Institute of Biomedical Science 12 Coldbath Sauare, London EC1R 5HL Tel: 188 E-mail: mail@ibms.org Website: www.ibms.org



Chief Executive David Wells MSc FIBMS CSci Hon DSc FRCPath (Hon)

Module 1 of the UK Covid-19 Public Inquiry Request for Evidence under Rule 9 of the Inquiry Rules 2006 Reference for Evidence – M1/IBMS/01

1. I am responding to the request for information under Rule 9 of the Inquiry Rules 2006 in my capacity as Chief Executive of the Institute of Biomedical Science (IBMS). I wish to state that this response forms the collective views and opinions of the IBMS, drawn from its collective knowledge and experience of the UK laboratory services and in the context of the COVID-19 pandemic and is separate and independent of the knowledge and views I hold by virtue of my previous role within NHSE during the time of the pandemic.

2. During the COVID-19 Pandemic, as Head of Pathology Consolidation for NHS England (April 2017 – June 2021) and Head of Pathology, COVID Testing Cell, NHS England (Feb 2020 – June 2021), I led NHS England's laboratory response across the country by managing and leading technology deployment, capacity development and forecasting, funding and workforce to ensure that all capacity requirements were met. The role included advising ministers and healthcare leaders whilst providing policy and strategic direction as a subject matter expert. The knowledge and insights I gained in my capacity during my employment in NHSE includes information that is not or may not be in the public domain and is therefore not reflected in the following IBMS statement. I would be happy to provide the Inquiry any information in a personal capacity separately if requested.

3. The IBMS is the UK professional body for biomedical science and the objects for which the IBMS was established are to support, progress and promote our members' careers and their professions and to ensure recognition for the important role that biomedical science plays in society. 4. The IBMS is a company limited by guarantee and also a registered charity (see footer of this statement). Founded in 1912, it represents approximately 20,000 members employed mainly in NHS pathology laboratories, NHS Blood and Transplant, Public Health services, private laboratories, research, armed forces (Royal Army Medical Corps), industry and higher education.

5. The IBMS is the standard-setting organisation for the profession, the primary provider of post-registration professional qualifications for its members and is also the awarding body of the Certificate of Competence that enables biomedical science graduates to apply for registration with the HCPC.

6. The majority of IBMS members are biomedical scientists, regulated by statute with the Health and Care Professions Council (HCPC). There are also a small number of members who are clinical scientists, also working in pathology laboratories and other individuals who work in biomedical science related fields but who are not registered as biomedical scientists. The majority of regulated IBMS members work in UK pathology laboratories that are accredited to ISO 15189 standards; the services they provide may also be regulated by the Human Tissue Authority and/or the Medicines and Healthcare Products Regulatory Agency.

7. Biomedical scientists contribute extensively to health and care in the UK, working to identify, research, monitor and treat diseases across the broadest areas of modern science, focusing on the complexity of the human body.

8. Biomedical scientists operate largely, but not exclusively, in laboratory settings. They are experts in analysing, blood, fluid and tissue samples from patients, identifying diseases and preparing reports that highlight the best possible options for treatment. Without biomedical scientists, other key aspects of the healthcare system, such as GPs, Cancer Care and A&E, would not be able to function.

9. The important role of biomedical scientists was made clear during the COVID-19 pandemic, as the nation's health planning and response largely relied upon laboratory testing undertaken by biomedical scientists and their skills testing innovation and technology deployment in hospitals and the home.

10. The NHS and public health pathology laboratories, although they had the capacity and capability to upscale their functions to enable delivery on much of the UK's testing requirements, were not in a state of preparedness to manage the demand for testing and disease monitoring at the time the pandemic struck. In comparison to many countries, particularly those in East Asia, the UK Government had previously made very limited attempts to develop emergency and pandemic resilience strategies and therefore was severely unprepared to respond to an outbreak of this kind.

11. The rush to establish the Lighthouse laboratories as part of the Test and Trace strategy without apparent exploration or understanding of the actual testing capacity that already existed within UK pathology laboratories illustrated the lack of understanding of capacity and capability within established NHS laboratories and those ISO:15189 accredited private laboratories providing laboratory services to the NHS.

