

Witness Name:  
Statement No.:  
Exhibits:  
Dated:

**UK COVID-19 INQUIRY**

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**WITNESS STATEMENT OF Helen Dent**

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I, Helen Dent, will say as follows: -

1. I am the Chief Executive of the British In Vitro Diagnostics Association ("BIVDA"). I have held this post since 19 September 2023 initially on an interim basis and then permanently from 22 March 2024. Between 29 June 2020 and taking up my post, I was the Chief Operating Officer for BIVDA. Prior to joining BIVDA I led the provision of managed service contracts for pathology laboratories at Abbott Laboratories and was involved in the negotiations with the Department of Health and Social Care for Covid-19 Antibody contracts.
2. I confirm that the contents of this statement are true and accurate to the best of my knowledge and belief.
3. BIVDA's previous Chief Executive was Doris-Ann Williams, who retired in September 2023. She was in post for the period of time the Inquiry has asked me to comment upon.
4. In order to complete this statement, I have reviewed records kept by BIVDA of our activities during the relevant period. I was not personally involved in all activities described.
5. BIVDA is the national trade association for in vitro diagnostics ("IVDs") in the UK. Formed in 1992, our approximately 240 members range from SME's to global enterprises. While we focus our efforts in the UK, the global nature of the IVD market means we work closely with European counterparts and many of our members have international portfolios. Many of our members offer products which test for Covid-19.

6. I report to a board of directors, all of whom have significant experience and expertise within the diagnostic and health industries.
7. Our mission is to place diagnostics at the heart of healthcare. We advocate for the industry into government and the NHS. We work in partnership with other trade associations, patient groups, academia and research facilities to ensure that the needs of patients and the industry are placed into policy. We also support members with training and networking events.
8. Our staff have significant expertise and experience in the development, procurement, and usage of IVDs. During the pandemic, IVDs were a key component of the government response. As a result, many of our members were involved in the response and approached BIVDA for support.
9. For transparency, two current members of BIVDA staff worked for NHS Test and Trace during the time this statement covers. A third worked for NHS Supply Chain.
10. Our President, Angela Douglas MBE, was the Deputy Chief Scientific Officer for NHSE from 2018-2023. She was seconded to the Department of Health and Social Care (DHSC) during the pandemic response, to provide scientific expertise and leadership. Angela worked with the Technical Validation Group (TVG), the Covid Genomics Group (COG-UK), and was part of the Variance of Concern Assurance Group (VOCAG) in UKHSA. Angela also chaired the NHS Pathology Quality Assurance Group and the NHS Clinical Engineers Assurance Network during the pandemic. After retiring in October 2023 from the NHS, Angela took up her BIVDA role on 1<sup>st</sup> December 2023.
11. Paul Fisher was a senior civil servant with DHSC and then UKHSA. He worked on the LAMP programme, ultimately leading it as programme director, and then led the regulatory approval of COVID-19 test devices ("CTDA") from May 2022. He also led the quality assurance team for COVID-19 for a short period of time and while at UKHSA, was responsible for some of the Science Directorates response to modules one and two of the Inquiry. Paul has been BIVDA's Director of Policy and Programmes since October 2023.
12. Beth Loudon has been BIVDA's Director of Market Access since September 2024. During the pandemic response she was Category Director for Pathology and Diagnostics at NHS Supply Chain and accountable for the initial sourcing strategy for swabs before transition of the activity into the Test and Trace programme. Additionally during the period, she was responsible for supplier negotiations and advising DHSC on contractual mechanisms for bulk purchase of vaccine refrigeration.
13. Prior to the pandemic, BIVDA were not involved in any pandemic preparedness activities with the NHS or Public Health England to the best of my knowledge or

belief.

