UK Health Security Agency

Final report of the Serious Untoward Incident investigation into the misreporting of PCR test results by the Immensa Health Clinic Limited

Contents

Glossary of terms used in this report

Assay	An assay is a laboratory test to find and measure the amount of a specific substance. Sometimes used to describe the coronavirus (COVID-19) tests carried out in a laboratory.
Audit Form	The formal documentation used by an independent team of clinical scientists working within NHS Test and Trace to audit and review laboratories' documents to assess quality, including the clinical sensitivity and specificity of their testing process.
Commercial Monitoring	The scheduled monitoring of contract delivery led by the NHSTT Commercial Team which is standard practice for all contracts.
Contain Programme	The function within NHSTT responsible for all aspects of tracing within the Test and Trace programme.
Daily Laboratory Monitoring	Daily monitoring of laboratories by the NHSTT Laboratory Operations Team, primarily used to allocate the distribution of samples to different laboratories to optimise meeting demand but also to understand any trends in laboratory performance[1].
Dante	Dante Labs Inc. is the parent company of Immensa.
DHSC	The Department of Health and Social Care is the UK government department responsible for health and adult social care policy in England. Beyond England, it is also responsible for elements of policy which are not otherwise devolved to the Scottish Government, Welsh Government or Northern Ireland Executive.
First Contract	The awarding of the first contract to Immensa by the UK government in 2020.
Framework	The Public Health England National Microbiology Framework was created in 2021. Lot 4 was for the provision "clinical laboratory diagnostic testing services". Providers interested in contracts offered within Lot 4 needed to be evaluated and pre-approved onto the Framework before bidding for contracts.
Incorrect reporting or misreporting	Immensa incorrectly reported COVID-19 PCR test results in September and October 2021 with the effect that there was an excess of 'false negative results' as defined by the US National

[1] Health and Safety Executive workbook Investigating accidents and incidents: A workbook for employers, unions, safety representatives and safety professionals HSG245

	Institute for Health ("A test result that indicates that a person does not have a specific disease or condition when the person actually does have the disease or condition").
Immediate Cause	The most obvious reason why an adverse event happens.
Immensa	Immensa Health Clinic Limited is a private clinical diagnostic laboratory provider that was contracted by NHS Test and Trace (UKHSA from 1 October 2021) to process COVID-19 PCR Tests. It is the UK subsidiary of Dante Labs Inc.
Immensa's Wolverhampton laboratory	The Wolverhampton laboratory is a private clinical diagnostic laboratory run by Immensa, located at the University of Wolverhampton Science Park.
Dante's Italian laboratory	Dante's Italian laboratory refers to a private clinical diagnostic laboratory located in Italy, run by Dante and used by Immensa to process COVID-19 PCR tests.
Missed Opportunity	In a SUI investigation, a missed opportunity describes a situation where reasonable management decisions were not taken or processes not put in place when they could have been. They are 'missed opportunities' because, if they had been implemented, the decisions or processes would have reduced the likelihood of the SUI occurring or mitigated the harm arising from it. In identifying missed opportunities, an investigating panel must be mindful it has the benefit of hindsight. In identifying a missed opportunity, the Panel considered the context at the time of the situation and applied a principle of reasonableness, taking account of the guidance and advice available at the time.
NHSTT	NHS Test and Trace was the organisation responsible for delivering the contact tracing programme for the COVID-19 pandemic. NHSTT was a team within DHSC and some activities, such as awarding contracts, were done in DHSC's name.
NHSTT Reviews	Activities undertaken within NHSTT to identify the causes of concerns raised about people who had positive lateral flow device (LFD) results followed by a negative PCR result in September and October 2021. These transferred into UKHSA from 1 October 2021.
NHSTT Testing Programme	The function within NHSTT responsible for all aspects of testing within the Test and Trace programme.

Operational Readiness Checklist	A document used by the NHSTT Laboratory Operations Team to assess if laboratory providers were operationally ready to deliver testing services.
PCR tests	The polymerase chain reaction (PCR) test for COVID-19 is a molecular test that analyses a specimen, looking for genetic material (ribonucleic acid or RNA) of SARS-CoV-2, the virus that causes COVID-19.
Performance Improvement Monitoring	The as-required monitoring of the performance improvement activities of each laboratory provider undertaken by the NHSTT Laboratory Operations Team.
PHE	Public Health England was an executive agency of the Department of Health and Social Care in England which began operating on 1 April 2013 to protect and improve health and wellbeing and reduce health inequalities.
Root Cause Analysis	A root cause analysis is a method for understanding the underlying cause of an incident. A RCA examines the incident's causal factors, focusing on why, how and when they occurred. The Health and Safety Executive define root cause as “an initiating event or failing from which all other causes or failings spring. Root causes are generally management, planning or organisational failings.”[2]
Second Contract	The awarding of the second contract to Immensa by the UK government in 2021.
Service Operations Centre	The SOC was a team within NHSTT primarily focused on resolving issues and incidents in the testing and tracing programmes.
SUI	UKHSA defines a Serious Untoward Incident as an adverse incident arising from its activity which results in a significant impact on the public’s health. The UKHSA CEO is responsible for determining when an adverse incident occurring in UKHSA constitutes a SUI and the Panel have interpreted its role as confirming to the CEO whether this was a SUI.
SUI Investigation Panel	The group of UKHSA employees, not involved in the incident, convened and led by the SUI chair to investigate the SUI.

[2] Health and Safety Executive workbook Investigating accidents and incidents: A workbook for employers, unions, safety representatives and safety professionals HSG245

Thresholds	Thresholds are set on the laboratory testing equipment to determine the amount of virus that would signal a positive result for COVID-19 on a PCR test.
UKAS	The United Kingdom Accreditation Service is the national accreditation body recognised by the British government to assess the competence of organisations that provide certification, testing, inspection and calibration services.
UKHSA	The UK Health Security Agency is the UK government agency responsible since October 2021 for England-wide public health protection and infectious disease capability, replacing Public Health England and NHS Test and Trace. It is an executive agency of the Department of Health and Social Care.
UKHSA Testing Group	This is the name used in the report for the team within NHSTT that ran the Testing Programme. The name changed several times during 2020 and 2021 but the report uses this name throughout, including for when it moved across to UKHSA on 1 October 2021.

Use of footnotes in this report

Footnotes are used throughout this report to indicate the evidence used to support the findings and recommendations. Where sources are available online, links are given.

Executive summary

1. On 15 October 2021, the UK Health Security Agency (UKHSA) announced NHS Test and Trace (NHSTT) had suspended testing operations provided by Immensa Health Clinic Limited at its Wolverhampton laboratory with immediate effect. Immensa is a private company providing clinical diagnostic laboratory services in the UK. UKHSA was created on 1 October from the merger of Public Health England (PHE) and NHSTT (including the Joint Biosecurity Centre).

2. There were 2 contracts with Immensa in 2020 and 2021, both of which provided additional polymerase chain reaction (PCR) testing capacity as part of the network of mass community testing for coronavirus (COVID-19). NHSTT had created this network at incredible speed in 2020 and 2021.

3. In September and October 2021, there had been reports of individuals having positive lateral flow device (LFD) results followed by a negative result from a confirmatory PCR test. Both the LFD and PCR tests were used to identify if an individual had COVID-19. If a confirmatory PCR test returned positive, the individual would be required to isolate. NHSTT, and subsequently UKHSA, undertook reviews into the reports of these concerns.

4. When UKHSA identified there was a problem with the PCR test results from the Immensa Wolverhampton laboratory on 12 October 2021, it immediately suspended testing at this laboratory. Immensa then undertook an internal review which identified that the immediate cause of the misreporting of PCR test results was the incorrect setting of the threshold levels for reporting positive/negative results by their staff in their laboratory in Wolverhampton. These findings were endorsed by the UKHSA Laboratory Validation Team (formerly within NHSTT).

5. UKHSA published its initial estimate that the error led to about 10% (representing circa 43,000 results) of the 417,00 tests performed by Immensa's Wolverhampton laboratory between 2 September and 12 October 2021 being incorrectly reported as negative when they may have been positive.

6. Although the immediate cause of the incident was within Immensa's Wolverhampton laboratory, the UKHSA Chief Executive Officer (CEO) decided that this incident should also be investigated under UKHSA's Serious Untoward Incident (SUI) policy and procedures. A Panel was established to undertake the investigation and this is its final report, submitted to the CEO of UKHSA. The SUI investigation has engaged with other pieces of work UKHSA has undertaken related to the incident, including understanding the public health impact and the

changes made to management systems within UKHSA which are published alongside this report.

7. In line with the UKHSA SUI policy, the investigation's terms of reference were focused on the role of the management systems in UKHSA and its predecessors, not the actions of Immensa. The Panel undertook a structured investigation drawing on interviews with witnesses and documents provided.

8. In summary, this SUI investigation has confirmed that this incident was a SUI under UKHSA's policy and procedures as it has identified failings, including missed opportunities[33] across multiple NHSTT management systems, which transferred into UKHSA on 1 October 2021. However, it cannot be concluded that any single weakness and/or gap in the contracting and monitoring by NHSTT could have prevented Immensa's errors in setting of the threshold levels for reporting positive/negative results of PCR samples for COVID-19.

9. The SUI investigation has looked at the role of NHSTT and UKHSA in:

(a) the procuring and awarding of the First and Second Contracts by the UK government with Immensa (in 2020 and 2021 respectively), their mobilisation and monitoring of Immensa's activity; and

(b) NHSTT's Reviews into concerns that were raised relating to individuals who had positive LFD results followed by negative PCR results in September and October 2021 and assessments of the potential public health impact associated with these concerns.

10. The Panel carried out a root cause analysis. This considered what processes or decisions could have potentially prevented or mitigated the incorrect reporting of negative PCR results or enabled UKHSA to identify earlier the incorrect setting of thresholds by Immensa. It also explored missed opportunities that could have reduced the likelihood of error within the laboratory or concluded the NHSTT Reviews more quickly.

11. NHSTT was not directly responsible for the incorrect setting of thresholds for reporting positive/negative results of PCR samples for COVID-19 within Immensa's Wolverhampton laboratory. However, as the responsible part of government for the mass clinical diagnostic testing service for COVID-19 and the holder of the contracts with Immensa, NHSTT had a responsibility to be assured of the quality of Immensa's service to the public through the way contracts were awarded and their delivery monitored.

[3] The term 'missed opportunity' is defined in the glossary of terms on page 2.

12. The Panel has found that, through the procurement and delivery of the First and Second Contracts:

- changes were made in the approach to the procurement of laboratory services that appropriately reflected the changing context of the pandemic – the First Contract was awarded under emergency procurement regulations while the Second Contract was awarded through a mini-tender within a procurement framework
- a process for assuring NHSTT of the quality of the clinical diagnostic laboratory services prior to mobilisation was quickly designed and implemented at the start of the pandemic which enabled COVID-19 testing to rapidly scale-up – however, there were no plans in NHSTT to transition to the standard laboratory accreditation process run by The UK Accreditation Body (UKAS) after the initial first wave of the pandemic
- there were weaknesses in the design of the quality assurance and governance mechanisms in relation to testing services operated by NHSTT, including some of the commercial processes for awarding and monitoring both the First and Second Contracts
- among staff in NHSTT, there were different understandings of key elements of NHSTT's remit in relation to Immensa and similar laboratories, including the role of accreditation

13. Several teams in NHSTT looked into the concerns that had been raised[44]. There were gaps and weaknesses in the NHSTT organisational processes and governance for reviewing these concerns which meant it took too long to identify the immediate cause of the incident in the Immensa Wolverhampton laboratory, though there was no deliberate decision to withhold information. The Panel found no evidence of deliberate decisions in NHSTT not to act on the concerns. However, information was available at the time that, had it been identified and considered in the NHSTT Reviews, would have led to an earlier identification that Immensa staff had set incorrect threshold levels in the Wolverhampton laboratory.

14. The regional UKHSA teams and the local public health system have stated that they received insufficient communications about the progress and outcome of the investigations, and they felt disempowered in seeking to protect the health of their communities. They felt that their concerns were not being investigated with the priority they believed was required.

15. Immediately after the immediate cause of the incident had been identified, UKHSA made improvements to the systems for monitoring and overseeing the performance of the laboratory

[4] Several pieces of work were carried out by different NHSTT teams in September and early October 2021 to look into the concerns being raised. These are referred to in this report as the 'NHSTT Reviews'.

network and additional requirements were put in place for laboratories joining the network. UKHSA also made changes to its incident management processes.

16. The recommendations in this report build on these changes by addressing the missed opportunities found in the engagement of Immensa's Wolverhampton laboratory into NHSTT's laboratory network and in the NHSTT Reviews into the concerns in September and October 2021. The key theme of these recommendations is to create a single system that combines multiple existing mechanisms and is designed for investigating issues and incidents with clear governance, supported by a culture of open communications and structured investigation processes.

Chapter 1: Introduction and scene setting

This chapter describes the Serious Untoward Incident (SUI) associated with the incorrect setting of the threshold levels by Immensa (section 1.2) and the nature of this investigation commissioned by the UK Health Security Agency (UKHSA) (section 1.3). The context and background to the SUI is described in sections 1.4 (Testing for COVID-19 during the pandemic), 1.5 (Legal and regulatory context), and 1.6 (Governance)

1.1 Introduction

1.1.1 UKHSA, and its precursor organisations Public Health England (PHE) and NHS Test and Trace (NHSTT), have all been central to the public health response to protect the nation's health during COVID-19. From providing expert advice to the public and the operational logistics of the vaccination programme, to the creation of a mass diagnostic and contact tracing service, the contribution and hard work of the staff across the organisations has been remarkable.

1.1.2 Globally, the pandemic has required nations to expand their laboratory capacity at an unprecedented speed and scale. There has been widespread innovation in testing technologies and processes, with the first test for coronavirus (COVID-19) assured in the UK by PHE in January 2020. NHSTT subsequently developed a laboratory network that has undertaken almost 150 million polymerase chain reaction (PCR) tests, with a peak capacity of over 580,000 PCR tests per day.

1.1.3 Through this investigation, the SUI Investigation Panel has been struck by the commitment and professionalism of staff with a universal wish to improve where things have not gone as well as planned. The Panel's investigation has taken place alongside the rapid learning from this incident and emerging conclusions have been shared throughout.

1.1.4 Staff interviewed during the investigation have talked about their profound regret for the impact the incident had on the lives of those affected, their family and friends.

1.2 The Serious Untoward Incident

1.2.1 On 15 October 2021, UKHSA announced it had suspended testing operations provided by the private company Immensa Health Clinic Limited at its laboratory in Wolverhampton, as a consequence of a series of internal NHSTT (and from 1 October 2021, UKHSA) Reviews into reports of people receiving negative PCR test results after a positive lateral flow device (LFD) test.

1.2.2 The Panel identified multiple teams within NHSTT which had looked into the concerns that had been raised about people receiving negative PCR test results after a positive LFD test in the period from mid-September to mid-October. In this report, these activities are collectively referred to as the "NHSTT Reviews".

1.2.3 The Service Operations Centre (SOC) in NHSTT was notified of many of these inquiries and investigations. It led many of the individual reviews into concerns and it then designated this issue as a formal incident on 22 September 2021. A more detailed description of the range of actions taken within NHSTT and the links with PHE are set out in paragraph 1.3.6. The concerns were increasingly being reported from the South West and elsewhere in the UK, across media outlets and on social media as well as within internal channels and from local authorities in September 2021.

1.2.4 UKHSA's announcement on 15 October 2021 stated "an estimated 43,000 people may have been given incorrect negative PCR test results between 2 September and 12 October, mostly in the South West of England"[5]. The geographical distribution of this estimated number extends elsewhere in England, particularly the South East, and Wales. Between 2 September and 12 October 2021, Immensa's Wolverhampton laboratory undertook 417,000 PCR tests. The estimate of circa 43,000 results being likely to have been incorrectly reported was calculated as the difference between UKHSA's projection that 52,000 tests would have been expected to be reported positive from the 417,000 (based on the results coming from asymptomatic workplace and care home testing and symptomatic drive-in or walk-in centre testing) and the 9,000 results that were reported positive. UKHSA has revised its estimate to circa 39,000 incorrect negative results from the laboratory than would have been expected had the samples been processed elsewhere during this period.

1.2.5 The UKHSA Chief Executive Officer (CEO) Jenny Harries also announced a SUI investigation into incorrect reporting of negative PCR results from the Immensa Wolverhampton laboratory. The investigation has been run under the UKHSA's SUI Policy and Procedures. Initially it was conducted in parallel to the UKHSA public health incident response led by the UKHSA Incident Director which was then closed down as the immediate public health requirements had been met.

1.2.6 The SUI investigation is one strand of the work undertaken by UKHSA in light of this incident. The following further actions have been undertaken separately in parallel:

a) A UKHSA Incident Management Team was set up and led an analysis of the public health impact.

[5] Testing at private lab suspended following NHS Test and Trace investigation

b) The UKHSA Commercial Team has led discussions with Immensa about re-analysis of the data collected from the tests.

c) The Public Health and Clinical Oversight team within UKHSA Testing Group undertook a desktop review into their processes in investigating the concerns and made changes to the Testing Group's systems.

d) The Validation Team within UKHSA Testing Group produced a report following a visit to the Wolverhampton laboratory on 18 October 2021 that covered the immediate cause within the laboratory.

e) The UKHSA Testing Group and Commercial Team have implemented changes since 12 October 2021 to enable earlier detection of any similar laboratory errors wherever possible. These are detailed in a report from UKHSA that is published alongside this report.

1.3 Scope of the investigation and its terms of reference

1.3.1 Under UKHSA's SUI Policy and Procedure, the CEO is accountable for ensuring that there is a management led investigation of all SUIs. The terms of reference and membership of the SUI Investigation Panel, detailed in Appendix 1, were agreed with the CEO and noted at Executive Committee on 28 October 2021.

1.3.2 UKHSA's SUI policy "covers all adverse incidents (whether healthcare-related or not) occurring in UK Health Security Agency (UKHSA) that arise from a UKHSA activity". Although the serious incident did not happen within UKHSA but was a contracted activity for UKHSA, the CEO decided that this should be investigated using the SUI policy and procedures.

1.3.3 The terms of reference for the SUI investigation covered the requirements set out in the UKHSA SUI procedures, including the need to create a complete and accurate timeline of what happened when; to explore the root cause of the incident; and to put forward recommendations on the lessons to be learnt. UKHSA's actions after the 15 October 2021 were out of the scope of this investigation.

1.3.4 The chair of UKHSA appointed Richard Gleave, UKHSA Director of Science Strategy and Development, as the chair of the SUI Investigation Panel. Five members were appointed from within UKHSA representing commercial, laboratory safety and clinical governance, incident management and data analytics. Two external advisers were appointed to provide perspectives about the regional and local public health system and the NHS laboratory system.

