

Witness Name: Geoffrey John Twist

Statement No.: 1

Exhibits: GJT/01 – GJT/16

Dated: April 2025

## UK COVID-19 PUBLIC INQUIRY

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### FIRST WITNESS STATEMENT OF GEOFFREY JOHN TWIST

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I, **GEOFFREY JOHN TWIST** of **ROCHE DIAGNOSTICS LIMITED WILL SAY** as follows:

1. I am the Managing Director for the UK and Ireland and Management Centre European Agents at Roche Diagnostics Limited. I was appointed to this role on 1 October 2017. In this role, I have responsibility in relation to the diagnostics organisation in the UK and Ireland, and the relationship with our agents in Malta, Iceland and Cyprus. I joined Roche in 1996 in its pharmaceutical division and have since then held a number of general management and commercial leadership roles in the business, across the UK and Ireland, the United States, Switzerland, Denmark and the Netherlands. I joined the diagnostics side of the business in 2003. More broadly, my professional background is in finance and accounting.
2. The Roche global business is headquartered in Basel under Roche Holding AG and is split into separate divisions, 'Roche Pharmaceuticals' and 'Roche Diagnostics', with each division being made up of a number of different legal entities, together known as the "**Roche Group**". Roche Diagnostics Limited is the sales affiliate for the UK and Ireland (which I refer to in this statement as the "**Roche Diagnostics Affiliate**") and sits within the Roche Diagnostics division. In this statement, where I refer to "us", "we" or "our" I am referring to the Roche Diagnostics Affiliate unless otherwise specified. For the purposes of this statement, I will refer to "**Roche**" or "**Roche Headquarters**" interchangeably when referring to any actions or decisions taken at a divisional or global level, rather than any specific individual entities unless it is relevant to do so. I explain

further the interaction between the Roche Diagnostics Affiliate and Roche Headquarters, so far as it is relevant to the issues in this statement, in Section B below.

3. I am authorised on behalf of the Roche Diagnostics Affiliate to make this witness statement in response to the 13 September 2024 letter from the UK Covid-19 Inquiry (the "**Inquiry**") (the "**Rule 9 Request**"). The Rule 9 Request asks that the Roche Diagnostics Affiliate identify an individual to provide a written witness statement in respect of certain matters detailed within that letter concerning the approach to testing, tracing and isolation adopted during the Covid-19 pandemic.
4. In making this witness statement, I have drawn on my personal knowledge and discussions with others in the Roche Diagnostics Affiliate during the relevant period covered in this statement; namely, Jo Williams (Senior Legal Counsel, formerly a Commercial Contracts Manager), Catherine Pawan (Director of Legal and Compliance), Chris Hudson (Director of Access and Innovation), Simon Thorpe (Senior Market Manager - Molecular Solutions), Alan Sumner (Head of Market Access and Public Affairs), Pierre Hazlewood (Global Chapter Lead, Roche Consulting formerly Director of Marketing for the Roche Diagnostics Affiliate), Jacqui Young (Public Affairs Manager) and Simon Parker (Senior Marketing Manager for Centralised and Point of Care Solutions). When I refer in this statement to the Roche Diagnostics Affiliate's understanding, this is based on discussions that I have had with the individuals listed above, which have informed my understanding as set out in this statement.
5. Save where I indicate to the contrary, the facts and matters contained in this witness statement are within my own knowledge. Where they are not within my own knowledge, they are matters of information or belief and I have identified the source of my information or the basis for the belief. This statement has been prepared through a series of meetings and emails with our in-house legal counsel and external solicitors.
6. I refer in this statement to various documents, copies of which are exhibited to this statement in chronological order in a series of exhibits marked '**GJT/[X] - INQ[X]**' and identified by the Inquiry's unique reference number for that document.
7. In this statement, I cover the following matters:

- a. The relevant background to the Roche Diagnostics Affiliate and its role in the pandemic;
- b. An overview of Roche Headquarters' involvement at the outset of the pandemic;
- c. The Roche Diagnostics Affiliate's role in testing in the UK during the pandemic;
- d. The Roche Diagnostics Affiliate's involvement in the UK's "Test, Trace and Isolate" system ("TTI");
- e. Vulnerability and inequalities considerations relevant to testing in the UK;
- f. Public compliance with the TTI system; and
- g. Lessons learned.

#### **A. BACKGROUND TO THE ROCHE DIAGNOSTICS AFFILIATE AND ITS ROLE IN THE COVID-19 PANDEMIC**

8. Roche is an expert in the field of preventing, diagnosing and treating health conditions and diseases. It aims to improve health outcomes and reduce costs for patients and healthcare systems. The overall goal of the Roche Diagnostics division is to provide testing solutions for the world's most challenging healthcare emergencies. Roche develops products and services that address the prevention, diagnosis, monitoring, screening and treatment of diseases. These products and services relate to the screening, detection and monitoring of a range of different diseases. This includes blood screening or testing/monitoring for cancer, heart disease, diabetes, hepatitis, and human papillomavirus.
9. Prior to the pandemic, the Roche Diagnostics Affiliate was (and continues to be) a longstanding supplier of diagnostic products and services through existing contracts and established supply chains with NHS laboratories and what was previously known as Public Health England ("PHE"). By way of overview, NHS contracts are publicly procured in accordance with relevant procurement legislation either via their standalone procurement exercise or by using a publicly procured framework such as NHS Supply Chain, PHE Microbiology Framework and NHS SBS Clinical Managed Services. All publicly tendered contracts are advertised and should be available on the Government Contracts Finder Service. Contracts range from the provision of instruments, reagents and consumables to large Managed Laboratory Services which include multiple laboratory disciplines. PHE was later replaced by the UK Health Security Agency ("UKHSA") and the Office for Health Improvement and Disparities. Prior to the pandemic

(and as at today), these products and services were (and are) supplied on a business as usual ("**BAU**") basis to NHS laboratories (and the PHE laboratories including those at Porton Down, Birmingham and Colindale) for the purposes of monitoring/testing for a range of diseases, as set out above.

10. Following the Covid-19 outbreak, Roche Headquarters assisted countries around the globe to control the outbreak of the virus by providing equitable access to diagnostic testing, based on the population of the country, the amount of existing equipment installed to run the tests (the "**install base**") and the capability for running tests. The Roche Diagnostics Affiliate was responsible for Roche's supply of diagnostic testing for Covid-19 in the UK.
11. During the pandemic the Roche Diagnostics Affiliate's involvement was primarily concerned with the supply of testing for NHS hospitals and clinics. The Roche Diagnostics Affiliate had no involvement in the 'trace' and 'isolate' elements of the UK's TTI system and had very little involvement in relation to the 'test' element insofar as it concerned mass testing of the general public. I therefore describe in this statement the Roche Diagnostics Affiliate's involvement as it related more broadly to testing during the pandemic. For the avoidance of doubt, any reference to 'testing' is therefore a reference to testing more broadly in the pandemic rather than a reference to testing within the system of TTI, unless I have specifically stated otherwise.

#### Overview of key decision makers within the Roche Diagnostics Affiliate

12. The key decision makers within the Roche Diagnostics Affiliate were as follows:
  - a. As Managing Director, I led the senior leadership team which included the directors in charge of each department, and together we were responsible for key decision making during the pandemic. I also represented the Roche Diagnostics Affiliate in a number of senior-level meetings and correspondence with Government (including the meeting on 17 March 2020 and the response to Boris Johnson's letter on 7 April 2020 as described below in paragraphs 41 and 49 respectively).
  - b. Chris Hudson is the Director of Access and Innovation for the Roche Diagnostics Affiliate and has held this role since 2018. Chris led the response team for molecular diagnostic PCR tests, handling discussions at a senior level.
  - c. Pierre Hazlewood was the Director of Marketing for the Roche Diagnostics Affiliate at the time. He initially worked to establish our involvement in antibody testing, as it was originally planned that this would be available to members of

the public. When antibody testing was selected for NHS staff and in-patient treatment and subsequently broader testing was introduced using Lateral Flow Tests ("LFTs"), he worked as a liaison between the Department of Health and Social Care ("DHSC") and PA Consulting, which was commissioned on a limited basis to roll out some of the testing using LFTs. To the extent that there were operational decisions around these topics, these decisions were referred to me.