12. The additional document accompanying this submission entitled "Update on the national testing strategy and lab capacity" provides evidence of the respective NHS and PHE laboratory capacities in the early stages of the pandemic (up to the end of April 2020) and the upscaling of test volumes; In between 20th and 27th April 2020 the NHS laboratories doubled their testing capacity. Instrument capacity was not an issue although it should be noted that the ability of NHS laboratories to upscale their testing happened despite all Thermo Fisher Scientific equipment and reagents being ringfenced for the Lighthouse Laboratories, requiring NHS staff to seek alternative equipment and reagent sources. It is the IBMS view that there was capacity within NHS laboratories to meet the 100,000 tests per day target and for this target to be achieved ahead of the Lighthouse labs if resources had not been directed away from the NHS labs (**DW/01 - INQ000108782**)

13. UK pathology services have undergone a radical restructuring that now offers a greater economy of scale; in England there has been the creation of twenty-nine pathology networks, with laboratory services delivered via a hub and spoke model. In the devolved countries of Scotland, Wales and Northern Ireland similar networking is occurring.

14. The resulting large, consolidated laboratory services can offer capacity via large volume analysers and larger concentrations of qualified staff enabling a pattern of shift working to maximise the operational time of high-capacity analysers. Conversely, the creation of the network model has also enabled the development of highly specialist regional/network services, including genomics services, which were involved in the identification and tracking of new and emerging strains of the COVID-19 virus. Both of these factors enabled a significant element of resilience and preparedness within the UK pathology laboratory services, but this was consequential of the way pathology services are now configured and not part of a specific plan for potential pandemic management.

15. When reflecting on the UK's response to the pandemic, it is clear that a significant weakness was the failure of senior officials to fully engage, collaborate and draw on the advice of relevant experts. Similarly, there was a lack of focus on pathology services where the advice of experts was again neglected and they was no engagement. This contrasts strongly with the Ebola outbreak of 2014 – 2015 in West Africa where UK expertise was drafted in as part of the UK government response to support diagnosis and containment. This effort involved significant input from IBMS UK biomedical scientists who were responsible for the strategy and subsequent setting up and running of a field-based testing and disease containment laboratory service. The key message here is that the laboratory expertise was present but was not used in the context of responding to and managing the UK pandemic.

16. Pathology is an essential component of preparedness and resilience considerations in the pre-preparatory phase of pandemic outbreaks. The pre-preparatory phase of a pandemic includes:

- · Horizon scanning of new and emerging risks to public health
- Identifications and planning of methods and approaches to identify new and novel infectious diseases
- Planning and identifying approaches to deal with mass casualty events
- Planning and identifying laboratory and clinical approaches to deal with pandemics

17. Within the World Health Organisation's (WHO's) Checklist for pandemic influenza risk and impact management which aims to build capacity for a pandemic response, the role of pathology is emphasized heavily. Included in the guidance is the essential need to:

- Review existing and proposed pandemic policies to allocate scarce resources (e.g., pandemic influenza vaccine, antiviral drugs and diagnostic laboratory testing)
- Plan access to laboratories with influenza diagnostic capacity to enable the quick confirmation of suspected human cases of a new influenza strain.
- Establish mechanisms to update national clinical and laboratory diagnostic algorithms.
- Develop or adapt clinical management guidelines for patients with suspected or confirmed pandemic influenza infection, addressing criteria for laboratory testing and advanced diagnostics.

18. The UK was not prepared for a pandemic of this scale, failing on many of the vital steps the WHO sets out above. The initial adoption of test and trace had been abandoned by early March 2020, and testing was restricted to patients admitted to hospital in order to manage the clinical and organisational challenge facing the NHS. SAGE and the test selection, evaluation and procurement advisory group had no NHS clinical virology non-reference-laboratory representative. The papers released from SAGE and statements at news conferences by the Chief Medical Officer and the Chief Scientist have confirmed that the UK abandoned the test, isolate and contact trace approach to Covid-19 at such an early stage because of the inadequate capacity and capability of Public Health England (PHE) to deliver this World Health Organisation (WHO) recognised and necessary approach to controlling the pandemic. Local services, which could have identified recently arrived travellers from disease areas, had been disconnected from a centralised capability to test.

19. Prior to 21 January 2020, the IBMS received no communication from the Government regarding the state of the UK's emergency and pandemic planning, preparedness and resilience. There were no established lines of communication set up between the Government and the IBMS, despite members having been involved in previous pandemics including Swine Flu in 2009. Seeking early advice from the IBMS and pathology experts would have greatly assisted with UK preparedness and enabled testing capacity to start earlier.

20. After 21 January 2020, and following the outbreak of the pandemic, the Government continued to make no attempts to contact the IBMS and continued to overlook pathology and diagnostic services.

21. As an organisation, the IBMS took the initiative to approach the Government to offer our support and insights but were treated as vendors and given no option but to join the queue of potential suppliers. (DW/02 - INQ000108783).

