing to Enable, and at this time NHSTT had not used DHSC/Innova 3/7 LFD self-tests for that purpose and (ii) messaging by NHSTT had been that the DHSC/Innova 3/7 LFD self-tests communicated that the person was not likely to be infectious, but they could still have been infected and should continue to implement COVID-19 precautions. As NHSTT complied with the terms of the MHRA's EUA, there was no requirement to recall the DHSC/Innova 3/7 LFD self-tests. When UKHSA became operational in October 2021, six months later, LFD self-tests were in use globally, and the market, availability and authorisation of LFD tests was more established.

4.195. In April 2021, the CTP transferred into NHSTT. Around this period, significant clusters of variants were found.

4.196. In mid-June 2021, the Prime Minister announced that the Universal Testing Offer would be extended to the end of July 2021, in line with the delayed date for the re-opening of society generally.

4.197. On 1 July 2021, CTP became the Targeted Community Testing service ("**TCT**"), supporting groups identified by the Cabinet Office and local authorities to provide testing to groups of people where specific local transmission risks had been identified.

4.198. The plan for Autumn/Winter 2021 was developed through a two-week cross government department project in August 2021. However, HMT were reluctant to approve proposals around universal testing due to cost implications. The policy approach went to COVID-O and No.10 for agreement. NHSTT prepared a demand model based on the agreed policy approach and HMT approved expenditure to the end of December 2021 based on that demand model.

4.199. In Autumn 2021, NHSTT (and then UKHSA) recommended procurement which would allow for more cost-efficient contracts. There were extensive discussions with HMT. The lack of formal permissions from the UK Government to make longer-term procurement decisions impacted the ability to achieve better value for money. However, without cross-government agreement for the policy position after January 2022, HMT's expectation/intention was that the Universal Testing Offer should cease at the end of 2021.

4.200. NHSTT, and then UKHSA when it became operational in October 2021, outlined alternative options for contingency (however small) and how any excess supply could be utilised efficiently in other ways, should it not be required for the originally identified purpose, in order to provide assurance to HMT for approval of funding for tests. However, the volumes that HMT would approve was kept at a low level until the Omicron variant emerged. HMT did approve expenditure to procure more LFD tests at that point, but again the approval required extensive conversations at both senior political and official level.

4.201. When Omicron emerged, press coverage of the new variant in late November 2021 increased the public's concern and demand for LFD tests. On 29 November 2021, UKHSA provided advice to the SSHSC which recommended operational routes to also increase PCR testing capacity **[Exhibit: SC/087 INQ000223462]**. The decision to increase PCR testing capacity reversed some of the decommissioning of the lab

network in that the process of decommissioning was paused in respect of the six (out of nine) labs that had been earmarked for decommissioning. The decommissioning process in respect of the labs earmarked had not completed, so no savings would have been made by leaving the six labs as standing capacity. Additional surge capacity was already contracted and on a cost per test basis, so if and when ultimately not needed, there were no resultant increased costs.

4.202. On 8 December 2021, the Prime Minister announced "Plan B", published on 12 December 2021, which included the requirement for a COVID-19 pass to attend events and the potential for earlier release from isolation. Daily testing was announced as an alternative to isolation for those close contacts who were fully vaccinated and had no symptoms. This move came as Omicron infections were rising significantly in the UK. Fully vaccinated contacts of a confirmed COVID-19 cases were advised to take daily LFD tests for seven days and a confirmatory PCR if they tested positive. LFDs became essential to everyday life for most people.

4.203. On 15 December 2021, the Government announced that pharmacies would be able to access 10.5 million LFD tests per week, an increase of 5.5 million per week.

4.204. On 5 January 2022, UK Government no longer required people to take a confirmatory PCR test for anyone testing positive with an LFD test but showing no symptoms; people were nevertheless required to self-isolate for seven days with a positive LFD test.

4.205. The Government announced its decision to end TCT, as well as the Universal Testing Offer, in its strategy on 'Living with COVID-19', published 21 February 2022. The service formally closed on 31 March 2022.

Procurement Response

4.206. With the implementation of the DPS for LFDs and Microbiology Framework, there became established routes to market to procure PCR and LFD tests.

4.207. The April 2021 announcement that free twice weekly testing with an LFD test would be available to anyone increased demand for LFD tests and required the procurement of sufficient tests to meet the potential all-citizen demand.

4.208. With infection numbers falling as a result of the vaccination programme and the end of winter 2020/21, the demand for PCR tests reduced. Nevertheless, it remained early in the roll out of the vaccine programme and variants of COVID-19 continued to emerge.

4.209. With a continued reduction in symptomatic cases, and subsequent low demand for PCR testing, routine operational lab capacity could be reduced, but surge testing contracts remained in place to provide the ability to scale PCR testing if demand required.

4.210. On 18 May 2021, following the NHSTT Investment Board's approval of the business case **[Exhibit: SC/088 INQ000514386]**, Ministers approved the proposal to procure 294 million self-test LFD devices (in packs of 7) through two mini competitions through the DPS. The first being for 150 million LFD tests to cover the period end-June to August 2021 and the second for 144 million LFDs for September 2021 **[Exhibit: SC/089 INQ000527700 ; Exhibit: SC/090 INQ000527689]**. Both took place in accordance with the terms of the DPS.

4.211. The first DPS mini competition was launched on 19 May 2021 with HMT and Cabinet Office approval. The prerequisite to entering the competition was that suppliers' products had passed the phase 3(a) validation at PHE Porton Down and had regulatory approval for their product - either a CE mark or an EUA from the MHRA. All suppliers had an obligation to ensure their product could detect variants of concern and the suppliers that competed had products that could detect the current known variants. The outcome is evidenced in **[Exhibit: SC/091 INQ000527685]**.

4.212. Following the mid-June 2021 announcement, an estimated 40 million additional LFDs were required to meet the need, at an estimated cost of £97 million. In July 2021, 57 million LFD tests were deployed for the Universal Testing Offer.

4.213. In July 2021, surge capacity was procured from commercial providers in response to increased demand for symptomatic PCR tests **[Exhibit: SC/092 INQ000223461]**. Following further discussions with Ministers, the opening of the mega-lab for PCR testing at the Rosalind Franklin Lab was announced in July 2021.

4.214. Demand for PCR tests in summer 2021 was approximately 120,000 to 300,000 PCR tests per day. Demand modelling anticipated that, during Autumn/Winter 2021/22,

capacity would be needed to process up to 860,000 PCR tests per day, albeit there was no definitive way to predict the arrival of new variants or changes in viral impact.

4.215. The decision not to fund a contingency of LFDs, and extensive discussion about procurement of LFDs before Omicron emerged, culminating in a decision to procure further tests late in 2021, left UKHSA's Commercial Team very little time to procure the required volume of tests anticipated for the increased demand and by new rules that were introduced by UK Government for LFD testing **[Exhibit: SC/093 INQ000501909]**.

