Anticipated acquisition by Roche Diagnostics Limited of certain entities held by LumiraDx Group Limited (in administration) and LumiraDx International Limited (in administration)

Decision on relevant merger situation and substantial lessening of competition

ME/7090/24

The Competition and Markets Authority's (**CMA**) decision on relevant merger situation and substantial lessening of competition under section 33(1) of the Enterprise Act 2002 given on 19 July 2024. Full text of the decision published on 28 August 2024.

The CMA has excluded from this published version of the decision information which the CMA considers should be excluded having regard to the three considerations set out in section 244 of the Enterprise Act 2002 (specified information: considerations relevant to disclosure). The omissions are indicated by [✂]. Some numbers have been replaced by a range, which are shown in square brackets.

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SUMMARY

1. The CMA has found that the proposed acquisition by Roche Group (**Roche**) of certain entities held by LumiraDx Group Limited (in administration) and LumiraDx International Limited (in administration) (together, **LumiraDx**) is a relevant merger situation that does not give rise to a realistic prospect of a substantial lessening of competition (**SLC**) as a result of horizontal unilateral effects.

2. Roche has agreed to indirectly acquire LumiraDx through its subsidiary Roche Diagnostics Limited, pursuant to an agreement dated 29 December 2023. The CMA refers to this acquisition as the **Merger**. Roche and LumiraDx are together referred to as the **Parties** and, for statements relating to the future, the **Merged Entity**.

3. The Parties both provide medical equipment for in vitro diagnostic (**IVD**) testing to take place at the point of care (**POC**). IVD testing involves taking a sample from a patient (such as blood or saliva) to detect or diagnose a disease or condition. IVD refers to the test occurring 'in glass' ie outside of the body. POC refers to the test being conducted near the patient. POC IVD tests can be contrasted with a laboratory diagnostic test (or lab-based test) where a sample is taken from the patient and then sent to a central laboratory. Roche also supplies lab-based IVD tests.

4. The CMA looked at whether the Merger would lead to an **SLC** as a result of **horizontal unilateral effects** by reducing the number of actual or potential suppliers in the supply of the several types of POC IVD tests in the UK:

   (a) The Parties both provide the following types of POC IVD tests: (i) POC IVD 'international normalised ratio' (**INR**) tests, which are used to measure coagulation; (ii) POC IVD D-dimer tests, which are used to measure coagulation; (iii) POC IVD natriuretic peptide (**NT-proBNP**) tests which are used to diagnose heart disease; (iii) POC IVD glycated haemoglobin (**HbA1c**) tests, which are used to diagnose diabetes; (iv) POC IVD C-reactive protein (**CRP**) tests, which are used to measure inflammation in the body; and (v) POC IVD Coronavirus (**COVID-19**) tests. As regards both POC IVD INR tests and POC IVD D-dimer tests, the CMA found that while Roche is a large supplier, LumiraDx is a very small supplier and the increments to Roche's market position are very small. For all other overlapping products, the CMA found that the Parties' products do not compete particularly closely. The CMA believes that in all of these markets, the Merged Entity will continue to face sufficient competitive constraints from multiple alternative viable suppliers. Consequently, the CMA does not believe that the Merger gives rise to a realistic prospect of an SLC as a result of horizontal unilateral effects in the supply of these POC IVD tests in the UK.

(b) Both Parties are developing a POC IVD high sensitivity Troponin test, which tests for damage to the heart; in addition, while Roche already has an existing POC IVD streptococcus A (**Strep-A**) test, LumiraDx is also developing a competing test. The CMA has found that any loss of the constraint posed by the Parties on each other resulting from the Merger would not give rise to an SLC in the supply of either of these types of POC IVD tests in the UK, and would be offset by the strong constraint from rivals. The CMA also found that the Merger will not reduce the Parties' efforts to develop and innovate in relation to these two types of POC IVD tests. Consequently, the CMA does not believe that the Merger gives rise to a realistic prospect of an SLC as a result of horizontal unilateral effects in the supply of high sensitivity Troponin or Strep-A POC IVD tests in the UK.

What happens next?

5. The Merger will therefore **not be referred** under section 33(1) of the Enterprise Act 2002 (the **Act**).

ASSESSMENT

1. PARTIES, MERGER AND MERGER RATIONALE

6. Roche is a global biotechnology company headquartered in Basel, Switzerland. Roche is active in the development and sale of, amongst other things, both POC and lab-based IVD equipment and reagents for medical research and medical diagnostic applications. The turnover of Roche in the financial year ending 31 December 2023 was approximately £53,286 million worldwide and approximately £[✂] million in the UK.[1]

7. LumiraDx is a UK-headquartered company that has developed a single portable 'handheld' instrument, which is designed to perform a menu of POC IVD diagnostic tests. Depending on the test being performed, patients' samples are placed on the test strip, which is then inserted into the device for assessment. The turnover of LumiraDx in the financial year ending 31 December 2023 was approximately £[✂] worldwide and approximately £[✂] in the UK.[2]

8. The Parties submitted that LumiraDx is currently dependent on funding from its secured creditors and has limited available funds.[3] On 29 December 2023, LumiraDx was placed into 'pre-pack' administration, which is an insolvency arrangement whereby the sale of a business (or its assets) is negotiated prior to the business being put into administration. The administrators then execute the sales agreement with the purchaser as soon as they are appointed.[4] Later on 29 December 2023, following appointment of the administrators, Roche agreed to acquire certain entities that comprise the vast majority of the LumiraDx business for approximately £[✂].[5]

9. Roche submitted that the Merger will allow Roche to expand [✂] its POC IVD portfolio by enabling it to provide better access to timely diagnostic results in decentralised healthcare settings (such as care homes, GP's offices, pharmacies, urgent care centres, etc) and, consequently, better compete [✂].[6] The CMA considers that Roche's internal documents generally support this rationale.[7]

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[1] Final Merger Notice submitted to the CMA on 23 May 2024 (**FMN**), paragraph 153.
[2] FMN, paragraph 155.
[3] FMN, paragraph 127.
[4] FMN, 124-125.
[5] FMN, paragraph 126. The remaining parts of the LumiraDx business that will not be acquired by Roche are principally active in the third-party distribution business. None of these entities sell to UK customers. FMN, paragraph 18.
[6] FMN, paragraphs 130; and 287–289. By contrast to decentralised settings, an example of a centralised setting would be a hospital ward.
[7] For example, Roche Internal Documents, Annex 38 to the FMN, December 2022, slide 5; and Roche Internal Document, Annex 72 to the FMN, August 2023, slide 12, which describes Roche's IVD business [✂] primary care ie community care and home testing, with the Merger being an opportunity for Roche to expand into those areas. See also Annex 44 to the FMN, March 2023, slide 21, which, when describing Roche's internal pipeline for POC products, notes that Roche currently possesses [✂] portfolio for the supply of POC devices for use in decentralised spaces.

10. The Parties submitted that the main strategic rationale for the Merger for LumiraDx is to maintain the value of the company, prospects for its future business and the ability to continue its development activity.[8] The Parties submitted that no additional sources of funding would be available absent the Merger.[9] The CMA has considered LumiraDx's options for funding in further detail in relation to the counterfactual.

2. PROCEDURE

11. The CMA's mergers intelligence function identified the Merger as warranting an investigation.[10]

12. The CMA commenced its phase 1 investigation on 23 May 2024. As part of its phase 1 investigation, the CMA gathered a significant volume of evidence from the Parties. In response to targeted information requests, the CMA received and reviewed internal documents from Roche and LumiraDx to understand how closely they compete with each other and the alternative constraints they face. The CMA also gathered evidence from other market participants, such as customers and competitors of the Parties. The evidence the CMA has gathered has been tested rigorously and the context in which the evidence was produced has been considered when deciding how much weight to place on it.

13. Where necessary, this evidence has been referred to within this Decision.

3. JURISDICTION

14. Each of Roche and LumiraDx is an enterprise. As a result of the Merger, these enterprises will cease to be distinct.

15. The Parties overlap in the supply of POC IVD tests in the UK. Based on the evidence received from the Parties and third parties, the CMA estimates that the Merger will lead to Roche and LumiraDx having a combined share of more than 25% by revenue, with an increment, in the supply of both (i) POC IVD tests in general and (ii) specific POC IVD tests (namely, POC IVD INR tests, POC IVD D-dimer tests, POC IVD NT-proBNP tests, and POC IVD CRP tests) in the UK, as indicated by the share of supply estimates presented later in the competitive assessment of this Decision. Therefore, the CMA considers that the share of supply test within the meaning of section 23 of the Act is met.

[8] FMN, paragraph 128.
[9] FMN, paragraph 127.
[10] Mergers: Guidance on the CMA's jurisdiction and procedure (CMA2) ,25 April 2024, paragraphs 6.4–6.6.

16. The CMA therefore believes that it is or may be the case that arrangements are in progress or in contemplation which, if carried into effect, will result in the creation of a relevant merger situation.

17. The initial period for consideration of the Merger under section 34ZA(3) of the Act started on 24 May 2024 and the statutory 40 working day deadline for a decision is therefore 19 July 2024.

4. COUNTERFACTUAL

18. The CMA assesses a merger's impact relative to the situation that would prevail absent the merger (ie the counterfactual).[11] In an anticipated merger, the counterfactual may consist of the prevailing conditions of competition, or conditions of competition that involve stronger or weaker competition between the parties to a merger than under the prevailing conditions of competition.[12] In determining the appropriate counterfactual, the CMA will generally focus on potential changes to the prevailing conditions of competition only where there are reasons to believe that those changes would make a material difference to its competitive assessment.[13]

4.1 Parties' submissions

19. The Parties submitted that the appropriate counterfactual is one that would involve, absent the Merger, the imminent and inevitable exit of LumiraDx.[14] LumiraDx has never been profitable or cash-generative, and is heavily reliant on POC IVD COVID-19 test sales to generate revenue. However, falling demand for COVID-19 testing in recent years has led to LumiraDx's financial distress (with LumiraDx's revenue falling 70% globally and [✂] in the UK year on year between 2022 and 2023).[15]

20. In March 2021, LumiraDx entered into a loan agreement with investment funds (the **Secured Creditors**). In March 2022, LumiraDx and the Secured Creditors amended the loan agreement to allow LumiraDx to [✂].[16] The Parties submitted that despite LumiraDx taking a number of management actions (such as implementing [✂]),[17] because [✂], it remains loss-making.[18] Between February 2023 and December 2023, various amendments and waivers were entered into in respect of the loan agreement, including waivers of [✂], and to provide [✂] for

[11] Merger Assessment Guidelines (**CMA129**), March 2021, paragraph 3.1.
[12] CMA129, paragraph 3.2.
[13] CMA129, paragraph 3.9.
[14] FMN, paragraphs 8b and 194.
[15] FMN, paragraph 212.
[16] FMN, paragraph 56.
[17] FMN, paragraphs 62, 218 and 220.
[18] FMN, paragraphs 217 and 236.