22. The lack of engagement with pathology experts and the IBMS was a failure of the Government's pandemic response and was a weakness and hindrance throughout the course of the pandemic.

23. 5th March 2020 - The IBMS published a message to all members to inform them that the Government's plans to significantly increase testing capacity for COVID-19. As part of NHS England & NHS Improvement's (NHSE/I) push to increase testing capacity, they formally asked us to disseminate the message to our members: *This week, NHSE/I have formally asked Pathology services across England to increase their testing capacity for COVID-19 as part of the ongoing preparedness planning. Working with their Pathology Network partners all NHS England Trusts should be working to scale up testing capacity as rapidly as possible. NHS Pathology Networks are asked to appoint a lead to head up this work and to ensure they are linked into the communication and planning meetings planned to commence on Monday 9th March. (DW/03 - INQ000108784)*

https://www.ibms.org/resources/news/covid-19-message-for-members/

24. 16th March 2020 - The IBMS issued specification for biomedical scientists who could be deployed to support the diagnostic virology laboratory service during the SARS-2/COVID-19 pandemic. The message included guidance devised by the IBMS Virology Scientific Advisory Panel, Laura Ryall (Chair) and Sarah Pitt (Chief Examiner) and stated: *In the event of an outbreak or emergency, there are many aspects of the public health response that non-microbiology staff can contribute to. Staff with suitable training and experience may become involved in specialist testing for respiratory viruses. However, support for all other aspects of the routine clinical service will also be required - particularly in the light of increased testing for seriously ill inpatients who will have complex medical needs. Therefore, biomedical scientists from other pathology disciplines could be deployed to run assays or*

perform other tasks not directly related to SARS-2/COVID-19 testing in order to support the virologists who are engaged in that work. (DW/04 - INQ000108785) https://www.ibms.org/resources/news/covid-19-supporting-the-virology-service/

25. 24th March 2020 - The IBMS wrote a letter of support for members to use. It followed the publication of a classification list of key workers by the UK Government as educational settings in England closed their doors, with exceptions for vulnerable children and the children of key workers. A number of IBMS members had reported that they were being denied their right to education provision by their children's schools - or the hub-school that had taken the place of their children's school. In response, a drafted letter of support was made available for IBMS members to use to make their case as key workers (DW/05 - INQ000108786). https://www.ibms.org/resources/news/letter-of-support-for-key-workers/

26. 29th March 2020 - In collaboration with professional bodies the Royal College of Pathologists, the Association of Clinical Pathologists, the Association of Clinical Biochemists and the IBMS issued joint guidance on the prioritisation of pathology testing during the COVID-19 pandemic. The guidance was approved by NHS England and NHSI as a guide to prioritisation of resources during the time of unprecedented emergency. (DW/06 - INQ000108787) https://www.ibms.org/resources/news/covid-19-recommendations-for-laboratory-work/

27. 1st April 2020 – The IBMS issues a response to a BBC news story on the use of "spare laboratory space" to test self-isolating NHS staff. IBMS President Allan Wilson comments: "Anybody who has spent any time in a functioning healthcare laboratory knows that these are busy and often confined spaces with lots of precision tasks occurring and sensitive machinery operating. There is not the space or functionality to conduct sample collecting – which is perhaps being confused with testing in this report". (DW/07 - INQ000108788)_ https://www.ibms.org/resources/news/ibms-response-to-using-laboratory-spaces/

28. 3rd April 2020 - The day after Matt Hancock MP promises 100,000 tests a day, the IBMS outlines through a press release the current situation with COVID-19 testing in the UK. Stating: On behalf of the biomedical scientists and laboratory staff of the NHS, the Institute of Biomedical Science (IBMS) wants to express the frustration of our members and clarify that we are testing to the limit of our materials and that we are ready to increase capacity – but only if we are given what we need. (DW/08 - INQ000128921)

https://www.ibms.org/resources/news/we-are-ready-to-test/

29. 16th April 2020 – The IBMS publishes a statement regarding the emergence of mass testing centres, restating that it is a global supply shortage holding NHS biomedical scientists back, not a lack of capacity. IBMS President Allan Wilson states: *"I speak on behalf of the biomedical scientists and laboratory staff working in NHS hospital laboratories across the UK and stress my concern about the shortage of COVID-19 testing supplies needed to meet the government's 100,000 tests a day target. The 17,000 NHS laboratory workers that I represent are increasingly expressing their frustration. They have applied themselves innovatively to increase COVID-19 testing capacity and have the platforms ready so that the NHS laboratories are able to meet the Secretary of State's ambitious target but they are still not able to source the testing kits and reagents they require."(DW/09 - INQ000108790) https://www.ibms.org/resources/news/the-uk-must-avoid-a-wild-west-*

testing-scenario/

30. 24th April 2020 – The IBMS states that Serology testing will play a significant part in getting the UK out of lockdown and produces information on what it entails.(DW/10 - INQ000108791) <u>https://www.ibms.org/resources/news/serology-testing-planning-for-the-exit-strategy/</u>