4.216. Whilst there had been discussions around the use of LFD tests to end self-isolation and as an 'access pass' for events, the confirmation of the policy in the Prime Minister's announcement on 8 December 2021 had been unexpected by the UKHSA Testing Ops team. Without a pre-existing contingent supply, the announcement plus the emergence of the Omicron variant put a strain on LFD stocks **[Exhibit: SC/094 INQ000514387]**. The UKHSA Testing Ops and UKHSA Commercial worked at pace and put in plans to manage the demand (see below).

4.217. 700 million LFD tests were procured through three rounds of procurement between 13 and 31 December 2021. This necessitated the use of direct awards and regulation 72 modifications to fast-track extra supply. The volume of tests required resulted in the need to procure additional transport to move stock received in the country to warehouses quickly and bypass the central holding phase so that tests reached end users at the earliest opportunity.

4.218. In order to manage available supply, whilst conversations were ongoing and pending the receipt of further supply, UKHSA set limits on the numbers of orders that could be placed by the public through the online portal, which meant that when the limit had been reached for the nation (England and DAs), no further tests could be ordered that day. UKHSA did not run out of supply; it managed access to the supply and capacity within supply chain and logistics arrangements, to ensure ordered tests could be delivered to recipients. If those limitations had not been put in place, demand would have outstripped supply. News reporting of the portal "running out" increased the numbers of people seeking to order LFDs, which in turn impacted when the portal limit would be reached.

4.219. After the UK Government's announcement on 5 January 2022 that there was no longer a requirement for a confirmatory PCR test after a positive LFD test, the demand for PCR tests reduced. As a result, by February 2022, the size of the lab network had been reduced in line with the demand profile. UKHSA maintained some lab capacity to respond to new waves, if required, recognising inherent uncertainties in the future trajectory of the COVID-19 virus.

4.220. From January 2022, ExCo agreed several measures to improve commercial practice, learning lessons from the COVID-19 pandemic (which is dealt with further in Section 8).

4.221. After "Living with Covid" was announced in February 2022, UKHSA reverted to "business as usual" practice.

Procurement Process

April 2021 until October 2021

4.222. NHSTT Commercial worked to the T&T end-to-end commercial process and toolkit above. Exhibited are further slide decks which show the procurement process from April to October 2021 **[Exhibit: SC/095 INQ000383544]**.

4.223. Between April 2021 and October 2021, as part of the transition planning, UKHSA started developing the first iteration of the UKHSA Commercial Strategy **[Exhibit: SC/096 INQ000421919]**.

October 2021 to June 2022

4.224. When UKHSA became operational in October 2021, UKHSA Commercial initially operated along similar process lines as NHSTT had but began developing its own commercial policy **[Exhibit: SC/097 INQ000421922]**.

4.225. The Approvals Secretariat managed spending approvals **[Exhibit: SC/098 INQ000421925]**. Temporary Standing Financial Instructions were applicable pending further approval from the UKHSA Audit and Risk Committee **[Exhibit: SC/099 INQ000501918]**. The exceptional commercial delegation of £150 million for HMT and Cabinet Office controls during the pandemic reverted to standard thresholds, bringing them in line with norms in the rest of government, from 1 July 2022. All UKHSA spend over £10,000 requires adherence to the UKHSA Investment Governance Model.

4.226. In March 2022, after the announcement of "Living with Covid" and Accounting Officer responsibility transferred to UKHSA, UKHSA rolled out the Target Operating Model for UKHSA Commercial Teams **[Exhibit: SC/100 INQ000501917]**.

4.227. UKHSA Commercial continued to use the post-NHSTT business justification template until October 2023, when it was replaced by the Sourcing Strategy Document.

SECTION 5. SUPPLY MANAGEMENT AND DISTRIBUTION

5.1. The Testing Ops teams, and the management of the supply chain to deliver the testing service for PCR testing kits and later LFD tests, went through multiple changes, improvements and refinements over the Relevant Period. Examples of which are exhibited **[Exhibit: SC/101 INQ000514400 ; Exhibit: SC/102 INQ000514401]**.

A. Logistics

5.2. The ability to distribute sufficient tests (PCR sample collection kits and LFD tests) faced different obstacles because the various potential test users had different requirements and needed different delivery mechanisms to acquire and access tests. These requirements included geographical challenges, such as how to deliver to and collect tests from remote areas. The distribution network also needed to cater for different testing policies set by UK Government.

5.3. At the outset of the pandemic, enabling people to access PCR tests required the rapid development of a large distribution network, akin to that of a large supermarket chain, that could house and deliver multiple different products, of different sizes, to thousands of locations at once. It required procuring both warehousing and shipping capability and linking these with test kit assembly and digital systems to take in and then deliver in accordance with demand from the sectors **[Exhibit: SC/103 INQ000527697]**.

5.4. In March and April 2020, three channels were set up for distribution of PCR sample collection kits:

5.4.1. The Satellite and Vulnerable communities ("**SVC**") Channel, which was set up distributed to care homes but later expanded to other organisations including prisons and hospices and became known as the Organisation Led Testing channel ("**OLT**");

5.4.2. The Home Channel (kits sent out to homes for home testing); and

5.4.3. The Physical channel (for mobile testing units and eventually regional and local test sites) – sites where people could attend to get tested split into Regional Test Sites ("**RTS**"), Mobile Test Units ("**MTU**") and Local Test Sites ("**LTS**"). Mobile testing had already been developed as a concept before NHSTT was launched. MTUs were trialled and scaled throughout 2020.

5.5. Sales & Operations Planning ("**S&OP**") is a standard process for any supply chain, which combines the opening stock with expected inbound (incoming) and outbound (demand) to give an operational/demand plan (based on the inventory position and movements planning to satisfy demand, i.e. what products, where they were going and when) and highlight any issues / decisions needed.

5.6. There were various logistical difficulties in respect of returning tests to the lab from each channel, which are set out below.

5.7. The Physical Channel faced similar challenges. Additionally, the Physical Channel involved setting up testing sites. Setting up a testing site required: the identification of large flat spaces; access to equipment that could be hired and delivered to the location (therefore the remoteness of a location from other resources was relevant); and the recruitment of thousands of staff to manage the sites and conduct the tests. These challenges were exacerbated by the fact that all these processes had to be bespoke to each testing site that was being set up.

5.8. Clinical validation was required for the kitting (putting together), the storage and delivery of PCR sample collection kits, which impacted all the aforementioned channels. As an example, arrangements had to be made so that used PCR sample collection kits could be transported in sufficient time, without temperature control, and still give a valid result, which required scientific evaluation to test the stability of the virus once collected.

5.9. A return logistics pathway (i.e. the way that PCR test samples would be collected and taken to labs for testing) was designed that mapped out how tests were taken back to the labs, reducing the number of couriers required, and streamlining the processes around dealing with samples once they got to the lab.