LumiraDx.[19] On 29 December 2023, the Secured Creditors served a declaration requiring all obligations under the loan agreement to become immediately due. LumiraDx was unable to meet these obligations.[20] The Parties also submitted that LumiraDx is reliant on funding from the Secured Creditors (provided primarily to facilitate completion of Merger) to continue trading.[21]

21. As set out in paragraph 8, the Parties explained that LumiraDx is in a 'pre-pack' administration, [22] where a distressed company is put in administration to facilitate a sale with reduced liabilities. The Parties submitted that LumiraDx has explored all other options for funding. In particular, in July 2022, LumiraDx sought to raise USD 100 million in new investment and only raised USD 8 million; in the latter half of 2022, LumiraDx (through an external adviser) engaged in a sales process, which was paused after no parties presented bids; and in June 2023, LumiraDx attempted again to raise investment but was unable to find equity investors to participate.[23]

4.2 CMA assessment

22. For the CMA to accept an exiting firm counterfactual at Phase 1, it would need to see compelling evidence that it was inevitable that, absent the Merger, the following conditions would be met:[24]

    (a) The firm is likely to have exited (through failure or otherwise) (**Limb 1**); and if so

    (b) There would not have been an alternative, less anti-competitive purchaser for the firm or its assets to the acquirer in question (**Limb 2**) (together, the **Exiting Firm Counterfactual**).

23. Where the CMA concludes that a merging firm would exit absent the merger and there would not have been an alternative, less anti-competitive purchaser for the firm or its assets, it will not find an SLC.[25]

4.2.1 Limb 1

24. As a starting point, the CMA notes that the fact that a firm has entered into administration may not be sufficient to demonstrate that the exit of the firm in question is inevitable or likely.[26] Moreover, only events that would have happened

[19] FMN, paragraphs 57-58.
[20] FMN, paragraph 59.
[21] FMN, paragraph 200.
[22] FMN, paragraphs 124-125.
[23] FMN, paragraph 262.
[24] CMA129, paragraph 3.21 and 3.23.
[25] CMA129, paragraph 3.23.
[26] CMA129, paragraph 3.27.

in the absence of the merger under review - and are not a consequence of it - can be incorporated into the counterfactual.[27] In this case, given the pre-pack administration was explicitly linked to (rather than taking place in isolation of) the negotiation of the Merger,[28] the CMA has not incorporated the fact of LumiraDx's administration into its counterfactual assessment.

25. In order to assess Limb 1, the CMA has considered (i) LumiraDx's overall financial outlook, and (ii) the decision-making process that led to the decision to proceed with a sale to Roche, by reference to the Parties' internal documents and third-party evidence.

26. First, the CMA notes that there has been a significant decline in LumiraDx's revenue from 2022 to 2023 due to LumiraDx diverting revenue and resources from development of other POC IVD tests to focus on developing and selling POC IVD COVID-19 tests.[29]

27. However, the CMA considers that while this evidence shows LumiraDx is facing challenges, it does not indicate that it is in terminal decline, such that its exit due to financial distress is inevitable. Rather, the evidence from each of the Parties' internal documents anticipate that LumiraDx is both likely to be profitable in the future and that there is value in the business. LumiraDx's internal forecasts show that LumiraDx is expected to be profitable in the future through significant revenue growth. LumiraDx's most recent financial forecasts prepared in July 2023 forecast LumiraDx becoming profitable on an EBITDA basis by 2026 (with EBITDA of USD [✂]). These profits then are expected to grow significantly in the following years with EBITDA of USD [✂] forecasted for 2028. This profit growth is driven by significant revenue growth from LumiraDx's POC IVD products outside of POC IVD COVID-19 tests.[30]

28. This revenue growth expectation is also reflected in Roche's own internal documents (albeit at a [✂] rate). Roche's 'base case' valuation model shows LumiraDx having strong revenue growth to USD [✂] million in 2027 and USD [✂] million by 2030 with LumiraDx becoming profitable by [✂].[31] Roche's internal documents identify multiple 'value drivers' in LumiraDx, including [✂].[32]

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[27] CMA129, paragraph 3.4.
[28] For example, LumiraDx Internal Document, Annex 147 to the FMN, October 2023, slide 8 in which a report prepared by an external adviser stated that the proposed transaction structure from Roche's counsel involved LumiraDx being placed into administration. See also LumiraDx Internal Document, Annex 152 to the FMN, December 2023 in which correspondence from the Secured Creditors reported the Secured Creditors' support of LumiraDx filing for administration so that the administrators could agree the Merger with Roche.
[29] FMN, paragraph 218. LumiraDx's internal documents (see, for example, Annex 13 to the FMN, December 2023, slide 12) indicate that its current financial position is due to a reduction in revenues due to declining POC IVD COVID-19 test revenues, as well as the delay in the regulatory approval and launch of core products.
[30] LumiraDx Internal Document, Annex 49 to the FMN, August 2023, slide 52.
[31] Roche Internal Document, Annex 28 to the FMN, August 2023, slide 7.
[32] For example, Roche Internal Documents, Annex 27 to the FMN, October 2023, slides 5–7; and Annex 30 to the FMN, August 2023, slide 8.

29. Further, several third parties indicated that LumiraDx's technology is highly regarded and of general interest to the wider industry.[33] Similar to the Parties' explanations above, some third parties suggested that one of the reasons for LumiraDx's financial position, was that LumiraDx's focus on COVID-19 negatively impacted LumiraDx as COVID-19 testing reduced.[34]

30. Second, the CMA considers that, absent the Merger, there may have been several options open to LumiraDx as an alternative to exiting the market, including through raising further debt or equity investment. The evidence does not indicate that, in the absence of the Merger, the Secured Creditors would necessarily have sought to liquidate LumiraDx over seeking to recover the debt owed through investment from third parties, especially given a liquidation would have resulted in significant value destruction.[35] Accordingly, the CMA believes that LumiraDx and the Secured Creditors would have likely sought to engage with third parties to secure alternative funding absent the Merger, and that there is a realistic prospect that such funding would have been forthcoming. Several third parties, in addition to Roche, were involved in discussions with LumiraDx and its Secured Creditors about possible equity investments in the company. Although discussions on these investments ultimately did not progress to an advanced stage, the CMA considers that this may have been as a result of the offer from Roche relating to the Merger, rather than because these third parties did not see LumiraDx as an attractive investment.[36]

31. Third parties have also indicated that in their view sufficient funding could have been made available [✂] to support LumiraDx through its period of financial distress.[37]

4.2.2 Conclusion on Limb 1

32. Therefore, the CMA considers that in light of there being some relatively positive aspects to LumiraDx's business outlook and the fact that further investment may have been forthcoming had the Merger not proceeded, it is not inevitable that, in the absence of the Merger, LumiraDx would have exited the UK POC IVD markets.

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[33] Note of a call with a third party, May 2024, paragraph 16; and note of a call with a third party, June 2024, paragraphs 14–16.
[34] Note of a call with a third party, May 2024, paragraph 15; note of a call with a third party, June 2024 , paragraphs 5 and 7.
[35] FMN, paragraphs 260 and 226 and Roche Internal Document, Annex 28 to the FMN, August 2023, page 33. See also, note of a call with a third party, June 2024, paragraph 17, where a third party [✂] explained that [✂].
[36] Note of a call with a third party, May 2024, paragraph 12; note of a call with a third party, June 2024, paragraph 12; and submission to the CMA from a third party, January 2024, paragraphs 124–127. See also LumiraDx Internal Document, Annex 149 to the FMN, October 2024, page 1, which outlines that LumiraDx understood that its Secured Creditors wanted to focus on the Merger and for LumiraDx to cease efforts on alternative arrangements.
[37] Note of a call with a third party, May 2024, paragraph 12; and note of a call with a third party, June 2024, paragraph 12.

4.2.3 Conclusion on Limb 2

33. The conditions required to find an exiting firm counterfactual are cumulative[38] and, as the CMA does not consider that Limb 1 is met, the CMA has not needed to conclude on Limb 2.

4.3 CMA's conclusion on the counterfactual

34. For the reasons set out above, the CMA considers the prevailing conditions of competition to be the relevant counterfactual. Specifically, the CMA considers that LumiraDx, absent the Merger, would have continued to operate and compete in the supply of POC IVD tests in the UK.

5. COMPETITIVE ASSESSMENT

5.1 Background

35. IVD testing involves taking a sample from a patient (such as blood or saliva) to detect or diagnose a disease or health condition. Lab-based tests involve the patient's sample being sent to a central laboratory for assessment, whereas POC tests involve the test being conducted near the patient.

36. The Parties both supply POC IVD tests, which are performed on testing 'systems' comprising of an 'instrument' to measure and present the results of a test and 'test strips' to carry out a test using a sample from the body.[39] Instruments may be suitable for a range of different tests, but test strips are usually specific to testing for a certain health condition. There may be also a number of different tests that can be carried out for each testing condition.[40] The CMA has focused its assessment on the specific tests that the Parties both supply.

37. In particular, the Parties currently overlap in the supply of the following POC IVD tests in the UK: POC IVD INR tests; POC IVD D-dimer tests; POC IVD NT-proBNP tests; POC IVD HbA1c tests; POC IVD CRP tests; and POC IVD COVID-19 tests.

38. In addition to these specific tests, suppliers also compete to develop new POC tests, especially as technology advances and demand for medical treatment increases. Both Parties are developing a POC IVD high sensitivity Troponin test to

[38] CMA129, paragraph 3.21.
[39] FMN, paragraph 285. Note that instruments are sometimes called analysers or devices and test strips are sometimes called cartridges, reagents or assays.
[40] FMN, paragraph 478. The Parties note for example that there may be many tests for Diabetes, such as Glucose, C-Peptide, ACR and other renal tests.

detect heart damage and LumiraDx is also developing a POC IVD Strep-A test, which Roche already supplies.[41]

39. In the UK, the customers for these testing systems are NHS trusts and hospitals, as well as some private healthcare providers. Customers usually purchase whole systems[42] directly from suppliers (or through distributors that suppliers work with), as well as by selecting suppliers following tender processes. NHS customers can also make use of NHS Supply Chain, which is a procurement enablement function that objectively assesses and awards non-commitment framework agreements to suppliers of medical products. Inclusion on framework agreements requires the supplier to meet a number of criteria relating to the supply of medical products, which means that where suppliers are included in the framework they must demonstrate that they are able to adequately supply NHS customers.