14. On 11 March 2020, following the declaration of a Pandemic by the World Health Organisation, Doris-Ann Williams of BIVDA sent a written update to members. Members were informed the MHRA intended to look pragmatically at the need to invoke the emergency derogation, or Emergency Use Authorisations (EUA) to allow non-CE marked products, if the pandemic meant further increases in testing numbers were required. Members were informed that not all EU competent authorities were taking this approach. I infer from this that there was communication between the MHRA and BIVDA. I exhibit a copy of the update as HD-7/01 - INQ000598535.
15. In March or April 2020, BIVDA were contacted by Ed James, who was Head of Procurement for the then Public Health England, seeking details of suppliers who the government anticipated may be able to assist in respect of testing. Mr James contacted Doris-Ann Williams specifically seeking information in respect of certain suppliers; Fortress Diagnostics and Una Health. I exhibit a copy of the email trail as HD-7/02 - INQ000598547.
16. The request was specific to these two companies and consequently BIVDA did not provide Mr James with information relating to other suppliers. In hindsight this was an error. It is now known the government would have been happy to receive details of other interested suppliers or for Mr James' request to be forwarded to BIVDA members. Arguably, had the government been in possession of fuller information about Covid-19 tests and their availability from established, reputable companies operating in the UK and supplying core laboratory tests to the NHS, the government's decision-making around relating to the testing capacity of a UK diagnostics industry may have been different.
17. As a result, BIVDA sent a Request for Information (RFI) to member companies asking to provide details of tests for Covid-19 that they were able to provide either through manufacture or supply, along with technical characteristics and availability of product. This built a database of tests to present to government if or when requested. Commercial details were not considered as outside the scope of BIVDA. I exhibit a copy of the RFI as HD-7/03- INQ000598548 and a copy of the database as HD-7/04 - INQ000598549.
18. BIVDA were involved in early government meetings under the leadership of Sarah-Jane Marsh, Director of Testing at NHS Test and Trace. We were a key contributor in meetings relating to testing which were led by Emma Stanton of the Supplies, Lab, and Innovation Team. This team was tasked with leading the expansion of testing supply, including labs, tests, consumables, reagents, and components. The team was also tasked with driving innovations to support the expansion of and improvements in the National Testing Programme, led by Alex Cooper to deliver testing outside of pillar one. A copy of the relevant report is

exhibited as HD-7/05 - INQ000598538.

19. BIVDA were asked to chair government run information webinars designed to communicate widely with the UK diagnostics industry suppliers towards the end of March 2020. These webinars supplemented the activity of the government testing task force groups.
20. BIVDA also supported members through liaison with government officials during online meetings, initially held weekly but reducing to fortnightly. These were hosted by Lord Bethell as a way of getting information to members for developments approved at top level. The government engagement process presumably required them to liaise with industry representatives and in the same way that ABPI, ABHI and BIA were also included in these meetings BIVDA were supporting the government by participating and commenting on the discussions. The meetings were commercial and in confidence and limited notes were sent externally. The context of what Trade Associations would contribute was product availability, regulatory challenges and industry readiness to support a ramp up in testing numbers and requirements to ensure product was available. There would be an element of technical input to assess proposals and solutions coming from Test and Trace development. There were existing relationships organisationally and personally from business as usual activity before the pandemic in this field. The meetings were hosted by government departments with defined Senior Responsible Officers and Ministers involved. They were on-line using GoTo Webinar or Zoom initially and then moved to TEAMS as the government adopted the platform more widely. Attendees should be recorded by the government and BIVDA does not have a record of the attendees.
21. BIVDA's External Affairs team regularly engaged with MPs and peers with a series of briefings throughout the period. Copies of the two briefing are exhibited as HD-7/06 - INQ000598536 and HD-7/07 - INQ000598537 respectively.
22. BIVDA were part of the government Testing Task Force via a roundtable/ discussion platform for raising sector questions. This involved a number of people from industry and was led by Chris Molloy, CEO of the Medicines Discovery Catapult, with PA Consulting as the Secretariat. BIVDA's role was to relay information and represent companies with regard to technical and policy queries that were discussed in this forum. It would be feedback to questions asked by the Testing Task Force to assess their policy and practice, and questions provided to BIVDA for resolution would have been asked of the managing team. Details of the questions will likely be held by PA Consulting or the government. Minutes were owned and circulated by government, not BIVDA. The context would be manufacture, specifications, raw materials, regulatory and product availability and viability.
23. BIVDA was part of a ministerial group, the COVID Response Group, which met weekly. Membership including life sciences organisations such as the Crick Institute, the MHRA as well as industry. The group was chaired by Lord Bethell and Nadhim Zahawi MP. This was paused in September 2020.