1.3.5 The Secretary of State also appointed Kate Lampard, Non-Executive Director at DHSC, to oversee the work of the SUI Investigation Panel, ensuring terms of reference were adhered to through a robust and rigorous methodology.

1.3.6 As set out in the UKHSA SUI procedures, the work of the SUI Investigation Panel is underpinned by the principle of objective and independent review to ensure robust recommendations within the final report. The chair was from a directorate not involved in the incident. None of the Panel members had been involved in the NHSTT Testing Programme nor in the events within the scope of the SUI investigation.

1.3.7 The SUI investigation covered 2 distinct areas of review related to the incorrect reporting of PCR tests by Immensa, detailed below:

(a) NHSTT's work to procure and award 2 contracts between the UK government and Immensa, and its mobilisation and monitoring of Immensa's activity under these contracts. The contracts in question were:

- the contract between Immensa and the UK government to provide PCR testing between September 2020 to March 2021, awarded via emergency regulations, referred to in this report as the "First Contract" – under the First Contract, samples were:
  (a) shipped and tested at a laboratory in Italy, run by Immensa's parent company Dante throughout the whole period of the First Contract
  (b) from December 2020 onwards, tested at Immensa's Wolverhampton laboratory
- the contract between Immensa and the UK government to provide surge PCR testing commencing September 2021, awarded under PHE's National Microbiology Framework (2021) Lot 4, referred to in this report as the "Second Contract" – under the Second Contract, PCR tests were conducted at Immensa's Wolverhampton laboratory; the Second Contract was suspended on 12 October 2021 as a result of NHSTT's Review into the concerns raised about people receiving a negative PCR test result after a positive LFD test

(b) NHSTT's Reviews into concerns raised relating to individuals who had a negative PCR test result after a positive LFD test result and assessing the potential public health impact associated with these concerns:

- the main NHSTT Review was led within NHSTT Testing by the SOC, but further analysis and enquiries were undertaken by other teams involving both PHE and NHSTT staff prior to 15 October 2021

- from early October 2021, a Public Health Incident Management Team was set up to focus on the public health elements of the reports of people receiving negative PCR test results after a positive LFD test.

1.3.8 In line with the UKHSA SUI procedures, the SUI Investigation Panel established:

- a timeline of the events relevant to the incident as set out in the terms of reference
- an examination of the relevant policies, management systems and processes within UKHSA (and its predecessor bodies)
- an analysis to identify any root cause within UKHSA that contributed to the immediate cause of the incorrect reporting of PCR results at the Immensa Wolverhampton laboratory

1.3.9 Appendix 2 provides more detail of the SUI Investigation Panel's approach to data collection and analysis, as well as the additional commissions and requests for information to develop a detailed understanding of the 2 areas described in paragraph 1.3.6. The SUI Investigation Panel has received assurance from the staff in UKHSA Testing Group that, to the best of their knowledge, they have shared all relevant documentation.

1.3.10 The SUI Investigation Panel has engaged many organisations, including the Welsh Government and NHS, local government in England and UKAS. Through these discussions, the SUI Investigation Panel has sought to appreciate the impact of the incident on the lived experience of members of the public.

1.3.11 As the SUI Investigation Panel progressed its investigation, areas of potential further inquiry arose. Decisions on whether to pursue these further areas of inquiry, which were approved by the CEO of UKHSA, were based on the criteria of whether the potential areas related directly to the SUI, gave rise to any further public health risks or were likely to result in lessons being learned. Two matters that were excluded from the investigation were the genomic sequence testing Immensa undertook for NHSTT, and the private commercial testing for travel and other purposes undertaken by Immensa. Whilst Immensa's delivery of private commercial testing was out-of-scope, the SUI Investigation Panel did explore the direct links between the SUI and Immensa's application to be accredited by UKAS for private commercial testing, discussed in Chapter 2, section 2.4.

1.4 Testing for COVID-19 during the pandemic

1.4.1 In August 2020, the then Secretary of State for Health and Social Care, Matt Hancock, announced the creation of a new executive agency, later known as UKHSA. The organisation brought together PHE, NHSTT and the analytical capability of the Joint Biosecurity Centre

under a single leadership team, with a single command structure and operating model to contribute to the COVID-19 pandemic response. On 1 October 2021, the functions of NHSTT and the health protection functions of PHE were formally combined to create UKHSA, reporting into the Department of Health and Social Care (DHSC).

1.4.2 PHE had been established in 2013 as the expert national public health agency with a remit across the 3 domains of public health (health protection, health improvement and public health functions within healthcare). PHE provided the public health laboratory functions in England, as well as specific diagnostic testing for COVID-19, and these functions transferred to UKHSA.

1.4.3 NHSTT was established in May 2020 to identify, contain and control COVID-19 through increasing testing and contact tracing, supported by data analysis, and partnership working with local government. NHSTT was a function within DHSC. Accordingly, the formal governance elements of NHSTT, including the awarding of contracts, were formally under the accountability and governance of DHSC.

1.4.4 In April 2020, the Secretary of State published a COVID-19 Testing Plan which set out an approach through a number of “pillars” to rapidly increase capacity for COVID-19 testing. This continues to be the basis of the approach to testing in the UK.

a) Pillar 1: PCR testing undertaken in PHE (subsequently UKHSA) laboratories and in NHS hospitals.

b) Pillar 2: PCR testing stream responsible for ‘direct to public’ swab testing of the general population, as set out in government guidelines[6]. This testing was undertaken as described in paragraph 1.4.5 below.

c) Pillars 3 and 4: included other types of testing and PCR testing for surveillance programmes. For these pillars, NHSTT commissioned PCR testing from the laboratories used for Pillar 2 testing.

1.4.5 The main delivery channel for the Pillar 2 testing provision was through the NHSTT Lighthouse Laboratories. These were mainly new laboratories created through collaborations between the government and different organisations (including the private sector, universities and NHS trusts) to provide high-throughput testing for COVID-19 PCR tests only. Alongside Lighthouse Laboratories were “partner laboratories” which provided “a high volume of testing for NHS Test and Trace alongside its usual activities acquired through partnership agreements with

[6] NHS Test and Trace: how we test your samples

the public, private and academic sectors"[7]. Immensa was one of these "partners" providing Pillar 2 testing for NHSTT – often as surge testing (proactive testing of non-symptomatic people in areas with rising case numbers) – alongside other testing activity for other organisations.

1.4.6 The incorrect reporting of PCR test results by Immensa investigated by the Panel is the only SUI identified across Pillar 2 at the time of writing.

1.4.7 The procurement methods for acquiring COVID-19 PCR testing capacity have evolved since the start of the pandemic, mirroring the UK government's pandemic response transitioning from an initial emergency response to establishing a 'living with COVID-19' strategy.

1.4.8 Early contracts could be awarded to providers through the utilisation of regulation 32(2)(c) of the Public Contracts Regulations 2015 (often called the "emergency regulation"). The First Contract was awarded through this process, which does not require a competitive process and assessment.

1.4.9 Later contracts used a widely-adopted cross-government procurement process which created a framework of qualified providers and runs specific rapid mini-tenders from the approved provider list. The Public Health England National Microbiology Framework, referred to in this report as the "Framework", was created in 2021. The goal of Lot 4 was to select providers of what the Framework called "Clinical Laboratory Diagnostic Testing Services". Providers interested in contracts offered within Lot 4 needed to be evaluated to ensure they were capable of meeting NHSTT's requirements and pre-approved for inclusion on the Framework before they were able to bid for contracts. The approval process required evidence to be submitted for review by the commercial and scientific teams within NHSTT. Mini-tenders were also launched through the Framework, such as the procurement mechanism used to award multiple providers' contracts for surge capacity in the summer of 2021. Mini-tenders are often used to quickly award refined contracts to suppliers who have already been approved on the overarching framework agreement. As Immensa was successful in its application to be on the Framework, the Second Contract was a result of the mini-tender. The Second Contract was operational from 2 September to 12 October 2021.

[7] NHS Test and Trace: how we test your samples

1.5 Legal and regulatory context for clinical diagnostic testing and incident response

1.5.1 The regulatory landscape for clinical diagnostic testing and pathology services is complex and requires interpretation. There is no definitive publication that sets out all the responsibilities of different organisations (see Appendix 3 for more detail). This is directly relevant to the SUI as it provides the foundations of the Panel's understanding of the accreditation status of Immensa's Wolverhampton laboratory – where the error led to the incorrect reporting of PCR tests – and the internal NHSTT methods of oversight of the laboratory, especially with regard to quality assurance of Immensa.

1.5.2 The 2006 NHS Act gives government bodies (DHSC, NHSTT, PHE, UKHSA, and so on), as well as the NHS, the power to award contracts to laboratory providers for diagnostic testing under Section 2A (clause 2b). This is the legal basis for NHSTT contracting with Immensa.

1.5.3 The core responsibility to run a high-quality and safe laboratory rests with the owner and operator of the laboratory, whether they are a government body, part of the NHS, an academic institution or a private company. Thus, there were clear responsibilities on Immensa for assuring the quality and safety of the testing at their Wolverhampton laboratory. In parallel, and outside the scope of the SUI Investigation, NHSTT and PHE had this type of responsibility as the provider of laboratories processing COVID-19 PCR tests.

1.5.4 The SUI Investigation Panel has been unable to locate an explicit statement about NHSTT's responsibilities for quality assurance when contracting with private providers to provide clinical diagnostic laboratory services, but understands Section 2A (clause 2b) provides the legal basis for its work. This states that "the Secretary of State must take such steps as the Secretary of State considers appropriate for the purpose of protecting the public in England from disease or other dangers to health [including] providing microbiological or other technical services (whether in laboratories or otherwise)".

1.5.5 Across the globe, the accreditation of laboratories is the key means by which quality is demonstrated and assured. Under statute, UKAS is the national accreditation body for the UK[8]. It describes accreditation as the mechanism to "provide confidence that accredited organisations are competent and can be trusted to deliver promised levels of performance and protection for the products and services we rely on"[9]. However, it is not a legal requirement for laboratories to be accredited to commence or undertake clinical pathology activities.

[8] Conformity assessment and accreditation policy

[9] Accreditation

1.5.6 The main international standard that forms the basis of accreditation of medical laboratories is ISO15189, though other standards cover other related types of laboratory work. For example, NHSTT referred to ISO17025 typically used in assurance of competence for testing and calibration laboratories. UKAS have a structured process to assess applicants and, if they meet the standards, applicants are formally accredited for named locations and tests.

1.5.7 In the early phases of the COVID-19 pandemic, UKAS paused performing on-site assessments for applicants and implemented remote assessments. On-site assessments resumed after an initial 6-month period (in September and October 2020) resulting in a significant backlog in accreditation visits. Arrangements for restarting visits to hospital sites where there were vulnerable patients were further delayed to ensure alignment with the government guidance at the time. Immensa's Wolverhampton laboratory was a stand-alone laboratory on a science park, rather than a hospital site, and as such would have been applicable for an on-site assessment and not limited by government guidance related to hospitals. Immensa was an applicant for UKAS accreditation through the scheme for private and commercial testing work.

1.5.8 There were several aspects to NHSTT's approach to accreditation that have been set out in section 2.4. The SUI Investigation Panel were unable to locate a definitive written policy or process on accreditation for COVID-19 PCR testing undertaken in NHSTT commissioned laboratories prior to mid-October 2021.

1.5.9 DHSC agreed with UKAS to establish a separate 3-stage accreditation process for privately funded COVID-19 PCR testing undertaken for purposes outside the scope of the NHSTT testing programme. This policy took effect from January 2021[10] with ownership of the policy becoming the responsibility of NHSTT in April 2021. This was predominantly for travel and work-related purposes and was mainly undertaken by privately owned laboratories. The legal basis of the DHSC and UKAS process was set out in The Health Protection (Coronavirus, Testing Requirements and Standards) (England) Regulations 2020. Immensa was a provider of private testing and so was required to follow this process for the private tests.

1.5.10 Evidence presented to the SUI Investigation Panel was not always clear about the difference between the 2 accreditation pathways, and the requirements on Immensa. The SUI investigation terms of reference are clear that privately funded tests are out of scope and the private pathways are only referred to when relevant to the SUI.

[10] Accreditation for COVID-19 testing and Government publishes list of approved COVID-19 test providers

1.5.11 In addition to accreditation, providers and commissioners of laboratories put in place a range of additional quality systems and assurance processes for clinical diagnostic testing and pathology services. NHS organisations have some statutory requirements for specific quality systems, such as clinical governance, but other quality systems, such as quality improvement methodologies are not a legal requirement but are widely-accepted best practice processes[11]. PHE and NHSTT both decided to adopt the statutory quality systems, such as accreditation and clinical governance, and most of the best practice requirements of the NHS, even though they were not NHS organisations.

1.5.12 The terms of reference also required the SUI Investigation Panel to look into the NHSTT Reviews into the concerns being raised about COVID-19 test results in September and October 2021. The need to undertake the NHSTT Reviews was required in order for NHSTT to fulfil its responsibilities, on behalf of the Secretary of State, under the requirements of the Civil Contingencies Act 2004, providing the legal basis for emergency preparedness and incident response.

1.5.13 The Cabinet Office's Principle of Emergency Preparedness describes the need for all government organisations "being properly prepared and having clarity of roles and responsibilities". In addition to the listed principles, enablers of good incident management include reporting and escalation within a culture of cooperation and communication, relying on a degree of transparency and trust. Within incident response, clarity on roles, responsibilities and the associated chains of command is crucial.

1.5.14 Whilst there is a legal requirement on NHSTT to investigate the concerns as part of the incident response, there is no legal framework prescribing the process in which these types of concerns should be reviewed. The SUI Investigation Panel understand these processes took place within the context of best practice for handling issues and potential incidents as part of a formal incident response.

1.6 Governance for clinical diagnostic testing for COVID-19 and incident response

1.6.1 As required by the terms of reference, the SUI Investigation Panel needed to understand the context in which management decisions were taken. Thus, the Panel asked interviewees and commissioned from the relevant parties details of the governance across NHSTT, PHE and then subsequently UKHSA.

[11] Pathology Quality Assurance Review and RCP The regulatory landscape for pathology services

1.6.2 The First and Second Contracts with Immensa were governed by NHSTT within the Testing Programme (see paragraphs 1.6.5 and 1.6.7). This programme was a distinct strand of work within DHSC from April 2020, though was not listed on the Government Major Projects Portfolio but was reviewed by the Infrastructure and Projects Authority[12].

1.6.3 Overall governance of government bodies derives from the designated role of the Accounting Officer, as described by the Cabinet Office's Code of Practice and the Treasury's Managing Public Money[13]. This role is personally responsible and accountable to Parliament for the use of public money and stewardship of public assets, providing assurance of high standards of probity in the management of public funds and assets. The Permanent Secretary is the Principal Accounting Officer for DHSC and she or he formally appoints Delegated Accounting Officers for specific elements of the DHSC budget.

1.6.4 The accounting officers of the bodies involved in the Testing Programme were:

- Public Health England – Duncan Selbie (CEO) until 31 August 2020, Michael Brodie (CEO) 1 September 2020 to 30 September 2021
- NHS Test and Trace through DHSC – David Williams (Second Permanent Secretary, DHSC until April 2021), Shona Dunn (Second Permanent Secretary, DHSC current) was the AO for NHSTT until 31 March 2022, Dido Harding (Executive Chair, NHSTT) had operational and executive leadership until 7 May 2021 and did not hold the accounting officer role
- Jenny Harries (CEO) started on 1 April 2021 as designate CEO and was Senior Responsible Owner and delegated budget holder for NHSTT from 7 May 2021 for the remainder of 2021 to 2022 – from 1 October 2021, UKHSA came into existence and Jenny Harries became the AO for the former PHE health protection budgets that moved into UKHSA

1.6.5 NHSTT had 4 main elements which were testing, tracing, contain and the Joint Biosecurity Centre. The Testing Programme was a distinct part of NHSTT with a designated senior leader from its inception until the move into UKHSA. It had a remit across the UK for ensuring that COVID-19 PCR samples were rapidly tested and accurate and that results were made available to the relevant stakeholders in the 4 nations of the UK. A formal agreement to deliver NHSTT activity on behalf of the devolved administrations was made in May 2021 and included the activity of both the NHSTT and Welsh Government's Test Trace and Protect programme.

[12] DHSC GMPP July 2021 DHSC Government Major Projects Portfolio Data March 2021

[13] Managing public money

1.6.6 Within the Testing Programme, specific responsibilities changed over the 18 months to October 2021. The following summary describes the position in September 2021 (prior to the transition from NHSTT into UKHSA) of the teams that were either engaged with Immensa or relevant to activity associated with Immensa:

- Laboratory Operations Team which ran the daily operation of testing through the network of laboratories – this team had primary responsibility for daily review of the metrics on laboratory quality and performance; the formal mobilisation of laboratories was part of Laboratory Operations team from early December 2020 but prior to that sat with a team that led on the new diagnostics workstream and had its responsibilities reallocated to other teams
- Validation Team which undertook the formal validation of providers meeting the required quality standards – this team were responsible for signing off each laboratories' Audit Report
- Public Health and Clinical Oversight Team (PHCO) in the Testing Programme which led on quality and clinical governance for most of the testing programme
- Operational Performance Team which ran the scorecard of performance metrics across NHSTT

Operational Engagement and Resilience Team which led on engagement with the devolved administrations and running the incident management systems in testing and tracing.

1.6.7 Across NHSTT and PHE, different teams were responsible for leading on incident responses, depending on the nature of the incident concerned. As a result, incident responses were subject to differing governance arrangements and accountabilities The NHSTT Reviews into concerns of people receiving a negative PCR test result after a positive LFD test was governed by NHSTT, within inputs from PHE and then brought together from 1 October 2021 within UKHSA.

1.6.8 Across the COVID-19 pandemic response of NHSTT and PHE, the specific responsibilities for reviewing and investigating issues and incidents changed over the 18 months to October 2021. The following summary describes the position in September 2021, prior to transition into UKHSA:

Service Operations Centre (SOC)

This focused on resolving issues and incidents in the Testing and Tracing Programmes, and possibly wider across NHSTT. The reporting arrangements for the SOC changed several times in 2020 and 2021. In September and October 2021, it reported through the Chief Operating Officer for Testing Programme to the designate Chief Executive of UKHSA.

National COVID-19 Response Centre (NCRC)

A coordinating function to bring together the local and national response across NHSTT, Joint Biosecurity Centre and PHE. This linked into the structures running the wider cross-government COVID-19 response. NCRC's approach was informed by PHE's National Incident and Emergency Response Plan adapted to the specific needs of the COVID-19 response, with its governance reporting to the Director General for Contain in NHSTT, separate to the Testing Programme.