31. 27th April 2020- The IBMS provides clarification and support to its members regarding the use of Personal Protective Equipment (PPE) in pathology laboratories. It would not be appropriate or possible, and would potentially be unsafe, to attempt to offer generic guidance that is applicable to everyone's working conditions while remaining meaningful. Instead the IBMS advocates following current Government advice. (DW/11 - INQ000108792) https://www.ibms.org/resources/news/ibms-statement-on-ppe/

32. 30th April 2020 - As the UK awaited the Government's announcement on its 100,000 'test' target, the IBMS issued a statement identifying key areas that needed to be addressed for COVID-19 testing and offers a four-point plan for the next stage of testing strategy. The three key areas that were identified that needed to be addressed going forward were: *"The creation of this parallel system has proved counterproductive and created competition for reagents and plastics and the underutilisation of staff and instruments in both systems. As a profession, we are concerned by the lack of accreditation and sustainability of the mass testing centres, the use of unregulated, volunteer staff and the risk to the quality of outcome.*

By-passing the significant testing resource that exits within NHS pathology networks and their laboratories and the existing local infrastructure to get samples to them, the creation of the remote drive-through sampling centres has created a major accessibility barrier to the people who need quick and local testing most – frontline staff in health and social care and their families." (DW/12 - INQ000108793)

https://www.ibms.org/resources/news/covid-19-testing-a-four-point-plan-for-the-next-stagestrategy/

33. 30th May 2020 - IBMS President Allan Wilson writes to members after a meeting with Director of Health Improvement at Public Health England, Professor John Newton. Allan comments: "After highlighting the main concerns of the IBMS membership (as I have previously done in the press and media), I was certain that Professor John Newton understood and recognised our issues. He praised the huge amount of work that we, as scientists, have done, and the high standards we employ in all our work. He said that he was extremely grateful for the outstanding contributions of Biomedical Scientists, Clinical Scientists and laboratory staff and that he was keen to engage the IBMS and utilise our membership's expertise, experience and insight much earlier going forward." (DW/13 - INQ000108794) https://www.ibms.org/resources/news/a-message-from-our-president/

34. 30th June 2020 - The IBMS issues a response to The Independent's news story "Failing the test: Slow start and flawed decisions in Britain's coronavirus testing have cost lives, warn health leaders". They state that given the situation described in The Independent's article, the IBMS is disappointed to learn that the government is considering expanding the Lighthouse laboratory network on the current model – as this will compound data connectivity problems.

"Whilst we recognise the need to rapidly upscale testing capacity and the fact that this will be an ongoing requirement, we have consistently voiced our members' concerns about the centralised approach to testing. This has led to the creation of the lighthouse laboratories as a parallel but disconnected testing stream for COVID-19 and there has been a lack of transparency around processes of clinical governance and, in particular, the limited IT connectivity of these laboratories to clinical systems already in place.

As the prevalence of this disease begins to decline, it is essential that any additional laboratory provision should be integrated with the NHS and results entered into NHS systems in a timely fashion. Careful follow-up of individual cases will be vital to ensure we continue to drive down the prevalence of this disease, but this will not be possible until the Lighthouse Laboratory reporting procedures are aligned with the NHS system. We are calling on government to support the integration of these lighthouse laboratories with accredited NHS laboratories, across the pathology networks, that are run with regulated staff." (DW/14 - INQ000108795)

https://www.ibms.org/resources/news/lighthouse-lab-expansion-will-compound-data-issues/

35. 13th August 2020 - IBMS Council delivers a position statement on the need for registered staff and accreditation in laboratories doing COVID-19 testing. Stating: *"the pace of upscaling testing capacity across the healthcare sector must not lead to a reduction in the quality of the diagnostic testing process. Before we set up more mass testing centres, we must work together to assure the quality of testing and the competence of staff and make sure that current and any future centres will be more closely integrated with National Health Service (NHS) systems.*

It is well known in laboratory medicine that the one thing worse than no result is the wrong result. Of particular note are the recommendations for quality governance and clinical governance. To ensure the process is undertaken to a suitably high standard the IBMS recommends that "the quality manager is a biomedical scientist and holds a recognised quality management qualification such as the Institute's Certificate of Expert Practice in Quality Management, in addition to a Masters level qualification such as an MSc or the Institute's Higher Specialist Diploma in either a scientific specialism or in Leadership and Management".