24. BIVDA stood up an expert group for Covid-19 called the Covid Task Force. This group was used by different government stakeholders to communicate with the diagnostics industry. Any mass correspondence, information or request for information from government was passed via this channel to our members. To prevent other disciplines and working groups being taken over with Covid related discussion or activity, BIVDA housed all our Covid-19 activities within this group. Companies providing Covid tests made up only part of the BIVDA membership, therefore a group that dealt with all covid matters was set up to avoid flooding other meeting agendas with covid related activity. Any questions, and proposals, consultations or issues with regard to Test and Trace would have been raised and addressed through this group, Elements that were discussed included but are not limited to the ability for service engineers to be allowed to travel during lockdown restrictions so that they could service the analytical equipment running the covid tests. Vaccination requirements for staff, requests for products and information relating to products to be used for Test and Trace and the laboratories running the services. Regulation and procurement relating to Test and trace would also be discussed in this group along with technical detail such as variant identification and genetic sequencing of the virus. There are four sets of minutes with relevant information. I exhibit these as HD-7/08 - INQ000598542 , HD-7/09 - INQ000598543, HD-7/10 - INQ000598541, and HD-7/11 - INQ000598540.
25. The first meeting in July 2020 covered the implementation of Pillars 1-5 from an NHS Trust Incident Director in the Southwest and Head of Diagnostic Transformation at NHS England, David Wells.
26. BIVDA regularly attended the COVID industry meeting with the Office for Life Sciences and a Testing Task Force meeting focusing on antibody and serology testing at this time. The context of what BIVDA contributed was product availability, regulatory challenges and industry readiness to support the government programmes for antibody testing, to see if there was immunity or how immunity may or may not wane. Also to manage the liaison across departments for regulatory requirements. There would be elements of technical input to assess proposals and solutions coming from Test and Trace development. There were existing relationships organisationally and personally from business-as-usual activity before the pandemic in this field. The meetings were hosted by government departments with defined Senior Responsible Officers and Ministers involved. Individual attendee names are not known by BIVDA, only that they are related to the managing government groups and consultants drafted in to support the government response to the pandemic.
27. In September 2020, Rachel Merelie and Paulo Andrade from Test and Trace consulted with BIVDA and our members about the New Supplier Mapping Labs, Supplies and Innovation programme which intended to bring together testing, contact tracing and outbreak management in an end to end service to help prevent the spread of the virus. This meeting is detailed in exhibit HD-7/11 - INQ000598540.

28. In October 2020, DHSC informed BIVDA they expected new testing technologies to become available and encouraged members to share innovation pipelines with DHSC. They explained that they were hoping to use the new testing technologies to test a higher proportion of the population over time. DHSC wanted to build on the relationship already established with BIVDA and the UK diagnostic industry, not just in the context of COVID, but for the handling of future pandemics. Topics included the use of PCR types for point of care testing. They also discussed a LAMP (Loop-mediated isothermal AMPlification) programme, lateral flow tests, and standing up a mass spectrometry work stream.
29. BIVDA were also members of an innovation fund set up to support UK diagnostics industry. BIVDA coordinated the applications and communications between government and industry for this fund.
30. In October 2020, the scope was changed following industry feedback to focus around pain points and market failures to pursue innovative solutions.
31. At this time, Chris Molloy, Chair of National Industry Consortium for COVID-19 testing, met with BIVDA and members to discuss the national need for more mass testing and how the UK diagnostics industry could assist the UK's programme access the reagents it required and the manufacturing capacity to deliver mass testing at pace. This meeting is detailed in exhibit HD-7/11 - INQ000598540.
32. The Consortium focussed on three themes; reagents and consumables, self-administered tests and lateral flow testing.
33. To meet the Consortium objectives there was a requirement to increase the manufacturing capacity of the UK dramatically.
34. In November, BIVDA informed members that the coalition were seeking companies with a lateral flow antigen test that hadn't been submitted through either the New Technologies Assessment Group (NTAG) or the COVID-19 National DiagnOstic Research and Evaluation (CONDOR). Industry had been asking for some time for government to stop direct awards without transparency or competition.
35. While this arguably falls within the scope of Module 5 of the Inquiry, I would place on record that had BIVDA been included in assessment and planning at an earlier stage, it is likely that some of the confusion and lack of information relating to tests, availability, regulatory compliance and performance and the subsequent consequences could very reasonably have been mitigated. BIVDA had a greater awareness of what tests were available, or what could reasonably be available in a realistic timescale, which would have been useful to the pandemic response. We also would have been able to work with members to inform government as they worked to ensure that there was an appropriate regulatory framework in

place, that was well understood ahead of time, and that industry were prepared to meet. The regulatory issues are set out in detail later in this statement.