5.10. In full scale operations, tests were being delivered daily to over 2,000 locations.

Orders

5.11. Orders for PCR, and later LFD, tests came through differing mechanisms:

5.11.1. Organisation who were served by the SVC/OLT Channel could order tests on an online portal, through a SalesForce system, and the tests would be dispatched to them. From December 2020, NHSTT used the SalesForce system to meet orders which allowed for social care settings to order stocks of PCR testing kits and LFDs using their unique organisation number. Delivery costs were not passed on to the settings that NHSTT (and later UKHSA) sent tests to. From January 2022 onwards, domiciliary carers were also supplied through the SalesForce system. A master report was generated daily and, from the master list, NHSTT (and then UKHSA) created a report per region recording the volume of tests ordered per day.

5.11.2. Members of the public could order through the online portal, and were served by the Home Channel. Initially, people could order PCR tests and later LFDs, which would then be sent to their home address. For PCR tests, the individual could then return the used PCR sample collection kit either by a Priority Post Box or they could call 119 to arrange a courier. Requests for tests received through the Home Channel were fulfilled in the order in which the requests were received. It was not possible operationally to prioritise orders placed through the home channel, even where there was a particular policy need or vulnerability which had prompted the order.

5.11.3. The testing sites, where people could attend to take their PCR test in person, were responsible for ordering the PCR tests to be available on site. The testing sites would feedback information to the Physical Channel who could fulfil the orders. Used PCR sample collection kits would be packaged and returned in bulk via Royal Mail relay depots to the labs for processing.

5.12. In or around June 2020, the Testing Ops teams managed supplier relations (post-contract award) and relationships with labs. The teams were split:

5.12.1. One team responsible for PCR reagents (used in labs) who would be in contact with suppliers and labs, and place requests for supplies and equipment to try and meet requests for testing kits.

5.12.2. One team responsible for "sample collection", who were ordering and allocating PCR sample collection kits' supplies and who organised logistics for supplies to be sent to the required locations.

NHS Trusts

5.13. NHS Supply Chain had initially held the stock for generic vials and swabs used in COVID-19 PCR sample collection kits. From March 2020, DHSC assumed control of the stock previously procured by NHS Supply Chain. Although ownership was transferred, the stock remained physically stored at the same facility that continued to operate under contract with NHS Supply Chain.

5.14. From April 2020, NHS Trusts were provided with individual PCR componentry, such as swabs, vials, and reagents, rather than complete test kits, by a push allocation model (i.e. stock was sent to NHS Trusts pro-actively rather than waiting for the NHS Trust to request the componentry). As the NHS Trusts already had testing capability, the PCR componentry was never assembled into test kits. The PCR sample collection kits would be used by nurses swabbing patients and sending the samples straight to their Pathology departments. The PCR componentry would be sent to NHS Trusts once a week. The aim was to top-up the NHS Trusts to have at least three weeks' worth of stock available on site. This number was based on their average testing levels for the preceding eight-week period.

5.15. NHS Trusts had the option to temporarily pause their allocations manually by email. The allocation model would also detect any drops in testing levels as well, so if the NHS Trust location site had more than three weeks' worth of stock, no stock would be sent to them until that dropped below three weeks. If a surge in testing was noted in respect of a particular NHS Trust, an emergency allocation could be made available.

5.16. LFD test order requirements for the NHS were agreed through daily calls between NHS Trusts and NHSTT. In early 2021, LFDs were sent to NHS Trusts in bulk, phased, deliveries. From April 2021, NHSTT moved to a pull model (i.e. where test had to be requested) where NHS Trusts could place their orders electronically on SalesForce. Each NHS Trust's regional co-ordinators would upload their requirements and delivery details onto SalesForce. A restriction on order volume by Trust was in place based on specific caps advised by the NHS for each NHS Trust. NHSTT had an emergency order process in place for additional orders if needed.

5.17. From the middle of 2021, NHS Trusts and its staff could order through the online GOV.UK portal. Individual orders through the GOV.UK portal formed the majority of orders, after April 2021.

5.18. In December 2021/January 2022, a one-off ad-hoc order of 8.8 million LFD tests, requested by the NHS, was sent to one central NHS location for onward management. This was at the height of Omicron and requested by the NHS to ease any fears that they could be impacted by stock restrictions. Transfer of responsibility for PCR testing provision from UKHSA to NHS took place in April 2023. Transfer of responsibility for LFD testing provision is explained above. As part of this, two million LFD tests were transferred from UKHSA to the NHS which could still be deployed. NHS Trusts can now order this stock through the NHS Supply Chain, which was the process before April 2020.

Care Homes

5.19. In May 2020, couriers were proactively booked to collect of used PCR sample collections kits from care homes, with the aim of making the return of PCR sample collection kits smoother. However, these couriers could not be cancelled by the care home if there were no used PCR sample collections kits to collect. This approach created additional unnecessary journeys and detours, which increased the time taken for used PCR sample collection kits to be returned to the lab. On 11 May 2020, an e-courier portal was created giving care homes control over when couriers were booked, thus replacing the centralised pre-booking of couriers. If demand spiked, additional motor vehicle transport was acquired to distribute the tests to meet the increased orders placed.

Assembly

5.20. PCR sample collection kits had a number of components and required assembling before they were ready for onward distribution. Each component in a single PCR sample collection kit needed to be labelled with the right bar code, for reporting results back. The bar codes were printed on labels in groups of fours (or fives depending on the product) on a label roll, but the bar codes were not sequential when printed onto the labels. It was a manual process.

5.21. There were several warehouses that managed PCR sample collection kits and assembly, because the PCR components were delivered to NHSTT separately and would be assembled in the warehouse (kitting). The number of warehouses used changed over time as warehouses were used and then stood down as demand for PCR sample collection kits varied. The total number of PCR Kitting Sites used reached 17, which all opened and closed at different times between 2020 and 2023.

The maximum number of PCR Kitting Sites operational simultaneously during the pandemic was 11.

5.22. The number of distribution warehouses open at any one time ranged from three to four. Similarly, these opened and closed at different times based on demand. Quality checks on stock were conducted by a third-party distribution company.

5.23. The expectation was that third party assembly sites were working to ISO13485, though without necessarily achieving ISO13485 certification. This was an accepted and agreed position with the NHSTT quality assurance team and checks were carried out to ensure that ISO13485 was complied with. The third parties would have their own quality control measures, and NHSTT also had a quality control team on sites. The other specification being utilized, in addition to ISO13485, was 'ISO9001 - Quality Management Systems', where appropriate, which was not specific to medical equipment, and the quality control teams checked against that standard for the third-party site's processes.

5.24. In around October 2020, NHSTT noticed on site there was a mismatching of labels across components in PCR sample collection kits. The issue was rectified by printing the label roll with a blank label between each group of labels in efforts to make the group of barcodes clearer when working at speed and using the same group of codes for each component of a single PCR sample collection kit.

5.25. Assembled PCR sample collection kits would be sent to the onward distribution centres. Deliveries to the distribution centres were managed by the third party who managed the manufacturing warehouse. LFDs were sent straight to central warehouses and distribution centres.

5.26. In 2020, there had been two warehouses that received LFDs from which orders would be fulfilled. This later expanded to three LFD warehouses.

