UK Health Security Agency

Validating COVID-19 tests in the private market

Title: Validating COVID-19 tests in the private market **IA No:** **Regulatory Policy Committee (RPC) Reference No:** RPC-DHSC-5073(2) **Lead department or agency:** Department of Health and Social Care (DHSC) **Other departments or agencies:**	Impact Assessment (IA) Date: 19 October 2021 Stage: Development/Options Source of intervention: Domestic Type of measure: Secondary legislation Contact for enquiries: joseph.hillier@dhsc.gov.uk
Summary: Intervention and Options	**RPC Opinion:** GREEN - Fit for purpose

Cost of Preferred (or more likely) Option (in 2019 prices)

Total Net Present Social Value	**Business Net Present Value**	**Net cost to business per year**	**Business Impact Target Status** Qualifying provision
£-50.0m	£-23.3m	£56.7 m	

What is the problem under consideration? Why is government action or intervention necessary?

Prior to the government introducing additional regulation in July 2021, entry into the private SARS-CoV-2 (Coronavirus (COVID-19)) test product market was controlled by CE (Conformité Européene) marking, a self-declaration process for most of the COVID-19 test products on the UK market. The performance declaration made as part of CE marking is not required to be independently verified ahead of sale for such tests and there is no legally-binding agreed process for establishing that performance. Further to this, there is no minimum threshold for performance of a test product in terms of its ability to detect positives and negatives accurately included in CE marking requirements. A significant number of tests have failed in to replicate their stated performance for their intended use during independent validation. Government intervention is required to legislate for, and enforce, standards of private COVID-19 test products in order to protect the interests of the public. The first step in addressing this problem was taken in July 2021, this impact assessment covers both that legislation as well as proposed further legislation for introducing laboratory validation on top of a desktop review.

What are the policy objectives of the action or intervention and the intended effects?

The desired outcome is that all mature (antigen and molecular detection) COVID-19 testing technologies sold on the UK market and used in testing activities meet a minimum standard of performance. This will be achieved through independent validation of those devices by UKHSA (UK Health Security Agency). Reduced false negative and false positive test rates will help to manage the spread of the disease and reduce needless self-isolation and contact tracing.

1. Correct the information asymmetry between consumers and sellers.
2. Establish a well-regulated minimum bar in COVID-19 *in vitro* diagnostic devices
3. Reduced false negative and false positive test rates will help to manage the spread of the disease, reduce incidences of unnecessary self-isolation and contact tracing.
4. Increased reliability of test products and easier comparability of their performance should drive increased take up of testing by employers and institutions.
5. Increased consumer confidence in tests and subsequently, increased volumes of private tests being reported; greater numbers of employers/bodies providing or requiring testing; and their general awareness of the validation programme will be key indicators. of success.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

Option 0: Do nothing.
Manufacturers will continue to self-certify COVID-19 tests against CE standards.

Option 1: Legislate market standards for COVID-19 tests.
On top of existing CE marking standards, this would introduce a mandatory requirement for validation.

Option 2: Voluntary validation.
A voluntary approach where the same central validation programme would be created at a smaller scale with the same thresholds for performance for tests but on a purely voluntary basis.

Option 3: 3rd Party Conformity Assessment.
This would require notified bodies (a private company) to verify the manufacturers findings.

Option 4: Government Monopoly.
The government expands the UTO to become the sole supplier to the market.

Option 1 is preferred. This was assessed as the only option that successfully aligned manufacturers' and consumers' incentives.

Will the policy be reviewed? It will be reviewed. **If applicable, set review date:** Before 31 December 2022

Is this measure likely to impact on international trade and investment?		Yes		
Are any of these organisations in scope?	**Micro** Yes	**Small** Yes	**Medium** Yes	**Large** Yes
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)		**Traded:** N/A	**Non-traded:** N/A	

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible SELECT SIGNATORY: ..... Date: .....

Summary: Analysis and Evidence

Policy Option 1

Description:

Full Economic Assessment

Price Base Year 2019	**PV Base Year** 2020	**Time Period Years** 10	**Net Benefit (Present Value (PV)) (£m)**		
			Low: -48.4	**High:** -119.2	**Best Estimate:** -55.3

Costs (£m)	**Total Transition** (Constant Price) Years		**Average Annual** (excl. Transition) (Constant Price)	**Total Cost** (Present Value)
Low	12.0	1	27.8	**273.4**
High	9.7		97.1	**925.5**
Best Estimate	10.2		59.7	**574.4**

Description and scale of key monetised costs by 'main affected groups'

Average annual costs to business are made up of £1.3m for the validation programme (which will operate on a 100% pass-through basis, with a 55% fee reduction for small to medium-sized enterprises (SMEs) and £54.6m in foregone profits for manufacturers either not applying for validation or whose products do not pass validation. As the UK COVID-19 diagnostic market shrinks, foregone profit falls year-on-year from approximately £219m in year 1 to £7m in year 10.

Other key non-monetised costs by 'main affected groups'

Validation costs may be passed through to consumers in the form of increased prices, however this is likely to be a small amount.

Improved testing quality will have a range of benefits to individual and public health, in control and containing the pandemic and subsequent flare ups.

Benefits (£m)	**Total Transition** (Constant Price) Years		**Average Annual** (excl. Transition) (Constant Price)	**Total Benefit** (Present Value)
Low	0.0		23.7	**225.0**
High	0.0		84.8	**806.2**
Best Estimate	0.0		54.6	**519.1**

Description and scale of key monetised benefits by 'main affected groups' Demand for test kits left unmet by the withdrawal of products failing validation, or those not presented for validation, is very likely to be fulfilled by the expansion of supply of products that do pass validation. The net result, rather than a complete loss of profit, will be a redirection of profit from manufacturers of lower-performing products to manufacturers of higher-performing products. The scale of this benefit mirrors the 'profit foregone' cost. Following RPC published guidance[1] this recovery of profit is considered as indirect and so is involved in Present Value calculations but not the EANDCB (Equivalent Annual Net Direct Cost to Business).
Other key non-monetised benefits by 'main affected groups' The validation programme will improve average test performance, increasing the successful detection of COVID-19 cases (reducing onward transmission and reducing the likelihood of future lockdowns and new variants) and decreasing false positives (reducing unnecessary self-isolation).

Key assumptions/sensitivities/risks **Discount rate (%)**	3.5
There is a low risk that validation will exclude so many products from the testing market that supply cannot meet demand, resulting in substantial price increases and lack of availability.	

Business Assessment (Option 1)

Direct impact on business (Equivalent Annual) £m:			**Score for Business Impact Target (qualifying provisions only) £m:**
Costs: 62.8	**Benefits:** 0.0	**Net:** 62.8	283.8

[1] Business Impact Target specific issues: direct versus indirect impacts

Summary

Problem under consideration and rationale for intervention

1. Validation of COVID-19 test devices for use in the national mass testing programme and parts of the NHS by the Lateral Flow Device Validation Group (LVG) and Technical Validation Group (TVG) established consistent disparities between manufacturers' claims (including field outcomes for selected products) for their devices and the actual performance of those devices, even for well-performing devices.[2] This may lead to an increased risk of inaccurate test results when used for testing. Whilst the government has undertaken extensive validation work to choose the most appropriate tests and understand their reliability for use in the NHS, this validation work is prohibitively expensive for most consumers to conduct individually.

2. Entry to the market was, until 28 July 2021, 'controlled' only by CE marking – a self-declaration process for the performance of this type of test kit/equipment. This performance is not independently verified ahead of sale. In addition, enforcement is reactive rather than proactive, so tests are only removed from the market if problems come to light.

3. Without additional regulation, consumer behaviour in terms of test kit/device selection will continue to be based on manufacturer-claimed performance which may be reliant on overstated performance permitted under CE marking, currently allowing performance to be evidenced as the manufacturer sees fit. This asymmetry in information has led to a market failure. As COVID-19 is a notifiable infectious disease, without intervention this could also mean results may be unreliable in tracking prevalence of the virus, which may undermine government decision making and management of the pandemic. This means the market failure would compound a major public health risk. There is a clear problem that the quality of tests available on the market were inconsistent in their real-world performance and so those relying on their results would risk relying on false results, potentially unknowingly spreading the disease.

4. To address the problem, the government has chosen to implement the policy in 2 stages. The government took steps to introduce legislation (on 28 July 2021), which introduced a mandatory requirement for antigen and molecular COVID-19 detection test products to undergo a 'desktop review' before being permitted for sale on the UK market. This next iteration of the Impact Assessment has been developed in advance of implementing a second stage of mandatory 'laboratory validation', which will introduce further scrutiny of COVID-19 test products, in addition to the 'desktop review' stage. This will ensure that test devices demonstrate with robust evidence that they meet the relevant minimum performance standards. Those tests that do not pass both stages of validation will not be

[2] To date, approximately 114 products have been through TVG the validation process and only 14 have been validated. This is similar for LFD validation, where 101 have gone through the validation process and only 20 validated.

authorised for sale in the UK. This Impact Assessment (IA) builds on a previous iteration published on 20 July 2021. In terms of scope, this iteration of the IA considers the impact of the policy in its entirety, including both desktop review and proposed laboratory validation.

5. The consultation held in April to May 2021 showed that 78% of respondents agreed that COVID-19 detection tests should be validated beyond the verification and assurance provided for CE marking. In the most recent consultation held in September 2021, 61% agreed or strongly agreed that the mandatory validation regime for COVID-19 tests 'helps to make the UK safer in response to this pandemic'.

6. A greater role for private sector provision of asymptomatic testing is expected during 2021 and into 2022 subject to policy requirements. It is considered essential that individuals are able to privately acquire dependable tests or testing services. For this reason, it is necessary to lay regulations to enforce and uphold uniform standards as soon as possible.

Proposed measure

7. Below we outline the preferred option taken to address the market failure identified.

Option 1: Legislate to introduce market standards for COVID-19 tests

8. As outlined above, implementation involves introducing the validation regime in 2 stages, via (1) desktop review and (2) laboratory validation of products. In addition to existing CE-marking standards, this option introduces a mandatory requirement for desktop review validation and minimum performance standards by test type. We have already introduced stage one of desktop review in legislation which came into force on 28 July 2021. Additional mandatory laboratory validation of devices represents stage 2, which would be applicable to those products that are able to pass a desktop review validation.