36. For example, at this point in 2020 there was a lateral flow workstream in the manufacturing coalition, working with 5 manufacturers. There was an antigen test available in the UK that met Public Health England's then requirements for validation. If approved, there were up to five companies able to manufacture 4,000,000 of these a day, sufficient to support individual testing at home. Test and Trace did not seem to be aware of this.
37. DHSC held a public consultation, opening from 8 April 2021 and closing on 5 May 2021, on its proposal to introduce a requirement that all COVID-19 tests placed on the UK market undergo a mandatory validation process to assess their performance, above and beyond CE marking. A copy of this is exhibited as HD-7/12 - INQ000598546.
38. BIVDA's position and consultation response was that the sector strongly opposed an additional regulatory regime. The additional cost and time to obtain the data required were considerable, even in the event of prompt review. A copy of our response is exhibited as HD-7/13 - INQ000598539.
39. This consultation was clear that it was related to private providers and population testing and industry responses reflected this. In August 2021, BIVDA were inundated with concerns from members as NHS Test and Trace had begun chasing them for their data as the deadline for providing data for validation was approaching and there had been an extremely low response. Members highlighted that they were not expecting to be required to provide data as they were out of scope of the consultation requirements because consultation referred to private testing and companies that supplied into the NHS were unaware that the new policy was to include NHS testing. It was unexpected and it was only in August when Angela Crockett started to call companies when the deadline to submit the data was approaching and they hadn't received any from suppliers. On receipt of these phone calls – members started to phone BIVDA and BIVDA were in the same position as BIVDA hadn't been notified of the inclusion of NHS provision. Companies didn't have the data available and were unprepared to complete this. Helen Dent from BIVDA called Angela Crockett to discuss and was informed that this did appear to be the case and it was different to their initial understanding however the data could be provided in any format and that there wasn't a template and for suppliers to just send in what they had and to contact Angela Crockett directly. It was at this point, that initial discussions about doing a webinar to inform companies of requirements began. BIVDA sent a notification to members to inform them of the deadline and to point out that it included provision to the NHS.

40. Without informing Industry or Trade Associations, the scope of the policy appeared to have changed and now included NHS testing. At the time BIVDA members primarily supplied into NHS with limited private and direct to consumer sales, so were neither informed nor prepared to provide this data.
41. This consultation led to the introduction of the Covid Test Device Approval Regulations, formally the Medical Devices (Coronavirus Test Device Approvals) (Amendment) Regulations 2021, usually known as "CTDA".
42. The context to this legislation is that before being allowed onto the market, tests must obtain regulatory approval to ensure they are safe and perform appropriately. In the UK, the lead agency for this is the Medicines and Healthcare product Regulatory Agency (MHRA).
43. BIVDA understand that the MHRA had a prepared plan for the regulation of IVDs as part of their pandemic preparedness. However, in the event, regulatory approval for IVDs was owned by NHS Test and Trace and then UKHSA. The MHRA focused on vaccine and therapeutics approval. This approach is not wrong in principle.
44. The reliance on EUAs as described earlier is, as the title suggests, suitable in the short term but is not a long-term regulatory option, particularly if policy drives an influx of tests onto the market. An EUA is a regulatory mechanism to facilitate the availability and use of medical countermeasures, including unapproved or investigational health products, during public health emergencies, such as the Covid-19 pandemic. National Regulatory Authorities (NRAs) can issue an EUA when certain legal criteria have been met such as a national health emergency and/or no adequate, approved, and available alternatives. By this stage in the pandemic, while the situation was serious and still changing, it was arguably not an "emergency" and adequate alternative approaches should have been available.
45. For this reason, the government developed the Technical Validation Group (TVG) and the subsequent Covid Test Device Approval Regulations (CTDA) to address these regulatory, quality, and performance matters. The regulatory piece is explained above. Once approved for use, the performance and safety of a test must be monitored by suitable quality assurance measures. In order to ensure tests are effective, performance requirements were set that tests needed to meet.
46. The TVG broadly worked well, but was not a long-term solution, hence its replacement by CTDA. This was described in its statutory review as being *"introduced in July 2021 in response to an influx of poor quality tests coming onto the UK testing market at a time when availability of accurate diagnostic test results had the potential to be an important part of the COVID-19 response."* A

copy of the statutory review is exhibited as HD-7/14 - INQ000598545.