The IBMS expects that all testing facilities performing COVID-19 PCR and serology testing seek appropriate medical laboratory accreditation as soon as possible." They also call for statutory regulation "due to the complexity of the testing being undertaken to detect the SARS-CoV-2 virus there is a need for a highly skilled and regulated professional workforce. For those providing a service for the NHS the Health and Care Professions Council (HCPC) is the regulatory body responsible for setting and maintaining standards of professional training, performance and conduct of the healthcare professionals that it regulates, including those practicing under the protected title of 'biomedical scientist'." (DW/15 - INQ000108796) https://www.ibms.org/resources/news/high-quality-staff-deliver-high-quality-services/

36. 27th August 2020 - The IBMS outlines and assesses the principal testing options currently available for the SARS-CoV-2 virus (COVID-19). Their statement aims to support scientists and other laboratory professionals in selecting and advising on the most

appropriate testing route for patients. The information is based on known clinical need, the requirement to support the management of patients within different care settings, and the limited supply of rapid testing kits. (DW/16 - INQ000108797)

https://www.ibms.org/resources/news/statement-on-sars-cov-2-testing-options/

37. 5th October 2020 – IBMS President Allan Wilson was invited to attend and give evidence at a COVID-19 hearing to an All-Party Parliamentary Group select committee of MPs and Members of the Lords. The All-Party Parliamentary Group, organised by March for Change, focussed on the government's response to the coronavirus pandemic and issues with the test and track system. Following written evidence submitted by the IBMS, Allan Wilson presented evidence alongside Rachel Liebmann from the Royal College of Pathologists and later took questions from the panel. (DW/17 - INQ000108798)_

https://www.ibms.org/resources/documents/ibms-submission-for-the-all-party-parliamentarygroup-on/

38. 26th November 2020 - The IBMS issues updated guidance that outlines and assesses the principal rapid testing options for the SARS-CoV-2 virus (COVID-19). The information aims to support scientists and other laboratory professionals in selecting and advising on the most appropriate rapid testing route for patients.**(DW/18 - INQ000108799)_** https://www.ibms.org/resources/news/sars-cov-2-rapid-testing-options/

39. 3rd December 2020 - Following the IBMS evidence submission and President Allan Wilson's recent presentation to an All-Party Parliamentary Group (APPG) coronavirus inquiry, a new parliamentary report was published. **(DW/19 - INQ000128922)_** <u>https://www.ibms.org/resources/documents/appg-on-coronavirus-interim-report-december-2020/</u>

40. 10th November 2021 – Following the suspension of a COVID-19 testing laboratory in Wolverhampton, the IBMS publicly reiterates the need for a regulated workforce and laboratory accreditation for mass testing centres.

41. In preparing for future pandemics, and as a key component of the UK's resilience strategy moving forward, it is imperative that pathology and diagnostics are fully recognised

for the essential role they play in enabling the mobilisation of a pandemic response, including helping to track and control the spread of disease.

42. To accomplish this, the Government must establish stronger relationships and methods of communication and information sharing with expert organisations in order to tap into the resources that professional membership bodies can provide. This would connect professional bodies like the IBMS with relevant government and healthcare bodies including between the devolved nations. These networks should exist not just across public health but also across diagnostics and laboratory services.

43. Establishing a collaborative network prior to the outbreak of a pandemic would irradicate delays in mobilisation which is imperative in disease management, particularly in the case of highly infectious and fastmoving diseases such as COVID-19. The willingness to better acknowledge and work in tandem with experts is a precedent that would lead to improved outcomes and efficiencies in many whole-system civil emergencies as well as epidemiological ones. To respond to a future pandemic, and even epidemics far less catastrophic than Covid-19, a formally co-ordinated national network of microbiology and molecular virology laboratories is needed, and this should include all NHS microbiology/virology networks (through the established 27 NHS pathology networks in England, and similar networks across the devolved nations) and those academic departments with research interests in these fields. The fragmented microbiology service has become more fragmented and progress in networking is still ongoing 18 years after it was suggested at the dissolution of the Public Health Laboratory Service. Laboratory networks do not all have molecular virology capacity and do not match geographically to existing health protection teams.

