Written evidence submitted by LumiraDx (CRV0066)

Executive Summary

This evidence submission proceeds as follows:

1. Background on LumiraDx
2. The vale of innovation in diagnostic technology as part of the recovery from the pandemic
3. Facilitating innovation in the area of in vitro diagnostics (IVD)

Key points:

- Multiplex testing should form part of strategies to manage and recover from outbreaks of COVID-19.

- There are innovative and effective diagnostic technologies currently developed within the IVD sector that can be deployed to support management of and recovery from the pandemic.

- The IVD sector has significant value for the UK health system and UK economy and its role should be recognised within the pandemic recovery.

- The Government must ensure that the IVD sector is properly supported and that opportunities for innovation to support pandemic recovery are recognised and utilised.

1. Background on LumiraDx

1.1 LumiraDx was founded in 2014 by a group of entrepreneurs with a successful track record in building and scaling diagnostics and health IT businesses, bringing expertise in a number of areas of technology and innovation, including:

- Developing, manufacturing and commercialising industry-leading point of care (POC) diagnostic platforms.
- Using cloud-based platforms to integrate health system networks and transfer of patient data.
- Using data to develop supported self-care plans to improve individuals' health and system-wide outcomes.

1.2 As a UK based company, LumiraDx is a key player within research and innovation in diagnostic technologies, providing employment to 1600 people and currently by far the largest UK manufacturer with manufacturing facilities in the UK in Stirling, Glasgow and Doncaster.

2. The value of innovation in diagnostic technology as part of the recovery from the pandemic

2.1 In the early response to the pandemic, laboratory testing focused on detecting sequences of the SARS-CoV-2 RNA genome from a nasopharyngeal swab, but this approach has several major limitations in that it is laborious and expensive; can limit access for under-served and vulnerable

populations; and has a slow turnaround time which can impact on endeavours to slow transmission through early identification of those who should self-isolate.[1]

2.2 There has thus been an **urgent need for innovation to improve access to point-of-care testing for SARS-CoV-2** during the COVID-19 pandemic[2] and SARS-CoV-2 antigen rapid diagnostic tests have increasingly been integrated in testing strategies around the world.[3]

2.3 Looking ahead at long-term recovery and management of COVID outbreaks, it has been recommended that **multiplex testing is incorporated into strategies for managing patients with respiratory symptoms**.[4] This is particularly important in relation to creating capacity within the health system, which will be confronted by the **dual challenge of outbreaks of COVID-19 and influenza**[5] and against the backdrop of the UK government's stated intention to cease the provision of Lateral Flow Devices (LFDs) for domestic use.[6]

2.4 The LumiraDx platform is one example of innovation in diagnostic technology that can support the ongoing recovery from the pandemic, providing effective multiplex testing at the point of patient care in minutes and at low cost. Indeed, the LumiraDx SARS-CoV-2 Antigen Test is the first rapid SARS-CoV-2 antigen test for use by healthcare professionals. In addition to being CE Marked it is also authorised under an emergency use approval (EUA) by the FDA and various other jurisdictions, demonstrating efficacy among asymptomatic individuals with COVID-19 when compared with PCR test results, offering significant advantages for identifying patients in the community and other settings.[7]

2.5 Throughout the pandemic, it has been clear that maintaining capacity within NHS services has been an underpinning principle of decisions to enter into lockdowns.[8] The welfare of the UK economy and its recovery is thus inextricably linked with strategies to manage outbreaks of COVID-19 and, consequently, the innovations in technology that surround this.

2.6 The Government has underlined the critical role of **effective testing programmes**, alongside vaccination, as a means of managing COVID-19, **reducing pressures on health services** and enabling individuals to manage risk in relation to themselves and others.[9]

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[1] Drain, P.K., Ampajwala, M., Chappel, C. *et al.* A Rapid, High-Sensitivity SARS-CoV-2 Nucleocapsid Immunoassay to Aid Diagnosis of Acute COVID-19 at the Point of Care: A Clinical Performance Study. *Infect Dis Ther* **10,** 753–761 (2021). https://doi.org/10.1007/s40121-021-00413-x

[2] Drain, P.K., Ampajwala, M., Chappel, C. *et al.* A Rapid, High-Sensitivity SARS-CoV-2 Nucleocapsid Immunoassay to Aid Diagnosis of Acute COVID-19 at the Point of Care: A Clinical Performance Study. *Infect Dis Ther* **10,** 753–761 (2021). https://doi.org/10.1007/s40121-021-00413-x

[3] Brummer LE, Katzenschlager S, Gaeddert M, Erdmann C, Schmitz S, Bota M, et al. (2021) Accuracy of novel antigen rapid diagnostics for SARS-CoV-2: A living systematic review and meta analysis. PLoS Med 18(8): e1003735. https://doi. org/10.1371/journal.pmed.1003735