Onward distribution

5.27. The ways in which testing kits were delivered from the distribution centres depended on the intended end user and channel (described above). The testing service mostly operated a pull model (i.e. responding to requests for supplies) to distribute PCR sample collection kits and/or LFD tests.

5.28. For pharmacies, a wholesaler, who worked with the pharmacy network, took orders from individual pharmacies and conducted their own forecasts, to place orders with NHSTT/UKHSA for the PCR sample collection kits to be sent to the distributor for onward delivery of the tests to individual pharmacies. There was a dedicated customer team in NHSTT/UKHSA who worked with the wholesaler.

5.29. In respect of GP surgeries, LFDs were generally distributed via NHS Trusts rather than directly from UKHSA.

5.30. Between 5 October 2020 and April 2022, the following stock issues have been identified by UKHSA in reviewing information for this statement:

5.30.1. There were 8 instances where schools stopped testing or could not provide enough LFD tests to take home for holiday periods; and

5.30.2. 49 instances where OLT settings had to stop testing whilst stock was awaited. It is not clear whether these stock issues related to the provision of PCR sample collection kits or LFD tests.

5.31. UKHSA had a programme to repurpose, sell or donate unused supplies **[Exhibit: SC/104 INQ000527708; Exhibit: SC/105 INQ000527701; Exhibit: SC/106 INQ000514399]**.

5.32. As a consequence of delivering the "Living with COVID-19" strategy to agreed budgets, consistent with the remit letters sent to UKHSA, UKHSA has decommissioned COVID-19 testing and tracing infrastructure. This included a reduction in the size of the Lighthouse Lab network and decommissioning of the national distribution network. UKHSA retains capacity and capability to scale up its organisational testing systems for an initial pandemic response with the need to draw on further funding availability for population wide testing requirements.

5.33. Additionally, aspects of the COVID-19 specific digital services are no longer maintained, such as the route for return results from testing sites, which are no longer in existence. COVID-19 specific digital services were designed for a specific use and need, were not cost effective to keep dormant.

Devolved Administrations

5.34. Professor Harries explained in INQ000251906_0039 at [151-153]:

"At the outset of the Testing Programme, the four nations' Chief Medical Officers

made a joint agreement that testing capacity would be allocated across the four nations based on population. The testing capacity percentages for the DAs were; Scotland 8.28%, Wales 4.78% and Northern Ireland 2.85%. It was also decided that actual testing capacity should be based on 80% of the total theoretical capacity of the system. The 80% capacity figure represents an international industry guideline, this is used as a 'rule of thumb' measure for operationally sustainable utilisation in large, high throughput labs. Lateral Flow Devices were allocated to DAs at the point of procurement based on population shares for each nation to use based on their policy decisions. If required, DAs could request additional procurement beyond their allocated percentage. The Testing programme supported DAs when their need for testing capacity went beyond this allocation. An example of this was in September 2021 when Northern Ireland experienced levels of PCR test demand significantly above their Barnett allocation of lab capacity. The Testing programme agreed to double the operational lab capacity for Northern Ireland and increase test booking slots for a period of time to help cope with the increase in demand."

5.35. NHSTT and later UKHSA worked in partnership with the DAs, who received a population share of testing programme capacity in lieu of the consequential funding they would otherwise receive from health spending in England. Test allocations for each nation were monitored by the Demand Modelling and S&OP parts of the Testing Ops team and were based on the volume assigned from each procurement and tests already dispatched to ensure all nations had access to their allocation.

5.36. Representatives of the DAs were embedded into the NHSTT supply chain teams and attended all routine meetings as part of ongoing process in addition to DA-specific meetings. There were weekly DA Policy and Operations meetings to discuss emerging policy and operational issues including PCR testing capacity, LFD test procurement, and if there were any related to supply chain and logistics. A daily S&OP meeting took place, including the DA representatives, to discuss supply and demand for PCR and LFD tests. These meetings were in addition to weekly meetings held between the four nations' health ministers to discuss critical issues, which would have been hosted by DHSC.

5.37. There were planned weekly meetings between DA representatives and NHSTT (and later UKHSA), but contact was regular and flexible. There were several occasions when DAs swapped LFD kits with each other and with England, however this was not

typical. At times of extremely high demand, DAs provided some of their share of PCR testing capacity to support each other and England, by agreement.

5.38. DAs could request additional procurement beyond their agreed allocated percentage, if required, along with appropriate funding, from the DA Support Team within Testing Ops. DAs were responsible for prioritising and setting out the criteria for eligibility for the testing of individuals in their own populations. DAs were responsible for managing their own stock levels, which was necessary because of the expiry dates associated with elements of PCR sample collection kits and LFDs.

B. Demand modelling

5.39. Demand modelling is often based on historical data, but – as the Inquiry will appreciate - in the first year of the pandemic there was no year-on-year data that allowed for comparison, or to estimate the increase in infection rate that may increase demand for tests. UKHSA understands that, from March 2020, COCTT working in DHSC Commercial were trying to gain almost real time understanding of stocks and supplies across the NHS network. However, the developing knowledge about COVID-19 and the course of the disease, global challenges in obtaining supplies, the speed and feasibility of scaling lab capacity, and policy changes, all made demand modelling challenging.

5.40. Elements factored in to demand modelling included:

5.40.1. Historical test demand.

5.40.2. Policy guidance.

5.40.3. Cohort information (population size and demographics)

5.40.4. Communications and press coverage impacts (the tone of press coverage impacted people's motivation to place orders for tests).

5.40.5. Prevalence factors (modelling the relationship of test demand to changes in infection rates for each use case, for example care homes and NHS workers).

5.40.6. Seasonality (time of year, school holidays and work patterns) - This is a common factor in demand for consumer products as people's social and working patterns change. For testing specifically, back to school periods could mean greater messaging for parents to test in the family and would often see a correlation to infection rates in the following seven to fourteen days.

5.40.7. Events (including Bank Holidays, celebratory events) - for similar reasons set out in respect of seasonality.

5.40.8. Behavioural insight - The more that was known about what people were doing from surveillance research, the better the supply chain teams were able to predict how a change would impact their testing.

5.40.9. Product and Operational requirements (type of product available, pack sizes, delivery timelines).

5.41. Every procurement business case needed to set out the demand reasoning, based on the above criteria. The supply chain teams would have regular discussions with the Investment Board, with business case representatives from demand modelling, commercial teams and finance teams.

5.42. The demand forecast for the ordering of PCR tests was firstly constructed from policy driven decisions and availability. There were numerous meetings of the various teams involved in the management of the supply, which varied through the Relevant Period. The frequency of S&OP meetings varied from daily to weekly at different points in the Relevant Period. As the pandemic progressed, more information became available to support the demand modelling approaches but in all cases the changing characteristics of the pathogen were unpredictable.

5.43. The demand forecast was converted into a dispatch plan. This process was aimed at giving an overarching view of all movement and fulfilment requirements for the procurement, distribution, and/or collection of tests, including internal transfers between different distribution centres. These plans had to take into account demand, expiry date of the tests, any need for quarantine, along with allocating the correct test stock to maximise usage and availability to be ordered, whilst limiting waste.