44. The NHS and public health pathology laboratories had the capacity and capability to deliver on the UK's testing requirements. The inquiry may wish to question and explore the justification for the establishment of the Lighthouse laboratories as part of the Test and Trace strategy, without apparent exploration or understanding of the actual testing capacity that already existed within UK pathology laboratories. It may be decided that the creation of the Lighthouse laboratories represented an expensive diversion of resources away from the already established and quality-controlled services, without adequate justification.

45. While the limited test repertoire of these services had a reduced need for senior staff, the impact was nevertheless to draw staff away from already stretched established laboratory services. Furthermore, the results generated by these laboratories did not link to the NHS electronic patient records system and consequentially are not part of patients' personal health records. The inquiry may wish to consider whether this could have had a negative consequential impact on other, non-COVID related diagnostic services, which may form part of the exploration of the actual capacity of pathology laboratories to handle large and sustained increases in workload such as would be occasioned by any future pandemic.

46. It is the view of the IBMS that pre-pandemic there was very little 'spare' body storage capacity in the system, even to deal with seasonal fluctuations in normal caseload, an example of which is the annual winter capacity pressures consistently experienced across the system. The contingency storage that had been procured by NHS Trusts, Local Resilience Forums and Central Government, such as the National Emergency Mortuary Arrangement (NEMA) was largely provided for the response to acute mass fatalities incidents, not for prolonged excess deaths scenarios, and was strictly ring-fenced as such to avoid the mass fatality incident capability being degraded by use for 'routine' capacity pressures.

47. Pandemic Flu exercises, such as Ex. Winter Willow in 2007 and Ex. Cygnus in 2016 made reference to the need for updated planning assumptions and detailed guidance "to help local planning for the operational aspects of increased death rates during a pandemic" (Department of Health, 2007), but the resulting guidance put more emphasis on increasing the business continuity of downstream death management processes, such as death certification and registration, funeral services and crematoria, with a view to effective resilience in these areas leading to "minimal impact on mortuary capacity" (Home Office, 2008).

48. Business continuity of the whole death management system is extremely important, but it is the IBMS view that concurrent investment in contingency body storage, specifically ringfenced for excess deaths, could have been made to provide robust assurance, in advance of a pandemic occurring, that the deceased could be dealt with in an appropriate, safe and dignified manner. 49. Department of Health (2007) Exercise Winter Willow: Lessons Identified. (**DW/20** - **INQ000187745)** <u>https://www.iaem.org/portals/25/documents/winter_willow_lessons.pdf</u> [Accessed17 February 2023].

Home Office (2008) Planning for a Possible Influenza Pandemic: A Framework for Planners Preparing to Manage Deaths. **(DW/21 - INQ000187746)**

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_da ta/file/62045/flu_managing_deaths_framework.pdf [Accessed 17 February 2023].

50. The WHO document "WHO global influenza preparedness plan: the role of WHO and recommendations for national measures before and during pandemics, 2005" (DW/22 - INQ000187747) <u>https://apps.who.int/iris/handle/10665/68998</u> identifies six phases in relation to pandemic influenza. These could be usefully applied to any zoonotic infection with pandemicpotential:

Interpandemic period

Phase 1: No new subtypes (i.e. virus strains or variants) of influenza have been identified in humans. An influenza subtype associated with previous disease in humans may be circulating in animals but the risk to humans is low.

Phase 2: No new subtypes (i.e. virus strains or variants) of influenza have been identified in humans. An influenza subtype associated with previous disease in humans may be circulating in animals but risk to humans is low.

Role of pathology at this stage: Surveillance; routine investigation of proportion of influenza virus isolates identified in humans by reference laboratories to check subtype and report human to human transmission if it is found to have occurred.

Pandemic alert period

Phase 3: A new subtype found in a person with influenza, but either no evidence of transmission to others at all or to only one or two very close contacts.

Phase 4: Small number of cases in restricted geographical area indicating virus subtype has limited potential to spread between humans.

Phase 5: Larger groups of linked cases (clusters); risk of developing into pandemic exists but that outcome is not inevitable.

Role of pathology at this stage: working to modify existing assays and / or develop new laboratory tests to detect new subtypes; **reporting cases to relevant public health**

authorities to contribute to monitoring and the planning of an appropriate response to outbreaks.

Pandemic period

Phase 6: Global, continuous human to human transmission; increase in cases reported. **Role of pathology at this stage:** Mass testing, providing personnel and resources to ensure turnaround time for results is a short as possible; contributing to planning and decision-making and communication of scientific and specialised technical information to governments, public health planners and also the general public.