13. As set out below in further detail, given that Roche's involvement during the pandemic was at a global level and not just limited to the UK, some key decisions (for example in relation to equitable testing distribution and pricing) were taken at a group or divisional level. Roche Holding AG was generally responsible for leading the Roche Group's strategic direction.

#### Overview of the Roche Diagnostics Affiliate's existing testing infrastructure

14. I set out below a brief explanation of the Roche Diagnostics Affiliate's relevant testing systems and products in order to put into context the existing testing infrastructure in the UK prior to the pandemic and how that was then adapted/developed for the purposes of testing for Covid-19.
15. The following components are required in order to carry out PCR-based laboratory diagnostic testing (whether for Covid-19 or other pathogens):
- a. Testing systems that will process a patient sample and provide results in relation to a specific disease.
  - b. The test reagents used by the testing system for identifying the presence of a particular pathogen within a patient sample itself.
  - c. A sample collection device (typically a tube with a transport media to preserve the integrity of the sample type being collected which is loaded onto the testing system).
  - d. System Consumables (typically unique plastic tips and plates used by the testing system to manipulate the patient sample and test reagents to generate a result).
  - e. System Reagents (additional reagents required by the testing system to process the patient sample and generate a result).
16. Roche is the legal manufacturer of all the components (a)-(e) set out above. Other manufacturers also provide alternatives to component (c) that Roche have validated for use in combination with components (a), (b), (d) and (e).
17. Components (a), (c), (d) and (e) were supplied by the Roche Diagnostics Affiliate to NHS laboratories and PHE prior to the pandemic for BAU testing/screening of other

diseases. Roche then developed specific test reagents (component (b)) for the purposes of testing for Covid-19 (as set out at paragraph 27 below). Subsequently, the Roche Diagnostics Affiliate supplied these components as adapted (where necessary) for testing for Covid-19 to NHS laboratories and PHE during the pandemic, although we were keen to reiterate throughout that no single company would be able to meet the demand for testing that was required.

18. In relation to testing systems, Roche has developed a number of relevant systems which I explain below.

*PCR testing*

19. **cobas® 6800 and 8800 systems:** Prior to the pandemic, the most common Roche systems used by NHS laboratories for BAU testing were the cobas® 6800 and 8800 systems. These are automated high-throughput systems held by only certain laboratories. Healthcare providers (physicians, health clinics, etc.) collect swab samples from patients and then send those samples to the laboratories for processing. Individual laboratories contracted with healthcare providers to process the tests.
20. The design of these systems enables them to be run 24 hours per day with a 1-hour interruption to testing once every 7 days for a weekly maintenance program. Each system can process 96 tests in 3.5 hours, and:
- a. the cobas® 6800 system could provide 384 results in eight hours; and
  - b. the cobas® 8800 system could provide 1,056 results in eight hours.
21. **cobas® Liat system:** This system was an important tool in the identification of Influenza, Respiratory syncytial virus and Strep A. These systems existed in limited number prior to the pandemic. However, given their ability to process tests at a quicker rate than the cobas® 6800 and 8800 systems and their much smaller size, the Roche Diagnostics Affiliate worked to rapidly increase the numbers of these systems available to support the triage of patients at NHS hospitals prior to them receiving a Covid-19 PCR test (for example, as part of A&E screening of incoming patients for Covid-19 during the pandemic).
22. **MagNA Pure and LightCycler® 480/cobas® z480 systems:** The Roche Diagnostics Affiliate had also supplied a limited number of systems called MagNA Pure and LightCycler®/cobas® z480 Analysers to NHS laboratories. The MagNA Pure is used to obtain the necessary extracts from a patient sample which is then tested on a LightCycler® 480/cobas® z480 system to determine whether the patient has tested positive for a particular pathogen.

23. The main difference between testing using the cobas® 6800/8800 and the MagNA Pure/LightCycler® 480 systems is the level of automation, with the former being fully automated (and therefore a 'closed system') while the latter require an experienced scientist to manually set up the purified sample and test reagents prior to loading onto the LightCycler® 480/cobas® z480 (and therefore an 'open system').
24. The MagNA Pure and LightCycler® 480/cobas® z480 systems often sit alongside the cobas® 6800/8800 systems in molecular laboratories for lower volume/specialist testing where a 'closed system' test compatible with the cobas® 6800/8800 systems is not available. The use of MagNA Pure systems for PCR testing in the UK was not widespread, as the Roche Diagnostics Affiliate was focussed on mobilising and expanding the test capacity using the cobas® 6800/8800 systems.

#### *Antibody testing*

25. **The cobas Elecsys® systems:** These analytical systems form the mainstay of biochemistry and serological testing in many busy hospital laboratories.<sup>1</sup> The Covid-19 antibody tests (there were two, one for the N or Nucleocapsid protein and one for the S or Spike protein) are examples of serology tests on this system. Once serum or plasma derived from human blood samples are introduced into the system along with the working reagents (ingredients to enable the test to function), the machine performs the test in 18 minutes and the results are available electronically. The N protein test (Elecsys anti-SARS-CoV-2) was the mainstay of screening and gives a qualitative result (reactive/non-reactive) in the presence of specific antibodies in human serum or plasma as a result of infection. The S protein test (Elecsys anti-SARS-CoV-2 S test) gives a quantitative result (in units/ml) of specific antibodies in human serum or plasma from infection or vaccine.

## **B. OVERVIEW OF ROCHE HEADQUARTERS' INVOLVEMENT IN TESTING AT THE OUTSET OF THE PANDEMIC**

### Development of a PCR test for Covid-19 to use on existing testing systems

26. Following the outbreak of Covid-19 at a global level in early February 2020, Roche Headquarters expedited its test development and commercialisation to support the urgent and unprecedented need for patient testing. Since early February, Roche had

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<sup>1</sup> Elecsys refers to the type of technology used (Electrochemiluminescence).

- been working with the U.S. Food and Drug Administration ("FDA") to produce a coronavirus test under Emergency Use Authorisation guidance.
27. On 12 March 2020, Roche received FDA Emergency Use Authorisation for the 'cobas® SARS-CoV-2 Test' to detect the novel virus that causes Covid-19 disease. This test, which I refer to in this statement as the "**Roche PCR Test**", was launched on 16 March 2020. Concurrently, Roche followed the path to CE-IVD certification under Annex III of EU Directive 98/79/EC [GJT/01 INQ000605506] (which was the industry-recognised certification used) so the test was also available in markets accepting the CE-IVD mark. The CE-IVD mark signifies that products sold in the European Economic Area have been assessed to meet high safety, health, and environmental protection requirements. Further explanation of the relevant certification requirements, in particular the Coronavirus Test Device Approvals ("CTDA") (which did not come into force until later in the pandemic), is set out at paragraph 78.d below.
28. The Roche PCR Test was specific to testing on the Roche cobas® 6800 and 8800 systems. Roche developed the Roche PCR Test such that it could be run in conjunction with other tests on the cobas® 6800/8800 systems. This was done to get the greatest testing efficiency out of the systems. Running multiple tests for different pathogens at the same time requires a specific chemistry that includes specially modified 'primer and probes' set for the SARS-CoV-2 virus, which resulted in the PCR test being incompatible with other systems other than the cobas® 6800/8800 systems. For the Roche PCR Test, individuals would be sampled via a nasopharyngeal swab which would be placed into a sample tube containing a transport buffer which was then tested on the Roche cobas® 6800 and 8800 systems. These systems already existed in certain NHS and PHE laboratories (as outlined above at paragraph 9).