PHE Enhanced Incident Management Team (PHE IMT)

The PHE IMT coordinated the PHE enhanced incident response and reported into NCRC. It was run by the PHE Strategic Response Director (SRD), who was also the Chief Medical Adviser to NHSTT. Formally the SRD (and the Strategic Response Group) reported through the Medical Director to the PHE CEO and then subsequently into the UKHSA CEO.

Chapter 2: NHSTT's award and management of the First and Second Contracts with Immensa

This chapter focuses on both the contracts NHSTT awarded to Immensa in 2020 and 2021. The chronologies of the contracts are set out (sections 2.1 and 2.2). Informed by the timeline, the root cause analysis and the identification of lessons, the SUI investigation has focused on 4 elements of the contracting process as follows:

a) Procurement and contracting (section 2.3)

b) Laboratory accreditation (section 2.4)

c) Laboratory validation and mobilisation (section 2.5)

d) Monitoring of contract delivery (section 2.6)

These sections review the management actions of NHSTT in relation to both the contracts and considers when and where decisions were taken. The SUI Investigation Panel has also considered where decisions were not taken but under reasonable management processes could have been expected, as these likely represent 'missed opportunities'. Each section concludes with recommended lessons for UKHSA.

2.1 Chronology of key events associated with the First Contract between NHSTT and Immensa

2.1.1 The chronology of key events in the First Contract are summarised in Table 2.1.

2.1.2 As described in paragraph 1.3.6, the First Contract awarded in July 2020 under the emergency regulations (Regulation 32) to Immensa for PCR testing ran formally from 4 September 2020 to 31 March 2021. This is consistent with many contracts for services associated with the early response to the pandemic. PCR testing was originally delivered by a laboratory in Italy run by Dante, the parent company of Immensa. In December 2020, under the terms of the contract, Immensa commenced delivery for PCR testing at the Wolverhampton laboratory. Both sites were then used through into March 2021 as part of this contract.

2.1.3 The First Contract was awarded as part of the preparations for the anticipated second wave of COVID-19 from autumn 2020 onwards, in which the capacity across the laboratory network was being increased. It was recognised that there would be an increase in the likelihood of transmission, especially with children and young people returning to education. Increasing testing capacity was a major priority of both NHSTT and the UK government. In

December 2020, the UK government was considering whether further restrictions might be needed to limit the transmission of COVID-19 and, in January 2021, the third set of such measures were introduced. The SUI Investigation Panel has been told that there were significant expectations throughout the pandemic, particularly during the rise in cases, about increasing testing capacity.

Table 2.1: Timeline associated with the First Contract with Immensa

Date	Event	SUI Investigation Panel's Comments
14 June 2020	First samples processed at Dante's Italian laboratory.	Date in spreadsheet data shared by Testing Programme. Some witnesses have reported a later start date.
27 July 2020	Audit Report for Dante's Italian laboratory signed off by Validation Team.	The Audit Report was an internal form developed by NHSTT for all laboratories prior to mobilisation based on the ISO standards used in UKAS's accreditation.
4 September 2020	Contract signed following 4 weeks of negotiations between NHSTT Commercial and Immensa, leading to formal finance approval on 3 September.	Contract awarded under Emergency Regulation 32.
7 September 2020	Completed Audit Report for Dante's Italian laboratory sent from Validation Team to NHSTT's Laboratory Operations Team.	Date on Audit Report.
26 November 2020	Design Authority Review (DAR) Group run by Laboratory Operations Team formally approve Dante's Italian laboratory for operational mobilisation.	The DAR Group was the formal process for approving laboratories as ready to be mobilised and this meeting was one of its last as from early December onwards, the Laboratory Operations Team used different processes.
Between 9 December and 16 December 2020	A separate Audit Report for Immensa's Wolverhampton laboratory commenced. It records 4 dates when partial updates for completing the Audit Report from Immensa was provided.	The Audit Report was not completed and thus not ready to be approved at this stage. There may have been a further date when information was provided – the Audit Report records additions dated 7 December 2020 but the chronological sequence suggests this may refer to information provided on 7 January 2021.

20 December 2020	Leader of Validation Team sends email confirming Immensa's Wolverhampton laboratory was approved to commence. The email states "lab is approved to receive samples for testing on the understanding that the full verification report and outstanding documents to support the national audit checklist will follow early next week w/c 21st December [2020]".	The reference to the "national audit checklist" is to the Audit Report and this was not completed in the week commencing 21 December (and was not completed for the remainder of the First Contract through to the end March 2021).
12 January 2021	First samples sent to Immensa's Wolverhampton laboratory.	Date in spreadsheet data shared by Testing Programme
Between 7 January and 15 March 2021	Seven instances of the Audit Report being updated to reflect new information from Immensa but none of these complete the Audit Report ready for approval.	The Audit Report was not approved or signed off for the duration of the contract to end of March 2021. Possible additional instance on 7 January 2021 to add in new information from Immensa but the record is unclear whether this was incorrectly dated and may have occurred prior to 20 December 2020 email.
31 January 2021	Sun newspaper ran a story about unsafe and poor working practices at the Wolverhampton laboratory.	NHSTT Laboratory Operations Team have told the SUI Investigation Panel that there was a strong operational response with Immensa to this news story. NHSTT SOC confirmed an investigation into the incident was conducted and the contracts of the temporary staff involved were terminated.
24 February 2021	Welsh Government's Test Trace and Protect (TTP) team raised a concern with NHSTT about positivity rate at Immensa Wolverhampton laboratory that had been raised by Public Health Wales (PHW). "The above observations raise significant concerns about a range of laboratory processes (including quality control of output) at the Immensa lab,	The concern was an observed unusually high positivity rate in results from asymptomatic care home staff in North Wales which went to the Immensa laboratory.

	which may be leading to inaccurate results."	
3 March 2021	Last samples processed at Dante's Italian laboratory.	Date in spreadsheet data shared by Testing Programme.
10 March 2021	Welsh Government TTP team chase NHSTT and NHSTT acknowledged receipt following day.	No comments.
17 and 25 March 2021	NHSTT respond to TTP saying that they have investigated and there are no issues.	NHSTT's response was "Based on the data reviewed, Immensa has followed their diagnostic standard operating procedure and the results are in accordance with the Instructions for Use (IFU) of the PerkinElmer® SARS-CoV-2 Real-time RT-PCR 3501-0010 assay".
31 March 2021	Formal end of the First Contract.	Date from contract documentation.
21 April 2021	PHW microbiologists follow up the March response and provide a detailed report on their concerns to NHSTT.	No response to this has been found in PHW or NHSTT.
12 May 2021	Final samples processed at Immensa's Wolverhampton laboratory.	Date in spreadsheet data shared by Testing Programme.

2.2 Chronology of key events associated with the Second Contract between DHSC/NHSTT/UKHSA and Immensa

2.2.1 The chronology of key events in the Second Contract are set out in Table 2.2

2.2.2 In autumn 2020, NHSTT put in place a competitive process to create a list of laboratory providers that could then be used to meet surges in demand for COVID-19 PCR testing. Thus a standard procurement process of creating a framework of approved suppliers from which mini-tenders could be run was set up. PHE were already developing a framework and NHSTT decided to add an additional lot for clinical laboratory diagnostics services – thus Lot 4 of the National Microbiology Framework was created by February 2021. Immensa was one of the approved laboratory providers on the Lot 4 Framework list.

2.2.3 The Second Contract was awarded during a period when the UK government pandemic response had moved into a new phase, with the vaccination programme making rapid progress.

The planning of the surge capacity procurement occurred as the Delta variant had caused a third wave of cases, with concerns about a rise in demand for COVID-19 PCR testing similar to the rises that had occurred in autumn 2020. The surge capacity procurement was set up to address this, in the context of delays to the phased opening of extra PCR testing capacity from the new Rosalind Franklin Laboratory.

2.2.4 The Second Contract was the result of the mini-tender for surge testing capacity from the approved laboratory providers who had been approved on Lot 4 of the Framework. Immensa was successful in the mini-tender and commenced testing PCR samples under the Second Contract at its Wolverhampton laboratory on 2 September 2021. The Second Contract was suspended on 12 October 2021 following the identification of incorrect reporting of PCR test results.

Table 2.2: Timeline associated with the Second Contract with Immensa

Date	Event	SUI Investigation Panel Comments
5 November 2020	Launch of the National Microbiology Framework, including Lot 4.	PHE co-ordinated the overall Framework but Lot 4 was led by DHSC/NHSTT.
21 December 2020	Applications to join Lot 4 of the Framework received including one from Immensa.	Immensa indicated that they were willing to seek accreditation through UKAS as part of their accreditation.
11 February 2021	Immensa was one of the laboratories announced going onto the Framework.	NHSTT undertook an assessment of applications against a series of criteria to select the laboratory providers going onto the Framework.
22 March 2021	Immensa Lot 4 Framework contract signed.	No comments.
8 July 2021	Investment Board approval of the case for surge testing.	No comments.
9 July 2021	NHSTT launch mini-tender for surge testing.	This went only to the providers on the Lot 4 Framework list.
16 July 2021	Receipt of bids for the mini-tender including one from Immensa.	Immensa indicated that they were willing to seek accreditation through UKAS as part of their bid.
29 July 2021	NHSTT make decision in principle to award Immensa through this mini-tender process.	NHSTT undertook an assessment of the bids.

30 July 2021	NHSTT and Immensa sign the Second Contract.	This was initially from 4 August to 26 September, with options to extend.
23 August 2021	Variation to amend the performance indicators signed by Immensa 20 August 2021 and DHSC/NHSTT 23 August 2021	The original contract (section 2.4) listed 5 groups of indicators and this was reduced to 2 in the variation (turnaround times and contracted capacity though the void rate is also included).
26 August 2021	Completion of the Audit Report by the Validation Team.	The Audit Report for the Second Contract was a continuation of the Audit Report partially completed for the First Contract.
27 August 2021	Laboratory Operations Team advised by Validation Team that the Audit Report was completed and signed off.	No comments.
31 August 2021	NHSTT Laboratory Operations ran a mobilisation call (also called an 'activation call' for Go Live).	Approval provided based on 2 mitigations about the capacity ramp up plan and validation/verification of Immensa.
1 September 2021	Second Contract extended to 14 November 2021.	No comments.
2 September 2021	First samples processed by Immensa's Wolverhampton laboratory.	Date in spreadsheet data shared by Testing Programme.
12 October 2021	UKHSA instructs Immensa to suspend testing at the Wolverhampton laboratory.	No comments.
15 October 2021	Final group of 2,037 samples processed at Wolverhampton laboratory.	The SUI Investigation Panel's understanding is that these samples were left over from before 12 October.
15 October 2021	UKHSA makes public announcement about suspending testing at Immensa's Wolverhampton laboratory.	No comments.

2.3 Procurement and contracting – NHSTT/DHSC/UKHSA management actions in relation to the First and Second Contracts with Immensa

2.3.1. The legal basis for the laboratory procurement process has been briefly summarised in paragraph 1.4.8 and 1.4.9, with further descriptions found in paragraph 1.6.2, 2.1.2 and 2.2.2. The SUI Investigation Panel established that the First Contract was awarded in the early stages of the pandemic which were led within DHSC, as NHSTT was still being created. Although the names of the teams working within NHSTT changed, the governance for procurement and contracting was that the team which subsequently became NHSTT Laboratory Operations managed the contracts and they received specialist commercial support from the team that subsequently became the NHSTT Commercial team.

2.3.2. The SUI Investigation Panel found that the governance and decision-making processes for procurements became more structured and explicit as the pandemic progressed. For example, there was a clear business case approval process for the NHSTT decision to request tenders for the surge capacity procurement.

2.3.3. The First Contract was awarded using the Emergency Regulations which was in line with government policy at the time – the speed of this process was to make a rapid contribution to delivering the Secretary of State's COVID-19 Testing Plan's[14] goal of rapidly increasing PCR testing capacity. The approach used to award the Second Contract was through usual procurement processes that were consistent with Cabinet Office guidance and the Treasury document Managing Public Money.

2.3.4. The SUI Investigation Panel found the main requirement used to provide assurance of the quality of the laboratory provider was related to accreditation with UKAS. An analysis of the key procurement and contract documents in both contracts (Appendix 4) shows that there were inconsistencies in the documents relating to both contracts.

2.3.5. The 2 contract documents stated that the laboratory provider needed to have accreditation from UKAS but these clauses were not applied. As described in paragraph 1.5.7, it was recognised by DHSC and UKAS that this requirement could not be met to deliver the needs of the pandemic in the early months of the response and so the formal legal position was that laboratory providers needed to confirm that they were willing to gain accreditation from UKAS.

[14] Coronavirus (COVID-19): Scaling up our testing programmes

This confirmation was gained through the laboratory provider answering “yes” or “no” to a specific question as part of the application to Lot 4 National Microbiology Framework and again in the bid for the surge contract – it was made clear that this was a mandatory response and a “no” response would lead to “automatic rejection”.

2.3.6. NHSTT adopted an alternative requirement to that stated within the contract documentation. This was that providers were willing to become accredited, but this was not set out in the contract documents themselves, thus making them inaccurate and inconsistent. This alternative requirement was retained for the first 18 months of the pandemic and was changed after the SUI occurred. Thus practice from October 2021 onwards was that new providers were required to have achieved accreditation prior to commencing COVID-19 PCR testing, while existing providers were encouraged to progress to accreditation as quickly as possible.

2.3.7. The NHSTT Validation Team were not involved in the drafting of contract documentation nor the assessment of applications to be on the Framework list or bids for the surge contract. However, this team were the NHSTT in-house experts on accreditation. The SUI Investigation Panel concluded that involving the NHSTT Validation Team would have been likely to improve the accuracy and consistency in the contract documentation and the assessment of providers and was a missed opportunity. It could be argued that keeping the NHSTT Validation Team separate from producing the contract documentation and assessing bids prevented any compromise to the rigour of the validation process. However, the SUI Investigation Panel concluded that the involvement of the NHSTT Validation Team would have given significant benefit in the precision and consistency of the contract documentation and the decisions on selecting providers and that this would have outweighed any risk from conflict of roles.

2.3.8. The unsuccessful attempts to complete the Audit Report for Immensa’s Wolverhampton laboratory for the First Contract, and the concerns raised by Public Health Wales about positivity rates at the Wolverhampton laboratory, were not part of the discussions at evaluation of the mini-tender. This was consistent with the requirements of the procurement process where only significant failures in past performance could be included in the evaluation of bids. In addition the SUI Investigation Panel considered whether these issues with the First Contract might have meet the provisions of the Cabinet Office’s Procurement Policy Note ‘Taking Account of Suppliers’ Past Performance’ (Action Note 04/15 25 March 2015) when the bids for the Second Contract were being evaluated. It is clear that this was not the case.

2.3.9. The SUI Investigation Panel has found no evidence of ministerial involvement in the procurement or with Immensa and all senior civil servant involvement was in line with the requirements of the procurement processes.

Recommendation 1: UKHSA should ensure that it has consistent documentation when procuring laboratory services. This documentation needs to be specific about key quality requirements from laboratory providers on issues such as accreditation and performance indicators. The documentation should be produced through engagement between clinical and commercial teams.

2.4 Laboratory accreditation: NHSTT/DHSC/UKHSA management actions in relation to the First and Second Contracts with Immensa

2.4.1. There is a consensus in the scientific and health communities that laboratories undertaking testing on human samples in the UK should be accredited, though this not a statutory requirement. As described in paragraph 1.5.5 and 1.5.6 UKAS usually accredit to ISO15189, the standard for medical laboratories. However, COVID-19 PCR tests were new tests and required a new accreditation or the extension of scope of an existing UKAS accreditation. This meant that the process of accreditation for COVID-19 PCR tests would be delayed by several months. DHSC/NHSTT, NHSE and UKAS agreed in May 2020 that it was not possible for laboratories to be accredited for the new COVID-19 PCR tests in the first phase of the pandemic. UKAS stated that laboratory providers would need to obtain their accreditation status as soon as this was practical. UKAS started on-site assessments again in the autumn 2020, though there was a backlog and they were sometimes undertaken remotely. NHSTT did not have a timetable for when it would start to require accreditation from its contracted laboratories, however it became a requirement after the 15 October 2021 announcement of the SUI.

2.4.2. Although the documentation for both the First and Second Contracts with Immensa required laboratories to be accredited, NHSTT developed 2 approaches in lieu of the formal UKAS accreditation process and status. Firstly, for the Second Contract only, laboratory providers were asked to confirm in their bids for the Framework and mini-tender for COVID-19 PCR testing, that they were willing to seek accreditation which has been described in paragraph 2.3.5. The SUI Investigation Panel found NHSTT had no formal process to follow up on the assertions made in the Framework and mini-tender for seeking application to UKAS accreditation.

2.4.3. Secondly, NHSTT required that the NHST Validation Team completed an Audit Report for all laboratory providers. The Audit Report was known by several names, including Audit Checklist, Validation Form or Verification Report. The SUI Investigation Panel was told by former NHSTT staff that in the decision making about whether to award a contract the completed Audit Report was accepted in lieu of accreditation, but this is not the case, as work on the Audit Report started after the decision to award a contract and that contract was signed.

It was finalised prior to mobilisation of provider to start testing. Thus, the Audit Report was not used to determine that the provider was of sufficient quality to be included on the Lot 4 Framework list or for being awarded a contract under the Framework. Instead, the Audit Report was a tool for validation of laboratory providers prior to mobilisation which is covered in more detail in Chapter 2 section 2.5. For Immensa's First Contract, the Audit Form was signed off for the Dante Italian laboratory, but not for the Immensa Wolverhampton laboratory.

2.4.4. There are important differences between the NHSTT Audit Report and UKAS accreditation. The NHS Audit report was an assessment for validating new laboratories against a list of criteria generated by NHSTT at a specific point in time and was completed based on documentary evidence. UKAS's accreditation is an independent evaluation of the competence and capability of the laboratory provider for a specified period of time when the laboratory's accreditation would be reviewed by UKAS. Thus, the requirement for laboratories to gain NHSTT approval through the sign-off of a completed Audit Report was not a substitute for accreditation. Rather it was part of NHSTT's process of deciding that a laboratory was operationally ready to start testing and so was a requirement for mobilisation. The timing of the completion of the Audit Report was prior to the final mobilisation rather than as part of the decision to put a laboratory on the Lot 4 Framework list or to award a contract.

2.4.5. Separate from the NHSTT process in lieu of accreditation, paragraph 1.5.5 explains the accreditation process for laboratories undertaking PCR testing for COVID-19 for private commercial purposes (that is paid by the customer for travel or other purposes) which commenced in January 2021.

2.4.6. Immensa was involved in all these processes. For NHSTT, Immensa confirmed that it was willing to seek accreditation in its application for the Framework and in the bid for surge testing (see paragraph 2.3.6) and there was a completed Audit Report signed off prior to the start of Second Contract but not for the First Contract at the Immensa Wolverhampton laboratory (see 2.3.8). As Immensa also undertook PCR testing for private commercially funded work at the Wolverhampton laboratory, it applied for accreditation for this work on 30 December 2020.