9. The validation process offering independent assessment of the performance a product is capable of minimising the cost to government by charging manufacturers for the service. Publishing the results of this process on a single GOV.UK page will ensure that the data are accessible and comparable. This should maintain consumer faith in testing sufficiently, so that test outcomes will be used to inform consumer behaviours (whether tests are government issued or not).

10. A mandatory approach, compelling COVID-19 tests sold on the UK market to go through validation, was assessed to be the only means to sufficiently minimise gaming of the proposed system.

11. Alternative options considered are described later in this IA.

Headline impacts

12. The direct costs to business of this policy comprise £1.3m (annual equivalent) for the validation programme and £54.6m in foregone profits for manufacturers either not applying for validation or whose products do not pass validation.

13. As the UK COVID-19 diagnostic market shrinks, foregone profit falls year-on-year from £219.2m in year 1 to £7.4m in year 10.

14. Demand for test kits left unmet by the withdrawal of products failing validation, or those not presented for validation, is very likely to be fulfilled by the expansion of supply of products that do pass validation or to a lesser extent recovered through reinvestment in failing products (such that they subsequently successfully validate). The net result, rather than a complete loss of profit, will be a redirection of profit from manufacturers of lower-performing products to manufacturers of higher-performing products at a net cost of £0.2m (that is, from reinvestment).

15. Costs arise to manufacturers from familiarisation with legislation (£0.3m) and transition costs (£0.7m) and to retailers from familiarisation (£0.04m) and transition costs (£0.02).

16. Government incurs programme costs that would otherwise accrue to small and micro businesses[3] (£3.4m) and communication costs (£1,500).

17. As legislation is being enacted through 2 separate Statutory Instrument's (SI), we have appraised these 2 elements separately. The first SI introduced a mandatory requirement for products to have their validating performance claims authorised through a desktop review process. The second SI is intended to introduce a requirement for products that are successful at the first stage of validation to undergo an additional independent laboratory testing to authorise its performance. The first SI accounts for:

    - 99.8% of profit effects – this is based on experience of the TVG where the overwhelming majority of products failing validation did so at the desktop stage
    - 20% of programme costs (and government mitigation costs[3])
    - 88% of familiarisation and 99.8% of transition costs
    - 50% of public sector communications costs

18. The policy will ensure that the average level of performance of test products available on the UK market will rise by removing poor performing tests from the market. It will likely bring about direct improvements in the performance and reliability of COVID-19 tests as manufacturers work to improve devices that fail to ensure they meet the new standards. More specifically, reducing the number of false negative results helps to reduce onward infections, improving health and wellbeing outcomes; and reducing the number of false

[3] That is, the 55% reduction in programme costs offered to small and medium enterprises.

positive results, removes unnecessary constraints on socioeconomic engagement, improving productivity and wellbeing of test participants.

19. The policy will provide clear and comparable information on each tests performance through a publicly available register. This register will replace the current confusion consumers face when purchasing and the reliance on their own validation, if they have the means to do, with a more equitable marketplace. It will correct the information asymmetry between buyers and sellers and more the market from the effective caveat emptor to one of proper accountability and remedy.

20. Furthermore, improved test performance can be expected to improve consumer, confidence, and drive up participation in testing. reduce the number of false negative results and increase the number of true positive results, correctly identifying those carrying COVID-19, reducing onwards infections and improving wellbeing, long-term health, mortality and socioeconomic engagement.

21. In these ways the policy will address the underlying market failure and allow the private market to effectively contribute to reducing the serious public health risk posed by the COVID-19 pandemic.

Background and scope

22. Testing for COVID-19 has been at the heart of the government's response to the pandemic as the means not only to detect the virus in individual cases and provide appropriate public health intervention, but in aggregate to understand its prevalence and movement in the UK. The government has worked to pick the most appropriate and where possible the best performing tests for government-led testing. To do this the government has conducted extensive validation of the performance of these test products, namely the ability to detect positive and negative cases accurately as well as other critical requirements such as the biosafety of these products in a laboratory.

23. However, as this section will explain in more detail, COVID-19 test products available on the UK market have not historically been subject to these rigorous validation processes.

24. The government has chosen to address the problem under consideration by introducing legislation in 2 stages. This Impact Assessment builds on a previous iteration published on 20 July 2021. Since publishing the Impact Assessment, the government took steps to introduce legislation (on 28 July 2021), which introduced a mandatory requirement for antigen and molecular COVID-19 detection test products to undergo a 'desktop review' before being permitted for sale on the UK market. This next iteration of the Impact Assessment has been developed in advance of implementing a second stage of mandatory 'laboratory validation', which will introduce further scrutiny of COVID-19 test products, in addition to the 'desktop review' stage.

CE Marking

25. Validation by the government was necessary prior to July 2021 because entry into the market for COVID-19 test products was controlled by CE marking alone. CE marking is currently a self-declaration process for most of the COVID-19 test products on the UK market. The declaration of conformity made as a part of CE marking is not required to be independently verified ahead of such tests being placed on the market and there is no legally binding agreed process for establishing that performance. A COVID-19 detection test is a General IVD (In Vitro Diagnostic Devices) (self-certified) in accordance with regulation 40(1) of the Medical Devices Regulations 2002. This means that manufacturers can lawfully self-declare the conformity of their device with the relevant requirements and place that device on the market, without any audit or conformity assessment from a Notified Body. Such an assessment is required for self-test devices where the patient assess themselves, for example, the rapid lateral flow tests the UK Government currently provides free of charge.

26. This means that it is possible for manufacturers to game the CE marking system by creating a testing environment for their product which is conducive for demonstrating high performance of their products. For example, a manufacturer may

prove the performance of its product by testing on 20 samples from individuals that are displaying strong symptoms and are therefore more likely to produce a positive result and 80 samples from individuals that are not symptomatic and have not recently been exposed and are therefore more likely to (correctly) test negative. Another product applying the same evidence requirements may choose to use 150 positives samples from individuals from high to low infectiousness which will likely result in fewer positives being accurately detected and 250 negative samples to prove the performance of their product. This example demonstrates that under the CE marking system, and without additional regulation, there is inconsistency in the design and execution of performance evaluations.

27. This gives too much scope for manufacturers to design performance evaluations with more favourable conditions. The result of this is COVID-19 test products can make higher performance claims which do not accurately represent their true performance. This leads to inequity in the market and the inability for consumers to make informed decisions when purchasing a product on the UK market. The robustness and reliability of the claimed performance from the second data set will be greater than the first and less likely to be inaccurate when the product is used in the laboratory or in the field. Further to this, prior to introducing the legislation in July 2021, there was no minimum threshold for performance of a test product. This includes in terms of its ability to detect positives and negatives accurately. A key objective of the validation policy is to set a minimum standard of performance for COVID-19 test devices so that they can be evidenced, enhancing consumer confidence in testing and public health.

28. The validation work conducted for government procurement inclusive of supply for most of the NHS provision found that a significant number of tests failed to match their claimed performance and a number of these test products deviated significantly from their claimed performance. During the validation process to inform DHSC procurement of lateral flow tests, it was determined that 75% failed at one stage of the multistage process or more. Overall, 277 molecular and antigen tests have been reviewed by DHSC, of which only 58 have passed to the point where they could be considered of sufficient quality for procurement. Whilst the DHSC can procure the test products that it wants and control which products it uses, this data and expertise is not easily available to the public and institutions when they are looking to find the right test to use.

29. There is already some demand for and use of private sector supplied tests, such as in the media, creative industries, sport and travel sector. There is currently little guidance on which is the appropriate test product to use. Most of the current demand for testing in the UK has been thus far met by free government provision. However, we expect a growing role for the private sector, and it will be necessary for a robust and reliable market to ensure a continued supply of privately supplied high-quality tests exists as a critical means of preventing transmission of the virus.[4]

[4] Please see Annexe 12 for further details of a case study showing an internal international comparator study in relation to Canada.

30. Therefore, government intervention is required to legislate and enforce standards for the most used COVID-19 test products to ensure that if a member of the public gets a test on the NHS or in a private setting that test will be meet a consistent minimum standard. Our plan for the introduction of minimum performance standards, a centralised desktop and laboratory validation process to confirm tests meet these minimum standards, and the publishing of results transparently on GOV.UK, will be key to addressing the problems identified in the market.

31. This proposed approach is in line with other legislative interventions to improve product standards for the benefit of health and consumer confidence. Examples include the 'Bread and Flour Regulations 1998' to fortify bread flour with 4 key nutrients and the 'Products Containing Meat etc. (England) Regulations 2014' setting minimum standards for meat products and providing consumer confidence on the quality of products they are purchasing.

32. As highlighted by the National Institute for Health Research, 'an increased understanding of performance variability with existing diagnostics and standardization of performance test protocols will effectively increase accessibility to the most robust and accurate diagnostics solutions'.[5]

Rationale and evidence to justify the level of analysis used in the IA (proportionality approach)

Evidence gathered

33. In the first instance we have sought to use information already in the public domain to establish the impacts of the proposed legislation. Where there are no reliable sources available, we drew on DHSC's past experience of validating test devices for use in the national testing programme inclusive of mass community testing, ASC and NHS through the LVG and TVG, sought views from over 75 industry representatives through an extensive public consultation, direct engagement and subsequent call for evidence and commissioned bespoke research from the University of Cambridge, the University of Sussex, including specialised centres of excellence such as the UK Trade Observatory, and private sector consultancies specialising in this market. We have also examined the regulatory regimes in other countries to identify comparators. There are instances where our academic and private sector partners have felt unable to provide estimates. The reasons include stakeholders being uncomfortable with providing information due to commercial sensitivity, or even there simply not being a clear answer that can be provided. For example, many stakeholders were unwilling to provide estimates of likely profit margins in the market due to commercial sensitivities. As a result, our best estimate

[5] Oyewole, A. and others. 'COVID-19 Impact on Diagnostic Innovations: Emerging Trends and Implications' Diagnostics 2021, volume 11, page 182

is based on a relatively low volume (and in some cases high level) responses to our consultation or call for evidence.

Familiarisation and transition costs

34. Part of the commissioned research from the University of Cambridge and University of Sussex estimated the costs of meeting new UK regulation. This section of the research was carried out by a regulatory academic who used past precedent of a range of comparable regulations brought into this industry and the necessary steps manufacturers would undergo to familiarise and transition. More details of this are explained in the manufacturers' familiarisation and transition cost section of the IA.
35. It was also important to understand the familiarisation and transition costs of this regulation incurred by retailers. We asked the University of Cambridge and University of Sussex to estimate the costs of meeting new UK regulation for retailers too, though due to time constraints this fell outside of their scope. Therefore, we followed alternative routes through the call for evidence and consultation, where we received responses from industry that informed the stages of familiarisation and transition as well as the work time taken and the cost of this.