5.44. The demand plan was then compared to inventory positions. The demand modelling and S&OP teams in Testing Ops would calculate how much stock was in each warehouse from the supplies received and the supplies distributed, and would forecast further stock requirements based on the policy applicable at the time, i.e. for instance, if the policy was to have capacity to process up to 800,000 PCR tests a day, the available stock and lab capacity would have been assessed against whether there was capacity in the end-to-end process to meet that demand. The process was aimed at ensuring stock was sent to the desired recipient or organisation, in accordance with the applicable policy, at the correct time, and at the agreed frequency.

5.45. At the height of the pandemic in 2020 and 2021, weekly forecasting was conducted for the following 12 weeks, then a monthly re-forecast of the full financial year. As necessary, forecasts were updated more frequently than weekly in line with new policy announcements and/or the prevalence of COVID-19 at the time. The Testing Ops team could not forecast the likely volume of tests over extended periods of time. Through 2021, it remained challenging to forecast demand for tests **[Exhibit: SC/107 INQ000514395; Exhibit: SC/108 INQ000514397; Exhibit: SC/109 INQ000514396]**.

5.46. As PCR sample collection kits were made up of different components, kitting plans were required to identify which components of the PCR sample collection kit were required and available in the stock held to assemble a full PCR sample collection kit for onward distribution through the distribution channels (explained above).

5.47. The Testing Ops team responsible for PCR capacity management would share a forecast of the demand, broken down by the use cases (as applicable at the time). The team created a kitting plan based on the forecasted demand and required stock levels for the PCR sample collection kit components. The team needed to send the requirements to the team responsible for PCR procurement, who ordered PCR sample collection kit componentry to meet the kitting plans' requirements, taking into account the lab capacity to process the volume of tests.

5.48. Testing Ops shared a forecast of the demand for PCR sample collection kits with supply partners, broken down by use-case and/or kit-type over the prospective 12 weeks.

5.49. Over time, Testing Ops were able to incorporate greater detail into anticipating demand for PCR sample collection kits due to the fact that feedback from the labs, gave the teams greater understanding of the demands. Information from the Laboratory Information Management System (also referred to as LIMS) that were processing PCR testing kits would inform Testing Ops about potential requirements for tests. A daily leadership call, “QuadOps”, took place with representatives from groups with responsibility for labs, delivery, commercial and finance. The daily call was used to assess overall PCR supply and demand and identify whether any limits were needed.

5.50. In respect of LFDs, real time data was available of orders being placed by settings (including care homes and prisons) through SalesForce or by members of the public ordering through the online portal.

5.51. The Operational Coordination and Prioritisation Board was the forum in operation in 2021 and up to February 2022. This was a forum which integrated operating decision making across NHSTT on the allocation of available capacity in support of local areas. UKHSA's Testing Supply and Demand Management team were responsible for demand modelling and is described in **[Exhibit: SC/110 INQ000421931]**.

SECTION 6. UKHSA'S REVIEW OF CONTRACTS

6.1. UKHSA does not repeat the summary of the UKHSA 2022 Review here.

6.2. In response to the Inquiry's questions, UKHSA has identified 2,244 contracts within the Relevant Period and relating to COVID-19. UKHSA anticipated that contracts for PCR and LFD testing, within the Inquiry's definition, would have been categorised as "Science" and "Logistics & Operations". To answer the Inquiry's questions requires reviewing every contract and the underlying contractual documentation, where available, which would be challenging and resource intensive. Taking a proportionate approach, by applying a contract value (not contract spend) threshold of £300,000 per contract allowed UKHSA to analyse PCR and LFD contracts by retaining 99.7% of the contract value for "Science" and "Logistics & Operations" but proportionately limiting consideration to 324 contracts awarded to 123 suppliers **[Exhibit: SC/111 INQ000514414]**.

6.3. DHSC's Standard Terms and Conditions for the Supply of Goods, and for Services were used for 108 contracts awarded, including those awarded pursuant to regulation 32. DHSC's Standard Terms and Conditions included:

6.3.1. Default provisions;

6.3.2. Payment processes, including refunds or non-payments;

6.3.3. Provisions on consequences for late performance or non-performance;

6.3.4. Mechanisms for ordering;

6.3.5. Termination clauses which covered expiry and incomplete/failed performance.

6.4. 21 contracts had additional specific clauses added to the DHSC standard terms, where there would normally be a Legal check but where UKHSA has not been able to confirm. The purpose of additional clauses was context specific.

6.5. 162 contracts identified were awarded pursuant to a framework agreement (under regulation 33). 13 contracts were awarded under PHE terms and conditions. Five contracts were awarded on suppliers' terms: three of which were for logistics (warehousing, kitting, and distribution) and two for PCR consumables, reagents and equipment. Seven contracts were based on purchase order terms and conditions. There were 10 contracts where DPS terms and conditions were used. There were three supplier contracts where UKHSA has been unable to find the contracts' terms and conditions.

6.6. Of the 324 contracts analysed by UKHSA:

6.6.1. 248 of contracts contained default provisions;

6.6.2. 127 contracts included terms on how payments would be refunded in the event of default/underperformance;

6.6.3. 128 contracts included provisions specifying which party bore the burden of checking technical specifications of goods;

6.6.4. 128 contracts included provisions specifying consequences for late delivery of goods;

6.6.5. 99 contracts included consequences of misrepresentation regarding the contractor, manufacturer or type or quality of the goods themselves;

6.6.6. 129 contracts included mechanisms for the increase or decrease of the volumes of goods ordered;

6.6.7. 250 contracts included an ability to end a contract for default, convenience, underperformance or late performance;

6.6.8. 204 contracts included other provisions permitting the necessary flexibility to address changed or changing circumstances during the period of the contract;

6.6.9. 1.2% of contracts (4) were terminated;

6.6.10. 39.5% of contracts (128) were awarded pursuant to regulation 32.

6.7. All but one of the LFD contracts were awarded through third party representatives, and not directly to manufacturers.

SECTION 7. CONTRACT MONITORING AND MANAGEMENT

7.1. Contract management comprises of operational management (including the operations of the labs, which is dealt with in the Science and Technical Statement) and commercial contract management.

7.2. The Contract Performance and Supplier Management Team ("**CPSM**") was established in the late summer of 2020, initially under DHSC but then under NHSTT. This team had responsibility for contract classification and contract management assurance.

7.3. Commercial contract management was led by the Commercial Teams in the applicable period. Each contract was classified under the Cabinet Office Model Services Contract Guidance and based on their complexity, risk and overall spend. The process to determine contract classification was a based on the Cabinet Office/GCO classification tool. The classification then determined the level of contract management resource required to manage that contract. Complex contracts required a more intensive level of ongoing contract management than less complex or transactional arrangements. In practice, application of this model and resource varied.

7.4. Contract management involves monitoring whether the essential elements of the contract were being performed. If performance issues were identified, improvement actions would be taken. These actions would be tracked against progress and rated red, amber, green. The data relating to performance issues would be included as part of Commercial senior leadership team reporting to ensure the relevant actions were being progressed and successfully completed.