#### Supply of Roche Headquarters testing at a global level

29. There were also certain decisions/steps taken at a Roche Headquarters level which I consider are important to explaining the context to the Roche Diagnostics Affiliate's involvement in testing in the UK during the pandemic.
30. As set out above, Roche Headquarters was involved at a global level in tackling the Covid-19 crisis, although it was made clear by Roche Headquarters that, given the scale of the challenge, Roche could not meet global supply alone without the involvement of other diagnostics companies. In the context where Roche had been the first supplier to be able to produce a reliable and CE-IVD approved, fully automated Covid-19 PCR test, and worldwide demand significantly outweighed supply for testing kits and equipment,

a coordinated Roche response at a global level was clearly required. The Roche Diagnostics Affiliate's involvement in the UK therefore has to be seen in the context of the support that was being offered by Roche Headquarters on an international level and we operated in alignment with decisions taken at that level.

31. At the outset of the pandemic I understand Roche Headquarters was aiming to supply as many tests as possible to be run on the cobas® 6800/8800 instruments globally, and to expand its capacity as quickly and as much as possible given the unprecedented and critical global need.
32. Given the urgency of the worldwide outbreaks, I understand Roche Headquarters decided to prioritise customers and laboratories with the highest ability to implement routine testing at speed together with the highest unmet medical need. From a practical standpoint, this approach considered:
  - a. Existing placement of high-volume cobas® 6800 and 8800 systems, on which the Roche PCR Test had to be performed (at least at the outset of the pandemic);
  - b. Ability of laboratories to quickly scale up testing; and
  - c. Availability of ancillary products required to run the tests (i.e., validated sample collection devices).
33. Throughout the pandemic I attended weekly meetings with Global Operations, the function within the Diagnostics Division responsible for manufacturing and the expansion of production capabilities. In these meetings we were told if there would be any deviation expected in the baseline commitment of the Roche PCR Test (and required consumables and reagents) to the UK. This informed the parameters within which the Roche Diagnostics Affiliate could make commitments to the UK (which I discuss further below in paragraph 46).
34. Roche Headquarters set a global uniform price for its Covid-19 tests, based on the rationale that in public health emergencies, cost should not be a barrier to accessing diagnostics.
35. In addition to the Roche PCR Test that was developed for testing on the cobas® systems, it was also possible to test for Covid-19 using specific test reagents on the MagNA Pure and LightCycler® 480/z480 systems outlined above. However, as set out at paragraph 28 above, in the UK, the focus in respect of PCR testing was on the supply of Roche PCR Tests that could be used on the cobas® systems.

### **C. ROCHE DIAGNOSTICS AFFILIATE'S ROLE IN TESTING IN THE UK DURING THE PANDEMIC**

36. In light of the existing testing infrastructure, technology and capacity in the NHS as outlined above, and the decisions taken at a global level, I set out below an explanation of the Roche Diagnostics Affiliate's role in supporting PHE and the UK Government to develop this for the purposes of Covid-19.

Overview of Roche Diagnostics Affiliate role in testing in the UK

37. The UK's testing strategy centred around five 'Pillars' which were established by the UK Government and first announced on 2 April 2020 [GJT/02 - INQ000605507] and then set out in further detail on 4 April [GJT/03 - INQ000106325]. These were set out as follows:

- a. Pillar 1: Scale up swab testing in PHE laboratories and NHS hospitals for those with a medical need and the most critical key workers.
- b. Pillar 2: Deliver increased commercial swab testing for critical key workers in the NHS, social care and other sectors.
- c. Pillar 3: Develop antibody testing to help determine if people have immunity to Covid-19.
- d. Pillar 4: Conduct UK-wide surveillance testing to learn more about the disease and help develop new tests and treatments.
- e. Pillar 5: Create a new Diagnostics National Effort to build a mass-testing capacity at a completely new scale.

38. Given our existing contractual relationships with NHS laboratories and PHE, and the validated Roche testing equipment/products already in place, the Roche Diagnostics Affiliate's involvement centred on working with these existing customers to support the additional in-patient and NHS staff testing during the pandemic. In more detail:

- a. At the outset of the pandemic, this involved us rapidly expanding and mobilising our supply of testing equipment/products using the existing infrastructure in place, in order to scale up testing capacity within the NHS. At first this focussed on molecular testing (commonly referred to as 'PCR' testing in the context of the pandemic). The supply of and support for PCR testing for the NHS fell under Pillar 1. Our involvement in this pillar was announced on 2 April 2020 when the Government first outlined its testing strategy. The 2 April 2020 announcement stated that Pillar 1 "*[benefitted] from PHE's partnership with Roche through a central UK allocation mechanism*" [GJT/02 - INQ000605507] set out further detail in relation to this below.

- b. Subsequently, we also developed and provided antibody testing capacity for NHS staff and patients (this was later focussed on "key workers"). The supply and assistance with antibody testing fell under Pillar 3. I set out further detail in relation to this below.
- c. We had limited involvement in relation to Pillars 2, 4 and 5. To the extent that we were involved in relation to these pillars, I have set out further detail in relation to this below.

How and when the Roche Diagnostics Affiliate came to be involved in testing for Covid-19 in the UK

39. Given our existing relationship, we reached out to PHE in early March 2020 regarding the development of the Roche PCR Test. A conference call took place between Duncan Selby from PHE and myself and Chris Hudson on Saturday 14 March 2020. I recall that, on this call, we were asked for our view on the existing capacity for testing for Covid-19 within the NHS and the scalability of this, i.e., how rapidly we could increase this testing capacity. We were also asked about the resources that the Roche Diagnostics Affiliate might be able to contribute alongside other industry partners in order to tackle the emerging challenges posed by the pandemic. The upshot of this meeting was that we carried out analysis of our deployed resources and subsequently presented this to PHE.
40. In advance of this call, also on 14 March 2020, Simon Thorpe, Senior Market Manager at the Roche Diagnostics Affiliate, emailed PHE setting out our initial proposal as to how we could support the upscaling of testing for Covid-19 in the UK [GJT/04 – INQ000605509]. The proposal set out how we could build upon the existing base of testing platforms we had in place across the UK to upscale testing capacity. In addition, the proposal referenced the newly launched Roche PCR Test (defined in paragraph 27 above) which could be used on Roche systems already in place at NHS laboratories across the UK.
41. The following Tuesday, on 17 March 2020, I attended a meeting at 10 Downing Street with representatives of Government including the then Prime Minister, Boris Johnson and the then Secretary of State for Health and Social Care, Matt Hancock. I had been invited alongside representatives from other major industry players including Thermo Fisher, Amazon and Boots. The Government outlined their approach to increase coronavirus tests every day, including by increasing NHS laboratory capacity, introducing swab testing for frontline staff outside the NHS, and introducing mass antibody testing for the public.