2.4.7. Although the private commercial work is outside the scope of the SUI investigation, the approach to accreditation for the private work is relevant as it was referenced by NHSTT in the work completing the Audit Report in August 2020. Accreditation is awarded on the basis of the specific test(s) being delivered, the method and platform it is undertaken on and the site from which it is being delivered. As such, the accreditation is for the operation of specific manufacturers' tests (or assays) and testing equipment that is the manufacturer is usually named in the accreditation.

2.4.8. Immensa ran 2 different PCR machines – one produced by Nonacus and the other by PerkinElmer. The SUI Investigation Panel understands through conversations with witnesses that Immensa decided to apply for accreditation (a) through the UKAS route set up for private commercial work, which had a set of milestones described above. This did not cover the work done for NHSTT; and (b) they decided to seek accreditation for only the machine on which they planned to undertake private work. Immensa subsequently changed their plans – the original application was for the PerkinElmer machine but on 26 July 2021 Immensa notified UKAS that this was changing to the Nonacus machine and on 17 August 2021 Immensa told UKAS that they were no longer using the PerkinElmer machine for private commercial work and so PerkinElmer was removed from the UKAS accreditation application.

2.4.9. The progress towards accreditation of the Immensa Wolverhampton laboratory was for the private commercial work on the Nonacus machine. The immediate cause of the SUI related to the NHSTT testing programme occurred on the PerkinElmer machine. Thus, the relevance of the progress on accreditation for the Nonacus machine was only of partial value to the Audit Report in deciding on the quality of Immensa's Wolverhampton laboratory.

2.4.10. The formal accreditation process and status of Dante's and Immensa's laboratories was not fully understood by all relevant parties within UKHSA. This is evidenced by the information given to the SUI Investigation Panel described above, the inaccurate statement on Immensa's accreditation status on 15 October 2021 and statements in interviews with all relevant parties during the course of the investigation.

2.4.11. In addition to the Panel's investigation into the UKAS accreditation status, it was noted that the accreditation section of the NHSTT Audit Report stated that the Dante laboratory in Italy was authorised by the Italian government to undertake COVID-19 testing. Authorisation is not the same as accreditation and there is no evidence that NHSTT sought clarity on Dante's accreditation status in relation to ISO15189, which would have come from Accredia, the Italian laboratory accreditation agency. Due to mutual recognition arrangements, accreditation by international organisations is regularly accepted in lieu of UK accreditation. The SUI Investigation Panel has contacted Accredia and established that the Dante Italian laboratory was registered but not accredited with them.

2.4.12 The SUI Investigation Panel have reflected that it would have been extremely challenging for the Wolverhampton laboratory to be accredited by January 2021 when the laboratory started to contribute to delivering the First Contract, even though this was what the contract document required.

2.4.13 Opening up a second laboratory (that is the Immensa Wolverhampton laboratory in addition to the Dante Italian laboratory) to help deliver the First Contract did not require any

changes to the contract or additional contract mechanisms in relation to accreditation. However, starting to send samples to the Immensa Wolverhampton laboratory did require NHSTT to use its mobilisation processes to confirm that any new laboratory was able to commence testing. The SUI Investigation Panel has been told that the NHSTT mobilisation process included completion of the Audit Report in lieu of accreditation. The SUI Investigation Panel has not been shown any evidence which establishes how the decisions on mobilising new laboratories were taken in December 2020 and January 2021 (further information on mobilisation can be found in section 2.5), and as such the email of 20 December which approves the Immensa laboratory for the commencement of testing did not fit within the SUI Investigation Panel's comprehension of the NHSTT mobilisation process. Therefore, the SUI Investigation Panel has concluded that the mobilisation process was not followed in December 2020 as there was no evidence of the completed Audit Report which was required for the approved commencement of testing at the Immensa laboratory for the First Contract.

2.4.14 The SUI Investigation Panel has asked whether any other laboratories started testing without a completed Audit Report and the Testing Group have not been able to provide a definitive answer from their records.

2.4.15 In the section on accreditation within the NHSTT's template for an audit report, it is not clear what the Validation Team required from all laboratories in order to sign off the accreditation section. Thus it was unclear what information NHSTT had about the accreditation position of the Immensa's Wolverhampton laboratory when the email approving mobilisation was sent on 20 December 2020. The SUI Investigation Panel understands from witness interviews that Immensa had made enquiries with UKAS, but that the formal application for accreditation had not been made. An application was subsequently submitted to UKAS on 30 December 2020, shortly after that email. UKAS have explained that this application was for private commercial testing under the system then run through DHSC rather than for the NHSTT contracted work.

2.4.16 Appendix 4 provides additional detail about the key events, accreditation application and status at the 2 laboratories used by Immensa to deliver the 2 contracts and NHSTT's requirements and its contemporaneous understanding of the position with Immensa.

2.4.17 Overall, there was a lack of clarity and consistency about NHSTT's approach to accreditation as a quality requirement to provide COVID-19 testing in Pillar 2. The SUI Investigation Panel has identified that NHSTT had 2 mechanisms to overcome lack of accreditation, both the assessment undertaken for the Audit Report and the statement from providers that they were willing to apply for accreditation. This was not formally agreed with UKAS, though the NHSTT Audit Report template had been shared. There are, therefore, some

important lessons for UKHSA about its approach to accreditation with respect to external providers of clinical laboratory services:

Recommendation 2: UKHSA should require the appropriate UKAS accreditation as the default requirement for external laboratory providers, to bring it in line with the policy for in-house laboratories. In the very rare situations where the public health requirement means that UKAS accreditation is not initially possible, a staged process to achieve accreditation should be published. This process should be agreed with UKAS and should be explicit about the expectations of laboratory providers at the different stages of the accreditation process. The length of time that this interim staged process operates for should be stated and reviewed on a regular basis.

Recommendation 3: UKHSA should proactively ensure that its approach to laboratory accreditation is aligned to the approach of UKAS, especially for handling new and emerging infections. This process should be agreed with UKAS and be explicit about the expectations of laboratory providers at the different stages of the accreditation process. This should include adopting UKAS's terminology and agreeing which ISO (International Organization for Standardization) standards should apply to which areas of UKHSA's activities.

2.5 Laboratory validation and mobilisation: NHSTT/DHSC/UKHSA management actions in relation to the First and Second Contracts with Immensa

2.5.1 As set out in Chapter 2 section 2.4, DHSC/NHSTT developed an audit report that was completed through NHSTT staff reviewing submissions and evidence from laboratory providers and determining whether the provider had an acceptable position prior to mobilisation on each of the criteria set by NHSTT. Developing and implementing this amidst the pressures of the first wave of the pandemic was a substantial achievement and the process enabled a wide range of different laboratories to mobilise and deliver Pillar 2 of the COVID-19 testing programme.

2.5.2 The process to sign-off the Audit Report was based on an assessment of the NHSTT template of the 34 criteria defined by the Laboratory Validation team. The report form was titled 'COVID-19 National Testing Laboratory audit report' (referred to as "the Audit Report" in this report). The 34 criteria broadly related to the elements of the UKAS accreditation process and the Audit Report template had been shared with UKAS for information. UKAS did not comment on or agree the form but there was an agreement between UKAS and NHSTT about sharing relevant information on laboratories undertaking COVID-19 testing. The Validation Team carried

out a desktop assessment of paperwork provided by the laboratory provider, though sometimes an on-line tour was undertaken alongside the completion of the from.

2.5.3 Completion and sign-off of the Audit Report was not part of the selection or contract evaluation process but was undertaken after selection and prior to the decision to mobilise the laboratory to receive samples from NHSTT. Approval for laboratory mobilisation from a quality perspective came from the Validation Team. The Validation Team described approval as “only once all of this has been completed and we have complete evidence that the lab has demonstrated operational readiness from start to finish are they onboarded.” There is not a contemporaneous procedure note that described the process of how the Audit Report was used but the SUI Investigation Panel have concluded from multiple witness interviews that it was usually considered at a meeting alongside other information to make the decision on mobilising the contract and on-boarding the laboratory to start testing.

2.5.4 The process for mobilisation changed during 2020 and 2021. Until early December 2020 the decision to proceed sat with the Decision Authority Review (DAR) Group. The SUI Investigation Panel has not been able to conclude what the process to approve mobilisation of laboratories was between the closure of the DAR Group in December 2020 and August 2021, when the NHSTT Laboratory Operations Go-Live Meeting made the decision.

2.5.5 The DAR Group had a clear role and approved the use of the Dante Italian laboratory (First Contract), although the formal approval took place several months after samples had started to be sent to the laboratory. The formal approval for mobilisation of the Immensa Wolverhampton laboratory has not been presented within the evidence provided. An informal approval was provided to the laboratory Operations team from the Validation Team in the email on 20 December 2020, which stated the Immensa Wolverhampton laboratory was approved to receive samples subject to the condition that the full Audit Report was completed. However, the request was not fulfilled (see 2.4.13 and 2.5.11). The approval of mobilisation of the Second Contract was through a clear process with the presentation of the Operational Readiness Checklist at the NHSTT Laboratory Operations Go-Live Meeting. The Operational Readiness Checklist was held by the Laboratory Operations team and covered all areas deemed important prior to mobilisation. It had 131 items that required sign off by NHSTT and included 7 items on quality that the Laboratory Validation team sign-off related to the completed Audit Report.

2.5.6 There were some issues about the relevant documentation still required from Immensa with no explicit record that the requests for subsequent submissions were met. The Validation Team were not sighted on these requests and, having reviewed the summary of the ‘Go Live’ meeting, they believe that the absence of a formal record of the requested actions being completed was not significant.

2.5.7 The format of the Audit Report and the process was the same from April 2020 to October 2021, with only very minor changes.

2.5.8 Each of the 34 criteria set by the Validation Team were the subject of a row or section within the Audit Report and were assessed by the Validation Team as being “approved”, “more evidence needed” or “not approved”. All 34 rows needed to be approved before the form was completed. However, there was not a clear description of what the precise threshold for approval was for each criterion on the Audit Report. For example, the criteria of “accreditation” was described as “evidence of ISO15189 and/or ISO17025 accreditation and details of scope, including if COVID-19 virology testing has been added to scope”[15]. Given NHSTT’s working position was not for laboratories to have completed accreditation, this statement is inconsistent with actual requirements. Thus, it is unclear how this criterion could be signed off by the Validation Team completing the Audit Report, unless they were working to another threshold for approval. Witnesses have suggested that members of the Validation Team were using a similar threshold for accreditation to that used in the Framework and mini-tender, which was a general statement of willingness to accept an undertaking to apply for accreditation from the laboratory provider.

2.5.9 The Audit Report also included a specific criterion called “Validation”. This is where the specially commissioned reports about the accuracy of the laboratories’ pre-mobilisation specimen tests were recorded, though this output linked with 2 other criteria – Internal Quality Control and External Quality Assurance. During the Panel’s investigation, it has become clear that some contemporary documents and information from witnesses were not specific about whether references related to the whole process of laboratory validation (i.e the completion of the Audit Report) or to the activities covered in the specific row labelled “Validation” in the Audit Report.

2.5.10 Appendix 5 sets out the key events in relation to laboratory validation and mobilisation processes between NHSTT and Immensa and the conclusions of a detailed review of the Audit Form for Immensa’s Wolverhampton laboratory.

2.5.11 The SUI Investigation Panel recognised the Audit Report was a useful tool that supported the decisions on mobilisation. It was not part of the selection of providers but rather was used to determine whether a provider could start testing. The Panel were clear that though this was a helpful element of the mobilisation process, it was not consistently implemented for the Immensa Wolverhampton laboratory.

[15] From the Audit Report for the Dante Italian laboratory and the Immensa Wolverhampton laboratory

2.5.12 For the First Contract, the decision on 20 December 2020 to approve the mobilisation of Immensa's Wolverhampton laboratory did not follow the principle that the Audit Report for the relevant laboratory needed to be completed prior to testing commencing at that site. Testing started at the laboratory in January 2021 and continued until the end of the contract without the Audit Report being completed.

2.5.13 For the Second Contract, the decision taken on 31 August 2021 that the Operational Readiness Checklist for the Immensa Wolverhampton laboratory and activity associated with the Second Contract was completed with all items marked as complete, including a completed and approved Audit Report[16]. Testing then started in early September 2021.

2.5.14 From a review of the Audit Reports, the SUI Investigation Panel identified some general issues with the process that NHSTT designed around the use of the Audit Report, some of which were recognised at the time. The SUI Investigation Panel agrees that a perfect process was not possible and that it was better to have an imperfect process than no process. However, there were opportunities over the circa 15 month period from the Audit Report being developed and its use in the Second Contract to have improved the process. Key issues with the Audit Form discussed between the Panel and witnesses were:

a) Senior staff who were in NHSTT have emphasised that NHSTT's assurance through the Audit Report was primarily approved on trust, based on documents submitted by the providers and was dependent on the laboratories' commitments to adhere to the procedures and process submitted to NHSTT. There had been suggestions from some interviewees that these commitments may not always have been adhered to. Although the context of the pandemic did not make the process of verifying key documents a possibility in the early phases, there would have been an opportunity to verify key documentation and undertake a site visit when work-related travel was allowed.

b) The specific requirements of the laboratory provider for each of the criteria in the Audit Report (that is each row) was not defined. Thus it is unclear what aspect of the provider's situation led to the criteria being approved by the NHSTT assessor (or not).

c) The desktop assessment used in completion of the Audit Report (with possible on-line tour) was not identical to the UKAS process for accreditation which included a site visit to inform a recommendation on accreditation. NHSTT staff gave the Panel different reasons for not undertaking site visits and there was confusion over whether there were restrictions on travel to a stand-alone laboratory (as distinct from a hospital site). However, the Panel felt that there would have been benefit from a site visit as part of the Audit Report process and this should have been possible, especially to laboratories not on hospital sites.

[16] Immensa – Surge Lab Operational Readiness Checklist

2.5.15 There were also issues with the specific Audit Report form that NHSTT staff completed for Dante's Italian laboratory in summer 2020:

a) For the Dante Italian laboratory, many of the documents were in Italian and so translations needed to be requested. This may have contributed to the lack of clarity on the situation in the laboratories.

b) The Audit Report for Dante's Italian laboratory records that the laboratory was "authorised" by the Italian government and on its list for COVID-19 testing. This is discussed above in paragraph 2.4.8. The validation section of the Dante Audit Report records that the laboratory was accredited under ISO13485 with the BSI. This is the ISO standard for medical devices and not the required ISO standards stated on the Audit Report, which were ISO15189 (medical laboratories) and/or ISO17025 (testing and calibration laboratories). UKAS have told the Panel that ISO13485 "is not a standard that will provide assurance of the competence of the laboratories to perform medical diagnostic tests".

c) The DAR Group signed off the Dante Italian laboratory alongside many other laboratories on 26 November 2020, approximately 3 months after the contract started.

2.5.16 There were issues with the specific Audit Report form that NHSTT staff completed for Immensa's Wolverhampton laboratory over the period from December 2020 to August 2021:

a) As with the Dante Italian laboratory, many of the documents applied to the Audit Report for the Wolverhampton laboratory were in Italian and so translations were also needed. As with Dante, this may have contributed to the lack of clarity on the situation in the laboratories.

b) As in the Audit Report for the Dante Italian laboratory, the Audit Report for Immensa's Wolverhampton laboratory states that the laboratory is accredited to ISO13485 (the medical devices standard). UKAS have explained this is a management certification system not used for accreditation, hence the UKAS public statement that neither Dante nor Immensa were accredited by UKAS.

c) As stated above and in Chapter 2 sections 2.4 and 2.5, the Audit Report was not signed off for the length of the First Contract. The email of 20 December 2020 from the lead for the NHSTT Validation Team to Immensa, copied to the Laboratory Operations Team in NHSTT, approved mobilisation subject to the Audit Report being completed the following week. This condition was not met and was left unresolved for the remainder of the First Contract.

d) The last recorded meeting of the DAR Group was on 8 December 2020. After this time the process moved into NHSTT Laboratory Operations Team and an Operational Readiness Checklist was expected to be completed. The SUI Investigation Panel understands this Checklist was in addition to the Audit Report. The process for the mobilisation of the Immensa Wolverhampton laboratory for the First Contract remains unclear as there is no evidence that a meeting took place to approve mobilisation of the Immensa Wolverhampton laboratory to start testing under that contract, nor has an Operational Readiness Checklist for the Immensa Wolverhampton laboratory starting in December 2020 been found.

e) From 9 August 2021, work re-commenced on completing the Audit Report for the Second Contract. On 26 August it was signed off with all 34 criteria marked as “approved”. There are several areas where the basis of this judgement is not clear and these are detailed below. It has not been possible to access detailed information about the completion of the form.

f) Similar to the Dante Italian laboratory Audit Report, the Immensa Wolverhampton laboratory Audit Report also states that the laboratory is accredited to ISO13485 (the medical devices standard). UKAS have explained that this is a management certification system not used for accreditation, hence the UKAS public statement that neither Dante nor Immensa were accredited by UKAS[17]. The Panel has explored the background to the approval of the validation criteria in the Audit Report. It has seen a report from Immensa dated 26 August 2021 which gives evidence of the work that they had done on the validation of the PerkinElmer test. This document reports 100% true positive and 0% false positive results when comparing the PerkinElmer test with the Nonacus results and the Milton Keynes Lighthouse Laboratory results. Further information would be needed to be clear on whether this means that the verification testing was not sensitive enough to identify the incorrect setting of the threshold levels and that this was the “immediate cause” of the incident, or that the incorrect setting took place after these verification tests and before the start of the actual testing for NHSTT.

g) A ‘Go Live’ meeting about mobilisation of the contract was held on 31 August 2021 for a 1 September mobilisation. A slide summarising the outcome was completed which identified “risks” on “going live”. One is relevant to the SUI which was “there is a risk that all formal documentations will not be provided prior to go-live”. The action for NHSTT was “all validation requirements have been met but a consolidated verification report has not been provided. It has been agreed with the Validation Team that verification summary will suffice for go-live and a full Verification Report will be provided within 14 days”. The Validation Team have told the Panel that they were not sighted on the request from the Go Live meeting, and there is no record of this full Verification Report being provided.

2.5.17 Together, the issues set out above constitute a missed opportunity as completing the Audit Report was an opportunity for NHSTT to set a clear standard with Immensa about its requirements on the quality oversight and assurance of Immensa’s Wolverhampton laboratory. The Audit Report was not completed for the length of the First Contract and then the version signed-off in August 2021 had a number of areas where there was a lack of clarity. As there was only one version of the Audit Report from December 2020 to August 2021 used for both Contracts, the issues where there was a lack of clarity from the assessment of the First Contract were carried forward into the assessment for the Second Contract.