51. The WHO document: A checklist for pandemic influenza risk and impact management: building capacity for pandemic response (comprises 8 sections, namely:

- 1. Introduction
- 2. Preparing for an emergency
- 3. Surveillance, investigation and assessment
- 4. Health services and clinical management
- 5. Preventing illness in the community
- 6. Maintaining essential services and recovery
- 7. Research and development
- 8. Evaluation, testing and revising plans

The checklist can be found here: **(DW/23 - INQ000187748)** https://www.who.int/publications/i/item/9789241513623

52. Each section includes areas to consider under each heading. For example, 'Preparing for an Emergency' has six subsections including 'response planning', 'legal and policy issues' and 'risk communication and community engagement'. For each subsection, there is a checklist of actions designated either 'essential' or 'desirable'.

53. This document is an important resource, compiled by experts from all continents with experience in all areas of pandemic management. It is difficult to assess this guidance exactly against the COVID-19 pandemic, in some areas since it assumes that vaccines and anti-virals exist, which they do for influenza, but did not for SARS-CoV-2 in 2020). Another assumption is that the virology is established, understood and predictable, which is correct

for influenza. For example, the mechanism of transmission is known and there is a defined set of "flu-like" symptoms. For COVID-19, people experienced a range of symptoms that appeared to change slightly with each variant and the contribution of aerosol transmission was underestimated at the beginning of the pandemic.

54. It is our opinion, although without direct evidence, that generally we are/were good at surveillance, but probably fell short in other areas.

55. The WHO convened an expert independent international panel to consider pandemic preparedness and response. The panel published its report 'COVID-19: Make it the last pandemic' in May 2021. The report can be found here: **(DW/24 - INQ000187749)_** <u>https://theindependentpanel.org/wp-content/uploads/2021/05/COVID-19-Make-it-the-Last-Pandemic_final.pdf</u>

56. Since the turn of the 21st century, successive governments have reduced the capacity for surveillance for infectious diseases, starting with the reduction in the number of local Public Health Laboratory Service (PHLS) laboratories in the early 2000s, then continuing with reorganisations, differences in each home nation (since health is a devolved function) and taking Public Health England (PHE now UKHSA) out of the health service and into the civil service. Covid-19 would have challenged any laboratory testing system, but PHE was shown to be unfit for purpose and unable to lead capability and deploy new diagnostic tests rapidly to laboratories outside its control, or to manage extensive contact tracing. The UK diagnostic capability would be much stronger if the recommendations of earlier Chief Medical Officer reports had been enacted in full, rather than in part, although the decision to transfer many Public Health Laboratories to the NHS did in part expose the country to risk. Reform is necessary to ensure that the country has a laboratory capability for public health to continue to deal with next microbial challenge. Past capability and performance justifies the NHS hosting and being responsible for the public health laboratory response to communicable disease. A UK-wide system of local laboratories carrying out routine surveillance for infectious diseases, population level immunity (e.g., to monitor vaccine effectiveness) and working with environmental health officers could have been deployed to COVID-19 testing. A group of experts in influenza / molecular virology reference laboratories across Europe developed a PCR assay and test protocol very rapidly. (DW/25 -INQ000187750) https://www.who.int/docs/default-source/coronaviruse/protocol-v2-1.pdf

57. This was implemented in the regional PHE laboratories. However, a decision was made not to make the protocol and reagents available to NHS diagnostic virology or microbiology laboratories. It was considered better for quality assurance purposes to wait for commercially available assays which could be run on standard analysers. However, there was no central procurement for assay kits or laboratory equipment, so individual laboratories were required to work with the variability in availability of supplies and also to borrow equipment (PCR machines, specialised pipettes) from local research laboratories (e.g. universities) which were closed during the lockdown.

58. At the same time, the Lighthouse laboratories were being set up. They were provided with equipment and reagents which could have been made available to existing diagnostic laboratories. Advice and input from qualified registered pathology professionals was extremely limited.

59. The UK has the intellectual and professional capacity and capability to develop new vaccines safely and at speed as was demonstrated by the response to the pandemic. However, the speed and efficiency of this response was only possible by the release of targeted funding.

60. In March 2020, the UK did not follow the WHO's advice to deal with the COVID-19 outbreak and undertake a comprehensive testing programme followed by isolation and contact tracing. This advice can be found here: (**DW/26 - INQ000187751**) <u>https://www.who.int/dodefault- source/coronaviruse/who-china-joint-mission-on-covid-19-final-report.pdf</u>.