7.5. The systems in place for monitoring the performance of a contract awarded varied between types of contracts. However, without reviewing each contract and all the associated documentation generated by contract management arrangements, it is not possible to confirm that each and every contract for a particular type of testing product or service had exactly the same monitoring arrangements in place and nor would they be expected to, given that contracts are managed according to their size, complexity, risk, nature of product or service, and value.

7.6. Where UKHSA has undertaken reviews and supporting investigations into the contract monitoring arrangements in respect of testing contracts, UKHSA noted that the arrangements for contract management were not as robust as would have been expected in non-emergency times, for instance UKHSA noted that there is incomplete documentation held for some contracts. Areas for improvement in contract management has fed into UKHSA's lessons learned and its 2024-2029 Commercial Strategy **[Exhibit: SC/112 INQ000421934]**.

7.7. UKHSA launched its UKHSA Contract Management Playbook in June 2022 **[Exhibit: SC/113 INQ000514402]**. It provides detailed guidance for contract managers as to how each classification should be managed, in accordance with the minimum standards set by the GCF. The UKHSA Contract Management Playbook provides access to a full suite of tailored UKHSA templates (including the contract classification tool) to support end-to-end contract management.

7.8. UKHSA contracts are classified into four groups: Gold, Silver, Bronze & Transactional. This classification determines the approach to contract management based on value, complexity, and risks associated with the contract. The UKHSA Contract Management Playbook provides detailed guidance for Contract Managers as to how each classification should be managed, in accordance with the standards set by the GCF.

7.9. UKHSA Commercial requires staff responsible for managing contracts were trained and accredited at the appropriate level. All relevant commercial staff have been accredited to at least foundation level of the Contract Management Capability Programme ("**CMCP**"), with contract managers of the most important "Gold" and "Silver" contracts currently undergoing accreditation at Practitioner or Expert level as appropriate. UKHSA Commercial continues to build contract management capability. It aims educate the wider organisation, in addition to the relevant commercial staff, on operational contract management, as well as commercial contract management. Recent restructuring of the Commercial Sourcing & Delivery function has taken place to ensure a specific focus on contract management delivery.

SECTION 8. SECTION 8: UKHSA'S APPROACH TO PROCUREMENT POST-PANDEMIC

8.1. As explained earlier in this statement, DHSC is the lead Government body for pandemic preparedness. UKHSA has an important and often specific contribution to

make in relation to the response to future pandemics. Government priorities for UKHSA, as set out in annual remit letters, include building upon the expertise developed during the COVID-19 pandemic. UKHSA is committed to learning from the COVID-19 pandemic, including in relation to procurement and commercial practice.

8.2. UKHSA provides scientific and clinical expertise as well as operational and commercial skills to support, initiate and deliver work within its public health remit to contribute to pandemic preparedness and response, however decisions on funding levels to boost capacity and research, both before and during incidents, rightly sit with the government of the day. Risk appetites can vary with circumstances and there are always competing spending priorities.

8.3. It is an obvious point that the next pandemic may involve a pathogen with very different characteristics to those previously encountered and require different policy, operational and commercial responses. In looking forward, UKHSA seeks to utilise its available resources to build capabilities that are pathogen-agnostic, flexible and capable of being scaled up as needed, subject to funding and the ability of markets to supply at the pace and scale required in a pandemic situation.

8.4. UKHSA routinely responds to public health threats. Many of the capabilities which enable this work were established within PHE prior to the pandemic. UKHSA has built and continues to build on these capabilities through, for example, strengthening our work on pathogen genomics to enable the characterisation of pathogens and of transmission pathways, the development and validation of diagnostic tools, the development and evaluation of countermeasures, domestic and international surveillance, and data modelling and analytics.

8.5. UKHSA's strong technical and clinical expertise is complemented by enhanced commercial capability to support the operational response to public health threats with as much speed and efficiency as possible. The experience of collaborating with industry during COVID-19 and responding at speed to policy decisions, as well as the opportunities offered by the Procurement Act 2023, have informed development of the UKHSA's Commercial Strategy **[Exhibit: SC/112 INQ000421934 above].**

8.6. Published in April 2024, the Commercial Strategy covers the period from 2024 to 2029. It sets out how UKHSA will prepare commercially to respond to a public health threat (including a future pandemic). While the strategy speaks to the width of

UKHSA's remit, what follows is directed towards pandemic preparedness and response and in particular diagnostic testing.

8.7. The Commercial Strategy focuses on five priorities each of which objectively respond to opportunities identified during the COVID-19 pandemic. These are stronger partnerships, effective commercial delivery, growth and innovation, operational excellence and people and commercial capability. Development of the strategy drew upon reviews and audits of pandemic commercial practice, as well as consultation with stakeholders, industry partners and commercial colleagues across the health system, and internal reviews.

8.8. The Commercial Strategy offers a flexible framework to scale a pandemic response at pace where requirements are known or can be predicted and to work with industry to develop new capabilities where these are needed. However, the scale and pace of the response will be conditioned by the availability of funding, the market's capacity to meet greatly increased domestic and global demand, and the resilience of international supply chains to the stress and disruption caused by a pandemic.

8.9. The purpose of the Commercial Strategy is to enable delivery of UKHSA's Strategic Plan, including preparations for and response to a future pandemic. The strategy is linked to the scientific work that has been and is being undertaken by UKHSA and it is important to have some sense of that work when considering how UKHSA will operate in the future in its commercial activities. UKHSA has kept in mind however that the Inquiry is likely to want to consider what lessons may arise from the science and technical work on testing in Module 7.

A. Innovative Science

8.10. Having the scientific capability to characterise the risk of a novel pathogen and to develop interventions and technologies to respond is at the core of pandemic response. Innovation between pandemics can improve our preparedness significantly but work will always be needed at the time of response. This requires the routine and robust availability of specialist staffing with in-depth technical knowledge

and scientific facilities, which must be built up in "peacetime" and developed alongside industry and commercial partners.

8.11. UKHSA's scientific expertise informs product development (in terms of diagnostic technologies and vaccines) and the prioritisation of new research and development into diagnostic and vaccine development and their evaluation **[Exhibit: SC/114 INQ000235220].** There are policy frameworks globally which seek to prioritise pathogens of pandemic potential, such as WHO's "Pathogens prioritization: a scientific framework for epidemic and pandemic research preparedness". UKHSA has been commissioned by the Cabinet Office, as part of the implementation of the National Biological Security Strategy to develop a specific UK-focussed approach to identifying priority pathogen families to inform decisions on research and development funding to protect health from biological risks. This work will also guide UKHSA's scientific activity, as well as inform market engagement by UKHSA Commercial and potential commercial partnerships.

8.12. This work also supports the 100 Days Mission, specifically, the ambition to ensure rapid availability of diagnostic tools and clinical countermeasures in a new pandemic.