42. The meeting was akin to a 'workshop' and I recall that we discussed how our companies could contribute to these aims. The content of our discussions later fed into what I understood to be the five pillars of testing strategy that I describe above at paragraph 37. From the Roche Diagnostics Affiliate's perspective, I set out that, in light of our existing expertise and relationships, we could best help in relation to supporting NHS laboratory capacity in light of the imminent challenges it was facing (i.e., the first limb of the Government's approach set out above which became Pillar 1). I set out below in further detail how this initial involvement developed over the pandemic.
43. Around the same time, we were also engaging with the Department for Business, Energy and Industrial Strategy ("BEIS") on the impact of the pandemic on Roche's supply chains, demand for Roche's products domestically and overseas, and on our UK workforce. I understand that this engagement included the Roche Diagnostics Affiliate responding to questions posed by BEIS through an online questionnaire in the week of 16 March 2020. I note that the questionnaire was hosted online and responses were submitted through an online form. I understand that we have not been able to locate a copy of the final responses as submitted, however I exhibit a copy of the draft responses (which also shows the questions that were asked) [GJT/05 - INQ000605510]

'Standing up' and expanding testing capacity for Covid-19

44. Following the meeting on 17 March 2020, the Roche Diagnostics Affiliate was involved in regular discussions with PHE and NHS England, focussing on how we could 'stand up' (i.e., mobilise) and rapidly expand the existing testing capacity for Covid-19 in the NHS across the UK. In practice, this involved (so far as possible) (i) supplying testing kits and the required consumables/reagents required for testing, and (ii) ensuring that the necessary Roche systems were in place and had the necessary software update to run the Roche PCR Test. Whilst the focus on 'standing up' testing focussed on PCR testing as the gold standard, I understand that the nature of Covid-19 as a novel pathogen meant that all forms of testing were being looked at to gain more data on the nature of the pathogen itself.
45. I set out below an overview of the Roche Diagnostics Affiliate's support in (i) supplying tests to the UK, and (ii) mobilising Roche testing systems across the UK. At the outset of the pandemic, this related to PCR testing, given that this was the earliest available method of testing, but other forms of testing for Covid-19 were developed subsequently.

*(i) Supplying PCR tests to the UK*

46. In relation to the supply of tests around the UK, we provided the UK Government with a baseline commitment of a number of tests based on what could be met by the Roche Diagnostics Affiliate consistently, and in light of decisions taken by Roche Headquarters at a global level. At around the time of our 14 March 2020 meeting (which I refer to in paragraph 39 above), per the decisions taken at a group level and what we considered was practically feasible, we communicated to the UK Government that we could commit to a supply of 5,000 Roche PCR Tests per day i.e. 35,000 tests per week and this formed our baseline commitment to the UK. We reiterated from the outset that the Roche Diagnostics Affiliate would not be able to meet the entire need for supply of tests alone, and that a multi-industry response was required.
47. On 18 March 2020, the Government announced its target to increase the number of people tested to 25,000 hospital patients a day by increasing PHE and NHS testing capacity [GJT/06 - INQ000605511] On 19 March 2020, Boris Johnson and Matt Hancock wrote to me and the CEO of Roche Holding AG. The letter thanked me for coming to the meeting at 10 Downing Street on 17 March (see paragraph 41 above) and requested that the Roche Diagnostics Affiliate supply additional capacity for testing to PHE "*to do up to 25,000 tests per day*" and for our support to deliver 100,000 tests per day [GJT/07 - INQ000605512] In our engagement with PHE we had made clear, however, that the Roche Diagnostics Affiliate could not meet the target of 25,000 tests per day alone.
48. Our commitment to 35,000 tests a week, as noted at paragraph 46 above, was the subject of regular discussions with the UK Government. On 3 April 2020, Boris Johnson wrote to myself and the CEO of Roche Holding AG [GJT/08 - INQ000605513] He recognised Roche's support to the UK healthcare system and noted that "*Roche is rapidly expanding capacity for testing to support patients and our front-line staff.*" His letter included requests that:
- a. Roche increase the number of test kits that it delivered to the UK from 5,000 per day to "*81,000 kits per day, with an equivalent number of Copan swabs for Cobas platforms*". This followed the Government's announcement that it intended to increase testing to 100,000 tests a day which had been announced on 2 April 2020 [GJT/02 - INQ000605507]
  - b. We make available our reagent specification such that if Roche was unable to supply a particular component, then this could be sourced via local manufacturers.

49. I responded on 7 April 2020 [GJT/09] INQ000605514 and I understand that the CEO of Roche Holding AG replied separately. In my letter, I made a number of points including:

- a. Given that demand for tests exceeded supply and would do so for the foreseeable future, healthcare systems needed to develop a prioritisation strategy for medical tests.
- b. While we did not have a role in determining what tests would be used for, I warned that the consequences of widely de-prioritising the critical tests carried out on the Roche platforms (for example, relating to blood screening, infectious disease and sexual health) would have serious implications in the healthcare system.
- c. In relation to the request for the specification of our reagents, I outlined that we already partnered with manufacturers around the world but that we would not be able to guarantee the safety and reliability of reagents required for our tests if these were manufactured outside of our network. I also outlined that, given the urgency for such reagents to be available, it would not be feasible for any other facility to order, receive, install and validate the equipment needed to manufacture such tests.
- d. In addition, I explained that *"our cobas® 6800/8800 Systems are not limited to running Roche's recently approved COVID-19 test"* but could *"be used to automate high-volume lab-developed tests, i.e., tests developed by third parties for use on Roche's systems."*
- e. I outlined that the Roche Diagnostics Affiliate was in frequent contact with Government *"to discuss the operational aspects of increasing daily testing numbers beyond 5000 per day"* and confirmed *"our offer of two full time Roche employees who can support Sam's [Roberts] team... We would very much welcome increased participation by all life science partners, putting all commercial interests aside to ensure we can collectively work towards delivering on the 100,000 tests per day."* I set out further detail in relation to these secondments at paragraphs 75-76 below.
- f. I stated that, in summary, Roche's commitment to the UK included increasing the global production of Covid-19 tests and expanding the install base of cobas® 6800/8800 Systems, which at that time consisted of six live sites with further installations planned to enable other sites to go live that month. I also stated that Roche was committed to providing the necessary infrastructure to run

laboratory-developed tests on our MagNA Pure and LightCycler® instruments (which are flexible systems that can use other suppliers' testing components. I expressed our belief that there was an urgent need for all laboratories to adopt and implement the UK-wide strategy for the scaling up of the testing programme and a need for increased participation by all life science partners to work towards the target of delivering 100,000 tests per day. Finally, I explained that swab and ancillary items, such as plastics and transport media are all *"critical products which we do not supply, however, are a rate limiting factor to testing."*

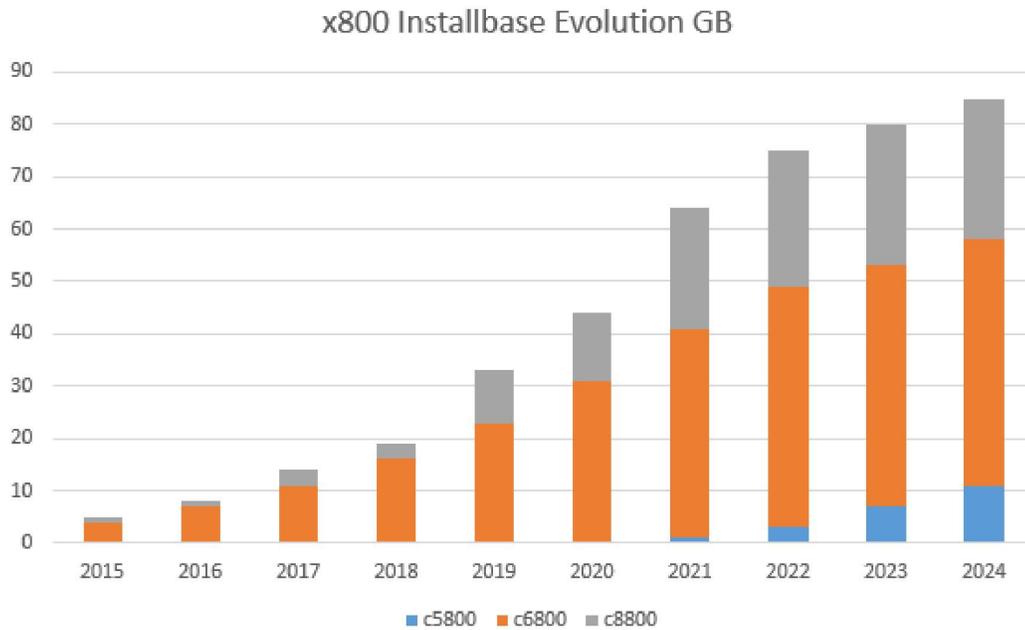
50. Our commitments were formalised in a contract signed by the Roche Diagnostics Affiliate on 27 May 2020 [GJT/10 INQ000605515] for the supply of the Roche PCR Tests to PHE as well as the purchase of an additional cobas® 8800 system, the relocation of a number of other cobas® 6800 and 8800 systems to PHE Porton Down and the relocation of one cobas® 6800 system to the Glasgow Royal Infirmary.
51. Ultimately, we delivered on these commitments, which I believe was a result of (i) our efforts to accurately forecast and assess supply, (ii) our operational and logistical efforts to get these tests delivered, and (iii) our prioritisation of supplying tests to the NHS over any requests we received from the private sector market.