47. The CTDA legislation set standards for tests to meet before they could be supplied on the UK market. These standards were new to manufacturers. It required manufacturers to pay an application fee before submitting data which was reviewed by NHS Test and Trace advisors (later UKHSA).
48. BIVDA began discussions with NHS Test and Trace to determine the expectations of the CTDA team. We met with Angela Crockett, DHSC, and Jane Mills, NHS England, to make sure that the manufacturers and suppliers of tests that were being used by the NHS had been approved through CTDA.
49. It became apparent that the process and outputs were not working. The CTDA team were not able to progress applications rapidly, there was confusion about acceptable data, and this led to a lack of approved tests being available. The CTDA team did not operate a prioritisation system, were not able to give applicants anticipated approval timescales, and initially would not meet with applicants – unlike international peers such as the FDA. The CTDA team were not able to progress applications rapidly, there was confusion about acceptable data, and this led to a lack of approved tests being available. The CTDA team did not operate a prioritisation system, were not able to give applicants anticipated approval timescales, and initially would not meet with applicants. From the end of August 2021 BIVDA met with the CTDA team and fed back the industry challenges and complaints through regular meetings and in written form and information tables. The UK IVD industry was prevented from selling products that had been developed (in some cases, in partnership with DHSC) and could get no return on investment or revenue. Many SMEs were under significant financial pressure. The backlog of submissions was extensive and there was a real risk that there would be no tests available for testing. In the event, this risk did not arise due to a new leadership team improving performance and the Secretary of State exercising his powers under the Medical Devices Regulation Act 2002 (MDR 20220. This is described further below.
50. 88 applications were made in August 2021. The failure to deliver described above led to significant concerns from industry, and BIVDA met regularly with CTDA staff to raise these and look to address. These included the cost of the process, the time taken for the process, CTDA being unable to give a timescale for completion, apparently inconsistent decision-making, and a lack of communication. 26 complaints were made in October 2022, and 35 the following month. These complaints will be held by UKHSA and are not held by BIVDA.
51. As a result, and in order to safeguard supply of tests, the Secretary of State exercised powers under regulation 39A of the MDR 2002 to publish a protocol list. This listed tests that had both passed public sector validation and have

lodged an application for validation through CTDA. Tests on this list were able to remain on the market until 28 February 2022 or until the outcome of their validation application had been determined. This list is dynamic and not held by BIVDA.

52. From November 2021, BIVDA held regular meetings with the CTDA team and began to demonstrate that implementation of the policy did not properly assess the availability of products on the market and how the legislated timescales could impact on this because insufficient assessment was made of the processes needed to meet the requirements. In November 2021 BIVDA called for an extension to the first deadline of January 2022 to allow data to be provided but this was not granted.
53. Two further protocols were published by the Secretary of State from 1 March 2022 of three months for professional use devices and six months for self-test devices. As before, these are not held by BIVDA.
54. From May 2022, a new management team significantly improved the CTDA process and by the time it was handed over to the MHRA in 2023 applications were being handled within weeks, rather than the five months taken initially. Complaints reduced to zero from June 2022 onwards. For transparency, Paul Fisher (who is now employed by BIVDA) led this new team. Angela Douglas, BIVDA's President, provided scientific guidance to the team.
55. While out of scope for the Inquiry, CTDA remains in force and means the UK has the most stringent COVID-19 regulatory regime in the world. This burden is discouraging market entrants to the UK, and evidences the long-term impact of legislation passed during a national emergency.
56. BIVDA recognise the huge efforts made during the pandemic response across the whole of society; from members of the public to politicians. We also recognise that decisions must be judged based on the information available at the time, and not with hindsight.
57. The pandemic was a national emergency almost without precedent. It is clear from earlier modules of the Inquiry that preparations for the pandemic were insufficient. This, in part, led to the establishment of Test and Trace. Clearly, in vitro diagnostics were a key part of any Testing pillar, and this should have been clearly understood prior to the pandemic.
58. The UK diagnostic industry, in common with life sciences as a whole, is strong. We have a presence from significant global enterprises, many effective and robust distributors and developers of tests, and many innovative SMEs and start-ups.