2.5.18 The Panel’s view is that no single issue on the final Audit Form would have directly reduced the likelihood of the error being made by Immensa, but a more precise oversight by NHSTT would have demonstrated to Immensa a much higher priority to the quality of their

[17] Statement on accreditation status of Immensa Health / Dante Labs

laboratory services. A thorough approach would have been a powerful signal to Immensa about NHSTT's expectations. It would be speculation to consider how Immensa would have responded and whether this would have had any impact on their approach to, and regular checking of, the calibrating equipment.

2.5.19 There are important lessons to be learned about the approach to mobilisation and validation of contracts between UKHSA and external providers of laboratory services. A validation process was quickly set up in the first wave of the pandemic which helped to enable a wide range of different laboratories to participate in Pillar 2. However, the design and operation of the different elements of the quality assurance systems and processes and the associated governance mechanisms had weaknesses. The lessons are that:

Recommendation 4: UKHSA should publish a policy statement on its approach to quality assurance for laboratory services, both in-house and externally contracted. This statement should demonstrate how the disparate approaches to quality found by this investigation should operate together as a single integrated system of quality assurance.

Recommendation 5: UKHSA should produce a document about the quality elements of each procurement for laboratory services. This should set out the specific quality requirements expected of the laboratory providers and how these will be assessed, both in the procurement process and in the monitoring of the on-going contract delivery.

2.6 Monitoring of contract delivery: NHSTT/DHSC/UKHSA management actions in relation to the First and Second Contracts with Immensa

2.6.1 From its investigations, the Panel has identified 3 main types of monitoring activity undertaken by NHSTT to oversee the delivery of both the First and Second Contracts with Immensa:

- firstly, the daily monitoring by the NHSTT Laboratory Operations Team, the primary purpose of which was to allocate the distribution of samples to the different laboratories in order to optimise capacity
- secondly, the monitoring of the performance improvement activities of each laboratory provider undertaken by the NHSTT Laboratory Operations Team
- thirdly, the scheduled monitoring of contract delivery led by the NHSTT Commercial Team which was standard practice for all contracts

2.6.2 The daily monitoring was a report that set out the performance of each laboratory in the previous 24 hours against the quality metrics and available capacity. Further details on how this operated in both the First and Second Contract is detailed in Chapter 3 as this is pertinent in understanding the NHSTT Reviews into concerns about PCR and LFD results that took place in September and October 2021.

2.6.3 The approach to the as-required monitoring of the performance improvement activities was described to the Panel as follows: "The team also provides ongoing quality assurance (continued standards compliance) with the above standards. This is undertaken by [NHSTT Laboratory Operations Team] working with Laboratory Clinical Directors and Quality Managers through weekly and fortnightly group meetings: using the principles of quality development and improvement, monitor and review incidents, identify trends, share best practice, and support laboratories to work towards full UKAS accreditation to ISO 15189/17025 standards where appropriate". There was no involvement in monitoring from the NHSTT Validation Team though they did review and approve ad-hoc change control requests made by laboratories, notifying the NHSTT Laboratory Operations Team of the outcome.

2.6.4 The commercial monitoring was led by the NHSTT Commercial Team, structured as a formal regular schedule of reviews of the contract, which is covered in more detail in section 2.6.10. The monitoring meeting specified in the contract did not happen because the contract had been suspended prior to the time when this would have taken place

Observations on NHSTT's daily laboratory monitoring of Immensa

2.6.5 The Panel looked for examples of approaches to monitoring laboratory work commissioned from an external provider. Best practice highlighted that, alongside the responsibility for quality of the laboratory owners and operators, commissioners should be looking at a range of quality indicators and metrics and be assured on the providers' quality systems on an on-going basis, including assurance of the accreditation status of providers[18].

2.6.6 The First Contract sets out the NHSTT processes to monitor quality and assure outputs through monitoring 3 metrics on a daily basis (void rate, process (turnaround) time and cost-efficiency)[19]. No witnesses raised any issues with the daily monitoring of the First Contract.

[18] For example the case study in NHS Pathology Quality Assurance Review

[19] First Contract dated September 2020 Schedule 5 Part A

2.6.7 The Second Contract commenced on 2 September 2021 and is formally recorded in an Order Form[20] between DHSC and Immensa. This has 5 Key Performance Indicators (KPIs) – laboratory void rates, cycle time (turnaround), flexibility (in receiving samples from different channels such as walk-in sites, home testing, mobile sites, and so on), capacity and frequency of data upload).

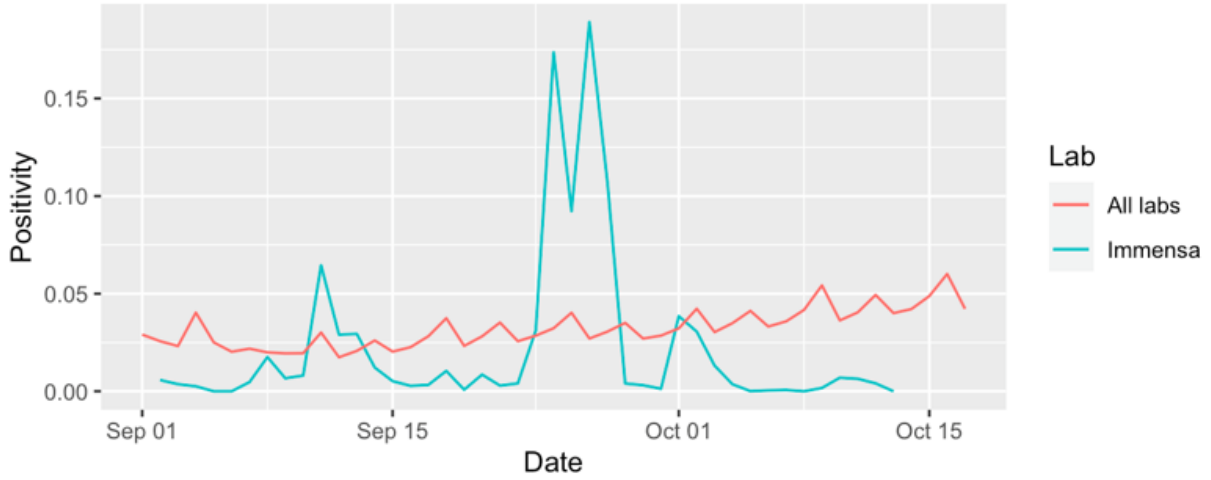
2.6.8 There was a daily monitoring report circulated by NHSTT's Laboratory Operations Team covering all laboratories in Pillar 2. The email was sent to a wide distribution in NHSTT each day with the data on 3 indicators (void rates, turnaround times and positivity rates) and a short commentary. The commentary focused on operational efficiencies in the patterns and trends in void rates and turnaround times. The daily data about the positivity rate at a laboratory level was reported but these were not being actively monitored by the Laboratory Operations Team as they found these varied depending on the mix of 'channels' that the samples came from. The challenges in interpretating the positivity rate are discussed in paragraph 4.4.14.

2.6.9 Figure 1 shows the pattern of daily positivity rates for this period (that is the proportion of all test results that were positive). Through September and October 2021, the Immensa Wolverhampton laboratory reported a very low positivity rate of below 1% for most days. However, there was a significant spike in the positivity rate for the Immensa Wolverhampton laboratory between 23 and 30 September up to 18.9%. In addition, there were 2 much smaller spikes (on 11 September to circa 7% and circa 4% on 1 October). This monitoring system could have been very important in the NHSTT Reviews of concerns of people receiving negative PCR test results after a positive LFD, but did not prompt any more detailed analysis. This missed opportunity is further addressed in Chapter 3.

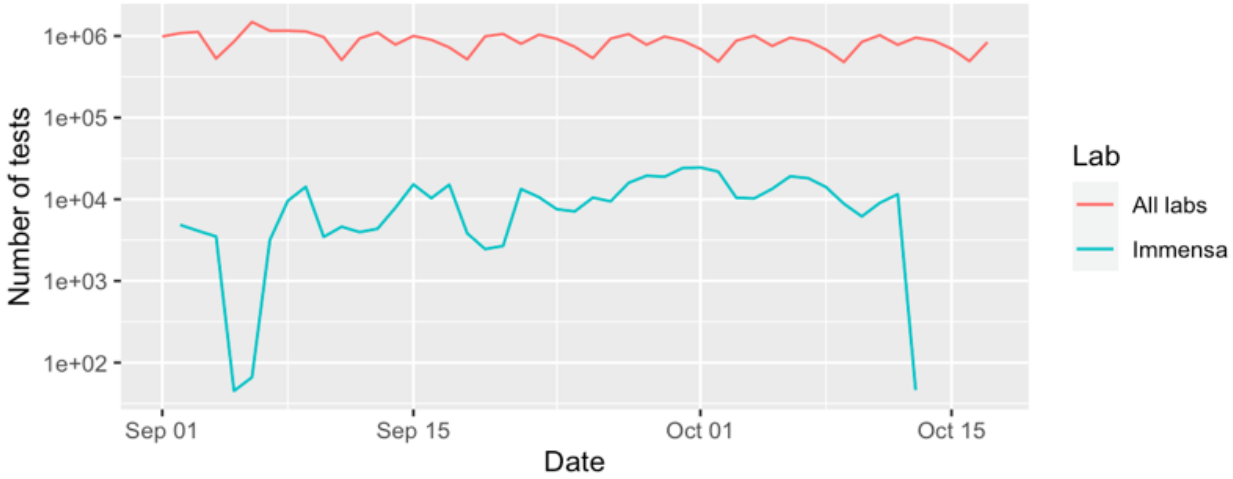
[20] National Microbiology Framework Order Form between SoS and Immensa signed and dated 30 July 2021

Figure 1: Positivity rates reported between 1 September to 17 October 2021 at Immensa's Wolverhampton laboratory compared to all laboratories in Pillar 2 (slide provided by UKHSA Data Analysis and Surveillance)

Over the period for which we have data, Immensa labs returned mostly negative tests with a much lower positivity rate relative to the rest of England, except for 3 "spikes" of high positivity. ->



These spikes do not appear to be noise due to low numbers of tests (particularly the largest spike of September 24–27).



2.6.10 The focus of NHSTT's monitoring of laboratories during this period was on operational performance, rather than both clinical quality and operational performance. The commentary in the report on each day's data flagged specific changes in the first 2 metrics (void rates and turnaround times) but not in positivity rates. It is not clear whether these spikes were identified by the team undertaking the monitoring but there was no analysis of the potential cause.

2.6.11 The positivity rate needs careful interpretation, and it is not a metric widely used in monitoring laboratory performance. It provides both epidemiological and laboratory performance insights, reflecting the prevalence of the infection in a geographical area or through a testing channel (home testing, surveillance, testing sites, and so on). NHSTT explained the basis of their approach to the Panel as follows: "One single data point was reported for all samples. This means the result can vary significantly due to the sample mix of channels with differing positivity rates. Hence, although monitoring was in place, the metric was not sufficiently sensitive to detect laboratory variances." Neither the 2 smaller spikes in positivity rates at the Immensa Wolverhampton laboratory nor the more pronounced spike between 22 and 28 September were identified – the team's explanation to the Panel was "since changes to the 'mix' of inbound samples drove major swings in positivity, longer term trend movements vs short term variations were unfortunately the focus of the reviews. Issues with data being uploaded later than expected that is longer lead times than expected, were more often the short term challenges."

2.6.12 There is no general guidance on post-mobilisation monitoring for pathology contracts but the Panel has been informed that NHS commissioners would typically look at a wider range of metrics. However, NHSTT was not part of the NHS and the arrangements in place might have been all that was possible given the restrictions of the pandemic, most notably in the spring and early summer 2020.

Observations on NHSTT's monitoring of commercial aspects of the contracts with Immensa

2.6.13 This is covered in Chapter 3 section 2 and will not be expanded on in detail here. On commencement of the Second Contract, NHSTT's Commercial Team designated the contract a "silver" rating, identifying the contract to be reviewed every quarter. Some UKHSA staff and the Panel agree that, with hindsight, a different classification with more frequent monitoring would have been more appropriate for a clinical diagnostic laboratory contract, though this would have been extremely unlikely to have contributed to an earlier identification of the immediate cause.

Observations on NHSTT's performance improvement monitoring of Immensa

2.6.14 The Panel also explored examples of the systems for clinical oversight and monitoring. There was no best practice identified but the regular communication between clinical experts,

such as virologists, working for the commissioner and the lead clinicians in the provider was important here. For NHSTT's approach to Pillar 2 laboratories, the model of clinical virology support and oversight of Immensa's contracts was less extensive than that provided for the NHSTT Lighthouse Laboratories. NHSTT stated that "each Lighthouse Laboratory was supported by an external expert clinical virology advisor who provided challenge and support to the laboratory team on behalf of NHS Test and Trace"[21]. NHSTT did not allocate additional clinical virologist input and support to Immensa for either the First or Second Contracts. The Panel was told that there were financial pressures.

2.6.15 As part of NHSTT's monitoring, data sets and test samples were shared between sites as part of an internal quality assurance system. The records are not clear whether surge laboratories in general, and Immensa in particular, were involved in this work.

2.6.16 When monitoring the internal quality controls and external quality assurance, the primary responsibility for reviewing these undoubtably rests with the provider itself, and the contract requires them to inform the commissioner of any issues. The Panel has found no evidence that NHSTT monitored Immensa's internal or external quality process once the contract had started to be delivered but the Validation Team would review the data as part of the process to approve changes in the testing pathway in all laboratories.

2.6.17 The Panel was told about a specific concern raised by stakeholders about the positivity rate of Immensa's Wolverhampton laboratory during the First Contract that had not been identified by NHSTT monitoring systems and processes. On 24 February 2021, the Welsh Government's Test Trace and Protect (TTP) Programme contacted NHSTT with a concern about an increase in asymptomatic positive results observed by Public Health Wales (PHW). This concern was not recorded with the NHSTT SOC (the formal NHSTT incident review mechanism described in Chapter 3) and so not handled through the agreed escalation and resolution route of the SOC. Rather it was handled informally within the Laboratory Operations Team.

2.6.18 There was no immediate response from NHSTT to this concern. On 10 March 2021 the TTP programme followed-up on their concern and NHSTT commenced an investigation. On 11 March 2021, a PHW senior microbiologist expanded on these concerns and was explicit that these included an observed unusually high positivity rate in results from asymptomatic care home staff in North Wales which went to the Immensa Wolverhampton laboratory. This email said "The above observations raise significant concerns about a range of laboratory processes (including quality control of output) at the Immensa lab, which may be leading to inaccurate

[21] NHS Test and Trace: how we test your samples

results." There was an immediate response the same day from NHSTT saying there would be an investigation.

2.6.19 NHSTT approached Immensa for their analysis on the issue, receiving a response on 17 March 2021. NHSTT told the Wales TPP that the Validation Team would review the Immensa response. However, on 22 March 2021 NHSTT sent the Immensa response to Wales TPP without further analysis or commentary. A direct response was also sent to PHW on 25 March 2021 which stated "Based on the data reviewed, Immensa has followed their diagnostic standard operating procedure and the results are in accordance with the Instructions for Use (IFU) of the PerkinElmer® SARS-CoV-2 Real-time RT-PCR 3501-0010 assay." Welsh colleagues undertook further internal analysis and a more detailed report was sent back to NHSTT on 21 April 2021. This was after the First Contract had ended. Neither NHSTT nor PHW can find a response to this more detailed report.

2.6.20 NHSTT did not completely resolve (or communicate back) in response to the concerns raised by PHW. Their concern was about a higher positivity rate, which is different from the incorrectly reported negative test results that happened in September and October 2021. Although the Panel has been told that the Laboratory Operations Team's view is that their investigation showed that there was not an issue with Immensa's positivity rate, there are 2 elements of the investigation that appear to have been left unresolved at the time:

- NHSTT requested detailed data from Immensa as part of an investigation into these concerns – Immensa provided this and their findings were 'cut and pasted' into the response to the Wales TPP (the Panel has asked what review of Immensa's conclusions took place within NHSTT but this has not been clarified)
- PHW felt that this did not address their concerns and so they later sent a detailed report with their concerns to NHSTT's Laboratory Operations Team, but there is no evidence that this was responded to

2.6.21 In conclusion, the primary responsibility of identifying the incorrect setting of thresholds for the PCR testing sat with Immensa. However, the approach to monitoring delivery of the contract by NHSTT could have enabled the immediate cause of the incident to be identified earlier. Thus, the important lessons to be learned about how to monitor future contracts between UKHSA and external providers of laboratory services are:

Recommendation 6: When awarding contracts, UKHSA should design the monitoring processes for commercial contracts to reflect the potential public health impact of the contract, alongside the existing obligation to ensure the commercial viability of service providers.

Recommendation 7: UKHSA should also design its operational service monitoring processes to reflect the requirements of a clinical diagnostic service. The monitoring processes should be consistent irrespective of the type of provider or size of the contract and be integrated into the overall approach to quality assurance. A comprehensive set of indicators for monitoring the performance of contracted laboratories should be developed – these need to be designed for the needs of that procurement and include performance triggers for when UKHSA should undertake detailed investigation.

Recommendation 8: UKHSA should formally record and thoroughly investigate concerns about laboratory services raised by internal staff and external expert partners. If necessary, a third party opinion should be sought.

Chapter 3: Investigation into the concerns being raised about reports of people receiving negative PCR test results after a positive LFD in 2 September 2021 and 12 October 2021

This chapter focuses on the NHSTT Reviews of the concerns about reports of people receiving negative PCR test results after a positive LFD in September and October 2021. After the background and context for the investigations (section 3.1), the governance of the investigation is described (section 3.2). The chronology (section 3.3) is followed by a review of investigations, leading to recommended lessons for UKHSA (section 3.4.).

3.1 Background and context

3.1.1. Under NHSTT's Second Contract with Immensa, the first testing samples were processed by the Immensa Wolverhampton laboratory on 2 September 2021. The contract was run by NHSTT until 1 October 2021, and then after that date, NHSTT transferred to UKHSA and there was no change in legal party running the contract. From the second week in September, concerns were raised by internal and external stakeholders about positive LFD results being followed by negative PCR results. NHSTT Reviews of these concerns over several weeks led UKHSA on 11 October to review specific barcodes for PCR/LFD discordant tests and determined they were undertaken at Immensa's Wolverhampton laboratory. This review concluded that there was a high probability of a significant number of incorrect PCR negatives and so UKHSA suspended testing at Immensa on 12 October. On 15 October 2021, UKHSA made a public announcement about the suspension and, over the following few days, members of the public whose samples had been tested at the Immensa Wolverhampton laboratory were texted a tailored message with advice on their next steps.