40. Suppliers of POC IVD systems compete on various parameters, such as price and customer service. The most important parameter is the performance, in terms of accuracy and reliability, of the test.[43] Customers may also choose POC IVD systems based on other features, such as:

    (a) The size of the instrument: instruments can generally either be small, handheld and portable, such as the LumiraDx instrument, or larger and sit on a benchtop, such as the Roche Liat. Portable devices may be used in community care settings or even for at-home testing, while benchtop devices are usually used in secondary care settings like in hospitals. The large majority of third parties that the CMA heard from during its investigation indicated that both types of device are used for POC IVD testing, because each has pros and cons.[44] This suggests that these tend to be complements for most customers, rather than direct substitutes.

    (b) The number of tests that an instrument can carry out: some instruments only perform one test whereas others perform a menu of multiple tests. For example, one of Roche's POC IVD instruments, CoaguChek, is used only for INR testing, while LumiraDx has one instrument that is used to perform the six current overlap tests mentioned above. One third party told the CMA that offering this menu of tests made the LumiraDx instrument 'unlike any other POC device' and would enable it to significantly disrupt the traditional IVD

[41] LumiraDx is also developing a POC IVD test for tuberculosis, but has no plans to commercialise the product in the UK; therefore, this test is not considered further in this Decision (FMN, paragraph 588).
[42] The Parties and some third-party suppliers have informed the CMA that they may provide instruments to customers for free, or even that instruments remain the property of the manufacturer while they are being used. This means that the CMA calculation of shares of supply in each testing area accounts only for the sales of test strips for that particular test. See FMN paragraph 495-498, Questions to the Parties of 18th June and response to the CMA questionnaire from a number of third parties, June 2024.
[43] Response to the CMA questionnaire from a number of third parties, June 2024.See also notes of calls with third parties.
[44] For example, handheld instruments are good for taking into different settings, but they can go missing and break more easily, while benchtop instruments are more robust and can assess more samples, but they are also more expensive.

market; however, the evidence gathered by the CMA is not consistent with this view. For example, there appear to be a number of suppliers (such as Abbott (eg i-STAT), QuidelOrtho (eg Triage and Sofia), Aidian (eg QuikRead go) and SD Biosensor (eg Standard F F200))[45] who offer an instrument with a broad menu of tests (although none of them offers exactly the same menu as LumiraDx)[46]. Customer feedback also indicated that offering a wide menu of tests is not an essential feature of a POC instrument.[47]

(c) Ease of use, with some systems requiring implementation from expert medical professionals, or requiring refrigeration of test strips.

41. The CMA has explored these factors throughout the competitive assessment.

5.2 Market definition

42. Market definition involves identifying the most significant competitive alternatives available to customers of the merger parties and includes the sources of competition to the merger parties that are the immediate determinants of the effects of the merger.

5.2.1 Product market

43. The Parties submitted that POC IVD testing is a separate market from lab-based IVD testing. They stated that, although both systems are capable of testing for the same parameters, there are, amongst other factors, differences in use-cases; in quality; and in the underlying economics for testing (and relatedly, price), as well as in relation to physical and workflow differences and in the breadth of their ability to vary out tests for different condition.[48]

44. The Parties also identified the possibility of segmentations within POC IVD testing, either at the thematic level (ie for infectious disease, cardiology, coagulation, etc) or at the individual test level. The Parties recognised that tests for each particular condition will not be substitutable for each other but maintained that the appropriate product market could be broader than these segmentations.[49]

45. The CMA first considered whether the markets for POC IVD tests should be broadened to include lab-based IVD tests. Roche's internal documents indicate the segmentation between point of care and laboratory businesses within Roche's

[45] Annex 63 to the FMN.
[46] FMN paragraph 368; and response to the CMA questionnaire from a number of third parties, June 2024.
[47] One customer stated that having extra tests on one device is only a bonus, while another stated that quality was more important. Another customer said that they did not want to have a single point of failure. See, response to the CMA questionnaire from a number of third parties, June 2024.
[48] FMN, paragraphs 380, 385 and 387.
[49] FMN, paragraphs 392–393 and paragraph 477.

diagnostics division.[50] Nearly all third parties that responded to the CMA's merger investigation stated that they saw benefits to both types of testing and that they are complementary to each other, as part of one IVD testing approach. For example, customers told the CMA that POC and lab-based tests 'can act harmoniously as one IVD system' and that they 'complement each other depending on need', while competitors noted that it is 'beneficial to offer both' and that both are often both required, especially where lab tests are done to corroborate POC tests. Only a minority of third parties noted limited situations where POC and lab-based testing may be alternatives to each other, with one third party suggesting that POC tests are getting close to replicating the appeal of lab-based tests and therefore exerting an important competitive constraint on lab-based tests.

46. The Parties submitted that there have been improvements in the quality of test results that are achievable with POC IVD systems,[51] and some evidence appears consistent with this trend.[52] However, many third parties still noted POC tests' lower accuracy and considered that lab-based testing remains 'the gold standard' for IVD. A clinical expert with responsibilities for evaluating POC and lab-based testing devices told the CMA that it was unlikely that POC testing would substantially compete with lab-based testing for at least the next ten years. Based on this evidence, the CMA considers that POC IVD testing should be considered separately from lab-based IVD testing.

47. Regarding the possibility of further segmentations within POC IVD tests, the CMA considers that each of these POC IVD tests should be considered separately (ie, such that INR tests are considered separately from the D-dimer test, and that HbA1c tests are considered separately from CRP tests etc). On the demand-side, each POC IVD test is done for specific diagnostic purposes and therefore cannot be substituted with another test. On the supply-side, and as considered further in the competitive assessment below, the CMA considers that the competitive landscape for each test is different, indicating differences in the competitive dynamics as between them. Further, there are examples of LumiraDx's internal documents considering the competitive dynamics of the market on a test-by-test basis.[53] Therefore, the CMA considers that different POC IVD tests for different conditions should be considered separately.

[50] Roche Internal Document, Annex 40 to the FMN, January 2023, slides 5 and 13; and Roche Internal Document, Annex 90 to the FMN, slides 3 and 5-7.
[51] FMN, paragraph 368. See also Roche Internal Document, Annex 100 to the FMN, February 2023, slide 14
[52] Roche Internal Document, Annex 15 to the FMN, August 2023, slide 13, which is a presentation from a third party that refers to a significant increase in POC IVD test options with 'good performance data that can match lab-based tests'.
[53] For example, see Annex 561 to the FMN, October 2022, in which LumiraDx assesses the competition landscape for each test separately.

5.2.2 Geographic market

48. The Parties submitted that the geographic market should be national in scope due to the need for rapid and reliable services and the existence of different regulatory frameworks in different countries.[54]

49. On the basis of the evidence received in this investigation, the CMA considers that a national market is appropriate. The Parties' internal documents show that [✂].[55] Several third parties stated that, even though they have similar offerings across geographies, there are some regulatory features that make national markets different from each other. They noted that this is especially true in the UK due to the NHS, which has a unique model of reimbursement and longer procurement times. The CMA has also not seen any evidence indicating that a broader or narrower geographic market would be appropriate. Therefore, the CMA considers that the market should be the UK.

5.2.3 Conclusion on market definition

50. In light of the above the CMA has assessed the impact of the Merger on:

(a) The supply of POC IVD INR tests in the UK;

(b) The supply of POC IVD D-dimer tests in the UK;

(c) The supply of POC IVD NT-proBNP tests in the UK;

(d) The supply of POC IVD HbA1c tests in the UK;

(e) The supply of POC IVD CRP tests in the UK;

(f) The supply of POC IVD COVID-19 tests in the UK;

(g) The supply of POC IVD high sensitivity Troponin tests in the UK; and

(h) The supply of POC IVD Strep-A tests in the UK.

5.3 Theories of harm

51. The CMA assesses the potential competitive effects of mergers by reference to theories of harm. Theories of harm provide a framework for assessing the effects of a merger and whether or not it could lead to an SLC relative to the counterfactual.[56]

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[54] FMN, paragraph 394.
[55] Roche Internal Document, Annex 42 to the FMN; July 2022; and LumiraDx Internal Document, Annex 54 to the FMN, October 2022.
[56] CMA129, paragraph 2.11.

52. In its investigation of this Merger, the CMA has considered the following theories of harm:

(a) Horizontal unilateral effects in the supply of POC IVD tests in the UK, and in particular, the supply of:

(i) POC IVD INR tests;

(ii) POC IVD D-dimer tests;

(iii) POC IVD NT-proBNP tests;

(iv) POC IVD HbA1c tests;

(v) POC IVD CRP tests; and

(vi) POC IVD COVID-19 tests.

(b) Loss of potential and dynamic competition in the supply of:

(i) POC IVD high sensitivity Troponin tests; and

(ii) POC IVD Strep-A tests.

53. Each of these theories of harm is considered below.

5.4 Horizontal unilateral effects in the supply of POC IVD tests

54. Horizontal unilateral effects may arise when one firm merges with a competitor that previously provided a competitive constraint, allowing the merged entity profitably to raise prices or to degrade quality on its own and without needing to coordinate with its rivals.[57] Horizontal unilateral effects are more likely when the parties to a merger are close competitors.[58]

55. The CMA assessed whether it is or may be the case that the Merger has resulted, or may be expected to result, in an SLC as a result of horizontal unilateral effects in each of the markets listed at paragraph 52(a) above. In doing so, the CMA has considered:

(a) the Parties' submissions;

(b) shares of supply;

(c) internal documents; and

[57] CMA129, paragraph 4.1.
[58] CMA129, paragraph 4.8.

(d) third-party evidence.

5.4.1 POC IVD INR tests

56. POC IVD INR tests measure the amount of time taken for a patient's blood to clot, and are used exclusively for patients that take the anticoagulant drug Warfarin.[59] Warfarin itself aims to reduce the risk of blood clots.