[4] COVID-19: Preparing for the future Looking ahead to winter 2021/22 and beyond, The Academy of Medical Sciences, July 2021

[5] COVID-19: Preparing for the future Looking ahead to winter 2021/22 and beyond, The Academy of Medical Sciences, July 2021

[6] COVID-19 Response: Autumn and Winter Plan 2021, Cabinet Office, September 2021

[7] Drain P, Sulaiman R, Hoppers M, Lindner NM, Lawson V, Ellis JE. Performance of the LumiraDx Microfluidic Immunofluorescence Point-of-Care SARS-CoV-2 Antigen Test in Asymptomatic Adults and Children. Am J Clin Pathol. 2021 Oct 20:aqab173. doi: 10.1093/ajcp/aqab173. Epub ahead of print. PMID: 34668536.

[8] 'Lockdown was the only way to stop the NHS being broken' - The Times Weekend Essay - GOV.UK (www.gov.uk)

[9] COVID-19 Response: Autumn and Winter Plan 2021, Cabinet Office, September 2021

2.7 The economic impacts of lockdown during the pandemic are well established[10] and, ultimately, **recovery will be slowed or halted if it is not possible to effectively manage transmission in the community and reduce pressures on health services** to ensure that additional restrictions are not necessary. Analysts at the Institute of Economic Affairs have outlined that a 3-month lockdown in **response to the new Omicron variant could result in a cost of £6bn per month to the economy**.[11]

2.8 The **UK diagnostics industry thus has a dual role in the pandemic recovery**, firstly in relation to **developing solutions to managing present and future outbreaks of COVID-19** itself and secondly, in relation to its **economic value** as part of the life sciences sector (see also section 3.1 below).

3. Facilitating innovation in the area of in vitro diagnostics

3.1 Research and development in IVD has a significant role to play in the future of the UK, both in relation to improving efficiencies in the health system and in relation to the UK economy. For example, as highlighted by the British Institute for In Vitro Diagnostics (BIVDA):

- 70% of clinical decisions are informed by IVD,
- The UK IVD sector employs over 8,000 people,
- The UK is a net exporter of IVD products, exporting £1.1bn in 2013.[12]

3.2 Nonetheless, there are a number of challenges that prevent the uptake and diffusion of IVD, despite the innovations that have been achieved in the sector across a range of disease areas, creating a 'glass ceiling' for implementing and maximising benefits from innovation.[13] This is underlined by the fact that less than 1% of the NHS budget is allocated to the uptake of new and innovative IVD products.[14]

3.3 Whilst the pandemic has presented a need and consequent opportunities for rapid innovation, additional statutory processes have also been introduced in relation to approving diagnostic tests for SARS-CoV-2 via the Medical Devices (Coronavirus Test Device Approvals) (Amendment) Regulations 2021.

3.4 Whilst we welcome a rigorous quality review process and have undergone numerous independent evaluations, we underline that the Coronavirus Test Device Approvals (CTDA) regime implemented through these regulations has impeded innovation and slowed access to diagnostic solutions in the UK that could strengthen ongoing strategies to respond to and recover from the pandemic.

3.5 Given the significance of testing strategies to pandemic management and recovery, we contend that there is a need to examine the efficacy of the CTDA process and assess the extent to which it is facilitating the IVD sector to offer effective solutions to support pandemic recovery.

3.6 We also highlight to the Committee the statutory review of the CTDA that is mandated under Regulation 10 of the Medical Devices (Coronavirus Test Device Approvals) (Amendment) Regulations 2021 and due for publication by the Secretary of State for Health and Social Care by 31 December 2021.[15] We contend that there **should be proper scrutiny of this review to ensure that the CTDA is**

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[10] A year of Covid lockdowns has cost the UK economy £251bn, study says | Economics | The Guardian
[11] Unemployment could soar under another lockdown — Institute of Economic Affairs (iea.org.uk)
[12] The Value of IVDs (bivda.org.uk)
[13] The Value of IVDs (bivda.org.uk)
[14] The Value of IVDs (bivda.org.uk)

fit for purpose and **enabling effective access to diagnostic solutions** that can support the pandemic recovery.

3.7 Going forward, it is important that the government take steps to **facilitate innovation in the IVD sector** and to act on the **opportunities that rapid diagnostics present** in relation to responding to and recovering from the joint challenge of COVID-19 and influenza, which are likely to increase pressures on the health system in forthcoming winters.[16]

December 2021

[15] Medical Devices (Coronavirus Test Device Approvals) (Amendment) Regulations 2021

[16] COVID-19: Preparing for the future Looking ahead to winter 2021/22 and beyond, The Academy of Medical Sciences, July 2021