B. Stronger partnerships

8.13. The Covid-19 pandemic showed that any future response will require a rapid and safe scale up of services and the procurement of consumable products, as well as the development of new technologies where these are needed to respond to an unfamiliar pathogen. Government will need to develop relationships with commercial partners who could be ready to deliver in the early stages of a response.

8.14. The Inquiry is familiar with the *Technical Report on the COVID-19 Pandemic in the UK* ("**Technical Report**") **[Exhibit: SC/115 INQ000203933]** published by the Office of the CMO on 1 December 2022 and prepared by the CMOs and DCMOs of all four nations, the Government Chief Scientific Adviser, and the NHS National Medical Director with input from distinguished scientists. The Technical Report is intended to inform the thinking of future CMOs, GCSAs, National Medical Directors and public health leaders. UKHSA personnel contributed to many of its chapters.

8.15. Chapter 6 of the Technical Report concerns "Testing". It explains that the "core capabilities needed to deliver effective testing at scale across the UK" included "product development: progressing concepts from idea generation through to market entry", "high throughput lab capacity", "access to a national distribution network", and "supply chain and logistics expertise".

8.16. The capabilities realised during the COVID-19 pandemic by accelerated innovation in diagnostics and vaccines and the development of a national testing infrastructure, in addition to the innovative science noted at para 1.9 above required collaboration with industry and significant public and private sector funding (see above in paragraphs 4.92, 4.93, 4.122, 4.125, 4.126, and the UKHSA Science and Technical Statement).

8.17. Replicating and developing the capabilities identified in the Technical Report requires the routine maintenance of relationships and the establishment of strategic partnerships with industry, academia and non-governmental organisations. This provides for the exchange of scientific information which can, in turn, inform, for example, testing technologies and product development for novel pathogens. That helps to meet the practical challenges of procuring products at speed and to scale.

8.18. We did not have sufficiently developed and appropriately structured existing relationships with industry bodies at the beginning of the pandemic that could enable the rapid development of necessary technologies. UKHSA is therefore developing a framework for strategic partnerships with industry partners, learning from the responsive commercial practice adopted during COVID-19 and our experience of engaging with industry since. The framework includes:

8.18.1. Pilots with selected organisations which will lead to collaboration agreements appropriate to the nature of the partnership. We are also working with other parts of government including the Office of Life Sciences to develop a cross-government partnership strategy for the life sciences sector.

8.18.2. Establishment of a market scanning team by the Commercial Directorate to assess market capabilities, resources and readiness, and provide insights into market developments and emerging innovation, which can then be integrated into UKHSA policy and planning.

8.18.3. Targeted market engagement to help develop and nurture potential suppliers able to meet gaps in capability, provide better value service, and make

supply chains more resilient to disruption, in preparation for future pandemics.

8.18.4. Engagement with industry including mechanisms to ensure that any use of public money for this purpose is transparent and based on robust commercial scrutiny and governance. UKHSA is developing guidelines for commercial engagement, to protect against conflicts of interest and a UKHSA Commercial Partnership Charter, which will establish common values, aims and behaviours for collaboration between the agency and industry. These guidelines will be finalised by the first half of 2025.

8.19. A lack of prior pandemic planning for rapid response engagement between government and industry reduced the opportunities in the early response to COVID-19. As industry will again be a key partner in any future pandemic response, UKHSA will work with industry so that they understand the likely requirements and roles and can prepare accordingly. Taking that step will help markets align with policies, direct innovation and prepare supply chains to increase overall resilience.

C. Effective commercial delivery

8.16. The COVID-19 pandemic highlighted the importance of having critical contracts already in place, having undergone sufficient scrutiny, and with sufficient budget rapidly available to mount an effective and efficient response. UKHSA is developing scalable contracts for key services and has access to a range of commercial frameworks that will enable a more effective response to a future pandemic.

8.17. Commercial frameworks provide quicker routes to market and assurance of value for money. UKHSA has access to its own UKHSA National Microbiology Framework and Crown Commercial Service frameworks, as well as frameworks set up by other public, academic, and private sector bodies. Learning from the pandemic, frameworks now have contractual financial capacity sufficient to meet the greater demand experienced in pandemic conditions. This was not the case with the pre-pandemic frameworks operated by PHE, which were more focused on routine business, but could not support a pandemic response.

8.18. A key change offered by the Procurement Act 2023 is the ability to establish open frameworks where suppliers can be added throughout the life of the framework, giving access to more innovative or better value capabilities, as well as simplified procedures

and greater flexibility to design procurements. This legislation, while applicable to public procurement generally, should make a material difference to the UK's ability to procure key testing technologies in any future pandemic. It also introduces new performance reporting and transparency requirements for all contracts over £5 million.

8.19. The Public Services (Social Value) Act 2012 requires public authorities to have regard to economic, social and environmental well-being in connection with public services contracts and for connected purposes. This legislation gives UKHSA a basis to use "Social Value clauses" in contracts to help address the health inequities experienced by marginalised or vulnerable groups. UKHSA will also embed measures to meet environmental sustainability and reduce carbon emissions and integrate an enhanced approach to quality management into contracts (see the UKHSA Health Protection Governance and Quality Strategy launched on 31 January 2024 **[Exhibit: SC/116 INQ000421935]**).

Scaling systems

8.20. UKHSA's operational challenge is to seek to provide an appropriate but proportionate response capacity to meet its required remit and using the resources it is provided. In the case of a diagnostic service to be built at pace, UKHSA's approach currently includes continuing to maintain a high-quality scientific estate to support the rapid development, assessment and validation of diagnostic tools to deliver core capacity. The scientific estate, including the facilities at Porton Down, Colindale and regional network, is discussed in the Science and Technology statement. UKHSA has led validation of LFD and PCR tests for MPox and avian influenza viruses. This work requires regular investment to ensure facilities are fit, incorporate the latest technology and retain a stable, appropriately trained workforce. For population level response wider contractual and delivery arrangements are required nationally.

8.21. From a commercial perspective the speed at which a response capacity can be scaled up to meet the demands of an emerging pandemic depend upon the level of pre-pandemic readiness. There is and would be significant cost to adopting an "always on" system that could move for example from conducting a few tests to hundreds of thousands in a matter of weeks. Facilities, testing equipment and stocks may only be appropriate for a narrow range of known pathogens and have a relatively short shelf life (a typical COVID-19 LFD for example has approximately a 2-year window for use) and therefore, even if maintained, need regular replacement. The recruitment of

suitably qualified and trained staff in sufficient numbers at short notice is a significant hurdle.

8.22. There is therefore a fundamental choice for the elected government of the day around their risk appetite and spending priorities. While resourcing is a matter for the elected government, a level of funding is needed to ensure the balance is maintained sufficiently to enable the stand-up of services within the timescales required. There is a trade-off between investment and the pace of stand up. Logically, standing up capability from a low level of readiness which can be expanded further is more expedient, and will be faster and less costly in the immediate term, than scaling from no readiness at all.

