Witness Name: Neil Evans
Statement No.: 1
Exhibits: 4
Dated:26/05/2025

UK COVID-19 INQUIRY

WITNESS STATEMENT OF Neil Evans

I, Neil Evans, will say as follows: -

Introduction

1. This statement is submitted in response to the Rule 9 request from the UK Covid-19 Public Inquiry (Module 7) and subsequent section 21 notice, examining the UK's approach to testing, tracing, and isolation during the COVID-19 pandemic, specifically focusing on the period from 1 January 2020 to 28 June 2022. The purpose of this document is to provide detailed insights based on my direct involvement and leadership roles within key testing facilities, highlighting my experiences, observations, and relevant contributions toward national pandemic response efforts.

Background

2. My name is Neil Evans. Between July 2020 and March 2022, I was actively involved in significant operational and leadership capacities within key COVID-19 testing facilities across the UK. My roles included strategic oversight, operational leadership, and quality assurance, each essential to the national response to the unprecedented public health crisis caused by the COVID-19 pandemic.
3. From July 2020 to September 2020, I was employed as COVID-19 Testing Facility Manager and Quality Lead at Cardiff University. My primary responsibility was to rapidly establish an automated asymptomatic COVID-19 testing facility. This involved designing and validating a multiplex qPCR assay, implementing

advanced magnetic bead nucleic acid extraction techniques, and establishing a comprehensive Laboratory Information Management System (LIMS) for sample and data tracking.

4. However, significant concerns arose during this process regarding Cardiff University's approach. The initiative, driven independently by the Vice Chancellor's office, aimed primarily to ensure student attendance—described colloquially as placing "bums on seats" for the 2020/2021 academic year—rather than integrating with the broader national public health effort. Despite my repeated advocacy for rigorous validation and benchmarking of the testing procedures against NHS laboratory standards, institutional pressures favored an accelerated deployment over thorough validation. Due to my professional commitment to diagnostic accuracy, patient safety, and adherence to quality standards, I formally expressed these concerns to senior management and consequently resigned from my position on 23 September 2020, before the testing programme launched.
5. From September 2020 to April 2021, I served as Laboratory Manager at the DHSC PerkinElmer Lighthouse Laboratory in Newport. This facility was integral to the UK Government's strategic response, forming part of the wider Lighthouse Laboratory Network managed initially by DHSC and later by UKHSA. These laboratories bolstered public health capabilities, complementing and significantly enhancing the capacity of existing NHS and academic laboratories initially managing COVID-19 testing. At Newport, my responsibilities included overseeing the full spectrum of laboratory operations (Accessioning, RNA Extraction, PCR, and Sign-Out), managing multidisciplinary teams, and ensuring strict compliance with ISO 15189 standards.
6. From May 2021 to March 2022, I held the role of Deputy Lead Scientist at the BSPS Lighthouse Laboratory in Bracknell, another critical component within the DHSC/UKHSA Lighthouse Laboratory Network. My role involved strategic operational management, ensuring high-throughput capacity and resilience. I managed a large, multidisciplinary workforce and ensured continuous compliance with regulatory and quality standards, even amid intense demand.
7. During this period, regulatory oversight for commercial diagnostic tests typically required CE marking and MHRA approval. However, recognising the emergency context, regulatory bodies introduced some flexibility, granting temporary allowances for certain testing kits without immediate CE marking. Similarly, the

Health and Care Professions Council (HCPC) provided emergency short-term registration for students enrolled in IBMS-accredited degree programmes, allowing them to join the workforce swiftly, significantly bolstering laboratory staffing capacity at critical moments.

8. My extensive experience, underpinned by professional qualifications in molecular diagnostics and quality management, provided me with a comprehensive understanding of the development, challenges, and efficacy of COVID-19 testing infrastructure in the UK throughout the pandemic.