57. Roche offers this test through the CoaguChek instrument series and LumiraDx offers this test (as with all its tests in the following sections) on its single portable instrument. These are both handheld devices.[60]

5.4.1.1 Parties' submissions

58. The Parties submitted that there is no realistic prospect of an SLC because their products are used in different settings (with Roche suitable for at-home testing and LumiraDx only for decentralised healthcare) and there are many other suppliers in this market, including large diagnostic companies like Abbott, Siemens, Werfen and BHR BIOSYNEX.[61]

59. The Parties also noted that the market is in steep decline,[62] as Warfarin is being replaced by direct oral anticoagulants (DOACs) on the basis that the use of Warfarin has become increasingly associated with a haemorrhage or stroke. According to NHS prescribing data cited by the Parties, in 2021-2022, Warfarin accounted for around 20% of anticoagulation prescriptions (a decrease from around 48% in 2017-18, which the Parties submitted was expected to decline further as patients continue to shift from using Warfarin to DOACs).[63] Finally, the Parties stated that test strips for INR are subject to the NHS Drug Tariff, which puts limits on the Parties' ability to increase prices.[64]

5.4.1.2 CMA assessment

60. LumiraDx estimated Roche's share in this segment to be above 70%, and their own share to be 1%.[65]

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[59] FMN, paragraph 325.
[60] FMN, paragraph 329.
[61] FMN, paragraph 432.
[62] FMN, paragraph 326.
[63] FMN, paragraph 327
[64] FMN, paragraph 330. The Drug Tarriff's Part IX is the mechanism by which the NHS determines the reimbursement that suppliers get for some medical appliances. See Drug Tariff | NHSBSA for more information.
[65] Parties' submission, Annex 640 to the FMN. Note that Roche also submitted share of supply estimates relevant to each test, but these were for different frames of reference and so have not been relied upon for the CMAs assessment.

61. The CMA gathered data from the Parties and third parties to reconstruct its own market share estimates, and the results of this for POC IVD INR testing are presented in Table 1 below.[66]

Table 1: Share of supply estimates in POC IVD INR testing, by revenue (UK, 2023)

Supplier	***%***
Roche	[90-100]
LumiraDx	[0-5]
Combined	**[90-100]**
Abbott	[0-5]
Siemens	[0-5]
Werfen	[0-5]
Total	***100***

Source: CMA's estimates based on Parties' and competitors' data.

62. The revenues data that the CMA received from third parties and the Parties indicated the total market size for 2023 to be very small (in the region of roughly £10-15 million), and likely to shrink further in future.[67] The data indicates that Roche is the market leader, and that the Merged Entity would be the largest supplier by revenue, with a very limited increment to Roche's existing market position resulting from the Merger. A number of other suppliers of similar size to LumiraDx would remain post-Merger, including Abbott, Siemens and Werfen.

63. However, the CMA considers that there are considerable limitations to these estimates, which mean that they are likely to understate the constraints imposed by alternative providers post-Merger. First, they do not reflect the increasing provision of DOACs in place of Warfarin as demand for Warfarin reduces. One third party corroborated the Parties' submissions in this respect, stating that cardiologists increasingly prescribe DOACs (instead of treatments that require patients to use Warfarin).[68] Second, third parties cited the market presence of some competitors whose activities are not accounted for in these sales, such as iLine Microsystems and BHR BIOSYNEX. Notwithstanding the fact that overall demand for Warfarin is reducing, the evidence indicates that market participants

[66] The CMA requested 2023 revenues from the Parties and their competitors in relation to this test and reconstructed market shares on this basis. The estimates therefore do not account for suppliers whom the CMA did not receive information from, and so they may overstate the Parties' shares and the shares of the competitors that are included.
[67] Whilst the CMA considers this data to be incomplete (as discussed at paragraph 63), the total market size based on complete data would remain relatively low, and below £20-30m, on the basis of consistent feedback that Roche is the largest supplier in this market. See discussion at paragraph 63 regarding the reducing demand for Warfarin.
[68] Note of a call with a third party, June 2024, paragraph 29. Note that the Roche's revenue for POC IVD INR tests decreased by [10-20]% from 2022 to 2023, which further supports the Parties' submissions that demand for Warfarin is decreasing. See Parties' response to the CMA's questions of 18 June 2024.

are incentivised to continue competing; at least one third party with no current sales in the market indicated its intentions to start supplying products in 2024.[69]

64. Therefore, while the CMA considers that these shares of supply estimates provide some useful information about the structure of the market and the relative presence of some other suppliers, this information must be considered in the round with other evidence on the closeness of competition between the Parties, and on the competitive constraints remaining post-Merger.

65. The Parties' internal documents indicate that while the Parties identify the other as a competitor, they do not see each other as particularly close competitors. The CMA notes that based on its analysis of Roche's submitted internal documents, Roche does not, broadly speaking, tend to monitor the competitive landscape on a granular, by condition/national basis in the ordinary course of business.[70] However, some of Roche's internal documents that were created specifically in relation to the Merger note several [✂] to LumiraDx's POC IVD INR offering relative to its own.[71] A Roche document prepared during due diligence on the Merger in March 2023 indicates that LumiraDx's POC IVD INR test has '[✂]'.[72] Another Roche document seeking internal approval for the Merger in December 2022 suggests that the LumiraDx instrument covers the same segment as the Roche [✂], but not the [✂].[73] Further, LumiraDx monitors other competitors in addition to Roche.[i] One LumiraDx document from October 2022 assesses the unique selling points and competitive landscape for each of its tests and compares LumiraDx's INR test with both Roche's [✂] and Abbott's [✂],[74] and another from 2023 also refers to the Abbott [✂].[75]

66. Most third parties that responded to the CMA's merger investigation indicated that the Parties compete to supply POC IVD INR tests for coagulation, indicating that they are close or very close competitors. However, and notwithstanding the fact that both Parties' products are handheld, several third parties noted differences in the Parties' respective product offerings and competitive strengths, with many

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[69] Response to the CMA questionnaire from a number of third parties, June 2024.
[70] The CMA reviewed several Roche documents from its ordinary course of business that reflected Roche's view of the competitive landscape in POC IVD tests overall. One document notes that Roche are [✂] globally [✂]Abbott and Siemens (Roche Internal Document, Annex 43 to the FMN, September 2022); while another shows that Roche monitors several other companies alongside LumiraDx for new developments, including BHR Pharmaceuticals and SD Biosensor who provide an INR solution (Roche Internal Document, Annex 90 to the FMN, June 2023). However, the CMA considers that the inferences that can be drawn from such a 'general' document in relation to POC IVD INR tests for coagulation specifically are limited, and has therefore not placed significant weight on these documents relative to other sources of evidence. The CMA considers this point (ie that Roche does not tend to monitor the competitive landscape on a granular basis) to be applicable to its competitive assessment of all of the markets considered in this Decision and has not repeated it in the sections of the Decision that follow.
[71] Roche Internal Document, Annex 28 to the FMN, August 2023, slide 76; and Roche Internal Document, Annex 29 to the FMN, August 2023, slide 76.
[72] Roche Internal Document, Annex 88 to the FMN, March 2023, slide 9.
[73] LumiraDx Internal Document, Annex 37 to the FMN, December 2022, slide 51. The CoaguChek XS+ product is a smaller version and is marketed as being suitable for self-monitoring whilst on vacation – see CoaguChek® XS system (roche.com) for details.
[74] LumiraDx Internal Document, Annex 561 to the FMN, October 2022, slide 9.
[75] LumiraDx Internal Document, Annex 552 to the FMN, April 2024, slides 20 and 23.

noting that Roche has a much stronger offering compared to LumiraDx.[76] For example, one customer stated that only Roche has a viable self-testing device, another customer noted that Roche's instrument is more widely used than LumiraDx, and a competitor stated that Roche has a stronger product range and customer base. Another competitor stated that Roche is a dominant player in both home and professional settings, but that LumiraDx were only in the professional setting and were a newcomer.

67. Further, although many third parties recognised Roche as being the market leader[77] (with nearly all respondents seeing Roche as a 'Strong' supplier for POC IVD INR tests), the third party feedback indicated that LumiraDx is a much weaker supplier. Only some (less than a third) of third parties described LumiraDx as a 'Strong' supplier, with other third parties either describing LumiraDx as 'Moderate' or not rating LumiraDx at all. One customer noted that LumiraDx has low NHS framework sales in POC IVD INR compared to other large suppliers.

68. With respect to competitive constraints, third parties identified several alternative providers of POC IVD INR tests. A number of third parties rated, in addition to LumiraDx, Abbott and Siemens as 'Strong' suppliers, and iLine Microsystems as 'Moderate' or 'Weak'.[78] Other suppliers such as Werfen and BHR BIOSYNEX were also mentioned. One customer stated that Werfen and Haemonetics saw significant sales to NHS customers, and that there were comparatively lower sales from Andrac, Diagnostica Stago, Abbott and BHR BIOSYNEX.[79] Further, as noted above, at least one third party with no current sales in the market indicated its intentions to start supplying products in 2024.[80]

69. Two competitors and one customer expressed concerns about the effect of the Merger on this market (one, that the Merger would strengthen Roche's already strong position in this market, another on the basis that they viewed as competition as already limited in this market, and a third, that Roche would offer LumiraDx's systems as an upgrade and create an unfair advantage over competitors). However, based on the above evidence, the CMA considers that LumiraDx is a very small competitor and that the effect of the Merger will therefore be limited. Further, a range of alternative suppliers will constrain the Merged Entity post-Merger (something that was explicitly acknowledged by one of the competitors expressing concerns).

[76] However, one customer stated that it would use LumiraDx for INR testing over Roche due to ease of testing and price.
[77] Note a call with a third party, May 2024.
[78] Products from Abbott and iLine are also on the NHS Drug Tarriff allowing pharmacies to be reimbursed or remunerated for prescribing them. NHS Tarriff Book (accessed June 2024).
[79] Note of a call with a third party, May 2024, paragraphs 33.
[80] Response to the CMA questionnaire from a number of third parties, June 2024.

5.4.1.3 Conclusion on POC IVD INR tests in the UK

70. For the reasons set out above, the CMA considers that while Roche has a significant market position, LumiraDx is a small competitor, the increment to Roche's market position as a result from the Merger is very small and the Merged Entity will continue to face a number of third-party alternatives, including three suppliers which customers have rated as 'moderate' or 'strong'.

71. For these reasons, the CMA believes that the Merger does not give rise to a realistic prospect of an SLC as a result of horizontal unilateral effects in the supply of POC IVD INR tests in the UK.