*(ii) Mobilising Roche testing systems across the UK*

52. In addition to the supply of test kits, it was critical to ensure there were sufficient testing systems/equipment across the UK to run these tests. We worked with NHS England, specifically David Wells (Head of Pathology Service Consolidation Programme) and Jane Mills in this 'mobilisation phase', to ensure that, to the extent possible, as many testing systems were in the most efficient locations they could be to maximise testing capacity in the UK. This included moving instruments such as the existing cobas® 6800/8800 systems around the UK and supporting the installation of new sites where these testing systems would be used.
53. As at 14 March 2020, when engaging with the UK Government as to how the Roche Diagnostics Affiliate could assist the NHS (as described above in paragraphs 39 and 40), there were already 34 cobas® 6800 systems and eight cobas® 8800 systems across the UK at various NHS laboratories which were being used on a BAU basis in relation to other diseases. In addition, the PHE laboratories had existing MagNA Pure 96 and LightCycler® 480 systems. These systems were central to expanding capacity for testing Covid-19 in the NHS particularly at the outset of the pandemic.

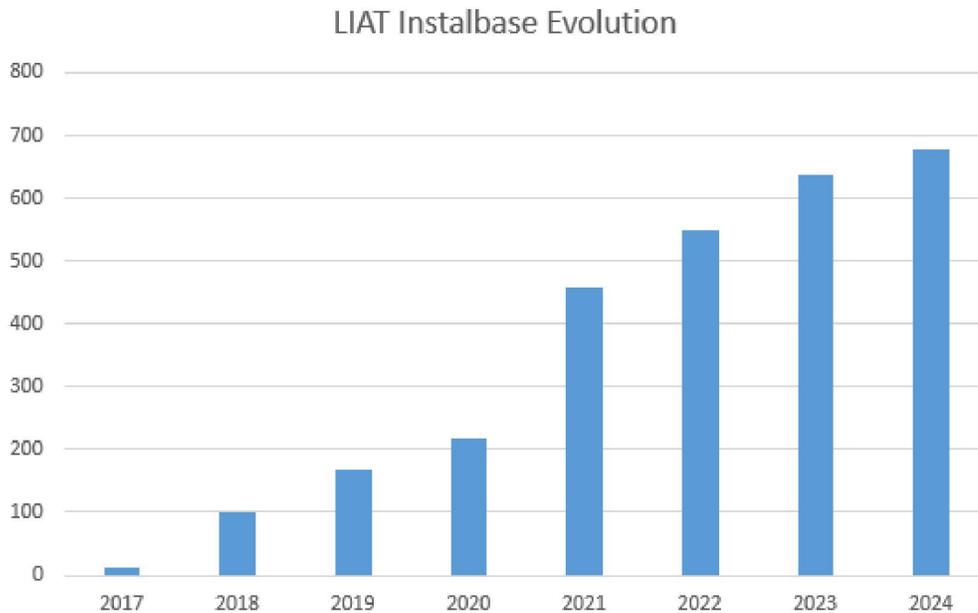
54. By 23 March 2020, we were working with PHE to enable six sites where testing for Covid-19 could be carried out, using existing sites which already had our cobas® systems installed. We were also mobilising the installation of these systems at three further sites including the PHE laboratory at Porton Down. The scaling-up of the testing site at PHE Porton Down involved us supplying and installing two further cobas® 6800 systems in addition to the systems that were already in place across the country. This was reflected in a contract we entered into with PHE for the supply of these cobas® systems dated 27 April 2020.
55. As at 2 April 2020, the number of sites where we were assisting PHE to launch Covid-19 testing had increased from six to 12 in addition to the three further sites where we were installing new systems. This was reflected in the briefing note published by the DHSC on 4 April 2020, titled "Coronavirus (Covid-19), Scaling up our testing programmes" under 'Pillar 1' [GJT/03 – INQ000106325] This referenced the "*public/private partnership with Roche to bring on line new testing capability*" and stated that, "*[t]he first partnership went live last weekend, based primarily in the NHS, with more sites coming on stream each week during the course of April.*" The Roche Diagnostics Affiliate was involved in facilitating the moving of systems as well as various installations across 2020 and 2021 where systems were supplied directly to sites.
56. By 14 March 2022, 29 NHS/PHE laboratories across Great Britain and Northern Ireland that had a combined total of 39 instruments had received Roche PCR Test allocations, initially from the central PHE contract for the supply of Roche PCR Tests dated 27 May 2020 (and subsequently from a UKHSA supply contract dated 26 May 2021). Growth in

the install base for cobas® systems in the UK from 2015 to 2024 is shown in the graph below.



57. In addition to mobilisation of the cobas® systems for testing around the UK, the Roche Diagnostics Affiliate subsequently significantly increased the number of LIAT systems that it could make available for testing. It deployed around 250 additional machines during the pandemic under central contracts for equipment and assays as well as providing systems direct to sites. On 10 November 2021, we signed a contract for the supply of up to 40 additional LIAT machines to be delivered between October and December 2021 and associated Covid/Flu multiplex testing kits to UKHSA on behalf of

the NHS [GJT/11 INQ000605516] Growth in the LIAT Install base in the UK from 2017 to 2024 is shown in the graph below.



Developing and mobilising new antibody testing technology developed by Roche following the emergence of Covid-19

58. I have explained above the Roche PCR Test that was developed by Roche Headquarters in early February 2020 for the purpose of testing for Covid-19.

59. Subsequent to this, on 17 April 2020, Roche Headquarters launched the 'Elecsys® Anti-SARS-CoV-2 serology test' which I refer to in this statement as the "**Roche Antibody Test**". Unlike the Roche PCR Test, which is a molecular diagnostic test, the Roche Antibody Test is a serology test that detects antibodies in people who had been infected with the SARS-CoV-2 virus, the causative agent of Covid-19 disease. This Roche Antibody Test could be run fully automated on the Roche cobas Elecsys® analysers which were already widely available throughout the UK laboratory infrastructure.

60. By 24 April 2020, we had installed the first cobas Elecsys® analyser into PHE Porton Down to run these Roche Antibody Tests and on 28 April 2020 the Roche Antibody Test was launched in the UK. We then engaged in discussions with the DHSC, the NHS and the devolved Administrations regarding a similar roll out of antibody testing to that of the Roche PCR Tests in Pillar 1. This led to us entering a contract with PHE to provide these Roche Antibody Tests in the UK on 21 May 2020 [GJT/12 INQ000605517] and these tests were first allocated on 29 May 2020. Whilst this contract contained minimum order

volumes for the Roche Antibody Test, these volumes were never required, and it was agreed between PHE and the Roche Diagnostics Affiliate that the minimum order provisions would not be enforced. As part of the effort to expand antibody testing, over 100 sites were set up in the UK by the Roche Diagnostics Affiliate for antibody testing using cobas Elecsys® analysers. This included installing two high throughput cobas® e801 systems into PHE Porton Down on 3 July 2020 at the request of PHE/UKHSA. This was reflected in a contract we entered into with PHE dated 8 October 2020 [GJT/13 INQ000605518]. The supply of Roche Antibody Tests to the NHS and PHE then became part of 'Pillar 3' of the Government's testing strategy. I understand that, at least initially, there were calls twice a week between the Roche Diagnostics Affiliate and the DHSC and NHS to discuss the Roche Antibody Test and that the discussions included topics such as the approval process/verification, numbers of Roche Antibody Tests to be provided, when the Roche Antibody Tests would become available, and discussion relating to test sites (both more broadly across the devolved nations and at a more granular level).