Infrastructure, Capacity and Technology

9. Prior to the pandemic, diagnostic infrastructure in the UK was predominantly geared towards routine testing within NHS and Public Health laboratories, which lacked scalability and integrated data management necessary for large-scale public health crises. Consequently, the initial response capabilities were severely limited.
10. At the onset of the COVID-19 pandemic in early 2020, the United Kingdom's diagnostic testing infrastructure was primarily concentrated within NHS and Public Health England (PHE) laboratories. These facilities were designed for routine diagnostics and lacked the scalability required for mass testing during a public health emergency. Consequently, the initial response was hampered by limited testing capacity, fragmented data reporting systems, and logistical challenges in sample collection and processing.
11. In response to these challenges, the Department of Health and Social Care (DHSC) initiated the development of the Lighthouse Laboratory Network. These high-throughput laboratories were established in partnership with NHS trusts, academic institutions, and private sector entities to rapidly expand testing capacity across the UK. The network included facilities in Milton Keynes, Alderley Park, Glasgow, and later, Newport and Bracknell, among others.
12. The Lighthouse Laboratories were equipped with advanced automation, robotics, and integrated Laboratory Information Management Systems (LIMS) to handle large volumes of PCR tests efficiently. This infrastructure enabled a significant increase in daily testing capacity, reaching over 750,000 tests per day by March 2021.
13. The Lighthouse Laboratory Network became a central component of the UK's NHS Test and Trace programme, managed initially by DHSC and later by the UK Health

Security Agency (UKHSA). These laboratories processed samples from various testing routes, including community testing sites, home testing kits, and mobile testing units, thereby playing a crucial role in identifying and isolating COVID-19 cases to prevent further transmission.

14. In contrast to the nationally coordinated efforts, Cardiff University independently established an asymptomatic COVID-19 testing facility in mid-2020. The initiative, driven by the university's executive leadership, aimed to facilitate the return of students and staff to campus for the 2020/2021 academic year. While the intention was to ensure safety and continuity of education, the programme operated outside the national testing framework and lacked integration with NHS and PHW systems.
15. As the COVID-19 Testing Facility Manager and Quality Lead at Cardiff University during this period, I was responsible for the rapid establishment of the testing facility, including the design and validation of a multiplex qPCR assay and the implementation of a LIMS. However, I raised concerns regarding the expedited timeline and the need for rigorous validation against NHS laboratory standards. Due to these unresolved concerns, I resigned from my position prior to the launch of the testing programme.
16. The Lighthouse Laboratories utilized commercial assays and automated systems to enhance testing efficiency and throughput. At the Newport facility, Perkin Elmer's commercial assays were employed, which were widely used across the Lighthouse Laboratory Network and public health laboratories both in the UK and internationally. These assays contributed to the standardization and scalability of testing processes.
17. At the Bracknell facility, the Thermo Fisher Scientific Amplitude Solution system was implemented. This high-throughput platform, incorporating Thermo Fisher's assays, was also utilized globally, reflecting its reliability and efficiency in large-scale testing operations.
18. The overall leadership and strategic direction of the NHS Test and Trace programme, including the Lighthouse Laboratory Network, were under the purview of Baroness Dido Harding, who was appointed as the Executive Chair of NHS Test and Trace in May 2020. In this role, she oversaw the implementation of mass testing and contact tracing programmes as part of the government's response to COVID-19. Baroness Harding reported directly to the Prime Minister and Cabinet Secretary.

19. Supporting the programme, Lord James Bethell served as the Parliamentary Under-Secretary of State for Innovation at the Department of Health and Social Care from March 2020 to September 2021. He was involved in scaling up the UK's testing network and played a role in the strategic development of testing policies and procurement during the pandemic.
20. Given the urgency of the pandemic, regulatory bodies introduced temporary measures to expedite testing capabilities. The Medicines and Healthcare products Regulatory Agency (MHRA) provided emergency use authorisations for certain diagnostic tests, allowing their deployment without the standard CE marking process. Additionally, the Health and Care Professions Council (HCPC) implemented emergency registration protocols, enabling final-year biomedical science students to join the workforce and support the increased demand for testing services.
21. From September 2020 to April 2021, I served as the Laboratory Manager at the DHSC PerkinElmer Lighthouse Laboratory in Newport. This facility was integral to the national testing strategy, processing up to 10,000 PCR tests per 12-hour shift. My responsibilities included overseeing laboratory operations, ensuring compliance with ISO 15189 standards, and collaborating with quality assurance teams to maintain high testing accuracy and reliability.
22. Subsequently, from May 2021 to March 2022, I held the position of Deputy Lead Scientist at the BSPS Lighthouse Laboratory in Bracknell. In this role, I provided strategic and operational leadership for a high throughput testing department, managing a multidisciplinary team and ensuring service continuity, quality, and compliance under intense operational pressures.