Programme costs

36. Programme costs were established by Lead Scientific Advisors from the NHS Test and Trace programme, now Testing Operations within UKHSA who had prior experience of running laboratories and validation programmes, including around what materials, staff, and equipment would be needed to provide the service combined with expected volumes.
37. The percentage of devices presenting for the validation programme is based upon those applying to the desktop review stage which came into force on 28 July 2021. We consider this to be the strongest indicator for this until we reach a steady state, post implementation.
38. Pass and failure rates for the validation programme are based upon TVG and LVG outcomes, which provide the closest comparable rates for this validation programme. We acknowledge TVG and LVG set different outcomes than will be considered for this validation programme and therefore make an adjustment to set a range, which is explained further in the annual programme costs section of this IA.
39. We engaged with manufacturers in the call for evidence on the life cycle of test devices. That is, the length of time before a change needs to be made to a test device. Several factors impact the life cycle of a test device including new variants of concern, new requirements from customers, as well as commercial considerations (for example, cost efficiencies and emerging markets). Of the stakeholders that quantified an estimate of the life cycle, all agreed that it is less than 5 years and the majority responded that it was between 1 and 3 years.

Profit loss

40. To understand the size of the private UK COVID-19 diagnostic market we obtained research from Orion Market Research[6] who initially forecasted the size of the market to 2026. We then acquired a bespoke extension to the forecast past 2026 until 2030 with Orion Market Research considering more market dynamics than our initial extrapolation had, improving the accuracy of our analysis.

41. We attempted extensively to engage with stakeholders to understand profit margins on test devices in this market through calls for evidence, consultations, and direct engagement. We also raised the question of profit margins within the remit of our market research, but our partners felt unable to comment. In total, 5 stakeholders were willing to share such commercially sensitive information. We acknowledge limitations to how representative this view is of the market overall, or sub-markets within it (for example the degree to which profit margins may differ depending on technology type and size of business). We believe a proportionate amount of resource has been spent on research and stakeholder engagement to answer this specific question throughout the IA process.

42. COVID-19 tests are currently provided in the UK for a range of use cases including both symptomatic and asymptomatic testing at no cost to users. The government plays a major role in the structure of the market, and the extent of their provision effects private firms' gross profit margins and the cost of tests to consumers. The Universal Testing Offer (UTO) has now been extended to December 2021, and whilst the UTO will continue to be reviewed, it has not been agreed if, when, or to what extent public provision would be scaled back. Having considered a range of possibilities for government support for testing, we consider the strongest assumption to be that the government will retain its current role (and so market structure and profit margins will remain as they currently are) for the duration of the pandemic. As a result, we cannot consider hypothetical scenarios of varying government provision on the structure of the market, gross profit margins and cost of tests to consumers. For this reason, the sensible course of action was to evaluate the future of the market assuming that government continues to play its current role throughout the evaluation period.

UK/Non-UK Business

43. To provide a reasonable estimate for the number of firms operating in the UK we commissioned more research from Orion Market Research on the volume of tests being produced by UK based firms compared with non-UK based firms. UK based firms represent 33% of the total volume of tests on the UK COVID-19 diagnostic market, with the remaining 67% taken up by non-UK based firms. Likewise, UK COVID-19 diagnostics market share by UK and non-UK based firm is 33% and 67% respectively. Orion Market

[6] This could be achieved at this stage in the policy's development by rolling back existing regulation. This could present costs to government in the refunding of fees and potentially other compensation. This hasn't been considered as part of this policy option.

Research classified a UK business as being headquartered in the UK and operating in the UK as UK-registered subsidiaries.

Education

44. We calculated the cost of the education campaign (including communications and stakeholder engagement activity) required to deliver the overarching policy objectives. The objectives of the campaign were to ensure manufacturers and retailers impacted by the legislation understand the requirements under the new legislation. This included preparing communications material and engaging with stakeholders through a series of roundtables. We sought the hours that officials in the Communications and Policy teams spent working on delivering this activity in preparation for the first Statutory Instrument and the cost per hour. Communications and Policy teams agreed that the education campaign for the second Statutory Instrument would involve the same communications package.

Enforcement

45. We consulted with the Medicines and Healthcare products Regulatory Agency (MHRA) who agreed that the regulation would cause an increase in enforcement spend on COVID-19 related investigation but were unable to break this down to target this specific regulation. Given this, we engaged with a Digital Intelligence and Investigations Consultant, an expert with extensive experience working on enforcement within Trading Standards, to understand the costs associated with enforcement activity. We also sought to understand whether there were any differences between enforcement for online versus high street retailers. Both sources confirmed that there would be no difference in the approach to online vs high street retailers which would impact the overall cost of enforcement, since a purchase and a site visit would likely still be conducted for a suspected breach from both an online or a high street retailer.

Areas of uncertainty

46. In addition to highlighting possible quantitative social impacts, we note qualitative impacts of unreliable tests on public and professional trust in COVID-19 testing results and compliance with self-isolation. Fully quantifying the test performance benefits of this proposed policy (for example, the quantitative social impacts of inadequate tests allowed to remain on the market) is problematic due to uncertainty of future pandemic parameters, hence modelling would be unlikely to deliver confidence around central predictions of the impact of this legislation. The complexity of the modelling that would be needed would also require resources beyond what is considered proportionate.

47. We do not consider there to be proportionate means by which to gather evidence that quantifies specific social impacts of poor test performance (for example, how users' behaviour will be affected when told their test may be or was incorrect) and the subsequent epidemiological impact of these – it is reasonable to expect distrust in test results to reduce both testing take-up and compliance with commensurate instructions

(that is, to self-isolate[7]), but the degree to which this is the case will be highly context-dependent, including on the general perception of testing quality, making the impact on the future spread of COVID-19 highly speculative.

48. While our expectation is that subsequent legislation will supersede this programme before it enters a second year, there is no end date specified in legislation itself. Therefore, in alignment with RPC appraisal period guidance, we cannot, at this point in time, justify moving away from the standard 10-year appraisal period.

49. Orion Market Research[8] forecasts the UK COVID-19 diagnostic market value until 2026. This IA uses this forecast and then extrapolates from 2026[9] to show 10-year business and market impacts with acknowledgement that these figures are highly speculative. The assumed lifecycle for a COVID-19 test is 1 to 3 years due to the risk that new COVID-19 variants and mutations render older tests obsolete or they are replaced by more innovative tests.

50. Stated (20%) gross profit margins for businesses producing COVID-19 tests have medium confidence. Despite evidence gathering discussed in paragraph 27, many organisations are not willing to provide such commercially sensitive information. We have directly engaged 12 stakeholders including manufacturers, government officials with experience of the sector and trade associations to seek information on profit margins, with relatively few being willing to respond to these specific questions. We also included a question on profit margins in both the consultation and call for evidence, with extremely limited response (with the majority of respondents citing commercial sensitivity as reasoning for providing no response).

51. We consider the approach we have taken to be proportionate to the impact of the legislation, which we anticipate being itself impacted within 12 months as the European Union (EU) moves to bring into force legislation requiring all COVID-19 testing products to go through a more stringent regulatory regime, including ongoing quality management. Whilst there is not a requirement to align with the EU process, manufacturers wishing to sell the same product in Europe will likely be applying this updated process and we have committed to reviewing the policy as this regulation develops.

[7] Rapid Research in COVID-19 Programme.
[8] Despite consistent decline between 2021 and 2026, we assume the market ceases to shrink from this point as it makes the analysis more conservative.
[9] Despite consistent decline between 2021 and 2026, we assume the market ceases to shrink from this point as it makes the analysis more conservative.

Description of options considered

Option 0: Do nothing

52. Manufacturers would continue to self-certify COVID-19 tests against CE standards. The problems of large differences between claimed and actual performance identified in government procurement would still persist because, as has been postulated by academics, the European framework for IVDs is weak in relation to technologies which are considered 'low risk', because it allows developers to independently self-certify that their SARS-CoV-2 diagnostics comply with the regulatory requirements (that is, self-award CE mark).[10] Risks around higher levels of false negatives and false positives to public health and local economies outlined in previous sections would remain, similarly risks around false positives to local economies remain.

53. The current information asymmetry and consumer confusion would persist, and would continue to benefits those bad actors in the market that seek to exploit this poor information held by many consumers. This is of particularly disadvantage to small and medium enterprises and other organisations which may wish to tests staff and customers but lack the resources to conduct their own validation.

    The consequences of the 'do nothing' option would mean continued, and potentially worsened, negative impact upon consumer confidence in testing. Since testing is a crucial part of the government's response to COVID-19, low consumer confidence in the performance of test products could reduce the volumes of testing undertaken. This could undermine interventions and actions taken to drive down levels of the virus, including non-pharmaceutical interventions which have proven to reduce the spread of the virus such as isolating following a positive test result.

    Ultimately, the 'do nothing option' would mean that government's options to combat the pandemic would be reduced, as testing through the private sector would not be sufficiently reliable.

Option 1: Legislate to introduce market standards for COVID-19 tests

54. This is the option that has been selected. On top of existing CE marking standards this introduces a mandatory requirement for validation. The validation process would offer independent assessment of the performance a product is capable of and minimise the cost of this assurance to government by charging for the assessment to maximise the recovery of programme costs. The results of this process would be published on a GOV.UK webpage to ensure that the data are accessible, comparable and

[10] Cruciani, Mario, 'COVID-19 Impact on Diagnostic Innovations: Emerging Trends and Implications' Diagnostics 2021, volume 11, page 182 (viewed 5 October 2021)

understandable to the lay person. This will address the information asymmetry in the market and should reduce consumer confusion over tests, empower them in purchasing decisions and improve faith in testing overall. This would enable test outcomes to be used to inform consumer behaviours whether tests are government-issued or not, helping to address the secondary objective of the policy around making selecting the right test an easier process. This option represents a balance between protecting public health through addressing a market failure and interference with the operation of the free market. As such it represents a proportionate intervention.

Option 2: Voluntary validation

55. A voluntary approach was initially considered where the same central validation programme would be created at a smaller scale with the same thresholds for performance for tests but on a purely voluntary basis[11]. This was discounted as it was assessed that there was insufficient incentive for manufacturers to apply to the process. A voluntary scheme would likely have lower uptake because the additional work and time required to achieve validation authorisation would be unattractive to businesses driven by profit and keen to get their product on the market and compete with other manufacturers that chose not to be as transparent in evidencing their performance.