3.1.2. Testing activity was high in September and October 2021 with around 400,000 tests undertaken per day, though capacity had been increased in early September so Pillar 2 could undertake over 800,000 tests per day. The government launched the Winter Plan on 14 September with a major focus on preparations across NHSTT and PHE. In addition, the petrol supply 'crisis' dominated the news in the last few days of September and early October, requiring logistics teams to factor in the impact of restrictions on road transport.

3.1.3. This chapter focuses on the management actions in the period between 2 September and 15 October 2021. Following the suspension of Immensa from PCR testing, UKHSA

undertook a number of important actions which are detailed in a Lessons Learned document from the UKHSA Testing Group titled ‘NHSTT Internal Desktop Review of incident TTIN1584’.

3.2 Governance of NHSTT’s reviews into concerns in September and October 2021

3.2.1. On 1 October 2021 UKHSA came into existence bringing together the health protection functions of PHE and NHSTT. During September 2021 the 2 organisations worked closely together to prepare for the changes including detailed work on bringing together the pandemic response activity in PHE and NHSTT, especially through 3 collaborative workshops (called Exercise Atlas) which explored internal and external ways of working in incident management.

3.2.2. The management of issues and incidents in the NHSTT Testing Programme was led and coordinated by the Service Operations Centre (SOC) which had been established in May 2020 to ensure operational issues in testing and tracing were addressed efficiently and quickly. The governance and reporting arrangements for the SOC had changed several times across the lifetime of NHSTT and, by September 2021, it was within the NHSTT Testing Programme that then transitioned into UKHSA Testing Group. Typically it logged 8,000 issues and incidents a month. The SOC daily meeting was attended regularly by representatives of most teams across the NHSTT Testing Programme, including the NHSTT Public Health and Clinical Oversight (PHCO) team and was supported by the NHSTT Integrator Team which collated the issues and incidents.

3.2.3. The clinical and public health contributions from NHSTT PHCO team included leading the Patient Safety Panel, which provided the clinical governance input and public health advice to issues and incidents in NHSTT. It reported through the NHSTT Clinical and Public Health Lead for Testing to the NHSTT Chief Operating Officer for Testing.

3.2.4. PHE’s National Incident and Emergency Response Plan (NIERP) set out the governance for incidents within PHE’s remit. This approach was overseen by the PHE Medical Director and, for COVID-19 related incidents, run through the PHE Strategic Response Group. It provided input to the joint National COVID-19 Response Centre (NCRC) that was the mechanism for NHSTT and PHE to work together on COVID-19 regionally and nationally. The PHE Strategic Response Director for COVID-19 was also appointed as the NHSTT Chief Medical Adviser.

3.3 Chronology of events related to the raising of concerns and their investigation

3.3.1. The key events in the timeline of the investigation in September and October 2021 are set out in Appendix 6. The first recorded issue about individuals having positive LFD results followed by a negative result from a confirmatory PCR test was a local incident on 8 September 2021 in Bristol, logged by the PHE South West Health Protection Team. An email from a local authority was received on 13 September flagging a similar issue in Swindon and this was shared with the NHSTT South West Regional Team managing testing with local authorities.

3.3.2. From 13 September onwards, a significant number of reports and concerns were raised through different routes including emails from PHE and NHSTT regional teams (often forwarding on concerns from local authorities), verbal statements at internal meetings, the public COVID-19 contact service (119), from the Department of Education interface team and local testing sites. The main focus of the NHSTT Reviews into these concerns was the accuracy of the LFD results.

3.3.3. On 22 September, several events raised the profile of concerns across NHSTT and PHE. The SOC registered these as an incident on their system for the first time, allowing them to collate information related to the concerns in a more systematic way. Some information received raised the possibility that the PCR test might be inaccurate but the main focus of the work by the SOC remained on LFDs.

3.3.4. The daily monitoring system described in chapter 2 section 6 did not identify the 3 spikes in positivity rates at the Immensa Wolverhampton laboratory. This monitoring system was not used in NHSTT Reviews nor was this data considered by the SOC when reviewing the concerns about the LFD / PCR results.

3.3.5. It is not directly within the terms of reference of the SUI investigation to identify a specific cause of these 3 spikes as it relates to actions undertaken by staff at the Immensa Wolverhampton laboratory.

3.3.6. On 7 October, UKHSA Epidemiology Incident Cell (previously within PHE) presented data within UKHSA that showed the discordant LFD / PCR results were geographically concentrated in particular regions of the country, specifically the South West. NHSTT's PHCO team in UKHSA Testing Group was tasked with undertaking a structured investigation into this issue.

3.3.7. Between 7 and 12 October, UKHSA teams progressed analysis to look at the laboratories undertaking PCR testing and this led to the decision to suspend testing at the Immensa Wolverhampton laboratory. UKHSA set up an Incident Management Team and made a public announcement on 15 October and the 'immediate cause' was set out in the report following a visit to the Wolverhampton laboratory on 18 October.

3.4 UKHSA/NHSTT/PHE management actions in relation to the NHSTT reviews

3.4.1 There were 2 parallel systems in place within NHSTT for managing issues and incidents related to delivering the COVID-19 response. They fulfilled different purposes and had contrasting governance systems, though there were some links between them. These 2 systems were:

- within NHSTT, the Service Operations Centre (SOC) had run since May 2020 under several different reporting arrangements – it focused on issues and incidents within the testing and tracing services run by NHSTT; in September 2021 it was part NHSTT Testing Programme, though also covered Tracing – PHE staff regularly attended SOC meetings
- NCRC co-ordinated the public health response – it was part of the Contain Team in NHSTT with PHE COVID-19 Incident response engaged as appropriate. It linked national teams managing the public health aspects of the response with the regional teams, which were composed of both NHSTT's Contain teams and PHE's regional Health Protection Teams; they worked closely together through the NHSTT regional partnerships that had been established in 2020 to engage with local authorities

3.4.2. Within PHE, there was also an incident management structure for the COVID-19 response in line with the requirements of the NIERP. This had oversight of all elements of PHE's response, thus issues and incidents within the testing and tracing services run by NHSTT were not their remit. This PHE incident management structure reported ultimately to the PHE CEO.

3.4.3. There were differences between these 3 systems, with the SOC focused more on disruptions to the supply chain, NCRC focussed on local authorities and the PHE systems focused on the public health aspects. This distinction was not explicitly set out, nor was the required approach to manage issues and incidents that had supply chain, local authority and public health implications. These systems essentially ran in parallel with points at which they linked together, rather than as a single integrated whole system.

3.4.4. Communication within each system was reasonably frequent and clear, but defined communication procedures and methods between the systems were not thoroughly documented, and less frequent. There was no mechanism to proactively identify and investigate issues and incidents where a single integrated approach was needed. For example, the request from SOC on 16 September for more information about the concerns went to the 119 network but not to the other local networks through regional partnerships teams that were part of the Contain workstream. Sharing it with local networks could have provided additional information and insights into the concerns being raised.

3.4.5. The Panel noted one opportunity where the organisations did informally join up to discuss concerns across the system. On 22 September at the PHE Strategic Response Group, where key staff from across PHE and NHSTT discussed the enquiries about testing accuracy and the logic of confirmatory testing that were being reviewed by the SOC. The meeting notes record the discussion as being about “accurate and reliable testing methods in the UK”. At the meeting the PHE Public Health Advice, Guidance and Evidence Cell was tasked with sharing the relevant publications, but there is no record of any follow up in the subsequent meetings until 13 October when the action is noted as closed on the 29 September. The meeting notes state that policy decisions had been submitted to ministers, stating “Nothing has changed yet. The PCR test remains the gold standard [for COVID-19 testing]”. When discussing this meeting with interviewees, there are varying recollections of both the discussion, the action required and the owner of the action. This was an opportunity to get closer collaboration between the various teams.

3.4.6. Thus the arrangements for the NHSTT Reviews of concerns did not enable effective join up between the service delivery and public health aspects of this SUI. This led to missed opportunities to enable the immediate cause of the serious incident to be identified quickly. Although the creation of UKHSA on 1 October 2021 was a major organisational change in the midst of NHSTT Reviews of the concerns, it did not lead to significant changes in systems and processes related to the handling of this incident in the period from 1 to 15 October. The Panel appreciates that there were good reasons for not making any organisational change on 1 October as it could have been very disruptive. The Panel’s conclusion is that more integrated arrangements could have been in place and then transferred across into UKHSA.

3.4.7. Key teams were not an active part of the NHSTT Reviews. Notably, the Laboratory Operations Team was not part of the discussions about the cause of the issue until about 7 October. The meeting structure within NHSTT was that this team did not routinely attend daily SOC meetings (though did receive the daily report from SOC) but there was a weekly meeting between SOC and Laboratory Operations. This created a gap for the SOC when they sought to establish clarity on all the information streams about the end-to-end testing pathway, and as such the SOC could only obtain partial information to establish the immediate cause of the SUI.

3.4.8. In addition, the descriptions given to the Panel in relation to quality assurance and clinical governance across the testing pathway highlighted an important separation across teams that contributed to only partial information being available to SOC. NHSTT PHCO were accountable up to the laboratory door and from the test result being produced. A separate accountability for quality assurance and clinical governance activities within the laboratories was the remit of NHSTT's Laboratory Operations Team. The Panel could not identify a clinical professional who was accountable for quality and clinical governance through the full 'end-to-end' process.

3.4.9. Within the NHSTT Reviews undertaken by the SOC and associated groups, there was not a systematic and structured investigation of the reports of people receiving negative PCR test results after a positive LFD test from mid-September onwards. The formal contemporaneous recording systems within the SOC were incomplete, though the team have been able to produce a detailed timeline in retrospect. The SOC did not have a proper incident response recording system but did use a 'ticket' system on an issue tracking software product called JIRA.

3.4.10. The SOC did have detailed procedures for handling routine issues and incidents, based on situations when the nature of the problem to be sorted was clear and agreed. This SUI was more complex, as there were different views about the nature of the problem and the source of the immediate cause. This required all possible causes of the incident to be investigated, and to only be rejected on the basis of clear evidence or data. In late September, there was informal advice from clinicians within UKHSA that a structured and systematic review of the concerns was needed, specifically that 3 groups of possible causes should be considered. Thus, there was no clear systematic and structured process for the SOC to follow in this situation.

3.4.11. The SOC sought public health advice from NHSTT PHCO Team and the NHSTT Patient Safety Panel as soon as it was aware of reports of people receiving negative PCR test results after a positive LFD. The advice from PHCO Team was clear and guided much of the SOC's review, PHCO stated that the cause of the issue was most likely to be with the LFD tests. The PHCO Team repeated this advice at SOC meetings. The UKHSA Testing Group's Internal Review (completed 22 November 2021) concluded that "one factor in particular led to the delay and it was the steadfast assumption that whatever the problem, it could not possibly be the laboratories or PCR tests". The evidence from many sources demonstrates that this was the case. Other perspectives that were questioning of this focus on LFD tests were not actively considered in the SOC meetings. This was a symptom of the design of the NHSTT Review processes and thus which teams within NHSTT actively participated in the reviews.

3.4.12. The views of local and regional stakeholders about the possible cause were not given a sufficient focus and priority in the NHSTT Reviews. There were 2 specific instances (22 and 30 September), of local teams from within NHSTT Contain and from a specific NHSTT Testing site

flagging a concern that the Immensa Wolverhampton laboratory may have been the immediate cause, noting that the positivity rate at the Weston-Super-Mare site had dropped since samples started going to this laboratory. The Panel has found no evidence that these specific issues were investigated, and so it was a significant missed opportunity.

3.4.13. Local government and other stakeholders reported to the Panel that communications were not always clear and timely and that the importance of this issue in specific parts of the country appeared not be recognised by all teams within NHSTT. They felt that their concerns and the perspective of people's lived experience were not given the priority they merited.

3.4.14. The Panel has sought to understand the experience of people affected by the SUI during September and October. The customer feedback on COVID-19 testing services in September and October shows only a small difference in trust in the tests between the South West (81%) and the nationally (87%), although the South West scores did rise to the national average in November and December. One of the free text comments reflected concerns that have been reported to the Panel by directors of public health and were being made on social media at the time:

> "It was a 10 day period of panic. I chose to ensure my daughter self-isolated, despite the negative PCR, as she had 2 of the main symptoms. I am however concerned that people who do test positive on LFDs and then test negative on PCRs are happily walking around with symptoms they now assume are a cold and infecting others like myself. What hope does anyone have."

3.4.15. During the investigation, it was apparent that there were opportunities for earlier identification of the incident through testing samples from the South West. Matching PCR and LFD results for named individuals would have progressed one element of the NHSTT Reviews and the Panel were told that this was delayed because the data was considered Patient Identifiable Information.

3.4.16. The Panel is clear that not using the data on positivity rates in the NHSTT Reviews was a missed opportunity and could have enabled the immediate cause of the incident to be identified earlier. Previously within the First Contract, in March 2021, Public Health Wales had looked at laboratory level positivity rates and flagged concerns about Immensa as an outlier (though with unusually high rather than low rates) (see chapter 2 section 6). Although the issues were not entirely comparable, there was then no consideration of the positivity rates of laboratories in the NHSTT Reviews in September and October 2021. Chapter 2 section 6 shows that there were 3 spikes in the positivity rate at Immensa's Wolverhampton laboratory in this

period which would have given an important additional dimension to the analysis. The incomplete investigation of the PHW concerns as well as the decision not to closely monitor positivity rates was a missed opportunity.

3.4.17. In addition to clinical quality and laboratory performance monitoring, NHSTT's Commercial Team had in place a contract monitoring process. This was not designed to identify this sort of serious incident. A contract review meeting was scheduled to happen every quarter as the contract had been classified within NHSTT as a 'silver' contract with intermediate level monitoring. The quarterly review would have been at the start of November 2021, however the suspension of the operations meant this did not take place.

3.4.18. The Second Contract required that Immensa reported any issues to NHSTT. There is no record that Immensa reported any issues with their testing to NHSTT, specifically not with the PerkinElmer assay in September and early October 2021, nor any unusual trends from their internal monitoring, such as the 3 spikes in positivity rates. The Panel have investigated whether there was a follow-up from NHSTT on the quality control systems in Immensa, It has not found any evidence that there were post-mobilisation assurance discussions, rather the pre-mobilisation checks were relied on.

3.4.19. The establishment of an Incident Management Team on 12 October brought greater pace and focus to the handling of the incident. Thus, public health staff from teams that had been within PHE became more actively involved and key baseline activities (such as a public health risk assessment) were undertaken. This led to the immediate cause of the incident being identified as within the Immensa laboratory in Wolverhampton and the suspension of testing on 12 October.

Recommended lessons for UKHSA about the investigation of concerns about testing

Recommendation 9: UKHSA should establish a single governance and reporting system for managing the response to incidents. There needs to be one process for commissioning, undertaking and reporting progress on the incident, operating under a single governance hierarchy.

Recommendation 10: UKHSA should produce revised guidance on undertaking complex and sensitive investigations to rapidly identify the immediate cause so action can be undertaken. These investigations should:

a. Start with a risk assessment of the public health and other impacts and this should be regularly updated as part of upwards reporting.

b. Have a single approach to collating and analysing concerns about an issue or incident, especially those that come from external partners and those that reflect the lived experience of members of the public.

c. Systematically identify the potential causes of the incident, rigorously analysing each using evidence and data.

d. Include all relevant parts of the organisation and key partners in the investigation, with clear remits on their roles and responsibilities and clarity on the single line of accountability.

e. Have a proactive approach to communications with external stakeholders about the progress of the investigation, recognising that this can be challenging while the process is ongoing.

f. Build in a process for external challenge.

Chapter 4: Conclusions and recommendations

This chapter is divided into 2 sections – the first (Part 4A) sets out some general conclusions from the SUI investigation and the second (Part 4B) presents all the recommendations together.

Part 4A: Conclusions

4.1. This report has gathered a large body of evidence across multiple elements of this complex investigation and provided a summary of the key events in the timelines across Chapters 2 and 3. When assimilating all that has been examined, the SUI Investigation Panel has identified some themes across its review of both the First and Second Contracts between NHSTT and Immensa and the NHSTT Reviews to address concerns raised about people who had positive lateral flow device (LFD) results followed by a negative PCR result in September and October 2021. These themes are key to the context within which the management actions took place and offer further lessons for UKHSA beyond those already identified through other analyses undertaken by UKHSA in relation to the incident.

4.2. The approach to quality within NHSTT has been a recurrent theme, and UKHSA has identified quality as one of its core responsibilities. The SUI Investigation Panel has focused on testing in Pillar 2 which was a key part of the comprehensive response to the pandemic. The investigation has considered coordination between Pillar 2 testing with tracing, contain and Pillar 1 testing, especially the requirement for end-to-end, integrated quality systems. Specific aspects of quality were designed into particular workstreams and projects and significant resource was invested in quality assurance for Pillar 2. However, there was no overarching written statement or policy about NHSTT's approach to quality, including clinical governance. Many teams within NHSTT had quality objectives and systems but these were usually siloed from each other. There was no designated lead for quality across all aspects of NHSTT, or even within the testing programme.

4.3. Figure 2 shows the many facets of quality of clinical diagnostic laboratory services that were important in the pandemic as well as in business-as-usual times. All these facets require a culture that is open and transparent in handling and resolving concerns, leading to learning from events and therefore improving services for stakeholders and the public. UKHSA is committed to putting quality at its heart and so there are valuable lessons from this investigation to help inform this ongoing work.

Figure 2: Elements of an integrated end-to-end quality framework for pathology laboratories

Drawn from NHS Pathology Quality Assurance Review (2014) and Royal College of Pathologists Regulatory Landscape for Pathology

4.4. Understanding the regulatory and legal framework for commercial clinical diagnostic laboratories was key to the Panel's analysis of the context of the incident, in fulfilling its terms of reference. Witnesses' varying interpretations and understanding of the complex existing arrangements were a contributing factor in the root cause of this incident. The regulatory and legal framework is complicated and primarily designed for the NHS, contrasting with the more extensive regulatory and assurance systems for food, plant and animal health laboratories. The Panel has heard different understandings and interpretations of the legal requirements for laboratories outside the NHS. This was most explicit in relation to the different pathways to accreditation for NHSTT-commissioned COVID-19 PCR tests and for laboratories undertaking private commercial PCR tests. Thus, there are lessons for UKHSA about its responsibilities as a provider and commissioner of public health laboratories that provide results and data about people's health, many of which are based on testing of human samples. This could be considered in the wider context of a more coherent and resilient framework for commercial clinical diagnostic laboratories.

4.5. The Panel has heard about the great pressures on staff working on Pillar 2 testing and working on the NHSTT Reviews. The pandemic response made unprecedented demands on staff across the public sector and beyond, and NHSTT and PHE were at the heart of the response. Though organisational culture was outside the scope of the SUI investigation, as part of the root cause analysis, the SUI Panel needed to consider whether these pressures could have been in conflict with the Civil Service Code. If so, then they could have impacted on decisions made or actions taken within NHSTT. Witnesses have described their motivation to get services mobilised and contribute to controlling transmission of the virus, and some witnesses have spoken of the exceptional pressures they were under, especially at key points in the mobilisation of additional testing capacity. The financial pressures and the need to find people with the right skills have also been mentioned. The investigation has found no evidence of bullying, harassment or other improper behaviours.