Overview and Development

23. At Cardiff University, an in-house testing laboratory was established where custom assays were developed based on RNA sequence data from published academic literature on the SARS-CoV-2 viral genome. The automation infrastructure comprised both new and second-hand equipment acquired from suppliers with available stock at the time. Extraction reagents were supplied by Dr Tomas Jurkowski, an academic employed by the University, via his newly established company, MagnaCell Ltd., at considerable cost to the institution.
24. The testing methodology employed high-throughput RT-PCR using saliva samples from university staff and students, rather than the more commonly used

nasopharyngeal swabs. Although the system was designed with a daily processing capacity of 2,000 samples, this volume was never fully realised.

25. At the PerkinElmer-operated Lighthouse Laboratory in Newport, most of the automated equipment and all reagents, including the test assay, were provided by PerkinElmer LAS Ltd and PerkinElmer Genomics (now Revvity Ltd). PCR instrumentation was sourced from Analytik Jena due to limited lead times from mainstream manufacturers.
26. At the Berkshire and Surrey Pathology Services (BSPS) Lighthouse Laboratory in Brants Bridge, all equipment, reagents, and assays were supplied by Thermo Fisher Scientific, with engineering support provided on-site.

Inequalities and Vulnerability Considerations

27. My role was confined to the high-throughput processing of anonymised samples, and as such, I not been involved in or had any oversight of the allocation or accessibility of testing services across demographic groups within the UK. At both the Newport and Brants Bridge sites, samples were categorised as either "Priority" or "Standard", with classifications predetermined by the Department of Health and Social Care (DHSC). My understanding is that these distinctions were based on clinical factors, such as symptomatic versus asymptomatic testing, rather than demographic or geographic considerations.

Robustness and Efficacy

28. I wish to highlight three key concerns regarding the robustness and efficacy of the testing regimes at the laboratories where I held managerial responsibilities:

29. The Cardiff University testing programme lacked sufficient validation prior to deployment. Given the novel use of saliva as a sample medium and the use of research-grade extraction beads, extensive validation against known standards should have been undertaken to establish diagnostic sensitivity, including the limit of detection. This concern was initially raised by Dr Cathrine Moore and Dr Robin Howe of Public Health Wales (PHW). Despite providing personal assurances based on my expertise in PCR diagnostics, I ultimately resigned from the project when the University's Executive Board proceeded with implementation against my

professional advice. This posed a significant risk of undetected false negatives that were provided to patients without question or confirmation. Individuals who tested positive through this system were directed to undergo confirmatory testing through PHW or government-operated facilities.

30. More serious concerns emerged at the Newport Lighthouse Laboratory regarding the reliability of the test assays supplied by PerkinElmer. Internal communications, including emails with senior personnel, document inadequate assay controls and the suppression of concerns regarding false negative results. These issues persisted during a critical period in March 2021 when contract extensions were under negotiation. Although the assays were CE-marked and had passed regulatory approval by bodies such as the MHRA and FDA, the deficiencies identified compromised test reliability and were not appropriately escalated.

31. The Thermo Fisher assay used at the BSPS laboratory, while CE-marked and regulator-approved, presented a potential flaw due to the absence of a human "housekeeping" gene control. The assay targeted three loci of the viral genome and incorporated a spiked extraction control, but did not include a means to verify human sample adequacy. In clinical settings with professionally conducted swabbing, this might be acceptable. However, the widespread use of self-swabbing introduced variability in sample quality, increasing the risk of insufficient samples yielding false negative results. I raised this concern with a senior staff member, who responded that proper swabbing technique should be assumed of the public—an assumption I believe to be professionally and diagnostically unsound.