56. As stated in earlier sections, it is expected that the findings of a validation exercise would show a small drop off in stated performance for test products compared with their claimed performance. Tests that did not subject themselves to a voluntary process would therefore be able to continue sell on the market and to claim their higher stated performance without independent contradiction. Manufacturers of poor-performing tests would also be highly unlikely to apply and pay for validation on a voluntary basis due to risks of failing the process and would therefore opt out of the process. To target the poor-performing tests, it was felt to be necessary to pursue a mandatory validation scheme.

57. This option would not address the market failure of consumers information asymmetry and leave the current costs and in balances in place. These costs would disproportionately have negative impacts the smaller the consumer is.

58. Voluntary incentives were considered in an original policy paper which included such methods as a communication campaign to the public and providers, stating that only tests which have been independently validated and published on GOV.UK are recommended for use. However, none of these incentives were deemed to outweigh the incentives for manufacturers choosing not to engage, as set out above. Therefore, this approach was not considered to be as effective as mandatory validation because tests could still be legally sold on the UK market without GOV.UK listing. It would continue to be difficult to obtain strong evidence of a breach of regulations. This is because there would be no

[11] This could be achieved at this stage in the policy's development by rolling back existing regulation. This could present costs to government in the refunding of fees and potentially other compensation. This hasn't been considered as part of this policy option.

alternative evidence to challenge their claimed performance.

59. It was also considered that manufacturers who had previously been unsuccessful for validating their product could apply (subject to a strong enough case) free of charge to the new Private Testing Validation Group (PTVG). However, a non-legislative approach would not bring the immediate results needed for the public need, whereas a strong mandatory validation regime was selected as meeting the immediate public health goals. This clear disincentive to apply with few concrete benefits meant a non-legislative approach was discounted.

60. Whilst validation for government procurement was voluntary, there was a clear benefit of a potentially significant government contract at the end which compelled manufacturers to comply.

61. A proxy for a voluntary process already existed before the legislation was made in July 2021. MHRA have published Target Product Profiles (TPPs) setting guidance on optimal and minimum performance and evidence requirements. The desktop review stage of the validation process, already in place, has shown that a significant number of manufacturers have undertaken minimal work to collect evidence on the performance of their device. The evidence initially provided in their applications has often fallen short of the requirements set out in the TPPs both in terms of quality of the evidence and the number of samples used to evidence that the device can detect the sample.

62. During the public consultation held in April to May 2021, we gathered some useful insights into general sentiment and feedback of the public and industry to the government's proposals to introduce mandatory validation for antigen and molecular COVID-19 tests.

    1. It was found that 78% of respondents agreed that COVID-19 detection tests should be validated beyond the verification and assurance provided for CE marking.
    2. Additionally, 73% of respondents to this question in the public consultation agreed that mandatory validation of tests prior to their entry on to the market is best approach given the need to establish confidence in them and to re-open the economy. A strong majority of 88% of respondents also agreed that a legally backed and enforceable UK wide regime is the best approach.
    3. Furthermore, 71% of respondents to this question also agreed that a mandatory validation process will not significantly reduce the supply of high quality COVID-19 detection tests.
    4. Finally, 79% of respondents to this question agreed that the proposed mandatory validation process set out in the consultation document will increase the safety of COVID-19 tests and reduce the risks presented by poor quality tests.

63. A mandatory approach, introducing minimum standards and requiring COVID-19 tests sold on the UK market to go through validation was assessed to be the only option where failure to apply and have a product scrutinised was not a 'better' option for manufacturers.

Option 3: third Party Conformity Assessment

64. This would require notified bodies to verify the manufacturers findings. It would align with wider reforms to the regulation of *in vitro* diagnostic devices currently being undertaken by the MHRA and DHSC.

65. It is common in many markets for private companies to provide independent verification of other companies products this is a common way to address the market failure of information asymmetry between consumers and sellers. The most commonly known such companies are the credit rating agencies that assess and rate the quality of financial products, the most notable of these companies are Standard and Poor, Finch and Moody's.

66. Such assessment involves a desktop review of the evidence provided by the good producing company by an employee of the assessor company.

67. In this approach, there would be no direct intervention to address the information asymmetry. As there would be requirement on the notified bodies undertaking the assessments to conduct their assessments to a single methodology. Even if choosing to do so there is no reason to assume consistency across multiple companies, in fact the opposite is more likely as companies would seek to innovate in their processes to provide a competitive advantage against other companies conducting assessments. Over time there may be some reduction in confusion as we would expect there to be fewer assessment companies than manufacturers this may allow for some limited comparison of products assessed by the same assessor company. As such the market failure would still exist in the short term when the public health risk is highest and would continue as part of the market even if in a potentially diminished state.

68. In conversations with existing notified bodies it was clear that they would need considerable time to transition to delivery conformity assessments for COVID-19 tests. Given the pressures of the pandemic this would likely mean they were not operational to well after the main public health risk had subsided.

69. Without proscribing large parts of how these companies conducted the assessments there was concern from scientific experts about achieving the quality and consistent of assessment required to meet the desired levels of rigour and to assure test sensitivity and specificity. Nor could any of the existing notified bodies provide a laboratory validation component currently, and new entrants would have even longer lead times to establish such a lab and obtain the samples required on the scale required.

70. UK Government considered and discounted such an option as being insufficiently rigorous to raise the quality of tests to the required minimum to address the public health risks quickly, nor address the market failure by producing clear and comparable public accessible data on all tests.

Option 4: Expansion of UTO to complete government control of the market

71. Government provided tests currently dominate the majority of the market via the Universal Testing Offer as well as provision to the NHS. It also constrains the growth of the private sector outside of specialised sectors. We know from engagement with one NI based retailer that the UTO undermined their attempts to sell Lateral Flow Devices (LFDs), to such an extent that after a relatively short period all stock was moved south to their operations in Ireland.

72. This makes it logical to consider rather than attempt to regulator the market the government moves to monopolise it, instead to address the public health risks during the pandemic.

73. Such an approach would involve government either free provision to all business and consumers or different prices charged to different entities or for different use cases. For example, Professional Sports like football may be charged a fee as they are for policing based on the scale of testing required. Another way such pricing could be differentiated is that free testing remains for individuals unless for the purpose of international travel when they would be expected to pay.

74. This approach, would give government complete control over the quality of tests available to all actors, complete control over pricing and complete control over the supply of tests. It would also remove all information asymmetry as consumers would no longer need to make decisions instead relying on government to do this from them.

75. This approach would save the cost of establishing a new validation regime instead relying solely on the ones already set up and operating as part of the government's large-scale procurement operation.

76. This approach would increase costs to government, as all testing activities currently undertaken privately would need to be funded by government. How much of these costs would be recouped through a pricing structure would depend on the exact approach taken.

77. As government is intending to draw down spending and transfer more responsibility to individuals this option has been discounted as an undue and overbearing interference into the operation of the free market and that it would not provide a more efficient distribution of goods than a regulated private market.

Implementation approaches to validation

78. In addition to regulation options, there have also been considerations of alternative approaches to validation, and these options remain under review until fully implemented. Since submitting the first IA, we have re-assessed the options and at this time, although we originally pursued option C, we have chosen to proceed with option B due to the issues that have emerged, as set out in more detail below.

Policy objective

79. The overarching objective is to ensure that any antigen or molecular test for COVID-19 in the UK, whether provided by the government, the NHS or by the private sector, meets a minimum standard of performance. This will ensure that people taking a test can rely on the result of that test being sufficiently accurate to inform their behaviour.

80. Key indicators of success will be:

- only the results of validated products being reported to UKHSA
- awareness of the thresholds and guidance amongst end users, manufacturers. and distributors
- engagement by test manufacturers with the validation process
- costs recovered from businesses as a result of applications versus cost of programme setup

81. In addition to this a sub-objective is to make it easier for those purchasing tests (for example, for commercial purposes or for employers to test their staff) to have confidence that the test they have chosen is not only good enough, but appropriate for the type of testing that they want to do. This will be achieved by publication of lists with the results of validation and through providing further guidance on what that test product should be used for.

82. Key indicators of success will be:

- increased take-up of testing products provided in the private market due to increased confidence in their quality and improved clarity of guidance
- key target stakeholders being aware the list exist
- minimal feedback from key stakeholders that continue to struggle to identify an appropriate test to use

83. Option A: publishing a methodology and standards to be conducted by accredited laboratories.

84. This option offers greater speed as it minimises the effort needed to procure, stand up and kit out a central laboratory. It would also allow manufacturers to work with a laboratory potentially nearer to their own facilities. However, the lack of oversight and control of the process; the lack of ability to guarantee capacity to test all products believed to be on the market; and difficulties in compiling the outcomes of each test product meant that this approach was unlikely to be able to achieve the 2 main policy goals.

85. Option B: use existing validation capacity and processes that are used for government procurement. (The chosen option)

86. This option again offers a quicker delivery timetable than option C and reduces issues with control over the quality of the process. However, the facilities and resources used were provided on a voluntary basis and as such, it was originally assessed that this option could not guarantee enough capacity to meet the potential demands of a mandatory validation programme. In addition, there were logistical challenges posed by the capacity of these laboratories to assess all the technology types in scope of the policy due to a lack of equipment and experience.

87. However, after the failure of option C we decided to pursue option B by formalising the relationships with those laboratories and providing them with more time to scale up capacity to the appropriate level.

88. Option C: Procure an independent laboratory group to conduct the validation work on behalf of DHSC, with review of findings by DHSC.

89. This option was originally selected because it allowed for sufficient control over the process; the final decision to sit with DHSC; minimised coordination costs between the Department and the laboratory group; and to guarantee that the laboratory have sufficient capacity and capability to complete the work on behalf of the department.

90. However, the public tender for a laboratory failed to produce a viable bidder which could meet the standards required for the validation activities. The principle negative impact here was in relation to the extra time taken to procure the laboratory to conduct the work which has meant a slower implementation of the policy and a delay to introducing legislation which mandates laboratory validation for antigen and molecular COVID-19 detection test products.

Summary and preferred option with description of implementation plan

91. The preferred legislative option (1) will involve 2 Statutory Instruments (SI) laid under the ‘Medicines and Medical Devices Act 2021’. Transitional arrangements will be necessary to help manage compliance for products already on the market by ensuring that the requirements come into force in stages.