5.4.2 POC IVD D-dimer tests

72. POC IVD D-dimer tests are used to help diagnose clotting problems by detecting the levels of D-dimer protein, which the body produces to break down blood clots.[81] Roche offers this test on its cobas h232 system, which is handheld.[82]

5.4.2.1 Parties' submissions

73. The Parties submitted that they both have a limited presence in this testing area and that LumiraDx's position is negligible. They also submitted that there are many suppliers of POC IVD D-dimer tests in the UK.[83]

74. In addition, the Parties submitted that the current Roche instrument for this test, the cobas h232, has been on the market for a long time, [✂].[84] They noted that the [✂] Roche instrument for POC IVD D-dimer tests would be a [✂] and [✂]. The Parties suggested that the [✂] instrument, [✂] compete less closely with the LumiraDx instrument.[85]

5.4.2.2 CMA assessment

75. LumiraDx estimated Roche's share to be 5-10% and their own to be 0.1%.[86]

76. Table 2 below shows the CMA's market share estimates for POC IVD D-dimer tests.

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[81] FMN, paragraph 331.
[82] See also paragraph 57, which explains that LumiraDx's instrument is used for all tests and is portable and handheld.
[83] FMN, paragraph 436.
[84] FMN, paragraphs 334–343.
[85] FMN, paragraph 333.
[86] Parties' submission, Annex 640 to the FMN.

Table 2: Share of supply estimates in POC IVD D-dimer testing, by revenue (UK, 2023)

Supplier	*%*
Roche	[30-40]
LumiraDx	[0-5]
Combined	**[30-40]**
Danaher[87]	[30-40]
QuidelOrtho	[20-30]
Siemens	[0-5]
BHR BIOSYNEX	[0-5]
SD Biosensor	[0-5]
Total	***100***

Source: CMA estimates based on Parties' and competitors' data.

77. These estimates show that Roche is one of the two largest suppliers in the market, and that the increment resulting from the Merger is small, given LumiraDx has a very small share of [0-5]%. Post-Merger, the Merged Entity will continue to face competition from two large-sized competitors; ie Danaher, which is of similar size to Roche ([30-40]%) and QuidelOrtho, which also has a significant share of [20-30]%. There are also a number of smaller competitors such as BHR BIOSYNEX, SD Biosensor and Siemens, each of whom have low shares of [0-5]%, [0-5]% and [0-5]% respectively. However, while the CMA again considers these shares to be indicative of the broad market structure, there are limitations that mean they are likely to understate the constraint from competitors to the Merged Entity post-Merger. The sales of Aidian, SureScreen and Accubio, all of whom were cited by third parties as being active in this market, are not accounted for in these sales. The CMA has therefore considered other sources of evidence, as explained below.

78. Overall, the evidence indicates that Parties do compete, but they have some significant points of difference in their product offerings that may limit the Parties' closeness of competition. Although both Parties offer handheld instruments, there are some differences between the two offerings. For example, a LumiraDx document from October 2022 identifies the Roche cobas h232 device as an alternative for D-dimer, alongside the QuidelOrtho Triage. However, this document also highlights that Roche's consumables must be refrigerated[88] while LumiraDx's consumables can be in ambient storage, which the CMA considers may lead to

[87] Note that throughout this Decision Danaher refers to the wider Danaher group, which includes various diagnostic businesses such as Beckman Coulter, Cepheid, HemoCue and Radiometer. See https://www.danaher.com/our-businesses/diagnostics for details.
[88] The fact that LumiraDx enables storage at room temperature is also noted as a point of differentiated strength against Roche's [✂] instrument by Roche in a document from 2023 (Annex 100 to the FMN, February 2023, slide 23).

differences in the care settings and applications for which these instruments can be used.[89] The CMA also considers that the fact that Roche's [✂] product [✂] for this segment [✂] will also limit the constraint it imposes on LumiraDx's offering, given ([✂]) that these types of products are better suited for different settings. Further, one Roche document from 2023 comparing LumiraDx against its [✂] instrument notes several comparative [✂] with LumiraDx's offering on key competitive parameters, including that LumiraDx was expected to have [✂] analytical and clinician performance, and [✂] performance and [✂] in the UK market.[90]

79. Roughly half of third parties who responded to the CMA questionnaires submitted that the Parties compete with each other to supply POC IVD D-dimer tests (indicating that the Parties were either 'Moderate', 'Close' or 'Very close' competitors to each other). However, several other third parties who responded said that they were 'Distant' competitors, with one explaining that Roche offers a 'qualitative' test, which requires interpretation to understand the result.[91] In contrast, LumiraDx's tests displays a quantitative result, which indicates the amount of D-dimer in the sample. The respondent indicated that qualitative and quantitative tests had different use cases.

80. One customer expressed concern that competition was already limited in this market. However, this view was not supported by the feedback overall, which indicated that the Merged Entity will face constraints from numerous alternative suppliers post-Merger. Third parties mentioned several other larger POC IVD companies as 'Strong' or 'Moderate' suppliers of POC IVD D-dimer tests, including Abbott, Danaher, Siemens, Aidian, SureScreen and Accubio. Third parties also pointed to a long list of companies who are 'Moderate' competitors for the supply of POC IVD D-dimer tests, such as QuidelOrtho and bioMérieux.[92]

5.4.2.3 Conclusion on POC IVD D-dimer tests

81. For the reasons set out above, the CMA considers that Roche is one of several suppliers (along with Danaher and QuidelOrtho) with relatively strong market positions, and that LumiraDx is a small competitor that will add a very limited increment to Roche's existing position. While the Parties do compete, there are several competitors, who will continue to constrain the Parties post-Merger. For these reasons, the CMA believes that the Merger does not give rise to a realistic prospect of an SLC as a result of horizontal unilateral effects in the supply of POC IVD D-dimer tests in the UK.

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[89] LumiraDx Internal Document, Annex 561 to the FMN, October 2022, slide 16.
[90] Roche Internal Document, Annex 100 to the FMN, February 2023, slide 23.
[91] Response to the CMA questionnaire from a number of third parties, June 2024.
[92] There was also one third party who stated that, in addition to the strong and moderate competitors discussed above, there were a very large number of 'Weak' suppliers.

5.4.3 POC IVD NT-proBNP tests

82. POC IVD NT-proBNP tests detect the level of NT-proBNP in the blood to help with the diagnosis of heart disease.[93] Roche offers this test through its cobas h232 handheld instrument.

83. The Parties submitted that the Merger cannot plausibly give rise to an SLC because LumiraDx has a negligible presence in this market and Roche is on the verge of [✂] on this test.[94] They also noted that the Roche's test can only be carried out by a more skilled healthcare professional compared to the LumiraDx test and that the cobas h232 instrument [✂].[95]

84. LumiraDx submitted that their shares are approximately 10-20% for Roche and 0.2% for LumiraDx.[96]

85. Table 3 below shows the CMA's market share estimates for POC IVD NT-proBNP tests.

Table 3: Share of supply estimates in POC IVD NT-proBNP testing, by revenue (UK, 2023)

Supplier	***%***
Roche	[40-50]
LumiraDx	[0-5]
Combined	**[40-50]**
Danaher	[10-20]
Menarini	[10-20]
QuidelOrtho	[10-20]
BHR BIOSYNEX	[0-5]
Total	***100***

Source: CMA estimates based on Parties' and competitors' data.

86. These estimates show that Roche is the largest supplier in the market and that the increment resulting from the Merger based on LumiraDx will be extremely small. Post-Merger, the Merged Entity will continue to face strong constraints from Danaher, Menarini and QuidelOrtho, all of whom have moderate shares of [10-20]%. However, as with the other overlapping markets considered in the competitive assessment section of the Decision, the CMA considers these shares to have limitations in understating the constraint posed by other suppliers, given the absence of share of supply of suppliers mentioned in other sources of

[93] FMN, paragraph 353.
[94] FMN, paragraphs 449 and 451.
[95] FMN, paragraph 359.
[96] Parties' submission, Annex 640 to the FMN.

evidence such as Boditech [✂], Accubio and bioMérieux, and has therefore considered these shares in the round with other sources of evidence.

87. LumiraDx's internal documents indicate that they compete with Roche to supply POC IVD NT-proBNP tests, with an October 2022 LumiraDx document viewing Roche's test as a competitor alongside the QuidelOrtho [✂].[97] This document notes some similarities between Roche's offering in terms of [✂], but also recognises several differences between the offerings. For example, the LumiraDx test is a diagnostic tool, while the cobas h232 also supports monitoring and risk stratification use cases; the LumiraDx test requires only a fingerstick blood sample, while the cobas h232 requires a venous blood draw; the LumiraDx test can be stored at ambient temperatures from 2-30 degrees Celsius, while the Roche test should be refrigerated or stored at room temperature (15-25 degrees Celsius) for a week maximum. A further document prepared for LumiraDx also includes the Boditech [✂] as a main competitor.[98]

88. Although some third parties considered the Parties to compete closely, others did not consider the Parties to be close or even moderate competitors. While some third parties noted that the Parties' tests have similarities, including that they are both performed on handheld devices, other third parties indicated that the Parties were distant competitors, because LumiraDx has limited sales of POC IVD NT-proBNP tests and its test is used for different use cases than Roche's qualitative test.

89. One third party told the CMA that it believed LumiraDx's instrument to have won tenders and to be replacing Roche's cobas h232 for POC IVD NT-proBNP testing in Wales and Scotland.[99] However, the evidence received by the CMA does not support this, as LumiraDx submitted it had not participated in a NHS Wales or NHS Scotland tender in the last [✂] years. Moreover, LumiraDx submitted evidence indicating that, within the last [✂] years, LumiraDx has only quoted [✂] values for supply of POC IVD NT-proBNP tests to customers in Wales and Scotland.[100]

90. Moreover, the feedback from third parties indicated that the Merged Entity will face constraints from numerous alternative suppliers post-Merger. Third parties mentioned Danaher as a 'Strong' supplier of this test and bioMérieux and QuidelOrtho as 'Moderate'.[101] Third parties also mentioned Pathfast and BHA as 'Weak' suppliers and one third party again stated that there were too many suppliers to list.

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[97] LumiraDx Internal Document, Annex 561 to the FMN, October 2022, slide 18.
[98] LumiraDx Internal Document, Annex 395 to the FMN, June 2023, slide 15.
[99] Submission to the CMA from a third party, May 2024.
[100] LumiraDx's response to the CMA's section 109 Notice, 5 June 2024, Tranche 2, paragraph 4.1-4.15.
[101] Response to the CMA questionnaire from a number of third parties, June 2024. Customers also perceived two suppliers, Abbott and Siemens as strong, [✂]. Siemens [✂].

5.4.3.1 Conclusion on POC IVD NT-proBNP tests

91. For the reasons outlined above, the CMA considers that while Roche has a strong market position, LumiraDx is a very small competitor and the increment from the Merger is very small. The Parties do not compete particularly closely and there are multiple competitors who will continue to constrain the Merged Entity post-Merger. Accordingly, the CMA believes that the Merger does not give rise to a realistic prospect of an SLC as a result of horizontal unilateral effects in the supply of POC IVD NT-proBNP cardiac marker tests in the UK.