61. A second antibody test was launched by Roche on 17 September 2020, though the first test remained the primary test of choice for screening in patients and individuals. Some laboratories ran both tests. The Roche Diagnostics Affiliate entered into a contract with PHE/UKHSA for the supply of both tests to PHE Porton Down and Colindale on 2 August 2021 [GJT/14 INQ000605519]

Other key points of engagement with the Government/PHE

62. Ultimately, the Roche Diagnostics Affiliate's involvement in relation to testing continued throughout the pandemic and involved regular communications in relation to what was possible from our perspective in scaling up this capacity as discussed above.
63. On 17 May 2020, I attended a virtual call with Baroness Dido Harding shortly after her appointment that month as the Chair of the Test and Trace programme. I understand that the purpose of the meeting was to update her on progress regarding our partnership approach to delivering across the various testing pillars of the Government's testing strategy. I understand that the Roche Diagnostics Affiliate's involvement by that point included the following:
- a. Pillar 1: our partnership with PHE to launch automated PCR testing sites and supply Roche PCR Tests across the UK as set out above at paragraph 50. Since 27 March, 240,000 Roche PCR Tests had been delivered across the various sites in the UK including the 16 sites that had gone live by that point. In addition,

we provided support for a significant proportion of the first wave of Covid-19 testing on the MagNA Pure 96 systems which were being used in seven key sites across the UK.

- b. Pillar 2: our partnership with AstraZeneca to supply 384-well LightCycler® 480 plates for Covid-19 testing to support the GlaxoSmithKline/AstraZeneca and University of Cambridge Testing Consortium. I discuss this further below at paragraph 74.b.
- c. Pillars 3 and 4: the launch of our Roche Antibody Test and the installation of the relevant testing systems as set out above at paragraphs 59-61.
- d. Pillar 5: We had seconded two of our experts to the DHSC as described in further detail below at paragraphs 75-76.

64. In addition to the key points of engagement set out above, we also attended regular 'stand up' calls during the pandemic which involved frequent updates and dealing with immediate queries and prioritisation, as well as the Government's plans for allocation. At the outset, these calls occurred daily and then became less frequent. These calls were initially typically held with David Wells and Jane Mills, and there were also meetings regarding the civil infrastructure for antibodies led by Angela Crockett (DHSC Deputy Director, Test and Trace) with representation from each of the devolved nations, including Myles O'Hagan (Senior Procurement Manager at Business Services Organisation Procurement and Logistics Services NI).

Centralised decision-making and allocation of test kits in the UK

- 65. My understanding is that public decisions about testing policies and strategies were in general developed and taken centrally (rather than at a local level). Decisions as to how to allocate test kits across the UK by region were taken on a UK-wide level by PHE and the Chief Medical Officers for each devolved nation (the "CMOs"). On a weekly basis, the Roche Diagnostics Affiliate would provide PHE with the total number of Roche PCR Tests available for distribution within the UK for that week. PHE would then instruct us as to the number of Roche PCR Tests and delivery locations of the allotted tests for that coming week. We were then required under the relevant contract to deliver the allotted amount of Roche PCR Tests to the designated laboratory within two working days.
- 66. We would receive allocation notices setting out the "proposed" allocation of Roche PCR Tests across the UK, though in practice we understood this to be an instruction as to where and how many of the test kits should be distributed across the UK. To the best of

my recollection, we were not at any point involved in any aspect of the discussions that led to the decisions set out in these allocation notices.

67. Throughout the pandemic:

- a. The PHE/CMOs set the allocation of test kits across the whole UK. The Roche Diagnostics Affiliate was provided with instructions on what percentage of its available test kits would be provided to each region of the UK, including the devolved nations. Within each region of the UK, we were also provided with instructions as to how many test kits should be delivered to units which contained existing suitable testing equipment. The regional units comprised predominantly NHS hospitals but also included units such as PHE, Public Health Wales: Pontyclun and the Scottish National Blood Transfusion Service.
- b. As per the maximum number of Roche PCR Tests that we were able to supply to the UK, the total allocation amounted to sufficient reagents and consumables to conduct 35,000 tests on the cobas® 6800 and 8800 platforms.
- c. The allocations each week proceeded on the assumption that there would be no remaining test kits by the end of the week and that all of the Roche Diagnostics Affiliate test kits supplied would have been utilised. In our experience, this assumption proved to be correct.

68. Once the Roche Antibody Tests became available, we also received allocation decisions in relation to those tests, which were similar to the allocation notices for PCR tests. The Roche Diagnostics Affiliate would provide PHE with a four-weekly forecast showing the total number of Roche Antibody Tests available for distribution within the UK for that allocation cycle. PHE would then provide the Roche Diagnostics Affiliate with the total number of Roche Antibody Tests to be allocated to each region of the UK, including the devolved nations, and any specified crown dependencies (namely Guernsey).

69. We were happy to provide the Government with information as to its estimates of how testing capacity could be increased and with technical information, for example in relation to the operation of its systems.

70. While the Roche Diagnostics Affiliate was not involved in any substantive or direct discussions relating to testing strategy or policy, I recognise that it is possible that the information we provided fed into the decision-making around the policies and strategies relating to testing (or even TTI more broadly).

71. For completeness, in terms of allocation of PPE, we also asked the Government to prioritise providing PPE for our engineers who were needed to mobilise and service the testing equipment in NHS laboratories and to support testing for key workers.
72. In terms of the impact of centralisation on the national testing programme and TTI, I can only provide comment on matters within our involvement in the pandemic as set out above. In our experience, the UK Government, with input from the four CMOs, possessed the data in order to make informed decisions regarding the allocation of testing resources and could make centralised decisions as to where the Roche Diagnostics Affiliate needed to send Roche PCR Tests.

#### **D. ROCHE DIAGNOSTICS AFFILIATE'S INVOLVEMENT IN THE TTI PROGRAMME**

##### Overview of the Roche Diagnostics Affiliate's role in TTI

73. As set out above, the Roche Diagnostics Affiliate's role in the pandemic was focussed on testing within the NHS. We had a very limited role in assisting the UK Government regarding the TTI infrastructure, systems and technology given that this related to mass testing of the public.
74. Roche Diagnostics Affiliate had no involvement in respect of the creation of the TTI infrastructure, however we had a limited role in contributing to the installation of the necessary technology which was used as part of the TTI programme:
- a. Roche Diagnostics Affiliate had a purchase order with the UKHSA dated 23 December 2021 for the delivery of 12 LightCycler® 480 QC Kits to be delivered to the Rosalyn Franklin laboratories in Leamington Spa. The Rosalyn Franklin laboratories were 'Pillar 2' Test and Trace laboratories used for running the tests done by the general public. This contract included the delivery of the LightCycler® 480s, as well as the installation, commissioning, training, maintenance call outs and software needed for the LightCycler® 480s to function. However, the LightCycler® 480 machines belonged to AstraZeneca and our involvement was limited only to moving the LightCycler® 480s and ensure they were properly installed to comply with the relevant qualification requirements.
  - b. Roche Diagnostics Affiliate had an existing supply contract with AstraZeneca to deliver plates for the LightCycler® 480. As far as I am aware, this partnership with AstraZeneca in relation to Covid-19 testing was to support the GlaxoSmithKline/AstraZeneca and the University of Cambridge Testing

Consortium. In May 2020, I understand that we had provided 650 plates to cover the Consortium's immediate needs, with a further 2,000 provided to AstraZeneca previously.