92. The first SI (Statutory Instrument) came into force on the 28 July 2021. Manufacturers of tests currently on the market must have applied for validation by desktop review by 1 September 2021 and have passed this validation successfully by 31 October 2021 in order to continue selling their tests on the UK market. Those tests that fail or have not passed the desktop review validation assessment by this date will not be legal for sale in the UK from that point onwards.

93. The desktop review will allow time for feedback to applicants and re-application after adjustments where relevant. The second SI is intended to be laid in Winter 2021. This will build on the desktop review with additional laboratory based technical validations of the tests. Mandatory laboratory technical validation processed are expected to begin in Winter 2021 with outcome reporting following afterwards. There will again be a transition period, but the length of this second period is still undergoing policy consideration and will incorporate lessons learned from the experience of the transition for business under the desktop review stage.

94. The SIs will make it a mandatory requirement for the COVID-19 tests placed on the UK market to pass or be in the process of passing the validation process to ensure that their performance meets minimum standards. The testing and removal of inadequate tests combined with the official approval of adequate tests is expected to reinforce public confidence in quality of testing. This base confidence in the product at the heart of testing can then be leveraged by further government policies to encourage private testing and individual behaviour change on receipt of COVID-19 test results.

95. The validation process, including the second stage of laboratory validation is outlined in figure 1 below, which includes governance and oversight, communications and the potential for appeals and complaints to the process.

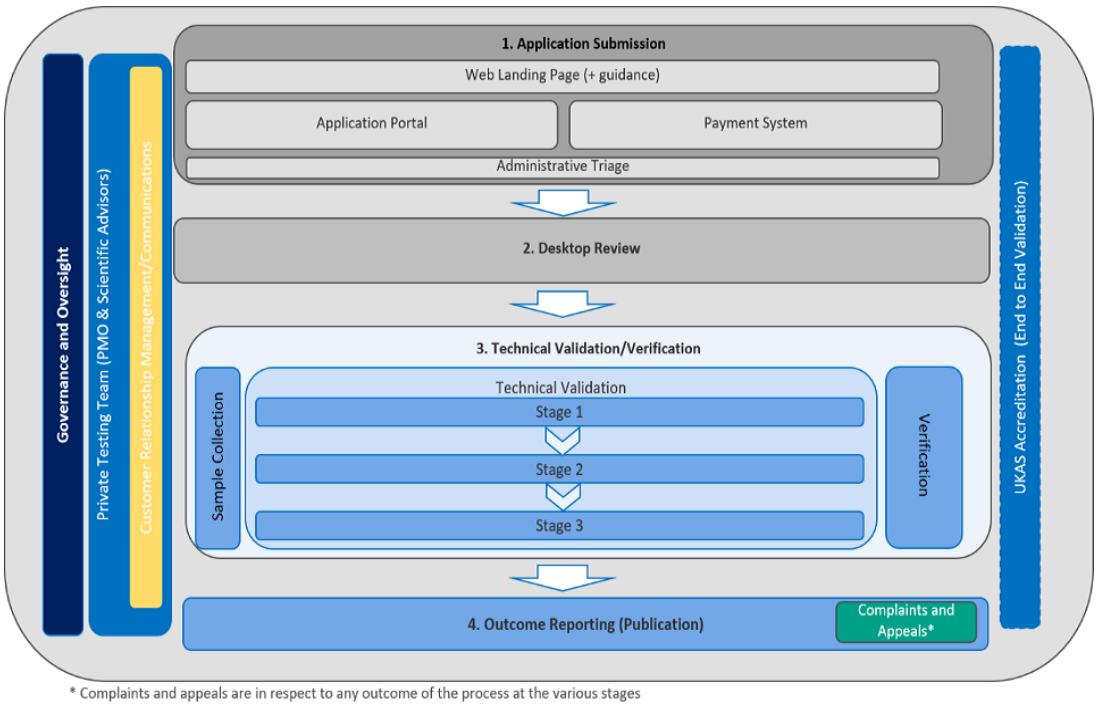

Figure 1. Overview of CTDA Desktop Review Process

Text version for Figure 1.

1. Application Submission

    1. Applicant must consult landing page and test device approvals guidance to begin application for COVID-19 test approval.
    2. Application portal to progress application.
    3. Payment system for approval.
    4. Submission is then triaged for administrative use. The information submitted will be reviewed to check for completeness and then passed to a scientific advisor who will undertake the initial assessment.

2. Desktop Review

    1. This review assesses the evidence a supplier submits against a minimum required data set.

3. Technical Validation and Verification

    1. The first stage of technical validation / verification is a review by a scientific advisor.
    2. Stage 2 of technical validation / verification involves the desktop review assurance group assessing the submission.
    3. Stage 3 of technical validation / verification is where the regulatory approvals committee then considers the submission.

4. Outcome Reporting

1. DHSC only publishes details of tests that have passed. Complaints and appeals can be used in respect to any outcome of the process at the various stages.

96. We recognise the need for time for the industry to comply with these extra requirements and therefore the obligation to have completed the stages of the validation process (application, desktop review, and following the second SI, laboratory review) was staggered for the first SI and a staggered approach will be taken for the second SI introducing laboratory validation.

97. UKHSA will be the statutory body responsible for the validation process on behalf of DHSC Secretary of State. The application submission and desktop review portions of the validation process will be managed by UKHSA. Technical validation services are intended to be contracted to a laboratory, though UKHSA retains responsibility for outcome reporting.

98. The stated approach is matched to an ambitious timescale to meet a programme critical path that coincides with the government's plans currently being implemented that reduces restrictions and strengthens the economy and need for a stronger private market to support international travel and allow those who wish to access tests to continue to do so if universal provision of free tests from the government for those without symptoms is scaled back.

Monetised and non-monetised costs and benefits of each option (including administrative burden)

99. There will be costs associated with familiarising, and transitioning into, this legislation for both manufacturers and retailers.

Manufacturer familiarisation and transition costs

100. To understand these costs for manufacturers, we obtained evidence from a regulatory academic as part of a commissioned report by the University of Cambridge and the University of Sussex. This used past precedent of a range of comparable regulations brought in and the necessary steps manufacturers would undergo to familiarise and transition.

101. For the desktop review, 3 key stages were identified for manufacturer familiarisation, including:

- preparation of a technical file according to requirements
- gap analysis of the technical file to check compliance with the essential requirements for safety and performance along with solution for non-conformities
- preparation of the performance evaluation report

102. For many companies, consultancy firms are used to assist with meeting these requirements. The cost of the consultancy will vary depending on the activity required by the manufacturer, but often range from £150 to 450 per hour[12] (or £1,200 to £3,600 per day). This variation reflects the skill set of the consultant required for the various technical documentation related activities. In general, consultancy fees for preparation of a technical file that complies with the regulation are usually lower, as this activity does not require the use of highly specialised consultants. However, to perform a comprehensive gap analysis or prepare a performance evaluation report requires a high level of expertise in regulation, the clinical aspects of the intended use, and the technology. This leads to fees that are at the higher end of the range described above. The following table provides an estimate of the costs based on fees charged by an established European regulatory consultancy firm.

    Non-wage uplifts have not been applied to these consultancy fees as they are already included in the price per hour of the consultancy firm.

[12] Fees from 2 established regulatory consultancies.

Breakdown of consultancy costs			
Consultancy activity	**Hours taken**	**Price per hour**	**Cost**
Desktop Validation:			
Preparation of the technical file according to the requirements	22.5	160	3,600
Gap analysis of the technical file to check compliance with the Essential Requirements for safety and performance along with solutions for non-conformities	30	373	11,200
Preparation/creation of the performance evaluation report	37.5	373	14,000
Sub-total	**90**		**28,800**
Laboratory Validation:			
Logistical costs of transporting of test kits to a UK-based laboratory	160	1,000	160,000
Engagement with government communications highlighting guidance or new regulations	160	1,000	160,000
Sub-total	**320**		**320,000**
Total	410		348,800

103. Those devices applying for validation will experience familiarisation costs of £28,800. Furthermore, if the device moves into the laboratory validation stage, manufacturers would also incur familiarisation costs for the laboratory validation including engagement with government communications and logistical costs of transporting test kits to a UK based laboratory. We have estimated these costs to be £320,000.

104. This estimate was informed by feedback from a small number of stakeholders through the call for evidence, despite best endeavours to engage with a variety of stakeholders through various means detailed in the ‘Evidence gathered’ section of the IA. We acknowledge this is not necessarily representative of the market as a whole, but given the resource spent on research and stakeholder engagement to answer this specific question throughout the IA process, we do not consider it proportionate to gather further evidence in this area.

105. Those devices applying for validation will experience familiarisation costs of £28,800. If the device moves into the laboratory validation stage, then the manufacturer will incur further familiarisation costs of £320,000.

Over the full validation programme, based upon the number of devices presenting for validation and those passing to the laboratory stage, aggregate familiarisation costs to manufacturers are estimated to be between £2.4m and £4.7m (£2.9m best estimate) in the first year only (See Annexe 4)

106. In terms of transition costs incurred by the manufacturer, these fall solely on the desktop review stage of the validation programme and surround addressing performance requirements. Prior to the desktop review, a manufacturer should have undertaken studies that will statistically and scientifically support claims on performance.

107. We obtained evidence from a regulatory academic as part of the commissioned report by the University of Cambridge and University of Sussex summarising fees charged by service providers for testing using clinical specimens to establish performance claims. Fees charged has been sought from a variety of sources, including a large US-based clinical research organisation (CRO), an EU-based provider of IVD testing services, and an Australian-based provider of IVD testing services. Each of the above has substantial experience in supporting the development of SARS-CoV-2 IVDs.

108. In consultation with scientific advisors we identified the most comparable performance evaluation requirements and made adjustments where necessary to arrive at the best estimate of fees manufacturers would pay to transition into the proposed regulation.

109. A total of 25% of devices met the data quality and quantity requirements of the desktop review stage which has already come into force. Therefore we treat these as not incurring this transition cost. The remaining 75% did not meet these requirements and therefore we treat these as incurring the cost to meet the additional evidence requirements.

110. Transition costs to manufacturers are estimated to be £6.8m in the first year only (See Annexe 5).

Retailer familiarisation and transition costs

111. A full breakdown of retailer familiarisation and transition costs is found in Annexes 6 to 7.

112. To calculate the number of retailers, these being the front-end providers who consumers approach in order to access testing services, which we believe to be in scope of the policy, we used the list of private providers who have self-declared against the government's minimum standards for general population testing, test to release and day 2 and day 8 testing (including their front-end providers), which captures the providers of Polymerase Chain Reaction (PCR) and Point of Care Testing tests that are based in the UK. As at 29th September 1,262 providers had been captured.