5.4.4 POC IVD HbA1c tests

92. POC IVD HbA1c tests measure levels of glycated haemoglobin in the blood, which helps in the diagnosis of diabetes.[102] Roche offers this test through its cobas b101 device, which is a benchtop instrument.

93. The Parties submitted that the Merger would not lead to an SLC in the supply of POC IVD HbA1c tests because they both have limited positions and there are many other suppliers.[103] They also noted that Roche's cobas b101 is designed for use in secondary and hospital settings, in contrast to the LumiraDx instrument, which is used in decentralised and community care settings.[104]

94. LumiraDx estimated that the Parties shares of supply for this test were minimal, with Roche at 1-5% and LumiraDx at 0.1%.[105] Table 4 below shows the CMA's market share estimates for POC IVD HbA1c tests.

Table 4: Share of supply in POC IVD HbA1c testing, by revenue, 2023.

Supplier	***%***
Roche	[5-10]
LumiraDx	[0-5]
Combined	**[5-10]**
Abbott	[40-50]
Siemens	[30-40]
BHR BIOSYNEX	[10-20]
Danaher	[0-5]
Menarini	[0-5]
Total	***100***

[102] FMN, paragraph 344.
[103] FMN, paragraph 441.
[104] FMN, paragraph 345.
[105] Parties' submission, Annex 640 to the FMN.

Source: CMA estimates based on Parties' and competitors' data.

95. These estimates show that Roche [5-10]% and LumiraDx [0-5]% are both materially smaller than Abbott, Siemens and BHR BIOSYNEX, all of whom have strong market positions of [40-50]%, [30-40]%, [10-20]% respectively, and that LumiraDx has a negligible share of less than [0-5] %. Danaher and Menarini have smaller shares than the largest suppliers; ie Abbott, Siemens and BHR BIOSYNEX. As with the other shares, these estimates also do not include other suppliers who have been mentioned by third parties regarding this test, such as Tosoh, GlucoRx, Accubio and Aidian.

96. LumiraDx's internal documents suggest that they do not monitor Roche in relation to this test. For example, a LumiraDx document from October 2022 identifies the Abbott [✂] and the Siemens [✂] as the main competitive devices,[106] while another document prepared for LumiraDx also includes the Siemens [✂] and the Aidian [✂].[107]

97. In addition, while some third parties did recognise that the Parties compete, customers and competitors mentioned other suppliers more frequently as 'strong' suppliers (particularly Siemens and Abbott), and a number of third parties either said that the Parties were distant competitors (because of differences in portability) or that they did not compete at all as they were unaware that Roche even offered an HbA1c test. Third parties also described a number of other suppliers as 'Strong', such as Tosoh, GlucoRx and Accubio.

5.4.4.1 Conclusion on POC IVD HbA1c tests

98. For the reasons set out above, the CMA considers that the Parties (and in particular, LumiraDx) have small market positions and that the increment from the Merger will be negligible, There are multiple competitors with strong market positions that will continue to constrain the Merged Entity post-Merger. Accordingly, the CMA believes that the Merger does not give rise to a realistic prospect of an SLC as a result of horizontal unilateral effects in the supply of POC IVD HbA1c tests for diabetes in the UK.

5.4.5 POC IVD CRP tests

99. POC IVD CRP tests are used to test for the presence of inflammation in the body. Roche offers the test on its cobas b101 benchtop instrument.[108]

100. The Parties submitted that the Merger would not lead to an SLC in the supply of POC IVD CRP tests because there are many companies which supply this test,

[106] LumiraDx Internal Document, Annex 561 to the FMN, October 2022, slide 14.
[107] LumiraDx Internal Document, Annex 395 to the FMN, June 2023, slide 18.
[108] FMN, paragraph 350.

including global, national and regional competitors as well as wholesalers and distributors.[109]

101. The Parties estimated their shares of supply for POC IVD CRP tests in the UK to be small, at [0-5]% for Roche and [0-5]% for LumiraDx.[110] Table 5 below shows the CMA's market share estimates for POC IVD CRP tests.

Table 5: Share of supply estimates in POC IVD CRP testing, by revenue, 2023.

Supplier	***%***
Roche	[10-20]
LumiraDx	[10-20]
Combined	**[20-30]**
Abbott	[40-50]
Danaher	[20-30]
BHR BIOSYNEX	[5-10]
SD Biosensor	[0-5]
Total	***100***

Source: CMA estimates based on Parties' and competitors' data.

102. These estimates indicate that Roche and LumiraDx both have moderate shares of [10-20]% and [10-20]% respectively. Post-Merger, they will face a much larger competitor (ie Abbott) and a moderate competitor of similar size (ie Danaher), as well as smaller competitors, such as BHR BIOSYNEX and SD Biosensor. The CMA also notes that there are multiple other providers whose presence has been cited by third parties during the course of the investigation, and who are not accounted for in these shares, such as SureScreen, Accubio, Aidian and bioMérieux.

103. LumiraDx's internal documents suggest that they do not monitor Roche as a competitor in relation to this test. For example, a LumiraDx document from October 2022 refers to the Abbott [✂] and the Aidian [✂] as competitors' products, but not to Roche.[111]

104. Third parties did not generally consider that the Parties compete to supply this test. Most third parties described the Parties as not competing closely, with only a few customers recognising close competition between them. Third parties also mentioned many other competitors to be either 'Strong' or 'Moderate' suppliers,

[109] FMN, paragraph 352.
[110] Parties' submission, Annex 640 to the FMN.
[111] LumiraDx Internal Document, Annex 561 to the FMN, October 2022, slide 12.

including Abbott, Siemens, SureScreen, Accubio, Aidian, Danaher and bioMérieux.

5.4.5.1 Conclusion on POC IVD CRP tests

105. For the reasons set out above, the CMA believes that the Merged Entity will have a moderate market position post-Merger; that the Parties do not compete closely; and that the Merged Entity will continue to be constrained by a number of competitors post-Merger, including Abbott and Danaher. Accordingly, the CMA believes that the Merger does not give rise to a realistic prospect of an SLC as a result of horizontal unilateral effects in the supply of POC IVD CRP tests for inflammation in the UK.

5.4.6 POC IVD COVID-19 tests

106. The Parties overlap in the supply of various POC IVD COVID-19 tests, which belong to a broader category of respiratory tests, such as respiratory syncytial virus and Flu A/B. Roche offers these tests on its benchtop Liat instrument. These tests made up the vast majority of LumiraDx's revenues in 2023 ([✂]).[112]

107. The Parties submitted that the Merger would not lead to an SLC in this testing area because their offerings are significantly different from each other and because there are multiple competitors who supply these tests in the UK.[113]

108. The CMA did not receive data in relation to this market on a consistent basis from suppliers and has therefore not relied on shares of supply (but, rather, on other sources of evidence) for its competitive assessment.[114] The evidence the CMA has considered indicates that there is a large number of suppliers operating in this market. LumiraDx's internal documents show that there are many alternative providers of POC IVD COVID-19 tests, including Becton Dickinson, QuidelOrtho, SD Biosensor, Abbott and Siemens.[115] Roche also submitted data from NHS Supply Chain that identified that it has [✂] suppliers of POC IVD COVID-19 tests, ranging from large global competitors to national competitors.[116]

109. Third parties similarly indicated that multiple POC IVD COVID-19 test suppliers exist. Large competitors such as Abbott, Siemens and Danaher were all

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[112] FMN, paragraph 316.
[113] FMN, paragraph 426. The differences that the Parties point to include the form factor of the instrument, the requirement for refrigeration of tests using the Liat, different price points and the fact that the Liat relies on molecular testing while the LumiraDx instrument relies on immunoassay testing, which impacts the settings that they can be used in.
[114] The submissions that the CMA received suggested that Danaher had a significant share of UK sales and that each of the Parties had a limited presence. However, due to discrepancies over the way suppliers had provided different types of tests in their data, the CMA does not consider the data sufficiently robust for a share data assessment.
[115] LumiraDx Internal Document, Annex 561 to the FMN, October 2022, slide 6; and LumiraDx Internal Document, Annex 395 to the FMN, slide 15.
[116] Specifically, of suppliers of COVID-19 antibody and antigen tests, COVID-19+Flu A/B, COVID-19+RSV (Annex 9 to the Final Merger Notice).

consistently mentioned as ‘Strong’ suppliers, as were smaller companies like Menarini, SD Biosensor, Abingdon Health, SureScreen and Accubio. There were also many other companies mentioned as ‘Moderate’ or ‘Weak’ suppliers.

110. Some third parties indicated that the Parties competed relatively closely for the supply of POC IVD Covid-19 tests.[117] However, several also stated that they were either ‘Distant’ competitors or that they did not compete at all. These respondents stated that this was because of different technologies behind the tests, with Roche using PCR testing and LumiraDx using an antigen method.

5.4.6.1 Conclusion on POC IVD COVID-19 tests

111. In light of the presence of a large number of other suppliers of POC IVD COVID-19 tests that would constrain the Merged Entity post-Merger, the CMA believes that the Merger does not give rise to a realistic prospect of an SLC as a result of horizontal unilateral effects in the supply of POC IVD COVID-19 tests.

5.4.7 Loss of potential and dynamic competition in the supply of POC IVD tests

112. Unilateral effects may also arise from the elimination of potential and/or dynamic competition. Mergers involving a potential entrant can lessen competition in different ways. First, a merger involving a potential entrant may imply a loss of the future competition between the merger firms after the potential entrant would have entered or expanded (loss of potential competition). Second, existing firms and potential competitors can interact in an ongoing dynamic competitive process, which may be affected by a merger (loss of dynamic competition).[118]

113. The CMA has considered these concerns in two POC IVD markets, namely the supply of POC IVD tests for (i) high sensitivity Troponin and (ii) Strep-A in the UK.