- c. Separately, the Roche Diagnostics Affiliate also entered into negotiations from September 2020 for the provision of a high throughput laboratory cell referred to as a "**Molecular Cell**" to be established in Bristol. Under the DHSC's Letter of Intent, DHSC agreed to purchase equipment, reagents/assays/consumables, services and software to be used for this purpose. Ultimately the Molecular Cell did not proceed as it did not receive the necessary Treasury funding, however most, if not all, of the assets were subsequently redeployed elsewhere in the NHS at DHSC's direction.

75. With respect to operational advice regarding the creation and implementation of Government strategies for TTI, the Roche Diagnostics Affiliate's involvement was also limited. The only involvement we had in this regard was the secondment of two Roche experts in Innovation and Business Development to the DHSC upon request via the Association of British HealthTech Industries. I understand that they were seconded as a MedTech Sector Specialist and Diagnostics Sector Specialist and were seconded to support the core team developing plans for Pillar 5. Both secondees were to dedicate 50% of their working time to the Roche Diagnostics Affiliate and 50% to the DHSC.
76. I understand that their roles when seconded to the DHSC were limited to assisting the DHSC in understanding diagnostics using their experience as experts in the industry, focussing on logistics such as company supply and testing capacity.
77. I understand that any other conversations with the UK Government concerning advice relating to TTI were at a technical level, for example, to test the feasibility of various UK Government proposals, rather than for us to provide any suggestions for proposed strategies. By way of example, with regards to molecular testing, the tests are complex and the Roche PCR Test could only be processed in a laboratory. I understand there were discussions around its use, for example whether it could be sent directly to patients and whether the testing pathway could be changed to accommodate any other adjustments (e.g. by changing the sample collection process), however insofar as any of these proposals were for "off label" use (ie, outside of the use that had received regulatory approval) that will have limited our opportunity to comment. In respect of the LFTs, there was pre-market engagement with us and other suppliers on the possibility of changing packaging to 5 or 7 tests per pack, but this was later tendered.

78. Roche Diagnostics Affiliate's involvement in TTI (including its role, functions and operations) was limited to the specific points detailed at paragraphs 73-77. To the extent it is helpful for the Inquiry's understanding, I also set out below some further detail regarding our engagement with the UK Government on TTI:

- a. Regarding integration services, Roche Molecular Solutions Inc (a US-based entity which forms part of the Roche Diagnostics business) developed an app called NAVIFY Pass. The app allowed users to receive, view and display test results that had been entered into the NAVIFY Pass system to other users, with the intention of assisting with the return to workplaces and the resurgence of attending events in person. I understand this was mentioned informally to the UK Government but Roche was told that there was already an app provider, and that any solution needed to connect into the NHS App (whereas the Roche solution was standalone). The NAVIFY Pass app was ultimately not used by the UK Government.
- b. Regarding the National Testing Programme, the Roche Diagnostics Affiliate was involved in initial discussions with Porton Down in 2020 about an antibody surveillance programme to better understand the role of antibodies in protection, but only regarding the programme's implementation rather than its design. I understand there were discussions around whether it would be possible to use capillary samples (instead of full blood draw) to test for antibodies, similar to when testing HbA1c (a test that monitors your average blood sugar level). As Roche had similar tests for HbA1c, we were already working to extend our antibody testing to include capillary draw. I understand that this programme was tendered in July 2021 and awarded to Thriva.
- c. The Roche Diagnostics Affiliate was involved in selling LFTs to third parties, who were likely to ultimately sell the LFTs to the adult social care sector. However, because the sector was generally serviced through independent care homes, we took the decision to sell via logistics distributors who would have ultimately contracted with the care homes. We also provided LFTs to other private companies, such as those involved in travel testing, for personal use through third party distributors. In any event, our understanding is that private sector provision of LFTs does not fall within the UK Government's TTI programme and the Roche Diagnostics Affiliate did not provide any LFTs to the UK Government's TTI programme.

- d. In addition, the Roche Diagnostics Affiliate was also required to comply with the new CTDA process which was applicable from 1 September 2021 (with transitional provisions until 31 October 2021) under Regulation 34A of the Medical Devices Regulations 2002, as amended by the Medical Devices (Coronavirus Test Device Approvals) (Amendment) Regulations 2021 [GJT/15 INQ000605520]. The Roche Diagnostics Affiliate was notified on or around June/July 2021 that we would need to submit all Roche in vitro diagnostic tests for SARS-CoV-2 for CTDA review and by 30 August we had submitted for review all the tests that Roche had on the market. I understand that the Roche Diagnostics Affiliate was also contacted by the Medicines and Healthcare products Regulatory Authority ("MHRA") while the CTDA process was being developed in order to provide advice as to what the CTDA process ought to entail.

#### Partnerships and Cooperation

79. In relation to the matters set out above, the Roche Diagnostics Affiliate had limited involvement during the pandemic with private sector partners:
- a. We had some initial discussions with PA Consulting in conjunction with the DHSC, as it was assisting the DHSC on some projects at this busy time. However, our discussions did not progress beyond an initial stage.
  - b. As set out above at paragraph 78.c, while the Roche Diagnostics Affiliate did not have a contract with the UK Government to supply LFTs (we had been unsuccessful in our tender for this business), we did have private sector partners in respect of the supply of LFTs within the private market (for example supplying private partners in the travel industry). However, this was unconnected to the UK Government's TTI programme.
80. In respect of public sector partners, as set out above Roche Diagnostics Affiliate had a number of major contracts in connection with NHS Covid-19 testing, namely for supply of the Roche PCR Test, the Roche Antibody Test and LIAT testing. However, these were generally upscaling existing relationships with NHS laboratories across the country, and supplying any additional equipment, consumables and reagents under existing frameworks which had been the subject of previous procurement and tendering exercises with the Roche Diagnostics Affiliate before the pandemic. As new tests were developed (such as the Roche Antibody Test), these were also added to the existing

PHE microbiology framework.<sup>2</sup> By way of summary, the public sector organisations we worked with as set out in this statement are:

- a. the UK Government, both through our interactions with individual ministers and with government departments, including BEIS and the DHSC;
- b. the NHS (including its laboratories), and NHS Improvement<sup>3</sup>;
- c. PHE (which was later replaced by the UKHSA and the Office for Health Improvement and Disparities), including the PHE laboratory Porton Down, and public health agencies in the devolved nations; and
- d. the MHRA (see paragraph 78.d above for further detail).

81. Roche Diagnostics Affiliate did not, however, directly work with local partners in relation to any of the limited involvement we had with the UK Government's TTI programme. We therefore do not have relevant knowledge as to what arrangements were in place to ensure that local infrastructure, and relevant local partners were involved and connected into the National Testing Programme and TTI more broadly.

82. In relation to the extent the Roche Diagnostics Affiliate worked with local health authorities in respect of the TTI programme, this was within the context of the centralised basis upon which that programme was run. In relation to those areas of testing where the Roche Diagnostics Affiliate was more involved as set out above in this statement, the UK Government set the centralised allocation of resources which was communicated to us as described at paragraph 65 above.

83. Given our position as a private sector company with existing contractual and working relationships with PHE and NHS laboratories, we are not well placed to comment more broadly on how other sectors (including the private sector) were utilised in the development of the testing infrastructure.

### Robustness of TTI and infrastructure systems

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<sup>2</sup> Framework arrangements provide for a wide scope of goods and services and generally last for four years. As a result, and in order to ensure access to new tests during the framework lifetime, if new products become available, a "range extension" is submitted to the framework provider. Such a document includes details of the new product, material numbers, information on CE marking, and costs. Once added to the framework it is then available for purchase if there is a requirement in the future. The original contract for PCR tests was made utilising the PHE microbiology framework (see paragraph 50 above)

<sup>3</sup> NHS Improvement was a non-departmental body in England, responsible for overseeing the NHS foundation trusts and NHS trusts, as well as independent providers that provide NHS-funded care. It became part of NHS England in July 2022.