113. Retailers of LFD tests are not on the UKAS list and so we undertook desktop research to identify our best estimate of the total number of LFD retailers. We identified 41 retailers of LFD tests in the UK, both online and in-store with an online presence, who are selling rapid self-use antigen tests for consumers to purchase privately. Our assessment is that retailers should have fewer steps associated with familiarisation and transitioning to a new regulatory regime than manufacturers, with smaller costs.

114. Associated with the overall process as a result. Consultation feedback indicated that purchasing practices for retailers meant stock was only held for a short period before being distributed and sold, making the transition period a 'buffer' for retailers to turn over stock purchased prior to the announcement of new standards. Nevertheless, we obtained information from retailers in the market that highlighted areas of familiarisation with, and transition into, the new policy which would present a cost to business. Despite our best endeavours to engage with retailers, including reaching out to multiple retailers and trade associations, we received limited response on this area. We acknowledge this is not representative of the market as a whole, but given the resource spent on research and stakeholder engagement throughout the IA process, do not consider it proportionate or worthwhile to gather further evidence in this area.

115. Familiarisation costs to retailers in the desktop stage include assessing guidance documentation produced by the government, engaging with government communications to gain awareness of the regulation and receive further guidance, as well as developing and disseminating internal communications across the relevant areas of business to create a shared understanding. These stages of familiarisation were tested with industry who provided information on the hours taken and cost per hour to their business (excluding non-wage uplifts, for example, national insurance and pensions contributions).

116. These stages of familiarisation are duplicated for the laboratory stage of the validation programme.

117. We use the hours taken and hourly cost for each stage of familiarisation and apply non-wage labour cost uplifts of 18%.[13] Over both stages of the validation programme, based upon the number of retailers in scope for this policy, familiarisation costs to retailers are estimated to be £0.3m in the first year only.

118. Transition costs to retailers in the desktop stage include cross referencing their current test portfolio against the GOV.UK approved list and assessing stock depletion timelines and future procurement of COVID-19 test devices. These stages of transition were tested with industry who provided information on the hours taken and cost per hour to their business (excluding non-wage uplifts, for example, national insurance and pensions contributions).

[13] 'Hourly labour costs ranged from €5.4 to €43.5 across the EU Member States in 2018'. Eurostat. News release

119. These stages of transition are duplicated for the laboratory stage of the validation programme.

120. Using the hours taken and hourly cost for each stage of familiarisation and applying non-wage labour cost uplifts of 18%13. Over both stages of the validation programme, based upon the number of retailers in scope for this policy, transition costs to retailers is estimated to be £0.1m in the first year only. We will continue to engage with stakeholders as part of Monitoring and Evaluation and we will review familiarisation and transition costs according to their feedback. This will mitigate the effect of the limited engagement we have received so far.

Annual programme costs

121. The cost of the programme will be passed through directly to manufacturers applying for validation. This cost depends on the number of devices that require validation in a given period and is higher for devices that progress further through the validation process (that is, devices that progress to technical validation following desktop review).

122. A December 2020 review[14] into the size of the private testing market identified 496 devices in circulation that would be eligible for validation and had been introduced since the start of the pandemic, and a further 204 either still in development or awaiting CE marking. Extrapolating this figure to the present day gives a high-end estimate of 933 devices eligible for validation in the first year. In August 2021, we engaged experts in The UK Trade Observatory at Sussex University regarding this question and they confirmed that estimating the size of the market was 'unknowable'.

123. The report acquired from the University of Cambridge identifies 995 marketed molecular, antigen and antibody SARS-CoV-2 tests in the EU. It is not currently possible to differentiate from this the number of tests on the UK market currently operating within EU regulation. Therefore, the number of tests marketed in the EU gives a suitable indicator of the UK market. Of the 995 tests, two-thirds are antibody tests, leaving 329 marketed antigen and molecular tests in scope of this regulation.

124. The LVG and TVG validated around 15% of devices presenting for validation, but there are strong grounds to believe that more will pass the process being established under this legislation:

    a. The minimum thresholds for sensitivity and specificity set by the LVG for lateral flow devices (that is, the performance tested at technical review stage) were higher than the limits being considered under the CTDA legislation.

[14] This involved collating data from the National Institute for Health Research Information Observation (NIHRIO) and the Medicines and Healthcare products Regulatory Agency (MHRA).

125. As such, we consider only those products that were not removed for commercial reasons as the basis for our central/best estimate pass rate (21%). We use 'corner' assumptions about what outcome commercials would have seen (had they progressed through the process) to generate high and low assumptions.

    1. The highest possible pass rate assumes that all of the commercial exclusions would have passed both desktop and technical evaluations, giving a pass rate of 49%.
    2. The lowest possible pass rate assumes that all of the commercial exclusions fail either desktop or technical evaluations without affecting the balance between those 2 outcomes (that is, the share of commercial exclusions failing at desktop vs technical evaluation is the same as for other products that failed one of those 2 stages). This gives a pass rate of 14%.

126. This effectively sets aside the point above about a reduction in the thresholds for sensitivity and specificity: unfortunately there is no information from the TVG[5] processes on which to base an adjustment to reflect this. This biases upwards our fail rate estimates and our estimates of impacts on business.

127. Based upon data from the desktop review stage, which came into force on 28 July 2021, 146 test devices have presented for the validation programme. Of the 329 antigen and molecular test devices in circulation, this constitutes 44%.

128. Without there being a central register of test products that would meet the entry criteria, judgements had to be made about the number of products presenting for validation and the proportion progressing through each stage. Low, high and best estimates were used with direction from scientific and project delivery experts who have managed the applications of test products undergoing validation for government procurement.

129. Under the worst-case scenario, 44% of devices present for validation, 15% of which progress at desktop review and 15% of which are validated in the technical review. Under the best-case scenario, 44% of devices present for validation, 49% of which progress at desktop review, 49% of which are validated in the technical review.

130. We will assess data as part of Monitoring and Evaluation to ensure we review pass and failure rates.

131. To redress the tendency of appraisers to be overly optimistic, adjustments have been made to the programme costs. With limited precedent of this type of appraisal, we have used the upper bound for optimism bias estimates (41%) recommended for project outsourcing, detailed in table 4 of the Green Book supplementary guidance.[15]

132. Orion Market Research shows UK based firms represent 33% of the total volume of tests on the UK COVID-19 diagnostic market, with the remaining 67% taken up by non-UK

[15] Supplementary Green Book Guidance – Optimism Bias

based firms. Likewise, UK COVID-19 diagnostics market share by UK and non-UK based firm is 33% and 67% respectively. Orion Market Research classified a UK business as being headquartered in the UK and operating in the UK as UK-registered subsidiaries. On this basis, programme costs will be between £2.2m and £2.9m in year 1, with £2.4m the most likely estimate.

133. We engaged with manufacturers in the call for evidence on the lifecycle of test devices, that is, the length of time before a change needs to be made to a test device. Several factors impact the lifecycle of a test device including new variants of concern, new requirements from customers, as well as commercial considerations (for example, cost efficiencies and emerging markets). Stakeholders acknowledged the uncertainty of these factors, but provided evidence on the basis of which they were planning future business. Of the stakeholders that quantified an estimate of the lifecycle, all agreed that it is less than 5 years and the majority responded that it was between 1 and 3 years. Based upon this our analysis takes the lifespan of a testing kit to be 2 years (with 1 and 3 years being the worst and best cases respectively) implying 50% (100% to 33%) of devices will be replaced each year and so need to undergo validation again, giving programme costs in subsequent years between £1.0m and £2.2m, with £1.2m being the most likely estimate.

134. A full breakdown of programme costs can be found in Annexe 1.

135. The 10-year NPV (Net Present Value) for total programme costs is -£11.3m (-£10.1m to -£19.2m).

Annual loss of profits

136. Current regulations require tests obtain a CE marking to be sold on the UK market. For many tests, this is a self-declared standard that allows significant latitude for manufacturers to set the contexts in which their products meet those standards (for example of sensitivity and specificity). As such, even products that fail to uphold those standards in independent testing would be unlikely to lose their CE marking (presuming that if control of the testing context reverted to manufacturers, those claims would be demonstrated). Therefore, these products are compliant with the current legislative standard, and so any loss of profit arising from the introduction of a new standard constitutes a direct cost to business, both where products fail to meet that standard and where they are not presented for validation (the latter presumed to be a signal of a manufacturer's expectation that the product would not pass, were it presented). Any recovery of profits resulting from reinvestment in products, or the expansion of supply of products that do meet the new standard, is considered indirect (as is the cost of that reinvestment).

137. Manufacturers whose devices do not pass the validation process may:

- withdraw the product from the market, forsaking any profits they otherwise expected the product to attract.

- reinvest in the product in order for it to ‘pass’ validation – reinvestment costs and the resulting recovery of profits are indirect costs and benefits (respectively)

The TVG process identified reinvestment taking place in only a small minority (1.6%) of cases where products failed validation. Our best estimate assumes that the same proportion of ‘failing’ manufacturers will reinvest under these SIs, with a high (worst case) assumption of 10% and low (best case) of 0%.

138. While ostensibly a positive response, reinvestment is characterised in this analysis as representing a higher cost means to recovering otherwise lost profits than the expansion of supply of products that are successfully validated at the first attempt. Those manufacturers who do reinvest in products are assumed to commit 50% of expected profits on average. This follows from an assumption of rationality: reinvestment can be presumed to cost more than £0 and less than the total of expected profit recovery (since no manufacturer could be expected to commit more to recovery than they expected to gain from it) and so a reasonable expectation is that average reinvestment costs for those incurring them will fall halfway between these 2 limits (that is, 50% of expected profits).

139. As suggested above, demand for test kits left unmet by the withdrawal of products failing (or not presented for) validation is very likely to be fulfilled by the expansion of supply of products that do pass validation. The net result, rather than a complete loss of profit, will be a redirection of profit from manufacturers of lower-performing products to manufacturers of higher-performing products. This recovery of profit is an indirect benefit and is described under the benefits section of this IA.