5.4.7.1 POC IVD high sensitivity Troponin tests

114. High sensitivity Troponin tests look for the presence of Troponin in the blood, which is a protein released following damage to the heart, to aid in diagnosing heart attacks. There are two types of Troponin (Troponin I and Troponin T) that

[117] One third party alleged at a very late stage of the CMA’s merger investigation that Roche’s Liat test had been replaced by LumiraDx’s product at a particular UK hospital, and that this could impact not just the Covid-19 market, but also other POC IVD markets by triggering hospitals to use the LumiraDx product for other POC IVD areas of overlap. The CMA believes that any switching that does occur between the Parties’ products would have a negligible impact on the POC IVD COVID-19 market in the UK, given the large number of alternative suppliers operating in this market. Further, given the common practice in the POC IVD markets of suppliers giving their instruments away for free (as discussed previously in footnote 42), the CMA does not consider the fact that a hospital originally obtained a LumiraDx product for one condition would necessarily affect its choice of supplier for other POC IVD markets.
[118] CMA129, paragraphs 5.1–5.3.

are released into the bloodstream as a result of this heart damage, which can both be tested for interchangeably.[119]

115. Neither of the Parties currently offers a POC IVD high sensitivity Troponin test, but both Parties have tests in development. Roche is developing a test for its [✂] instrument, which is expected to launch in [✂], whilst LumiraDx is developing a POC IVD high sensitivity Troponin test for its instrument, which is not scheduled for release until [✂] at the earliest.[120]

5.4.7.1.1 Parties' submissions

116. The Parties submitted that even assuming the Parties' respective pipeline products launch in the next two to three years, overall, the Merger will not result in a loss of potential competition because the development activities of Roche and LumiraDx are complementary to each other and [✂].[121]

117. As regards high sensitivity Troponin specifically, the Parties noted that the developments are complementary because:

(a) They are suitable for different clinical settings [✂].

(b) Roche's [✂] will be able to [✂] but LumiraDx's test is likely to [✂].[122]

Due to this complementarity, the Parties claim that they will continue the development of [✂] POC IVD high sensitivity Troponin tests.

118. The Parties also submitted that post-Merger Roche would have the incentive to continue the development of [✂] test [✂], given their suitability for different settings.[123]

119. The Parties also submitted that there is a large number of alternative providers of these tests, either being already available in the market or currently in development. They listed Abbott, Pathfast, QuidelOrtho, Danaher/Radiometer, BHR BIOSYNEX and Siemens, as well as others like ProlightDx in development.[124]

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[119] Roche's response to the CMA's section 109 Notice, 5 June 2024, Tranche 1, paragraphs 3 and 4.
[120] FMN, paragraph 574 and 577.
[121] FMN, paragraph 565-571.
[122] Parties' response to the CMA's questions of 5 June 2024, paragraph 25. The Parties also claimed complementarity based on Roche's product testing for [✂], and LumiraDx, [✂]. However, the CMA has not placed weight on this point of differentiation, as it received mixed evidence as to the relevance of this distinction. One third party indicated that there was a significant difference between interpreting the results from Troponin I and Troponin T tests. However, another third party involved in the clinical evaluation of Troponin testing explained that there was no meaningful distinction between Troponin I and T tests, because Troponin tests are not standardised and all report results in different ways, meaning that even those that measure the same type of Troponin have significant differences.
[123] FMN, paragraph 578.
[124] FMN, paragraph 575.

5.4.7.1.2 CMA assessment of loss of potential competition

120. The CMA has considered whether the Parties would be likely to enter and expand into this market absent the Merger, and whether the loss of the constraint posed by the Parties on each other as a result of the Merger would lead to a realistic prospect of an SLC in the supply of POC IVD high sensitivity Troponin tests in the UK.[125]

121. The internal documents from both Parties recognise the importance and opportunity that this testing area provides and suggest a strong incentive of both Parties to enter the market; [126] some third parties also commented that many suppliers are expecting high demand for this test.[127] Roche stated that it is committed to releasing the [✂] instrument (that will be used to test for high sensitivity Troponin, amongst other things) and this test will be an important feature of that, comprising approximately [✂] of the cost to develop the [✂].[128] Roche's internal documents also indicate a strong intention to enter the market; for example, one internal document from 2023 cites the [✂] launch for POC IVD high sensitivity Troponin testing as planned for [✂], and contains detailed analyses of its intended '[✂]' role in its POC IVD ecosystem.[129]

122. Notwithstanding LumiraDx's aspirations regarding high sensitivity Troponin, the CMA notes that the exact scope and availability of the investment that would have been required to take LumiraDx's pipeline activities through to commercialisation in the counterfactual is unclear.[130] However, the CMA considers that irrespective of whether both Parties would have entered the market absent the Merger, the loss of the constraint posed by the Parties on each other as a result of the Merger would not give rise to a realistic prospect of an SLC in this market.

123. First, the evidence does not indicate that the Parties' products would compete particularly closely. The fact that one is [✂] and the other [✂] is significant; a Roche document also notes that as against its [✂] product, the LumiraDx instrument has [✂] differentiating features due to its different [✂] and the [✂]; the same document also goes onto cite as a [✂] differentiating feature, the fact that the LumiraDx product will have likely [✂].[131] One third party also stated that the

[125] CMA129, paragraph 5.7.
[126] For example, Roche Internal Document, Annex 897 to the FMN, October 2023, slide 47 which describes adding high sensitivity Troponin [✂] as a priority; Roche Internal Document, Annex 28 to the FMN, August 2023, slide 77, which states that LumiraDx having compliant Troponin performance is a requirement for Roche [✂]; and LumiraDx Internal Document, Annex 195 to the FMN, August 2022, slides 26 and 44, which mention the unmet need for high sensitivity Troponin testing and projected that revenue attributable to high sensitivity Troponin could account for 15-20% of LumiraDx's total revenue in 2025.
[127] Note of a call with a third party, June 2024; note of a call with a third party, April 2024, paragraph 16; and submission to the CMA from a third party, January 2024, paragraph 50.
[128] Parties' response to the CMA's questions of 5 June 2024, paragraph 15.
[129] Annex 100 to the FMN, February 2023.
[130] See further Counterfactual section; Roche also noted in a 2023 document for [✂] LumiraDx [✂] (Annex 100 to the FMN, February 2023, slide 23).
[131] Roche Internal Document, Annex 100 to the FMN, February 2023, slide 23.

ability to rule out a diagnosis is valuable, supporting the Parties' submission that it is relevant that the Parties' products will have slightly different diagnostic abilities.

124. Further, the Parties would also face significant competitive constraints from other existing suppliers of POC IVD high sensitivity Troponin tests, as well as from potential entrants. For example, a LumiraDx document from October 2022 compares the LumiraDx POC IVD high sensitivity Troponin test to tests from Siemens and QuidelOrtho,[132] whilst a more expansive LumiraDx document from July 2022 also lists tests from Abbott and Pathfast, in addition to Siemens and QuidelOrtho, as POC IVD high sensitivity Troponin tests.[133]

125. Third parties have confirmed that there are several strong suppliers who already offer or are developing a POC IVD high sensitivity Troponin test. For example, a clinical expert noted that Siemens is the leader in this market, followed by QuidelOrtho, and that Abbott is developing a test for the i-Stat system.[134] These companies were also mentioned by third parties in the market outreach, with Siemens, QuidelOrtho and Abbott all referenced by third parties as 'Strong' suppliers of this test already.

126. The presence of other suppliers has also been confirmed in the third-party revenue data the CMA has received. This data confirms that SD Biosensor, Siemens, and QuidelOrtho have each generated UK revenues from sales of POC IVD high sensitivity Troponin tests and that revenues of Siemens and QuidelOrtho are significant.[135] One other third party also told the CMA that it expects to launch this test in 2026.

127. One third party raised concerns that Roche's strong position in lab testing for high sensitivity Troponin would translate into prominence for POC testing, because clinicians want to test for the same type of Troponin (I or T) at POC as they would in the lab, and the Merged Entity would be the only company able to offer both types of tests at POC. However, and as explained in footnote 122, it is not clear that the ability to offer both tests I or T is significant, given other third party evidence indicates that customers can use either Troponin I or T POC tests, regardless of the type of Troponin that they would test for in the lab. One third party stated that this is because there is no material difference between the two types when testing for cardiac diseases, and that for this test clinicians would usually either perform a lab based or a POC test on a patient, but not both.[136] Based on the above evidence, the CMA considers that irrespective of whether either Party would have entered absent the Merger, any loss of the constraint

[132] LumiraDx Internal Document, Annex 561 to the FMN, October 2022, slide 20.
[133] LumiraDx Internal Document, Annex 631 to the FMN, July 2022.
[134] Note of a call with a third party, June 2024.
[135] The revenues imply market shares of [50-60]% for QuidelOrtho with [40-50]% for Siemens and [0-5]% for SD Biosensor .
[136] Roche's response to the CMA's section 109 notice, 5 June 2024, paragraphs 1–10; and note of a call with a third party, June 2024, paragraph 17.

posed by the Parties on each other resulting from the Merger would not give rise to an SLC and would be offset by the strong constraint from rivals.

5.4.7.1.3 CMA assessment of loss of dynamic competition

128. The CMA has also considered whether the Merger would lead to an SLC in the supply of high sensitivity Troponin tests by removing the threat of entry by either Party, and reducing the competitive pressure they impose on each other, thereby leading the Merged Entity to reduce either Party's efforts towards entry or expansion.

129. The CMA considers that the evidence indicates that the Merger would be unlikely to reduce the Parties' respective efforts to develop this test and enter the market. In particular:

(a) The Parties' internal documents indicate that the Merged Entity would continue to develop high sensitivity Troponin tests on [✂] post-Merger. For example, a Roche internal document describes the Merged Entity continuing to develop [✂].[137]

(b) As noted at paragraph 124 above, the CMA considers that the evidence indicates that the Parties' pipeline products would not compete particularly closely, given material differences between the high sensitivity Troponin test offerings the Parties are developing, such as the different settings that they will be used in (with [✂] being '[✂]' and LumiraDx's pipeline offering being handheld) and the different medical diagnoses that they will be able to make. This suggests that the Parties do not exert a strong dynamic competitive constraint on each other in the present, which indicates that the Merger would be unlikely to affect the Parties' incentives to develop their respective tests, particularly in light of the significant market opportunity each of the Parties has identified for their different tests.[138] As explained above, there are multiple competitors who already supply, or who like the Parties are seeking to supply, this test. The CMA considers that the Parties are competing more strongly against those suppliers who already have a presence in the market,

[137] Roche Internal Document, Annex 38 to the FMN, slide 5. The CMA notes that Roche also considered a '[✂]' scenario, where Roche's [✂]. However, this scenario is considered in an earlier planning document from 2022, and the CMA understands from Roche's submissions that this was based on a less-developed understanding of LumiraDx's technology. A subsequent document evaluating the Merger from 2023 where Roche no longer considers a '[✂]' scenario, and instead anticipates [✂] alongside LumiraDx's test, corroborates this. Parties' response to the CMA's questions of 5 June 2024, paragraphs 7 and 8; Roche Internal Document, Annex 28 to the FMN, slide 24.
[138] For example, Roche Internal Document, Annex 897 to the FMN, October 2023, slide 47; and LumiraDx Internal Document, Annex 195 to the FMN, August 2022, slides 26 and 44.

than against each other regarding the development of their POC IVD high sensitivity Troponin test.[139]

130. One third party told the CMA that the LumiraDx instrument poses a substantial threat to Roche's position as a supplier of lab-based high sensitivity Troponin tests and that there may be the possibility of a 'killer acquisition' strategy due to this.[140] However, and as noted above at paragraphs 45 and 46, the CMA considers that POC IVD tests are broadly speaking, complementary to (rather than being in direct competition with) lab-based IVD tests. Further, the CMA did not see any Roche internal documents that supported this allegation. In the event that POC IVD tests did pose a strong constraint on lab-based tests in high sensitivity Troponin, Roche would continue to face strong competitive pressure from multiple other POC IVD suppliers post-Merger.