59. This is supported by a robust network of UK Approved Bodies (UKABs) who support the regulation of medical devices. The MHRA, while currently undergoing post-Brexit challenges in legislation and the consequent loss of EMA funding, are well understood by the industry.
60. The UK also has a deep, talented and broad scientific community, with the infrastructure and expertise to develop and refine new technologies rapidly.
61. If utilised correctly, these capabilities should be a critical advantage to UK pandemic preparedness and response.
62. During the period this statement covers, the UK's testing response was predominately that of PCR and LFD tests, supported by genomic surveillance. Other testing technologies, such as antibody testing and LAMP testing, played a smaller part. This approach spread risks and ensured supply chain resilience. While increasing costs, it is hard to argue that as a reactive strategy it could be improved on.
63. The national call to arms in the early part of the pandemic reflected the very challenging position the UK found itself in. It was unclear how effective the mass deployment of LFDs could be, and there were legitimate concerns about PCR capacity. It was sensible to look to alternative testing methods – not least to ensure supply chain resilience and maintain performance against variants of concern (VOCs).
64. However, the call for tests had significant consequences. There was a significant influx of new tests to the market. An example of the breadth of testing considered is the use of medical detection dogs at Heathrow Airport. Many of these new tests were scientifically sound, safe to use, and of the appropriate sensitivity and specificity performance for the use case. However, others were not.
65. There were a number of new entrants to the market. Some of these were keen to assist the national response. Others were motivated by commercial opportunity. With lockdown rendering many industries unviable, some new entrants pivoted from industries such as aviation, hospitality, or media production. These entrants faced a lack of knowledge of the science, industry and regulatory requirements.
66. Established diagnostics companies, while possessing strong sector knowledge and well-established regulatory and quality assurance systems, also faced the challenge of pivoting from predominately professional use-only tests to self-use tests.
67. A number of suppliers may have found tests from manufacturers or other suppliers based in other countries, which they offered, but did not have their own

internal scientific personnel or processes to undertake their own quality assurance checks. This resulted in a reliance on information provided by the manufacturer or other third parties being taken at face value.

68. This early term of attempting to obtain, identify, and develop diagnostics tests was described in an email dated 2<sup>nd</sup> April 2020 between senior civil servants as 'our "buy any test you can find" phase' (exhibit HD-7/15 - INQ000598544). This accurately reflects BIVDA's experience. The need to obtain tests rapidly, without a clear strategy for doing so, and with significant international supply chain pressures, whilst in the early stages of a pandemic, led to decisions being taken reactively and at pace. The comments attributed to these senior civil servants also reflected feedback we had from members – that there was no clear strategy and a lack of knowledge of what was available.
69. This influx of offers was not matched, initially, with an effective government response. An effective response would have seen a clear appraisal of the utility, performance and availability of the test, followed by rapid adoption or rejection. The decision should be communicated transparently. The sheer volume of offers made to government and the lack of preparation made assessing these tests very difficult. There was limited capacity within the then Public Health England, and later NHS Test and Trace, to assess test performance. There were limited clinical samples available; a key requirement for test assessment. These factors, combined with a relatively limited pool of staff to draw upon and unprecedented demand, made prior planning essential. This preparation did not appear to have taken place before the pandemic to the required standard or scale. This goes beyond procurement; assessing the performance of tests was key to informing testing policy and ensuring that tests performed to the appropriate quality and performance standards.
70. Offers of assistance were submitted through a variety of channels. The main routes were a purpose built gov.uk portal and four dedicated DHSC mailboxes. Some offers of help were also routed through Ministers' offices, parliamentarians or senior officials. The four shared mailboxes used were for 'COVID testing priority contacts', 'COVID19 innovation', 'COVID testing triage' and 'COVID19 offer triage'. These inboxes were used at different points between March 2020 and October 2021.
71. Additionally, clear requirements for tests were not initially set. This is understandable in context, with the sudden emergence of COVID-19 and the lack of information in 2020, but it exacerbated the issues set out in this statement.
72. The background to this work was a very challenging environment, with national lockdowns, moves to working from home, supply chain pressures, and global demand. This naturally increased pressure on both government and industry.