4.6. The mobilisation of a large workforce from a standing start, during a pandemic, was a major achievement. The unprecedented rate at which individuals were recruited into both PHE and NHSTT incident management of the COVID-19 response led to a significant number coming from backgrounds unrelated to either the health system or emergency response. Although this brought many strengths to the response, there was a varying level of understanding and expertise in handling issues which could have an impact on the public's health. The Panel has highlighted the need for incident management training, which should in particular include the approach to investigating concerns with a potential public health impact. It is recognised this is among the many priorities for rapid training as part of the workforce expansion in a pandemic surge response.

Recommendations about corporate working for UKHSA

Recommendation 11: UKHSA's approach to assuring the quality of laboratory services should be based on a quality framework that covers the end-to-end process and integrates the diverse elements of clinical and service quality. This investigation has focused on contracted laboratory services but the framework must align with the quality systems and process used by its in-house laboratories. UKHSA is reviewing its approach to clinical governance and quality and this recommendation can inform this work.

Recommendation 12: UKHSA should build on its work on organisational culture and stakeholder relationships so that its approach is inclusive across all partners, at local, regional, national and UK-wide levels, ensuring those raising concerns feel heard and are appropriately responded to.

Recommendation 13: UKHSA should consider training on incident management systems and especially on the skills required to objectively investigate concerns with a potential public health

impact. This training needs to be part of preparedness and mobilisation in a surge scenario and would be for a wider cohort of staff than the Incident Director.

Recommendation 14: UKHSA should use this opportunity to clarify its role and the implications of the regulatory and legal framework for public health laboratories when commissioning laboratory services.

Part 4B: Lessons learnt

4.7. The teams in UKHSA took immediate actions after 12 October to prevent a similar incident occurring. The SUI Investigation Panel has shared its emerging findings and potential lessons with colleagues through the process of the investigation to help inform this process.

4.8. The SUI policy and procedure requires the SUI Investigation Panel to identify lessons for UKHSA and 3 groups of lessons have been identified:

a) Lessons about the procurement and quality assurance of contracted laboratory services

b) Lessons about the investigation of concerns with a potential public health impact

c) Corporate lessons for UKHSA from the investigation

Recommendations

Procurement and quality assurance of contracted laboratory services

Procurement and contracting:

Recommendation 1: UKHSA should ensure that it has consistent documentation when procuring laboratory services. This documentation needs to be specific about key quality requirements from laboratory providers on issues such as accreditation and performance indicators. The documentation should be produced through engagement between clinical and commercial teams.

Accreditation

Recommendation 2: UKHSA should require the appropriate UKAS accreditation as the default requirement for external laboratory providers, to bring it in line with the policy for in-house laboratories. In the very rare situations where the public health requirement means that UKAS accreditation is not initially possible, a staged process to achieve accreditation should be published. This process should be agreed with UKAS and should be explicit about the expectations of laboratory providers at the different stages of the accreditation process. The length of time that this interim staged process operates for should be stated and reviewed on a regular basis.

Recommendation 3: UKHSA should proactively ensure that its approach to laboratory accreditation is aligned to the approach of UKAS, especially for handling new and emerging infections. This process should be agreed with UKAS and be explicit about the expectations of laboratory providers at the different stages of the accreditation process. This should include adopting UKAS's terminology and agreeing which ISO standards should apply to which areas of UKHSA's activities.

Mobilisation and validation

Recommendation 4: UKHSA should publish a policy statement on its approach to quality assurance for laboratory services, both in-house and externally contracted. This statement should demonstrate how the disparate approaches to quality found by this investigation should operate together as a single integrated system of quality assurance.

Recommendation 5: UKHSA should produce a document about the quality elements of each procurement for laboratory services. This should set out the specific quality requirements expected of the laboratory providers and how these will be assessed, both in the procurement process and in the monitoring of the on-going contract delivery.

Contract monitoring

Recommendation 6: When awarding contracts, UKHSA should design the monitoring processes for commercial contracts to reflect the potential public health impact of the contract, alongside the existing obligation to ensure the commercial viability of service providers.

Recommendation 7: UKHSA should also design its operational service monitoring processes to reflect the requirements of a clinical diagnostic service. The monitoring processes should be consistent irrespective of the type of provider or size of the contract and be integrated into the overall approach to quality assurance. A comprehensive set of indicators for monitoring the performance of contracted laboratories should be developed – these need to be designed for the needs of that procurement and include performance triggers for when UKHSA should undertake detailed investigation.

Recommendation 8: UKHSA should formally record and thoroughly investigate concerns about laboratory services raised by internal staff and external expert partners. If necessary, a third party opinion should be sought.

Investigation into concerns with a potential public health impact

Recommendation 9: UKHSA should establish a single governance and reporting system for managing the response to incidents. There needs to be one process for commissioning, undertaking and reporting progress on the incident, operating under a single governance hierarchy.

Recommendation 10: UKHSA should produce revised guidance on undertaking complex and sensitive investigations to rapidly identify the immediate cause so action can be undertaken. These investigations should:

a. Start with a risk assessment of the public health and other impacts and this should be regularly updated as part of upwards reporting.

b. Have a single approach to collating and analysing concerns about an issue or incident especially those that come from external partners and those that reflect the lived experience of members of the public.

c. Systematically identify the potential causes of the incident, rigorously analysing each using evidence and data.

d. Include all relevant parts of the organisation and key partners in the investigation, with clear remits on their roles and responsibilities and clarity on the single line of accountability.

e. Have a proactive approach to communications with external stakeholders about the progress of the investigation, recognising that this can be challenging while the process is ongoing.

f. Build in a process for external challenge.

UKHSA corporate recommendations

Recommendation 11: UKHSA's approach to assuring the quality of laboratory services should be based on a quality framework that covers the end-to-end process and integrates the diverse elements of clinical and service quality. This investigation has focused on contracted laboratory services but the framework must align with the quality systems and process used by its in-house laboratories. UKHSA is reviewing its approach to clinical governance and quality and this recommendation can inform this work.

Recommendation 12: UKHSA should build on its work on organisational culture and stakeholder relationships so that its approach is inclusive across all partners, at local, regional, national and UK-wide levels, ensuring those raising concerns feel heard and are appropriately responded to.

Recommendation 13: UKHSA should consider training on incident management systems and especially on the skills required to objectively investigate concerns with a potential public health

impact. This training needs to be part of preparedness and mobilisation in a surge scenario and would be for a wider cohort of staff than the Incident Director.

Recommendation 14: UKHSA should use this opportunity to clarify its role and the implications of the regulatory and legal framework for public health laboratories when commissioning laboratory services.

Appendix 1: Terms of reference

Part A: Terms of reference for the Serious Untoward Incident investigation into PCR testing at the private laboratory October 2021

Under the UKHSA's SUI procedures, the terms of references are agreed by the Chief Executive and the following have been agreed:

1. To confirm (or otherwise) the analysis undertaken by the Incident Team on scale of incorrect reporting of COVID-19 PCT test samples by Immensa Health Clinic Limited to NHSTT/UKHSA.

2. To describe the arrangements put in place by NHSTT with Immensa Health Clinic Limited to work with and contract for COVID-19 testing and the role of accreditation in the decisions made. This will consider the context within which decisions were made and cover the period from initial engagement between DHSC/NHSTT and Immensa Health Clinic Limited.

3. To describe the selection process for testing providers and ongoing contract management arrangements, including quality assurance, performance management and audit.

4. To describe how concerns about the differences between positive COVID-19 lateral flow antigen test results and the results of COVID-19 PCR testing subsequently carried out by Immensa Health Clinic Limited were handled within UKHSA/NHSTT. This will consider the context within which decisions were made.

5. To determine the root cause(s) of the reasons for the incorrect reporting of these samples and why this was not identified until October 2021.

6. Subject to the findings of the investigation and identification of root cause(s), to identify lessons for UKHSA to implement.

7. To make recommendations for UKHSA on the implementation of these lessons including:

- systems and processes for managing contracts with private laboratory providers especially with regard to quality assurance and the monitoring and oversight of reporting
- systems and processes for identifying concerns, investigating these and escalating where required

8. If through the investigation there are wider lessons for the wider public health and healthcare systems, these should be described for UKHSA to raise with other parts of government.

Part B: SUI investigation panel

Richard Gleave, Director of Science Strategy and Development, UKHSA (chair)

Jenifer Mason, Consultant Microbiologist, (and Head of Clinical Governance, Science Group) UKHSA and Cambridge University Hospitals NHS Trust

Gwyn Morris, Deputy Director, Colindale Site and National Standards, Quality and Safety, Science Group UKHSA (until February 2022)

Rob Nixon, Director Commercial Group, UKHSA (until March 2022)

Paul Sutton, Director of EPRR, Clinical and Public Health Group, UKHSA

Dr Nick Watkins, Deputy Director – Data Science and Visualisation, Data Analytics and Surveillance Group, UKHSA

Secretariat

Charlotte Slater, Head of Four Nations and EU, Health Protection Operations, UKHSA

Philippa Simmonds, Engagement and Communications Lead, Health Protection Operations, UKHSA (until November 2021)

External advisers

Dr Ian Fry, former Consultant Pathologist and Clinical Director, Berkshire and Surrey Pathology Network, Frimley Health NHS Trust[22]

Professor Debbie Stark, Regional Director of Public Health, Office for Health Improvement and Disparities, Department of Health and Social Care and NHS England

Appointment by the Secretary of State

Kate Lampard, Lead Non-Executive Director for DHSC

[22] The organisation which hosts Dr Ian Fry (BSPS) was (and remains) a laboratory within the Pillar 2 network.

Appendix 2: Detail of data collection and analysis

1. Data collection

The SUI Investigation Panel has collected data both from verbal and written statements from participants/witnesses, and from documents (emails, contemporaneous reports, post-incident reviews and so on).

(A) Interviews

Supported by the terms of reference, the Panel developed a set of 'key lines of enquiry' (KLOE) focussing on the 2 core issues in the investigation (the engagement of Immensa and the handling of the incident). These KLOE were used to inform the approach to interviewing witnesses with an outline of areas of questioning produced for the Panel. The relevant groups in UKHSA were asked to identify an initial list of potential witnesses within the organisation and initial interviews were held with the most senior individual in each group, before a second set pf interviews with staff from their teams. Each interviewee received in advance the terms of reference of the SUI investigation, as well as the principles of the SUI Interview for consistency. Two members of the Panel were present at all interviews. The initial interviews were undertaken to gather information on how individuals and teams responded to the incident across a pre-determined timeframe and focused on fact-finding. The second set of interviews were conducted with senior leads across the group to discuss possible root causes and lessons, as well as address any gaps or points of clarification. Additional interviews were undertaken with key external stakeholders, including local authorities. An interview with Immensa had been requested but, in light of legal proceedings, a written statement was instead submitted addressing key questions from the SUI Investigation Panel.

(B) Documents

The Panel has analysed a wide range of different types of document. Broadly they can categorised as either contemporaneous records (emails, notes of meetings, reports, forms, contracts and so on) or post-incident documents, many of which were specifically requested by the SUI Investigation Panel.

There was important analysis undertaken by colleagues within UKHSA, separate to the SUI Investigation, notably: the public health incident report from the Incident Management Team ('Low positivity rates at the Immensa Wolverhampton laboratory: Incident Management Team Report'); the 'Internal Review Report' which was a desktop review by the Public Health and Clinical Oversight Team (PHCO) within the Testing Group; and the 'UKHSA Laboratory Final Validation Report: Immensa Health Clinic Ltd Incident,' by the Validation Team from Testing Group.

2. Analysis of evidence

(A) Timeline

The Panel approached the timeline of events across 3 distinct periods:

- the first being up to April 2021, to consider the wider pandemic context, management systems and processes within which decisions were made prior to the initial engagement between NHSTT and Immensa PCR surge testing contract
- the second being April 2021 to the period of activation of the Immensa Contract on 2 September 2021, to consider the procurement infrastructure and selection process for testing providers utilised in the surge contracts and ongoing contract management arrangements, including quality assurance, performance management and audit
- the last period being from the first time a potential problem was identified, to consider how concerns and investigations into the differences between LFD and PCR results were handled as well as to consider the analysis undertaken by the Incident Team on the scale of incorrect reporting

The Panel recognised the need to understand the contemporaneous context within which decisions were made in 2020 and 2021 and, as such, constructed a detailed timeline that identified key ministerial and policy decisions relevant across the time period.

To ensure key dates and decisions from all organisations were captured as part of the investigation, key groups were asked to provide a timeline of events perceived by individuals and/or teams as material to the investigation. The timeline commission covered any direct interactions with Immensa on any topics; any important internal discussions and decisions about engaging Immensa or arrangements with all laboratories as a group (including or potentially including Immensa); and engagements or agreements with other parties (that is outside UKHSA) about Immensa specifically or about arrangements for all private laboratories including Immensa.

Lastly, interviewees were asked to provide information on the governance structures that have been in place across the groups and directorates up to October 2021, to seek absolute clarity on the remit of key roles, accountabilities as well as to understand key meetings in which decisions relating to the contracting with private laboratories and this incident took place.

(B) Detailed analysis of key topics

To cover the breadth of issues that were in the terms of reference, Panel members focused on specific topics to assess the information collected and address key questions and themes:

i. Design and governance

An examination of how the 2 main areas of the SUI investigation (the contracts with Immensa and the investigation in September and October 2021) were shaped and impacted by the design of organisational structures, systems and processes and the subsequent governance of contracts and the incident.

ii. Commercial processes

An analysis of the commercial processes in 2020 and 2021, and how they complied with legal requirements and good practice

iii. Laboratory validation and quality assurance

A detailed review of the NHSTT Laboratory Assurance Team's Audit Report for Immensa's laboratory in Wolverhampton.

iv. Use of data and intelligence

A study of the information systems set up by NHSTT to collect and analyse the appropriate laboratory information to (a) manage the contracts of private laboratory providers and (b) manage a serious clinical incident in private laboratory providers.

v. Incident management

A review of the incident handling processes in September and October 2021 in light of best practice for handling incidents in a clinical service, including how UKHSA (and predecessors) engaged with local teams and partners.

vi. Root Cause Analysis (RCA)

The Panel collectively undertook a root cause analysis of the possible causes. The starting point was that the 'immediate cause' had been the error in setting the threshold levels for reporting results by Immensa. The Panel considered a number of approaches to RCA that have been used by the NHS, governments and the Health and Safety Executive. The method selected was a systems-based technique for accident analysis, specifically for analysing the causes of accidents and incidents that occur in complex socio-technical systems, called Accimap[23]. This has been used in public health outbreaks as well as other sectors and was seen as more flexible than the 'five whys' method referred to in the UKHSA SUI procedures. The approach to Accimap developed by the Australian government was followed[24]. The RCA did not identify a single root cause. This was not surprising given the complexity of this incident

[23] Rasmussen Jens. 'Risk management in a dynamic society: A modelling problem' Safety Science 1997: volume 27 issue 2-3, pages 183-213

[24] Branford K, Naikar N, Hopkins A. 'Guidelines for AcciMap analysis' In A Hopkins (Ed.) Learning from High Reliability Organisations 2011: pages 193-212

in a clinical service that had been contracted from a private provider. The Panel found Reason's 'Swiss Cheese Model'[25] more helpful in considering the missed opportunities to mitigate or prevent harm. The outcomes of the RCA helpfully provided the Panel with a list of contributory causes, defined by severity and organisational accountability.

In the final stages of evidence analysis, the Panel identified important areas requiring further clarity from witnesses, so a range of follow-ups were undertaken before providing final recommendations.

In addition, the Panel explored 3 specific areas. Firstly, there were on-going discussions and interviews with colleagues in national and local government and NHS in Wales as a significant proportion of the misreported results were on samples from Wales. Secondly, there were discussions with local government and with the team in UKHSA that survey people who have been tested in order to enable a fuller understanding of the impact of the incident on the lived experience of members of the public, their family and friends. Thirdly, there were considerations of the organisational culture, specifically to understand the pressures that existed on staff.

[25] Reason J. 'Human error' Cambridge University Press 1990

Appendix 3: The legal and regulatory framework for laboratories in England

i. Prior to the COVID-19 pandemic, nearly all clinical diagnostic tests (that is tests on samples from humans) were undertaken in the NHS. The NHS typically undertakes 1 billion tests a year, of which about 5% are microbiological test requests[26]. Some NHS hospitals had contracted with the private sector to provide diagnostic testing and these private laboratories also supported the private healthcare sector. PHE provided the public health laboratory service in England and also had some small contracts with the NHS and private laboratories. Its network undertook reference, surveillance, research, outbreak management and limited diagnostic testing. Universities and research institutes, including public sector research institutes, undertake testing of human samples, primarily for academic purposes but sometimes for specialist diagnostic data.

ii. A 2017 document by the Royal College of Pathologists[27] provides a very helpful description, by a key professional body, showing the complexity of different elements of the landscape and the responsibilities of various organisations.

iii. The responsibilities of providers and commissioners of laboratory services in the NHS are described in the NHSE 2014 Review of Pathology Quality Assurance. This stated “under the commissioning framework, commissioners have a duty of care to ensure all commissioned services are safe and of agreed quality”[28]. Section 1A sets out the Secretary of State for Health’s duty in relation to the health service for improvement in the quality of services, including services for the protection of public health, which include securing outcomes that show the safety of services.

iv. Clause 2b of Section 2A of the 2006 NHS Act sets out that the Secretary of State must take the necessary steps to protect public health from the threat of disease and other dangers including by “providing microbiological or other technical services (whether in laboratories or otherwise”. NHSTT contracting for private laboratories to provide clinical diagnostic laboratory services is within this scope however, as it was not an NHS body but part of the Department of Health and Social Care, the duty in Section 1A to health services may not automatically apply.