61. The testing regime should have been earlier and more comprehensive, including care homes and the community as well as patients and staff in hospitals right from the outset. One of the main reasons for this failure was that the country did not have a network of laboratories ready to ramp up their testing programmes to cope with a major outbreak of this nature. Furthermore, it seems that the Government did not know the testing potential capacity of either PHE or NHS laboratories combined.

62. Before 2003 an adequately funded, closely cooperating network of microbiology laboratories existed – functioning together with a purchasing strategy led by people who

understand microbiology and the requirements of the service. The public health microbiology service was closely linked to communicable disease monitoring and surveillance. At the time of the COVID-19 outbreak, PHE had the formal responsibility for controlling the outbreak but proved unable to undertake the testing itself or to coordinate operations effectively within the NHS.

63. NHS laboratories were asked to undertake COVID-19 testing. Even though these NHS laboratories were reportedly underused, the Government set up the 'flagship' Lighthouse Laboratories to collect and test samples. Poor turn-round-times in certain PHE referral labs providing COVID-19 test results led to an increased requirement for NHS labs to test their patient and staff samples in their own labs. In addition, PHE was not forthcoming in supplying samples to other labs to validate their tests as covered by The Daily Telegraph here: (DW/27 - INQ000187752)

https://www.telegraph.co.uk/global-health/science-and-disease/exclusive-private-labs-claimphe-refusing-share-blood-samples/. Some NHS laboratories reported that their planned purchases for COVID-19 testing kits / equipment were stopped as the equipment was diverted elsewhere deemed to be of higher priority.

64. The lack of testing facilities was engineered through conscious decisions made by governments of all parties since the mid-1990s including abolishing the coordinated service that once existed. Between 1946 and 2003 the network of laboratories – the Public Health Laboratory Service (PHLS) – provided over 50 laboratories specifically intended to be the first line of defence for England and Wales in the event of major public health outbreaks of infectious diseases. However, especially since 2003, this network was dramatically reduced, resulting in a very significant diminution in capacity for large-scale testing. While from the NHS perspective the creation of networks have offered consolidation of expertise and economies of scale, it should also be recognised that localised testing also has the advantage of existing close links with clinical services together with existing surveillance mechanisms for monitoring the outbreaks and reporting centrally.

65. The key claim made here is that had the PHLS network of laboratories at 2003 been maintained, there would have been – at the least – many more microbiological laboratories available and appropriately equipped to deal with the COVID-19 outbreak. Furthermore, as the PHLS existed, in part, specifically to coordinate responses to outbreaks of this nature, it

seems most likely that there would also have been a better co-ordinated response to the pandemic. We suggest therefore, that there is a pandemic resilience capability within UKHSA and the NHS to enable the delivery of an integrated laboratory system with appropriate technology, standardised, validated methods, a digital plan and an identified workforce plan in readiness for when this is next needed.

66. We need to ensure that the country will once more have the ability to respond to future outbreaks – such as that seen with COVID-19. New infections continually emerge - in the last 25 years, 5 different significant viruses from animals have emerged causing varying levels of disease in humans (Nippah, Zika, SARS, MERS and SARS CoV2 (Covid-19). It is indisputable that the UK will be faced with a disease threat again.

67. The recently published Department of Health and Social Care report entitled "*Technical report on the COVID-19 pandemic in the UK*" is a comprehensive analysis of the impact and consequential actions taken by the Government in response to the pandemic. However, it fails to adequately consider the role of the diagnostic pathology laboratories, despite 'testing' being mentioned. There is discussion of infection prevention and control but it does not address how the infection is diagnosed effectively in a population so that prevention and control can follow. Furthermore the report omits to recognise the impact of the pandemic on the day to day work of laboratories that continued throughout the pandemic, or the backlogs of patients with malignant or potentially malignant diagnoses that are presenting for diagnosis in large numbers post pandemic.

68. The IBMS has offered its perspective openly and objectively to enhance the fullness of understanding of the role of diagnostic laboratories in the pandemic response. Further to the information disclosed in paragraph two of this response, the Inquiry may wish to also seek the views of the Royal College of Pathologists (RCPath) and The Association of Anatomical Pathology Technology (AAPT), which are associated organisations with which the IBMS and our members work closely. In addition, if an diagnostic industry perspective is sought, the Association of British Healthtech Industries (ABHI) and British In vitro Diagnostics Association (BIVDA) could provide the inquiry further insight to the questions posed.

69. 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.

Personal Data

Signed:

David Wells MSc FIBMS CSci Hon DSc FRCPath (Hon) FAHCS (Hon) Chief Executive, Institute of Biomedical Science

Dated: 12th June 2023