84. As a supplier of products, the Roche Diagnostics Affiliate's role in respect of quality assurance was principally to ensure that the products it provided met the required quality assurance standards for those products. In addition to the regular CE-IVD process, one specific quality assurance standard for Covid-19 tests was the new CTDA accreditation. As noted in paragraph 78.d above, the new CTDA accreditation was passed into law in 2021 under The Medical Devices (Coronavirus Test Device Approvals) (Amendment) Regulations 2021 which were made on 27 July 2021 and came into force 28 July 2021 [GJT/15 INQ000605520] and assessed the validation of antigen and molecular Covid-19 detection tests and required antigen and molecular Covid-19 tests to undergo mandatory desktop review by the MHRA to assess their performance before being put into service or placed on the market. I understand that the purpose of this additional CTDA process was to add a further level of testing and approvals, above the regular CE-IVD process, to ensure that Covid-19 tests in the market were robust and effective. As discussed above at paragraph 78.d, Roche's PCR Test was submitted for approval under the CTDA and was approved.<sup>4</sup>
85. Given our limited role in the TTI programme beyond the supply of testing equipment to PHE and NHS laboratories described above, we are not in a position to comment on the adequacy, robustness or effectiveness of the UK Government's TTI infrastructure, or to provide an evaluation of the existing infrastructure, nor did we have a role in ensuring the robustness or effectiveness of the TTI infrastructure. Insofar as the Roche Diagnostics Affiliate was involved in providing Covid-19 tests in line with the UK Government's allocation, I understand that the use of pre-existing frameworks for the supply of products and the methodology that we used to distribute its Covid-19 tests was robust. We are not aware of any concerns with the Roche Diagnostics Affiliate's performance of its contractual obligations with PHE/the UKHSA and DHSC in relation to testing.

## E. VULNERABILITY AND INEQUALITIES CONSIDERATIONS

86. As discussed above, the Roche Diagnostics Affiliate was not involved in any decision making in relation to the allocation of its Covid-19 tests. The Roche Diagnostics Affiliate was instructed by the UK Government and other relevant authorities on the deployment of tests.

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<sup>4</sup> The Roche Antibody Test did not require CTDA approval.

87. In contracting with the UK Government, we were mindful that the tests ought to be distributed fairly across the four nations of the UK and thought that this would be best achieved based on a centralised decision by the UK Government as to allocation.
88. Given our lack of involvement in decision-making on allocation or the TTI programme, we are unable to provide any further comment in relation to issues relating to vulnerability and inequality as it related to the TTI programme and/or testing in the pandemic more broadly.

## **F. COMPLIANCE**

89. To the best of my knowledge, the Roche Diagnostics Affiliate did not have any involvement in producing guidance in relation to public compliance to ensure that the TTI processes were effective, such as getting tested, or not leaving the house.

## **G. LESSONS LEARNED**

90. Roche is dedicated to ensuring its global understanding and awareness of diseases is continually improved. In relation to learnings from previous diseases and pandemics, Roche entities (including the Roche Diagnostics Affiliate) each have their own business continuity plans which are regularly updated (including to take into account developments such as Exercise Cygnus 2016<sup>5</sup>). There is also an emerging pathogens infrastructure at a global level which looks at the developments and strain variations of pathogens. In relation to the advisory systems that were in place, Roche Headquarters has a background in manufacturing and was informed by its own internal expertise. In terms of external advisory systems, the Roche Diagnostics Affiliate refers to guidance from the World Health Organisation ("**WHO**"), such as the WHO watchlist, the Centers for Disease Control and Prevention and the UK Government (through PHE and its health administrations). These practices generally informed the Roche Diagnostics Affiliate's approach to its role in Covid-19 testing.
91. The Roche Diagnostics Affiliate operates an ISO 22301 Business Continuity Management System which includes a periodic and regular review, testing, training and

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<sup>5</sup> Exercise Cygnus was a cross-government exercise delivered by PHE on behalf of the Department of Health. The aim of the exercise was to assess the UK's systems in response to a serious influenza pandemic and identify strengths and weaknesses in the UK's response plans, to identify learning outcomes which would inform improvements in the UK's resilience to such a pandemic.

internal and external audit of our incident response. We have therefore conducted a lessons learned review with the key individuals and teams across the business who supported our Covid-19 response. In addition, working with Pathology leaders, the Roche Diagnostics Affiliate conducted an exercise aimed at learning from some of the best practices seen during the pandemic in the hope that Roche Headquarters could make tests to detect cancer, heart disease and Alzheimer's as rapidly available as Covid-19 tests had become available at the outset of the pandemic. In addition, the Roche Diagnostics Affiliate conducted an exercise in July 2021 to understand what positive developments had come from the pandemic [GJT/16 – INQ000605521]. In particular, we noted the *"unprecedented collaboration between the NHS, Government, the pathology sector and the diagnostics industry in the UK."* The document, titled 'The Future of Diagnostics Delivery in the UK', outlined three key areas to develop, being (i) *"the expansion of the UK pathology sector..."*, (ii) *"the embedding and integration of the most effective elements of the testing infrastructure created to table COVID-19"* and (iii) *"a rapid and effective increase in the uptake of the latest innovations in diagnostic testing into the NHS."*

92. The Roche Diagnostics Affiliate's focus since the end of 2022 has been to ensure a managed and effective exit from the pandemic and transition out of central contracting but also to ensure that the additional instruments purchased during the pandemic could be redeployed across the NHS to the extent that it is efficient and cost-effective to do so. I also understand that we have had discussions with the UKHSA regarding pandemic preparedness for 'Pathogen X' and we have also reached out to the new Government for a conversation.
93. The Roche Diagnostics Affiliate is not in a position to comment on what ought to have been done differently in relation to the UK Government's decision to use private suppliers for testing, given our limited role in this area. However, generally, based on our experience, we would call for all laboratories which are involved in providing diagnostic testing services to be properly accredited. We understand that every pathogen throws up its own challenges, however, there were lessons that could be taken from the pandemic, in particular in relation to innovations such as take-home testing and other methods for taking samples. We also think that there could be opportunities in a future pandemic to learn more quickly how to characterise a virus, regarding whether it is airborne, how long it can live on a surface, and other key characteristics.

94. It is our view that multinational diagnostics companies will be crucial in building up a UK diagnostics industry (which I understand to be one of the UK Government's aims). Infrastructure that has been established during the pandemic, such as the Rosalyn Franklin laboratories in Leamington Spa, could be used to develop and boost the UK diagnostics industry and support the NHS in providing novel testing solutions.

**CONCLUSION**

95. I am proud of the role the Roche Diagnostics Affiliate played in the UK's fight against the Covid-19 pandemic. Roche was the first company to release a diagnostic test for SARS-CoV-2, almost immediately after the WHO declared the novel coronavirus (Covid-19) outbreak a global pandemic. We then worked closely with the UK Government, regulatory bodies, national agencies and the NHS to get this test to the frontline as quickly as possible.

96. Throughout this unprecedented medical emergency, we offered our diagnostic expertise, and portfolio of products and testing platforms, to help monitor and suppress outbreaks of the virus; support the national effort to manage the pandemic; and play our part in helping safeguard the health of the public and the NHS.

**STATEMENT OF TRUTH**

I believe the content of this statement to be true. I understand that proceedings may be brought against anyone who makes, or causes to be made, a false statement in a document verified by a statement of truth without an honest belief of its truth.

Signed: Personal Data \_\_\_\_\_

Dated: 30-Apr-2025 | 04:21 PDT \_\_\_\_\_

Witness Name: Geoffrey John Twist

Statement No.: 1

Dated: April 2025

**UK COVID-19 PUBLIC INQUIRY**

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**WITNESS STATEMENT OF  
GEOFFREY JOHN TWIST**

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