D. Growth and innovation

8.23. To better be able to respond to a future pandemic, the United Kingdom will want access to innovative products and UKHSA would seek to have processes in place to surge its testing and evaluation of such products. UKHSA's business development function works with UKHSA scientists and clinicians and with public and private sector organisations to identify innovations with health benefits that can be brought to commercial scale. These collaborations also generate external income that supports the delivery of UKHSA's health security mission. In particular, the business development function is providing support to two key UKHSA initiatives for pandemic preparedness:

8.23.1. The Vaccines Development and Evaluation Centre ("**VDEC**") is part of UKHSA's core capability for pandemic and epidemic preparedness and response, and also supports endemic disease control. The business development function supports VDEC to work with industry and academia in line with the ambitions in UKHSA's science strategy.

8.23.2. The Diagnostic Accelerator programme has been established to secure learning from the pandemic and advance our preparedness by ensuring more rapid development and roll out of diagnostics tests. It uses UKHSA expertise and insight to support commercial suppliers and test developers in swiftly developing new commercial diagnostics solutions to scale up diagnostics. The Accelerator will allow UKHSA to evaluate and validate diagnostics and new technologies more rapidly when a new pathogen emerges which has the potential to cause a pandemic.

8.24. We have learnt from the COVID-19 pandemic that businesses of all sizes and of widely varied product focus are critical for national response. Business development collaborations also bring Small and Medium Sized Enterprises ("**SME**") into contact with larger enterprises and government to help them develop innovations that can have both public and commercial value. UKHSA is developing an SME Action Plan to increase the share of funding that goes to SMEs as suppliers as well as supporting them to collaborate in business development initiatives, recognising their key role in driving growth and innovation in the wider economy. The SME Action Plan will be published in 2025.

E. Operational excellence

8.25. Effective pandemic procurement requires clearly navigable processes and access points for industry. These processes must also be fair, transparent, clinically safe, and achieve value for money. Although the response to COVID-19 benefited from closer working and greater flexibility in the relationship between suppliers and government (addressed above), consultation with industry has shown that commercial processes can still be onerous or difficult to navigate for many organisations. To improve operational response in the event of a future pandemic while maintaining assurance of fair commercial treatment and value for money, UKHSA has developed, and is continuing to develop, a number of transparent processes, including:

8.25.1. A "Front Door" for industry which provides a single point of access for potential suppliers and industry to contact UKHSA and for the agency to triage offers and process them efficiently and transparently.

8.25.2. A Source 2 Pay system to automate routine procurements so that UKHSA can track funds from source to payment more easily, speed up the "business as usual" procurements that support the agency's day to day work, and realise bulk savings. The system also helps guard against fraud and provides an audit trail of decisions. The first phase of this project has now been completed.

8.26. UKHSA's Investment Governance model seeks to apply proportionate scrutiny to the approval of contract spend with a graduated system of approval thresholds, delegations and Boards. It has streamlined approvals for low value spend, while ensuring that high-value, complex, or higher risk contracts receive greater assurance and approval at a higher threshold. All contracts for professional services and consultancy require Board approval, whatever their value.

8.27. Since the pandemic, UKHSA has used technology to improve its commercial approvals process. The urgency and pace of procurement in the early months of the pandemic as well as the use of different systems by seconded staff resulted in unexpected gaps in the document trail, as already noted above in respect of the Randox contracts awarded in Spring 2020 and noted in the UKHSA 2022 Review of predecessor procurement (see above at paragraphs 1.9 and 4.97).

8.28. UKHSA has now introduced an app and automated workflow for approval of spend cases up to £2 million. Its purpose is to make routine spend approvals more efficient, ensure proper scrutiny and due diligence to obtain good value for public money, maintain a centralised record of contract approvals that is fast and user-friendly and guard against fraud risk.

8.29. The app is a centralised platform for UKHSA commercial staff to submit, view, and make decisions on business cases for low value spend cases where senior commercial and finance staff have final approval authority. Approvers with the appropriate delegation list are automatically selected for review and approval or rejection. Once a decision is made, all relevant parties are notified, all decisions are logged, and documents saved for audit purposes, with the approval email serving as evidence to proceed. The app is only functional for low value approvals; all other approvals are routed through the Investment Governance Model via the appropriate approval boards.

F. People and capability

8.30. PHE had few Civil Service commercial staff at the outset of the COVID-19 pandemic and NHSTT and UKHSA were new organisations which had to develop commercial practice while responding to a global crisis. In both contexts there was an urgent and extensive recruitment requirement with the majority of roles needing to be filled with personnel from the private sector. These new recruits offered additional and necessary capacity but had a steep learning curve to familiarise themselves with public procurement procedures, which differ from private sector practice. Onboarding, induction and training was undertaken at pace, but it took time to match relevant expertise to roles.

8.31. We have recruited and are developing further a professional Civil Service commercial function in UKHSA to provide the core commercial capacity to respond to a future pandemic. We would approach the GCO to supplement our core capacity with

commercial professionals seconded from other government departments, should this be required. Contingent labour would only be recruited once GCO options had been explored.

8.32. Since it became operational, the Commercial Directorate has developed policies, processes, and guidance to improve commercial capability and assure quality:

8.32.1. The Directorate's contract management staff are accredited to at least the foundation level of the cross-government CMCP as set out above, with contract managers responsible for the highest value "gold" and "silver" contracts expected to attain the higher Practitioner and Expert levels.

8.32.2. Commercial staff are undertaking training on how to make best use of new provisions in the Procurement Act 2023 when the latter comes into force on 24 February 2025.

8.32.3. The Commercial Directorate is undertaking activities to increase commercial awareness for non-commercial staff, with additional training for staff in specific roles, particularly contract management. This will strengthen communication, handover, and clarity in the division of roles and responsibilities between scientific, operational and commercial teams and improve the quality and speed of response to a future pandemic.

8.33. The cross-government Commercial Continuous Improvement Assessment Framework ("**CCIAF**") measures the commercial capability of all government departments and agencies. As explained in UKHSA's Commercial Strategy, UKHSA's first cross-government CCIAF assessment conducted in April 2022 confirmed that the agency's procurement and commercial systems were "Good" and that UKHSA was considered to be at "Developing" stage in the other themes. UKHSA has put in place a progressive Improvement Plan which sets out measures to attain a "Good" overall rating by the end of financial year 2024-25. The longer term aim is to achieve "Better" overall by the end of the period covered by the commercial strategy.

Conclusion

8.34. It may be helpful in concluding this section to give a recent example of the interplay between the scientific and commercial elements of UKHSA's work when responding to a public health incident.

8.35. Earlier this year, there was an outbreak of Highly Pathogenic Avian Influenza ("**HPAI**") H5N1 in US cattle herds. In response, UKHSA set up a contingency planning team.

As well as developing surveillance and case management protocols specific to this risk, UKHSA commercial teams undertook a market analysis of available diagnostic tools which the UKHSA scientific teams were able to rapidly validate against new and known strains of avian influenza. Based on this work, the Commercial Directorate then worked through procurement frameworks at speed to procure a small number of LFDs that could be deployed in the event of a UK outbreak to support investigation and outbreak management.

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: 03 December 2024