[26] NHS England National Pathology Programme Digital First Report and Lord Carter Report (2008)

[27] The Regulatory Landscape for Pathology Services

[28] NHS Pathology Quality Assurance Review

v. Commercial law provides the legal basis for the procurement and contracting for goods and services. Specific government regulations and best practice documents provide additional information about the requirements on public bodies. There are no specific requirements for the procurement of clinical diagnostic laboratories. Specifying requirements, evaluating tenders to award contracts and monitoring delivery are all important formal mechanisms through which the commissioner delivers its responsibilities. However, best practice in both contract management and commissioning health services has shown the importance of non-legal mechanisms to deliver high quality services, though specific guidance on commissioning pathology services in the UK has not been published[29].

vi. UK legislation requires various competent authorities to verify compliance with regulations and to award and review licences. By means of The Accreditation Regulations 2009 (SI 2009 3155), the United Kingdom Accreditation Service (UKAS) is appointed as the national accreditation body for the UK[30], and therefore the responsible body for determining the accreditation status of Immensa. Prior to 2013, medical laboratory accreditation was run by Clinical Pathology Accreditation, which transferred into UKAS in October 2013.

vii. Thus, UKAS is the national designated and recognised accreditation body for medical laboratories undertaking diagnostic testing. The main international standard that forms the basis of accreditation of medical laboratories is ISO15189, though other standards cover other related types of laboratory work. Typically, UKAS undertake an on-site assessment, sometimes conduct sampling exercises and engage with a range of staff including clinicians and consultants responsible for the laboratories. The process is not undertaken to achieve a blanket accreditation for a laboratory, but is test- and site-specific.

viii. Prior to the pandemic, accreditation was not mandatory but NHS England[31] and PHE[32] endorsed having all medical laboratories accredited with UKAS. The process for laboratories to achieve an accredited status took anywhere between 6 and 12 months.

ix. There are some additional legal and regulatory conditions for NHS laboratories, but these are not directly relevant to this incident. The Care Quality Commission regulate sites that deliver healthcare services to the public. As most NHS laboratories are on such sites they are covered by this regime. The policy and delivery frameworks developed by NHSE/I for the NHS do not cover Pillar 2 testing, though they may be a source of good practice advice.

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[29] NHSE/I indicated in 2019 that they planned to produce guidance on this issue for the NHS, but it has not been published

[30] Conformity assessment and accreditation policy

[31] NHS England, NHS Improvement and Care Quality Commission's position on Diagnostic Accreditation Schemes

[32] PHE Quality Strategy 2020, paragraph 6.4

x. In the COVID-19 pandemic, the initial position on accreditation was set out in a letter from UKAS to all applicants and accredited providers of medical laboratories that stated "You will be aware that from 16 March 2020 UKAS ceased performing on site assessments and started implementing remote assessments. Whilst many UKAS customers are able to accommodate remote assessments, it is apparent that this is not possible for the healthcare services that are impacted by this crisis." UKAS resumed assessments after the initial 6 month period (September/October 2020) and whilst assessments did continue remotely during the various lockdown periods, there were no further periods where assessments were intentionally postponed[33]. There was a significant backlog in accreditation visits resulting from the 7-month delay. Immensa's Wolverhampton laboratory was a stand-alone laboratory on a science park rather than on a healthcare campus.

xi. In December 2020, DHSC and UKAS announced a formal 3-stage process for achieving accreditation for private laboratories undertaking commercial PCR testing (that is for travel and other purposes) that was brought in from January 2021[34]. Each stage set out the required progress through the accreditation process within defined timescales. Immensa applied for accreditation through this route on 30 December 2020. This function transferred from DHSC to NHSTT in April 2021.

xii. Health and healthcare organisations need a wide framework for quality issues. There is a statutory duty for NHS bodies to have clinical governance systems and a range of other quality systems and processes – including assurance of both in-house and contracted services. Clinical governance is "the system through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which clinical excellence will flourish."[35] Clinical governance encompasses quality assurance, quality improvement and risk and incident management[36]. Neither PHE nor NHSTT were NHS organisations and so the formal requirement to establish clinical governance systems did not apply to them although both decided it would inform their work.

[33] Communication with UKAS including a copy of the letter

[34] Accreditation for COVID-19 testing

[35] 'Clinical governance and the drive for quality improvement in the new NHS in England' British Medical Journal 1998: volume 317, page 61

[36] Clinical governance and Governance, patient safety and quality

Appendix 4: Additional information about accreditation and Immensa

(A) Timeline of Immensa's application for accreditation

Immensa applied for accreditation with UKAS through the route for laboratories undertaking private commercial work that had been created specifically for these laboratories and was run by DHSC (moving to NHSTT in April 2021). An application for accreditation for the contracted work for NHSTT would have been through the normal route into UKAS.

Timeline for the application for the private work

30/12/20	UKAS first received an application from Immensa for the PerkinElmer assay at Wolverhampton.
21/2/21	Stage 2 review for the PerkinElmer assay submitted to UKAS.
26/7/21	Updated application via an email from Immensa's Quality Manager that included Nonacus assay.
17/8/21	Preassessment meeting with the laboratory at which they informed UKAS that they were no longer using the PerkinElmer method (note that Immensa have said that they reverted to using the PerkinElmer assay for delivery of the NHSTT work when they were awarded the second contract which started on 2 September 2021 and this is the assay with which there was an error in setting the threshold levels).
17/09/21	UKAS team made a conditional recommendation following the initial assessment for testing as a private provider (stage 3 assessment for private provider). The recommendation was for Nonacus only and not PE. The conditions included submission of further evidence and close out of key findings from the assessment and the final decision would have been with an independent decision maker within UKAS.
26/10/21	UKAS retracted the above recommendation made on the basis that the testing was no longer being performed at the location where it had been assessed.

(B) NHSTT's stated requirements about accreditation and Immensa's response

The description of the requirement on accreditation in the different documents was as follows:

Record of statements about NHSTT's requirement on accreditation

Document	Date	Wording			Comments from the SUI Investigation Panel
NHSTT/DHSC statement of requirements for testing in summer 2020	No date	No wording			No documents found
Contract with Immensa	Sept 2020	4.6 "Supplier shall, at its own cost, be solely responsible for performing the Services, and ensuring that all Supplier Parties perform the Services, at all times in accordance with … (d) in compliance with UKAS accreditation requirements, or the requirements of any successor or replacement body of UKAS;"			Though this is what the contract says, DHSC and NHSTT decided any clauses in the contract about accreditation would not apply. This was not documented anywhere.
National Microbiology Framework Lot 4	February 2021	2.5.4	Desirable	(*) Is your laboratory accredited to ISO 15189?	The wording in 2.5.6 and 2.5.9 makes clear that any company bidding either says "yes" or withdraws. The Panel has not found any record of the checking that an application had been made, though we know that Immensa had made
		2.5.5	Desirable	If you answered yes to Q2.5.4 please provide the certificate.	

		2.5.6	Mandatory	(*) If your laboratory isn't accredited to ISO 15189 please confirm you are willing to become accredited as part of any Call-Off Contract which is let. Scoring No = Automatic Rejection.	an application that was progressing through the commercial work route established in January 2021. The Panel has identified a much more tangible and simple alternative question which was “have you made a formal application to UKHSA to seek accreditation for ISO xxxx?”. Immensa answered • no to 2.5.4 • yes to 2.5.6 • no to 2.5.7 • yes to 2.5.9 • ISO13485 to 2.5.10
		2.5.7	Mandatory	(*) Is your laboratory usually accredited to ISO 17025?	
		2.5.8	Desirable	If you answered yes to Q2.5.7 please provide the certificate.	
		2.5.9	Mandatory	(*) If your laboratory isn't accredited to ISO 17025 please	

				confirm you are willing to become accredited as part of any Call-Off Contract which is let. Scoring No = Automatic Rejection.	
		2.5.10	Mandatory	(*) Please provide details of any other accreditation schemes your laboratory adheres to.	
Invitation to apply for surge mini-tender in summer 2021	9 July 2021	Lot 4 Template Order Form			This required labs to be accredited and again the Panel has been told that NHSTT did not apply this requirement. The Panel has not identified any document that explains this. Immensa accurately stated it was not accredited.
		“Samples”	means the samples relating to the provision of Tests required to be retained by UKAS guidelines;		
		“UKAS”	means the United Kingdom Accreditation Service being national accreditation body		

			recognised by the British government to assess the competence of organisations that provide certification, testing, inspection and calibration services (or any successor or replacement body of UKAS) or any equivalent EU certification agreed in writing in advance with the Authority;	The Panel have been told that NHSTT should have added a variation to the clauses about accreditation to state that there was instead a requirement for a NHSTT validation process (the Audit Report) to be completed prior to mobilisation (though this would be after the decision to award was made). Immensa's bid against this mini-tender did not mention accreditation (and it was not required to).
		2.1.6	Maintain UKAS accreditation in respect of the Facilities;	
		3. Operation of the Services	3.1 The Supplier shall provide the Services 3.1.1 in accordance with Good Scientific Practice; 3.1.2 in compliance with UKAS accreditation requirements	
		3.4.5	to ensure and guarantee any Sub-contractor appointed by Supplier to provide any element of the Services is	

			UKAS accredited at the time of providing the relevant part of the Services	
		9 Additional Supplier Warranties	9.1 The supplier to warrants and undertakes that: 9.1.1 during the Term, the Facilities will be operated in a manner that is compliant with, and has all necessary consents in relation to standards set down by UKAS;	
Contract with Immensa for surge contract	30 July 2021	3.1, 3.1.5 and 3.1.6 say “The supplier shall … ensure that all relevant consents, authorisations, licences and accreditations required to provide the Services and the Supplier Facilities are in place at the Services … Commencement Date and are maintained throughout the Term; ... maintain UKAS accreditation in respect of the Facilities;“		Though this is what the contract says, the Panel has been told that NHSTT decided the requirement to maintain UKAS accreditation in the contract would also not apply to this the second contract with Immensa. The Panel has not seen any document recording this. The contract was signed prior to the completion of the pre-mobilisation Audit Report process which included an assessment of the validation status of the provider (which was, in Immensa’s case, not accredited).

(C) NHSTT's records of Immensa's accreditation application and status

Laboratory	NHSTT records on accreditation status	Commentary
Dante Italian laboratory	NHSTT records are that the laboratory was accredited in Italy for COVID-19 and so it was approved against the accreditation requirement.	It was not accredited with UKAS though it may have been recognised for UKAS accreditation if it was accredited with Accredia, the relevant Italian agency through the International Laboratory Accreditation Cooperation (ILAC) – UKAS. The Panel has contacted Accredia and established that the Dante Italian laboratory was registered but not accredited.
		The NHSTT auditor's comments on the Audit Report for Dante does not comment on ISO15189 for medical laboratories (instead commenting on accreditation for ISO 13485 for medical devices). The NHSTT auditor statement that the laboratory is authorised by the Italian government is not supported by the documents that were submitted to NHSTT. These were for local health bodies and did not include anything from Accredia.
Immensa Wolverhampton laboratory	NHSTT record is that the laboratory was approved as passing the accreditation row in the audit form but unclear when this approval was made.	Immensa's submission on the NHSTT Audit Report was dated 18 December 2020 and states "We have requested ISO15189 accreditation to include COVID-19 tests" with a link to a letter from Immensa enquiring about the accreditation process to UKAS on 16 December 2020. Later on the Audit Report states "we … have an

	The Panel understand that passing the accreditation row on the Audit Report is not the same as accreditation.	active application in place" but it is not possible to be clear when this statement was made. However, the 18 December 2020 entry and linked email from Immensa is not a 'request' nor an 'active application' but an enquiry.
		An application for accreditation to ISO 15189 was received by UKAS on 30 December 2020 from Immensa through the private commercial work route. The preassessment visit covered the Nonacus assay, which was used for the private commercial work in Summer/Autumn 2021
		On 1 February 2021, the NHSTT validation form reads "Seen an email to UKAS making enquires. UKAS agreement signed seen the certificate". The meaning of this is not clear (and it has not been possible to contact the person who made the entry) but it appears to support that an application had been made and acknowledged by UKAS.

Appendix 5: Key events in relation to NHSTT's laboratory validation and mobilisation processes for Immensa

Date	Action	Commentary
27 July 2020	Audit Report for Dante's Italian laboratory is completed.	No commentary.
26 November 2020	Design Authority Review Group met and approved Dante Italian laboratory.	This was about 3 months after the start of the contract.
c.9 December 2020	Work started on the Audit Report for the Immensa Wolverhampton laboratory	No commentary.
20 December 2020	Email from Validation Team lead saying Immensa's Wolverhampton laboratory was approved and the documentation needed to be completed the following week.	Approval to start testing prior to completion of the Audit Report and without a mobilisation meeting was unusual, possibly unique.
December 2020 to March 2021	Six or 7 unsuccessful attempts to complete the Audit Report between 20 December 2020 and end of March 2021 (the formal end of the contract).	The Audit Report was not completed for the period of the first contract.
c.19 August 2021	Work started on outstanding Audit Report.	No commentary.
26 August 2021	Audit Report signed off as completed.	No commentary.
31 August 2021	Go Live Meeting approved Immensa to start testing.	No commentary.

Appendix 6: Detail of the timeline for the NHSTT review in September and October 2021

Date	Event	Commentary
8 September	PHE South West Health Protection Team (SWHPT) logged a local incident that 62 people tested positive using LFDs at a school in Bristol and 60 of these had negative PCR results.	This was not escalated to the SOC but logged on the PHE Health Protection Zone IT system, as part of the PHE recording of managing the outbreak.
11 September	First spike in the positivity rate from Immensa Wolverhampton laboratory (10/09 rate was 0.8% and it rose to 6.9% on 11/09, falling to 0.5% by 15/09).	This was not picked up at the time.
13 September	An email from within NHSTT Contain Team to Testing Incidents email address sharing an email from Swindon local authority about discordant LFD and PCR results.	It is unclear what the response had been to this email.
15 September	At the NHSTT South West Test Trace Contain Enable Board, reports were noted from local directors of public health on discordant results and an action agreed to collate all reports of the issue from local authorities.	This board was formally part of NHSTT's internal governance but also part of the regional partnership arrangements between PHE and NHSTT.
16 September	NHSTT Integrator Team raised concerns with Testing SOC around increase in issues being reported to them.	Integrator and SOC were part of the same Directorate in Testing Group.
	119 national COVID-19 advice service and NHSTT SOC discussed the increase in calls that raised the issue of positive LFDs followed by negative confirmatory PCRs.	No commentary.
	In response, NHSTT SOC requested that 119 collected all such issues and report them into the SOC team.	No commentary.

	PHE SWHPT escalated issue to testing and NHSTT Public Health and Clinical Oversight team.	
17 September	PHE SWHPT escalated issue in their section of the NCRC COVID-19 Situational Awareness Regional Report which noted working with national teams to investigate reports of discordant results.	This was primarily within PHE governance though linked into NHSTT through NCRC
22 September	NHSTT Patient Safety Panel reported back on the discordant results from a request from SOC a few days earlier. The focus remained on issues with LFDs.	No commentary.
	NHSTT SOC raised a 'ticket' about discordant LFD and PCR results. Reports arrived into SOC this day including an email from the Weston-super-Mare testing site (which stated that the site thought that the positivity rate had dropped since samples started going to Immensa's laboratory in Wolverhampton), and concerns from the SW Regional Contain and HPT teams at the SOC meeting.	This is the first formal record of this as an incident, but no record of investigation into positivity rate or Immensa laboratory.
	PHE Strategic Response Group discussed the concerns which the notes record as being about "accurate and reliable testing methods in the UK". PHAGE (Public Health Advice, Guidance and Evidence) Cell was tasked with sharing the relevant publications. There is a general agreement that in addition to the South West Partnership Team (the regional Health Protection and Contain Teams) continuing to link with the SOC, PHAGE would link to the Public Health and Clinical Oversight (PHCO) team in the Testing Programme.	There is no record of any follow up in subsequent meetings until 6 October when the action is noted as closed with a note stating PCR remains the gold standard, PHCO team received a report from PHAGE and actioned it in their work with the SOC.
23 September	A short slide pack was sent to SOC from the South West Regional Partnership Team. This was part of their local work looking for possible causes and the slides	The slide pack and emails from the PHE field service within the Partnership Team and then sent to SOC outlined the local team's view

	had been escalated from discussions within the region on 16 September.	that 3 possible causes of the positive LFD/negative PCR issue (sampling (timing and/or technique), LFD and PCR) needed to be investigated.
24 September	NHSTT advised stakeholders and clinical leads that PCR was the gold standard test and thus PCR results should be used by members of the public and professionals as the basis for actions.	No commentary.
23 to 27 September	The daily monitoring reports showed a second spike in positivity rates in Immensa's Wolverhampton laboratory (0.4% on 22/9 and then 3.1%, 17.4%, 9.2%, 18.9%, 10.8%, and then 0.4% on 28/9)	This was not identified at the time.
30 September	NHSTT SOC received a review of a small sample of the original tests for 11 citizens where the PCR test went to the Immensa Wolverhampton laboratory. Among the 11 samples, 7 citizens had initially received positive LFD/negative PCR results. Two of these 7 had a negative PCR from Immensa and the review showed the subsequent PCR from another laboratory was positive.	This is a very small sample thus the percentage of inaccurate PCR results was c.29%. It is unclear what action was taken.
1 October	UKHSA created from PHE and NHSTT.	No commentary.
1 October	The daily monitoring reports showed a third spike in Immensa positivity rate (30/09 rate was 0.1% and 01/10 was c4% and then 0.4% by 04/10).	This was not identified at the time.
7 October	A further communication from former NHSTT to local authorities was planned and a senior clinical leader felt that this needed to be updated rather than the same message being sent out again.	This event prompted wider discussions about what was happening to address the concerns.
	Former PHE Epidemiology Incident Cell presented data that showed the variable geographical distribution of the 'rescind' rates that is a clear geographical pattern	This was the first time that errors in PCR were seriously looked at in detail.

	of where the discordant results were being recorded.	
	The former NHSTT Public Health and Clinical Oversight (PHCO) team in Testing Group was tasked with undertaking a structured investigation into the issue of discordant results.	This was paused to deliver the response from 12 October onwards.
8 October	A joint commission from former PHE and NHSTT senior leaders to Testing Group to analyse the positivity rate in laboratories prompted by the Epidemiology Cell's presentation. This was to be delivered through the SOC.	This was undertaken over the weekend and on the Monday 11 October a meeting was held to look at laboratory positivity rates alongside other relevant data.
12 October	The former NHSTT Laboratory Operations Team identified that the positivity rate from the Immensa Wolverhampton laboratory was exceptionally low.	No commentary.
	UKHSA meeting with Immensa to suspend testing with immediate effect.	No commentary.
	A Rapid Incident Management Team (IMT) was convened by the Interim Group Lead for Clinical and Public Health as part of the COVID-19 response through the NCRC and Contain structures. This undertook a public health risk assessment and managed the response to the incident.	No commentary.
15 October	UKHSA make announcement on the suspension of testing at the Immensa Wolverhampton laboratory.	No commentary.
18 October	A visit to the Immensa Wolverhampton laboratory by former NHSTT Validation Team members to help inform a report they produced.	Report is titled 'UKHSA Laboratory Validation Final Report Immensa Health Clinic Ltd Incident'.

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UKHSA is responsible for protecting every member of every community from the impact of infectious diseases, chemical, biological, radiological and nuclear incidents and other health threats. We provide intellectual, scientific and operational leadership at national and local level, as well as on the global stage, to make the nation health secure.

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