Supply chain

140. There will also be implications for the supply chains associated with tests that are not presented for validation or fail the process. These impacts are difficult to quantify due to complex and globalised nature of diagnostics supply chains and the relationships between suppliers and manufacturers being widely variable. Diagnostics supply chains will also vary according to technology types (for example, PCR tests require additional steps to account for sample collection and processing often being separated by additional logistics as well as additional processing steps). In some cases, products could be withdrawn from the UK market but continue to be manufactured and sold elsewhere, whilst in others, the test could cease to be manufactured completely. There are a range of implications that could occur as a result, though these will be highly context specific to the manufacturer, situation and suppliers involved. This is particularly important to the NHS.

141. This complexity has suppressed consultation responses: those stakeholders who did engage were not able to present any real-world examples on which we could base an assessment of the scale or likelihood of these impacts, and when considering hypothetical scenarios, postulated a very wide range of highly nuanced outcomes. We will continue working with NHS officials to understand the impact and mitigate risks.

142. Given the significant complexity and difficulty in obtaining real-world examples of supply chain implications and the scale of analysis that would be needed to accurately monetise these impacts, we have taken the decision not to monetise this at this stage, but will address in our Monitoring and Evaluation what market impacts have arisen throughout the supply chain.

143. Analysis from Orion Market Research[16] values the UK's PCR and antigen COVID-19 diagnostic market at £3.7bn in 2021, falling year-on-year to £0.13bn in 2030. Annexe 1 details the forecasted annual market value from 2021 to 2030.

144. The development of a completely new suite of diagnostics in 2020 in line with their use during the pandemic has seen substantial growth in 2020 to 2021, however, assessments by Orion Market Research propose that is likely to decrease over time.

145. Their assessments are in line with current widely held assumptions on the impact of the pandemic declining over time, but COVID-19 remaining an endemic disease in the UK. This is likely to involve the overall prevalence and burden of disease caused by COVID-19 reducing over time due to an increasing protection from vaccinations and improved treatment options. This view that we cannot eliminate but will learn to live with COVID-19 is shared across government[17] and widely accepted within academic communities.[18] DHSC assumes that there will be an ongoing need for COVID-19 diagnostics, particularly for clinical settings, but that the current level of testing that is justified for a novel disease is unlikely to carry into the medium and long term. The growth we have seen in this sector will, in time, present opportunities for many companies to diversify into diagnostics for other conditions or diseases, but this is an area of significant uncertainty.

146. This policy covers all use cases in the market that are not covered by government exemptions. A growing role is expected for the private sector in the provision of COVID-19 testing during 2021 to 2022, subject to policy requirements. The opening up of international travel and the requirement for private tests on entry will see a significant increase in demand for private testing. Acknowledging this, the profit loss section of this IA considers the overall market to ensure the policy impact is not underestimated.

147. Advice submitted to DHSC's consultation suggested typical gross profit margins in the diagnostic market of around 20% (10% to 30%) detailed in Annexe 3.

148. We attempted extensive engagement with stakeholders on understanding the gross profit margins of test devices in this market through calls for evidence, consultations and less formal routes. Few were willing to share such commercially sensitive information, resulting in 5 stakeholder responses. We therefore acknowledge the limitations of this data set as not being completely representative of the market or the sub-markets within this, for example the degree to which profit margins may differ depending on technology type and size of business.

[16] 'UK COVID-19 Diagnostics Market: Analysis Report, Share, Trends and Overview 2021 to 2027', published 28 April 2021
[17] PM statement at coronavirus press conference: 14 June 2021
[18] Phillips, N. 'The coronavirus is here to stay — here's what that means' Nature, News Feature

149. Currently there is free public provision of COVID-19 tests in the UK for a range of use cases including both symptomatic and asymptomatic testing. The government plays a major role in the structure of the market, and the extent of their provision effects private firms' gross profit margins and the cost of tests to consumers. The Universal Testing Offer has been extended to December 2021, and whilst the UTO will continue to be reviewed, it has not been agreed if, when or to what extent public provision would be scaled back. As a result, we cannot consider hypothetical scenarios of varying government provision on the structure of the market, gross profit margins and cost of tests to consumers. For this reason, the sensible course of action was to consider the future based on current levels of government provision.

150. With UK business making up 33% of the UK COVID-19 private diagnostic market this gives annual profits of around £121m to £364m (£243m best estimate) in 2021, falling year-on-year to £4m to £12m (£8m best estimate) in 2030 as the market shrinks. Annexe 1 details the annual profits from 2021 to 2030 based upon Orion Market forecasted market value.

151. While our expectation is that subsequent legislation will supersede this programme before it enters a second year, there is no end date specified in legislation itself. Therefore, in alignment with RPC appraisal period guidance[13], we cannot, at this point in time, justify moving away from the standard 10-year appraisal period.

152. Taking the failure and withdrawal assumptions outlined in paragraph 137 gives profit losses of £95.0m to £340.4m (£219.2m best estimate) in 2021, falling year-on-year to £3.2m to £11.5m (£7.4m best estimate) in 2030. (See Annexe 8).

153. The 10-year NPV for profit losses is -£225.0m to -£806.2m (-£519.1m best estimate). (See Annexe 8)

154. With firms withdrawing from the market, it is also important to consider the impact on market power and supply of products.

155. The report by the University of Cambridge and University of Sussex provides insight into the impact of regulation on competition in the COVID-19 test device market. The report analyses 4 countries (USA, Canada, South Korea and Australia) who impose premarket authorisation. Though premarket authorisation was relaxed throughout the pandemic there remained elements of premarket control, providing a suitable comparison to the proposed regulation in the UK. The headline finding in this section of the report was that it is possible to impose a level of regulatory control and still support a significant degree of competition. Furthermore, the success of SMEs in navigating emergency use authorisations in these countries shows it is possible to impose regulatory control whilst allowing different sized firms to gain access to the market.

156. Taking an extremely conservative view of the number of devices presenting for validation and applying a worst-case 15% validation rate, there would still remain 10 products in the market. So, even in a worst-case scenario, the market would not be sufficiently concentrated to generate serious competition concerns. Therefore, we have no reason to believe consumers would face a rise in the price of private COVID-19 tests through concentrated market power.

157. The same report from the University of Cambridge and University of Sussex using case studies across 9 firms demonstrated the ease with which manufacturers were able to ramp up capacity during the pandemic and establish new production facilities, shift to 24-hour production, and navigate supply chain issues. Together Advice from industry suggesting that sunk costs represent a substantial part of the overall cost of test products, with marginal costs of producing kits themselves being very low; the expansion of one supplier's business to accommodate the contraction of another's is probable and could reduce average costs overall, even where the expanding business is delivering a higher quality product.

Price rise on consumers

158. Whilst not monetised in this IA, it is important to consider the impact on consumers of recovering the costs of the programme from business, where in particular validation costs may be passed on to consumers in the form of increased prices of tests.

159. It is unclear how far an increase in the price of tests might lead to a contraction in demand from consumers, and the degree to which this could be offset by an expansion relating to improved quality (and consumer confidence).

160. The extent of both these effects depends on how much of the programme cost (and the cost of any reinvestment) is passed on to consumers, as well as the price elasticity of demand for private COVID-19 tests.

161. We have made best endeavours to answer the question of who would bear the costs of regulatory compliance. We commissioned the University of Cambridge and University of Sussex to consider the question and they confirmed the question is unanswerable and likely to be extremely variable. We also asked stakeholders during the consultation and they corroborated that the answer is highly variable.

162. Therefore, onward impacts on the likelihood of breaking chains of transmission, prevalence, hospitalisations, deaths and restrictions are challenging to analyse.

163. Price rises will still place an additional burden on consumers, particularly those from lower socio-economic backgrounds where the private test market becomes disproportionately more unaffordable.

164. However, adding a worst-case £2.9m of programme costs into a market with £243m of profit (year 1) and assuming this is passed onto consumers suggests prices rise by around 1.2%.

165. Additionally, greater regulatory control via this policy could protect vulnerable people who may be less able to defend themselves from unscrupulous sellers, particularly if a low/high quality market emerges with no or little control.

166. In the absence of this proposed legislation it is likely there would be inequality in access to better performing tests on the private market.

167. An Equalities Impact Assessment has been conducted alongside this IA to capture distributional and equality impacts of the proposed policy.

168. We will assess market data as part of Monitoring and Evaluation to ensure we review whether this regulation does in fact change prices of tests on the private market.

Total costs

169. Across programme costs and profit loss, plus familiarisation and transition costs the direct policy NPV totals -£0.2bn to -£0.8bn (-£0.5 bn best estimate).

170. A full breakdown of NPV over 10 years can be found in Annexe 8.

Profit gain (indirect) benefit

171. Data from TVG suggests 2% of products enter the validation process a second time after being unsuccessful. It is anticipated that these cases will have reinvested in their product in order to meet validation requirements. There is no independent data on the amount that businesses will reinvest in their product. Further, stakeholders are unable to foresee the outcome of their product in the validation programme and therefore have not been able to provide a cost for this upon consultation.

172. This results in a situation where reinvesting firms recover lost profit at a cost of reinvestment. Demand for test kits left unmet by the withdrawal of products failing validation, or those not presented for validation, is very likely to be fulfilled by the expansion of supply of products that do pass validation. A report from the University of Cambridge using case studies across 9 firms demonstrated the ease with which manufacturers were able to ramp up capacity during the pandemic and establish new production facilities, shift to 24-hour production, and navigate supply chain issues. The net result, rather than a complete loss of profit, will be a redirection of profit from manufacturers of lower-performing products to manufacturers of higher-performing products.

173. Following RPC published guidance on direct and indirect impacts, this recovery of profit is considered as indirect so is included in Present Value calculations but not the Equivalent Annual Net Direct Cost to Business (EANDCB).

Performance benefits

174. The exclusion from the market of lower performing devices by definition improves average performance. Specifically, this will:

    1. Reduce the number of false positive results/increase the number of true negative results for individuals not carrying COVID-19 at the point of testing.
        1. By removing constraints on social/economic engagement (that is, removing the need to self-isolate), reducing false positives will increase the productivity and wellbeing of test participants.
        2. Reduces the likelihood of businesses closing unnecessarily.
        3. It will also reduce cost pressures on the test and trace system, and the need for contacts to self-isolate (therefore also improving their productivity and wellbeing).