73. The outcome of these policies and actions included an influx of less effective tests being offered to the market, a significant quality, regulatory, and approval burden on Test and Trace and successor organisation, the delay or prevention of tests from established manufacturers entering the market, and lasting friction between government and industry.
74. It is arguable that this response to the national call to arms was foreseeable. Better planning would have mitigated some of the consequences, such as appreciating the likely response, making a more focussed ask, and being prepared to deal with the flood of offers. Best practise would have been to have a much clearer understanding of the requirements of a diagnostic response and for government to have a clearer idea of what solutions the diagnostic industry can offer, along with their needs. There are encouraging signs that this is slowly beginning, for example with Innovate UK's work on mpox, and work must continue to link industry to government more closely. BIVDA submit that addressing these issues is key for future pandemic preparedness and should form part of the Inquiry's recommendations. In our view, many of the failings were caused by a lack of preparedness. Specific policy recommendations to mitigate this are set out below.
75. A future pandemic response is likely to involve a response including diagnostics, therapeutics, and vaccines. This will impose significant regulatory burdens which may, again, require non-traditional regulatory agencies to support. The Inquiry should recommend this forms part of pandemic preparedness activities. As far as possible, the need for new legislation should be avoided.
76. Beyond regulation, there were also challenges around quality assurance and assay development. Laboratories, particularly when handling dangerous pathogens, are required maintain rigorous quality assurance (QA) standards. They must ensure the performance of assays, known as verification and validation (V&V).
77. With any significant increase in laboratory activity, there will be pressure placed on QA.
78. One area which slowed QA and V&V activities was a lack of available COVID-19 clinical samples. Industry needed these to develop and approve tests, and NHS Test and Trace labs required them for V&V/QA activities. In BIVDA's view, this is likely to be an issue in any future pandemic. The use of frozen samples is possible but sub-optimal, as frozen samples give different results. If the test is to be performed on fresh samples in the clinical settings, quality and performance assurance must be undertaken on fresh samples.
79. The establishment and maintenance of such a sample bank is a key enabler for the development of tests and the scale up of mass testing. It must not be

underestimated the quantity of samples required to scale up mass testing. While this requires horizon scanning for threats and ongoing resource commitment, reliance on obtaining samples during a pandemic will undoubtedly prove challenging again.

80. Whatever form the next pandemic takes, diagnostics will be a key part of the response. There must be better planning around what tests are available, how they can be procured, and how new and evolving tests will be regulated. The time for these measures to be put in place is not during a crisis – it is before. Regulatory and quality systems need to be stress-checked as part of pandemic preparedness just as much as supply chains or procurement. This should form part of the Inquiry's recommendations.
81. There should also be a recognition that manufacturers will not produce and submit for regulatory approval tests without a commercial benefit. It is not realistic to expect tests to be developed and regulated on a readiness basis. This means in the event of future pandemic, there is likely to again be a lag as tests are developed and/or scaled up. In BIVDA's view, one solution is for government to take ownership of developing such tests, and then enter into commercial arrangements for large scale delivery if required. There are signs that UKHSA are adopting this approach, for example with Avian Influenza, which is encouraging.
82. As a trade association, BIVDA rely on having a deep understanding and knowledge of our members and their capabilities. If this had been utilised more fully, and earlier, in the pandemic some of these challenges may have been addressed and or/mitigated. Ideally, this would have included involvement in pre-pandemic EPRR activities.
83. BIVDA, and other trade associations, also rely on effective communication with members. A deeper relationship earlier in the pandemic, ideally predating the pandemic as part of EPRR activities, would have enabled the government to communicate much more effectively with industry and vice versa. There are encouraging signs that this is happening with organisations such as the Office for Life Sciences, the MHRA, and Innovate UK being in contact with BIVDA and utilising our networks.
84. A phrase used regularly within NHS Test and Trace was "the art of the possible". The closer government are linked to industry, the clearer "what is possible" becomes, and the easier it is to deliver. These links enable better policy and a more effective response but take time to build and maintain.
85. In closing, the areas of testing policy and delivery during the COVID-19 pandemic that were most effective were those where partners, including industry and government, worked closely together with a clear strategic objective. Trade

associations are a vital link in this area, and we offer our fullest support to achieving stronger, closer industry and government relations in the future.

**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:** PD \_\_\_\_\_

**Dated:** 28.5.2025