131. Based on the above evidence, the CMA considers that:

(a) the Merger would be unlikely to reduce the Parties' respective incentives and efforts in the present to develop their respective tests and enter the market; and

(b) the Merged Entity would face significant competitive constraint (both from current suppliers and potential entrants) and so any potential loss of dynamic competition brought about by the Merger would not be significant.

5.4.7.1.4 Conclusion on POC IVD high sensitivity Troponin tests

132. For the reasons set out above, the CMA believes that the Merger does not give rise to a realistic prospect of an SLC in the supply of POC IVD high sensitivity Troponin tests in the UK as a result of a loss of either potential or dynamic competition.

5.4.7.2 POC IVD Strep-A tests

133. Strep-A bacteria causes an infectious disease and can be tested for via POC IVD tests. Roche already offers this test on its Liat instrument, while LumiraDx is developing a test for its instrument.

5.4.7.2.1 Parties' submissions

134. The Parties submitted that the existing Roche test on the Liat test would not compete closely with the LumiraDx test, should the latter be successfully

[139] For instance, a Roche document from November 2023 compares Roche's [✂] to the other large players in the market, namely Abbott Danaher and Siemens rather than LumiraDx; Roche Internal Document, Annex 24 to the FMN, November 2023, slide 9. Similarly, a LumiraDx document from October 2023 assesses the 'competitive positioning' in POC IVD high sensitivity Troponin, and compares LumiraDx's solution to Siemens and QuidelOrtho's solutions.
[140] Submission to the CMA from a third party, May 2024.

launched, because Roche's test is benchtop and therefore aimed for secondary care settings, as opposed to the LumiraDx's instrument suited for decentralised settings. The Parties also provided a non-exhaustive list of suppliers of POC IVD Strep-A tests: Abbott, Danaher, Meridian, QuidelOrtho, Aidian, SD Biosensor and Zoetis.[141]

135. As regards the possibility of LumiraDx's entry, the Parties submitted that it will take at least [✂] more years before release, that there is still an estimated development cost of around USD [✂] million, and that the test still needs to undergo a [✂] before being available.[142]

5.4.7.2.2 CMA assessment of loss of potential competition

136. The CMA has considered whether LumiraDx would be likely to enter and expand in this market absent the Merger, and whether the loss of the constraint posed by the Parties on each other as a result of the Merger would lead to a realistic prospect of an SLC in the supply of POC IVD Strep-A tests.[143]

137. The CMA considers that the evidence on whether LumiraDx would have entered this market absent the Merger is inconclusive. On the one hand, LumiraDx's internal documents indicate that the test is [✂] and that LumiraDx has seen rising interest from customers in early diagnosis of Strep-A.[144] On the other hand, the exact scope and availability of the investment required to take Lumira's current pipeline activities in Strep-A through to commercialisation is unclear.

138. Irrespective of whether LumiraDx would have entered this market absent the Merger, the CMA considers that the loss of the constraint posed by the Parties on each other as a result of the Merger would not give rise to a realistic prospect of an SLC. First, the evidence does not indicate that the Parties' products would compete particularly closely and also show that the Parties would face significant competitive constraints from other suppliers of POC IVD Strep-A tests.

139. As noted previously, the CMA considers that the distinction between benchtop and handheld instruments is an important differentiating feature. Furthermore, although LumiraDx's internal documents mention Roche as a competitor, they focus on products from QuidelOrtho and Abbott when comparing technical capabilities.[145] Another document compares LumiraDx's test to tests from QuidelOrtho and BD, and not to Roche's test. [146] The CMA also received data indicating that at least four other companies had revenues for this product in 2023 – Danaher, Abbott,

[141] FMN, paragraphs 582–584.
[142] FMN, paragraphs 580–581.
[143] CMA129, paragraphs 5.1–5.3.
[144] LumiraDx Internal Document. Annex 52 to the FMN, April 2023, slides 3 and 13.
[145] LumiraDx Internal Document, Annex 561 to the FMN, October 2022, slide 22.
[146] LumiraDx Internal Document, Annex 190 to the FMN, July 2023, slide 44.

SureScreen and QuidelOrtho – with two of these being significantly larger than Roche.[147]

140. Third parties also refer to several other companies as 'Strong' suppliers of this test in the UK, such as SD Biosensor, Abbott, Accubio, Siemens, and to several 'Moderate' and 'Weak' suppliers like Boditech, bioMérieux and BHA Medical.

141. Based on the above, the CMA considers that irrespective of whether LumiraDx would have successfully developed its POC IVD Strep-A test and entered the market absent the Merger; any loss of the constraint posed by the Parties on each other as a result of the Merger would not give rise to an SLC and would be offset by the constraint from rivals.

5.4.7.2.3 CMA assessment of loss of dynamic competition

142. The CMA has also considered whether the Merger would lead to an SLC in the supply of POC IVD Strep-A tests by removing the threat of entry by LumiraDx, thereby leading the Merged Entity to reduce LumiraDx's efforts towards entry or expansion.

143. As noted above, Roche already offers a POC IVD Strep-A test and LumiraDx is seeking to develop one.

144. The evidence seen by the CMA indicates that the Parties do not pose a strong dynamic competitive constraint on each other, which indicates the Merger would be unlikely to affect the Merged Entity's incentives to reduce LumiraDx's efforts towards entry or expansion. In particular, the CMA considers that there are material differences between the POC IVD Strep-A offering that LumiraDx is developing and Roche's POC IVD Strep-A test (see paragraph 139 above).

145. In addition, as noted in paragraph 140 above, third-party evidence indicates the presence of strong suppliers of this test in the UK, such as SD Biosensor, Abbott, Accubio and Siemens.

146. Based on the above evidence, the CMA considers that:

(a) the Merger would be unlikely to reduce LumiraDx's efforts to develop this test and enter the market; and

(b) in any event, the Merged Entity would face significant competitive constraints and so any potential loss of dynamic competition brought about by the Merger would not be significant.

[147] The market shares estimated by the CMA for 2023 are Danaher with [50-60]%, Abbott with [30-40]%, Roche with [0-5]%, QuidelOrtho with [0-5]%, and SureScreen with [0-5]%.

5.4.7.2.4 Conclusion on POC IVD Strep-A tests

147. For the reasons set out above, the CMA believes that the Merger does not give rise to a realistic prospect of an SLC in the supply of POC IVD Strep-A tests in the UK as a result of a loss of either potential or dynamic competition.

5.5 Third-party views on the Merger

148. In addition to the assessment of each of these theories of harm, the CMA has taken into account views of third parties (including customers, competitors and other industry participants) on the impact of the Merger.

149. The vast majority of customers and competitors were either 'Neutral' or 'Positive' about the Merger. Some of these third parties did not consider that the Merger would have any impact on their businesses, while others suggested that there are many other suppliers across the broad spectrum of POC IVD testing markets and that competition would not be affected or that in any event there would not be a significant loss. The positive views pointed to the benefits of having Roche's resources (such as finances, IT equipment and infrastructure) contributed to LumiraDx's instrument. Three other industry participants had neutral or positive views about the Merger. One participant pointed to a large number of suppliers in the market and said that they had no views on the impact of the Merger on competition; the second participant did not raise any concerns, and the third one thought that the Merger could have a positive impact on the market by injecting more resources into LumiraDx's distressed business.

150. A small minority of third parties thought that the Merger would have a negative impact on competition generally and in relation to some of the markets above. These generally pointed to the strength of Roche's offering, with no respondent identifying any particular strength in LumiraDx's product.[148] The CMA has considered complaints specific to certain theories of harm in the sections dedicated to these theories of harm above.

151. One third party also alleged that the Merger could lead to vertical foreclosure of rival POC IVD suppliers who rely on LumiraDx's platform to distribute their tests. However, the CMA did not consider that the Merged Entity would have either the ability or the incentive to foreclosure rival POC IVD suppliers. The CMA

[148] In addition, three competitors expressed broader concerns that could be interpreted as suggesting the Merged Entity would use its broad portfolio of lab-based and POC IVD products to provide a 'total offering' that may prevent other suppliers from competing effectively, across POC and lab-based IVD. The CMA does not consider that the Merged Entity would be able to use its post-Merger portfolio of products in this way. First, no customers responding to the CMA's questionnaire considered it important for a supplier to offer a combination of lab-based and POC testing, with all customers expressing a view considering it either irrelevant or less important, and one customer explaining that no bearing is given to whether a supplier also provides lab-based products in addition to POC IVD products. Moreover, even if the Merged Entity had the ability to leverage its lab-based and POC IVD product portfolio when negotiating with customers, the CMA does not believe that LumiraDx's limited sales and commensurate market position would result in an increase of the Merged Entity's incentives to engage in such leveraging.

understands that LumiraDx is the only supplier of test strips for its instrument, and did not receive any evidence suggesting that LumiraDx has enabled other companies to supply their tests through the instrument, reflecting the fact that LumiraDx's system, as well as most other POC IVD systems, is proprietary, which means that it only works with test strips from the same manufacturer.

6. ENTRY AND EXPANSION

152. Entry, or expansion of existing firms, can mitigate the initial effect of a merger on competition, and in some cases may mean that there is no SLC. The CMA will consider entry and/or expansion plans of rivals who do so in direct response to the merger as a countervailing measure that could prevent an SLC. In assessing whether entry or expansion might prevent an SLC, the CMA considers whether such entry or expansion would be timely, likely and sufficient.[149]

153. As the CMA has concluded that the Merger does not give rise to competition concerns, it is not necessary to consider countervailing factors in this Decision.

[149] CMA129, paragraph 8.31.

DECISION

154. Consequently, the CMA does not believe that it is or may be the case that the Merger may be expected to result in an SLC within a market or markets in the United Kingdom.

155. The Merger will therefore not be referred under section 33(1) of the Act.

Elie Yoo
Director, Mergers
Competition and Markets Authority
19 July 2024

[i] The references to 'Merger' should be read as referring to previous discussions between the Parties in relation to a potential acquisition of LumiraDx.