32. Notwithstanding the concerns previously outlined, it is important to acknowledge the substantial and commendable contributions made by academic institutions, commercial partners, and the NHS in establishing a national COVID-19 testing infrastructure at remarkable speed, under extraordinary circumstances. Despite inevitable initial challenges, a largely inexperienced workforce—comprising recent graduates and students whose studies were disrupted by the pandemic—adapted to the demands of a highly regulated clinical diagnostics environment.
33. While early issues were widely reported, including the investigative *Panorama* exposé of practices at the Milton Keynes mass testing site, many of these shortcomings were progressively addressed. As new laboratories became

operational, improvements were implemented and lessons learned. The Government played an increasingly effective role in setting and enforcing key performance indicators, including a 2% void rate and an 8–12 hour turnaround time, with penalties for non-compliance. The dedication and engagement of staff were critical to achieving these standards, and in this regard, both the Newport and Brants Bridge facilities performed exceptionally well.

34. The requirement for scientific personnel to work 12-hour continental shift patterns—both day and night—represented a significant departure from their usual working conditions, which had previously involved only occasional unsocial hours through "on-call" duties. Furthermore, the concept of large-scale molecular testing was largely unfamiliar prior to the pandemic. Many existing laboratories, often located in outdated facilities, lacked the capacity to scale operations rapidly. In this context, the private sector—particularly commercial organisations with established supply chains and equipment reserves—played a pivotal role in rapidly establishing extensive laboratory infrastructure within a matter of months.
35. It must also be acknowledged that instances of misconduct did occur, with certain private entities prioritising profit over patient care, thereby undermining broader public health efforts. The Immensa laboratory testing failure in late 2021 serves as a stark example, as does the mishandling of my internal concerns by Perkin Elmer, as outlined previously. However, these regrettable episodes should not overshadow the collective achievement: a coordinated national effort, spanning laboratories from Glasgow to Plymouth, which succeeded in delivering a mass testing programme that would have seemed inconceivable mere months prior.

Adequacy and Lessons for the Future

36. In retrospect, it is evident that the United Kingdom was insufficiently prepared for a pandemic driven by a viral pathogen. In my professional opinion, this lack of preparedness was primarily attributable to the chronic underfunding of the pathology sector. Additionally, high-throughput molecular diagnostic testing has not historically been a routine component of NHS laboratory services, largely due to limited demand.

It is therefore imperative that the infrastructure developed in response to the COVID-19 pandemic be preserved for future use. I understand this has been

achieved at the Brants Bridge Lighthouse Laboratory (LHL), operated by Berkshire and Surrey Pathology Services (BSPS). However, this does not appear to be the case at the Newport LHL, where the infrastructure may not have been retained—possibly due to its remaining under commercial ownership.

36. It is also my view that a significantly higher level of expert oversight is required from the Medicines and Healthcare products Regulatory Agency (MHRA) in the evaluation and approval of clinical diagnostic tests. On this occasion, there was a clear regulatory failure. While this may have been due in part to the overwhelming volume of commercial assays entering the market in rapid succession, it is more likely that the MHRA lacked sufficient specialist expertise to assess the internal control mechanisms critical to the performance of molecular diagnostic kits. This deficiency stems from the limited use of such tests in the UK prior to the pandemic and should be urgently addressed to safeguard public health in future emergencies.

Further Information

37. There are clearly members of the Perkin Elmer Ltd senior staff who had overall responsibility for the service they provided to the DHSC at Newport and Charnwood namely Ian Jarvis (Country Laboratory Lead), Miles Burrows (Managing Director (UK and Ireland)), Ephrem Chin (Director, Global Laboratory Operations, Perkin Elmer Genomics) and Madhuri Hegde (Senior Vice President and Chief Scientific Officer Perkin Elmer Genomics) who could provide reasons for the delay in remedying the flawed test kit and also the lack of transparency to maintain an established and win a second lucrative contract with the DHSC running to a cost upwards of approximately £500 million to the British taxpayer.

Statement of Truth

I believe that the facts stated in this witness statement are true. I understand that proceedings may be brought against anyone who makes, or causes to be made, a false

statement in a document verified by a statement of truth without an honest belief of its truth.

Signed: Personal Data

Dated: 28th of May 2025