    2. Reduce the number of false negative results/increase the number of true positive results for individuals who are carrying COVID-19 at the point of testing.
        1. By correctly identifying more individuals who are carrying COVID-19, this will reduce the spread of the virus through self-isolation and contact-tracing of carriers, which by reducing onward infections improves wellbeing, long-term health, mortality and social and economic participation through prevented onward infections.
        2. Improves public health
        3. protects vulnerable individuals by reducing the risk that their carers or visitors are unknowingly caring the virus.
        4. This will also marginally reduce the likelihood of future disruption to business resulting from high prevalence of the virus and marginally slow the emergence of new strains of the virus.

175. We acknowledge that the policy will not completely eliminate the possibility of false positives and false negatives arising from tests. There are a number of variables which may cause a false result, including human error during the test process particularly in relation to self-tests carried out by individuals without clinical training. However, we expect that validation will hold manufacturers to account in meeting higher performance standards, in addition to consumers having access to information which enables them to choose higher performing tests, which therefore ultimately will reduce the likelihood of false results.

176. While nascent models exist to describe the R-reduction implications of improved test performance, attempts to monetise these effects have so far been extremely limited and are highly dependent on input assumptions around factors like current virus prevalence and the demographics of the test participants. As such, we describe these effects in qualitative terms only.

177. In order to quantify (with a view to monetising) these effects we would need:

- a clear view of the distribution of standards of tests in use in a counterfactual world – we can reasonably expect to build a picture of tests presenting for validation through the implementation of the first SI, but have no access to this information at present
- an assessment in the resulting improvement in average sensitivity and specificity
- an assessment of the use cases in which each of those different types of tests is deployed, consumers' behavioural response particularly in terms of isolation, contact reporting and contact isolation
- assumptions about the future prevalence and infectiousness of dominant strains of COVID-19 and coverage and resistance imparted by vaccines (and consequent health implications for individuals who contract COVID-19)
- assumptions about the policy response in the counterfactual in
- access to a cost-benefit framework robustly to evaluate these impacts
- access to an epidemiological model to identify likely caseloads on the basis of those input assessments and assumptions

178. The construction of an epidemiological model is a months-long endeavour requiring the attention of teams of data scientists at costs beyond what is considered proportionate for this IA, and given uncertainty around the input assumptions (to which it would be highly sensitive) would be unlikely to deliver confidence around central predictions of the impact of this legislation. For this reason, we are also unable to consider the break-even point, at which the returns from this legislation could be expected to outweigh its costs.

179. Further qualitative benefits centre on overcoming information asymmetry and instilling public confidence in privately available tests and subsequent behaviours associated with this. No matter how a test is provided to an individual, through government-led or private provision, it is necessary that the public have (well-founded) confidence in the tests they are using.

180. During the consultation, we found that many stakeholders also commented on the benefits in making the market more equitable for manufacturers. That is by ensuring strong performing products were not undercut by lower performing products purporting high or equally high performance.

181. The benefits outlined here are contingent on the behaviour of individuals. Testing must be accompanied by the following of government guidelines, and with compliance with self-isolation requirements as measured by the ONS currently standing at 92%[19] it is not unreasonable to assume that this will remain high.

182. The lack of a mechanism to enforce minimum standards for testing products, or ensure that manufacturers' claims are delivered in live environments, risks undermining consumer confidence in COVID-19 tests and supressing use of the technology, either disengaging from social and economic activity or engaging on an 'at risk' basis. Poorer average test quality will result in more false negative results (increasing onward transmission and the

[19] Coronavirus and self-isolation after being in contact with a positive case in England

likelihood of future lockdowns and the emergence of new variants) and more false positive results (increasing unnecessary self-isolation).

183. We will assess data on test performance as part of Monitoring and Evaluation to capture the impact of this regulation on test standards.

Potential implications for innovation, non-UK business and trade

184. Despite growing domestic manufacturing capability, with new SME participants emerging throughout the UK, The UK still imports the majority of its tests by volume and the majority of the players currently in the UK market are foreign. The majority of tests imported to the UK appear to be done so by air freight with London Heathrow the most common point of landing. North American companies cited Liverpool, London Gateway and Belfast as entry ports for maritime freight, Companies whose goods arrived from Europe and Africa, and Asia cited Felixstowe and Dover primarily. The UK's 3 biggest import partners for tests were China, USA and Germany.

185. A key theme drawn from the public consultation was that respondents had concerns about the potential impacts upon innovation in COVID-19 diagnostics. However, the scope of the legislation intentionally covers existing mature technology (antigen and molecular detection tests), and therefore we have assessed that the risk that this regulation will present a barrier to innovation is limited. Wholly novel technologies that do not use these processes are not in scope of these regulations, though could use the Target Product Profiles as a baseline to align to. Taken together, we do not anticipate that these regulations serve as a significant barrier to innovative new COVID-19 test technology, improved tests using existing technologies or existing antibody tests which obtain CE marking and seek to enter the UK market.

186. The regulations have also been framed to provide clear standards for those wishing to innovate on or improve existing antigen and molecular detection technologies, ensuring current and future tests of these types are of high quality.

187. Orion Market Research provided data on the volume of tests being produced by UK based firms compared with non-UK based firms. UK based firms produce 33% of the total volume of tests on the UK COVID-19 diagnostic market, with the remaining 67% taken up by non-UK based firms. Likewise, UK COVID-19 diagnostics market share by UK and non-UK based firm is 33% and 67% respectively. Orion Market Research classified a UK business as being headquartered in the UK and operating in the UK as UK-registered subsidiaries.

188. Non-UK produced tests make-up the majority of the UK COVID-19 diagnostic market. The measures outlined in this IA will apply equally to both foreign and domestic

products/manufacturers, with no expectation of a disproportionate impact on either. The regulation would constitute a technical barrier to trade to non-UK based businesses. The World Trade Organisation and all members have been notified of these measures and the implications for international businesses. Facilitated by colleagues in the Department for International Trade we have engaged with the governments of USA, India and Canada regarding the regulations.

189. Non-UK business will face the same costs of the regulation as UK business, including already outlined familiarisation and transition costs, programme costs and profit loss. The evidence and calculations methodology behind these costs are the same as described in each relevant section of the IA, but across a larger proportion of the market. These costs are summarised below:

190. The familiarisation cost for non-UK manufacturers is £6.1m (£5.0m to £9.7m) in year 1 only.

191. The transition cost for non-UK manufacturers is £14.0m in year 1 only.

192. The 10 year NPV[24] programme costs for non-UK business is -£23.4m (-£20.9m to -£39.7m).

193. The 10 year NPV[24] profit loss for non-UK business is -£1.1bn (-£0.5bn to -£1.7bn).[20]

194. The 10 year NPV[24] total cost for non-UK business is -£1.1bn (-£0.5bn to -£1.7bn)[21]

195. Assessments of the importation of COVID-19 tests (or where not directly available Medical Devices and Clinical Consumables as a category that would include COVID-19 diagnostics) into the UK has shown that the majority of these devices will enter the UK via the channel ports for goods from the EU, or through air freight into England for goods from the Rest of the World. These represent the most common routes for these products given the timelines for delivery and their origin. We do not anticipate changes to these trade flows as a result of these regulations but will assess this as part of the monitoring and evaluation of these regulations.

196. To understand whether the proportion of tests imported to the UK is likely to change after the introduction of the regulation, the University of Cambridge and University of Sussex report turns to the question of whether the aforementioned Emergency Use Authorisation regimes impacted trade flows in other countries. Data offered only limited insights because multiple factors are in play, but there was a growth in imports in the EU and in the 4 EUA jurisdictions that were analysed. It would appear that in 2020 there was significant increases in imports across trade codes relevant to SARS-CoV-2 test kits for most jurisdictions. The limited growth in imports in South Korea is probably explained by the country's reliance on domestic firms. Here we see the challenge of interpretation: trade flows as measured by imports can be explained by strength of domestic supply, and/or the scale of testing within a country/region (relatively low in Australia), as well as by

[20] The 10-year NPV profit loss for non-UK business is -£1.07bn (-£0.47bn to -£1.67bn).
[21] The 10-year NPV total cost for non-UK business is -£1.12bn (-£0.51bn to -£1.73bn).

the impact of regulatory barriers. This makes it challenging to assess the impact this regulation may have on trade.

197. We will assess data on trade flows as part of Monitoring and Evaluation to understand any unanticipated impact on trade.

Enforcement

198. This legislation will use the existing enforcement mechanism for medical devices. In practice, this will involve a combination of intelligence-led enforcement by the MHRA, focused on the manufacturers of non-compliant test products, while work by Local Authority Trading Standards units will focus on retailers, and will ensure unvalidated tests are not on shop shelves. These enforcement processes will use existing regulatory powers and pathways already in place and will primarily focus on activities that involve non-compliant devices.

199. We consulted with the MHRA who agreed that the regulation would cause an increase in enforcement spend on COVID-19 related investigation but were unable to break this down to target this specific regulation. Given this, we engaged with a Digital Intelligence and Investigations consultant, an expert with extensive experience working on enforcement within Trading Standards, to understand the costs associated with enforcement activity. We also sought to understand whether there were any differences between enforcement for online vs high street retailers. Both sources confirmed that there would be no difference in the approach to online versus high street retailers which would impact the overall cost of enforcement, since a purchase and a site visit would likely still be conducted for a suspected breach from both an online or a high street retailer.

200. The Digital Intelligence and Investigations consultant set out the stages of an investigation which included initial triage, site visit, inspection, collating evidence, and legal engagement with the hours they would expect the relevant professional to spend on each activity. Applying the hourly wage of an investigator and a legal professional from the Annual Survey for Hours and Earnings plus a non-wage uplift of 18% we costed an average investigation at £475.

201. Based upon evidence from the enforcement organisations on the number of investigations that have been carried out in a year and adjusting this for subsequent years based upon the size of the market, the 10-year NPV[24] for enforcement costs is -£0.1m.

    There will be no costs to businesses in terms of preparing for investigations: in principle these only happen where there are instances of non-compliant or counterfeit devices are reported. Following feedback from MHRA, their assessment is that the risk of investigations involving companies with compliant devices and disruption to businesses as a result is very low (partly as a consequence of initial intelligence-gathering exercises by MHRA) with estimated associated activity likely to involve a small quantity of administration in the few instances (1%[22]) in which this may occur. The investigations they

[22] This figure relates to MHRA activities not relating to COVID-19 test devices; activities in relation to COVID-19 test devices have all been in relation to non-compliant devices.

have undertaken for COVID-19 tests have only involved non-compliant devices, with no disturbance to businesses with compliant devices on that basis.

We will assess data on MHRA investigations as part of Monitoring and Evaluation to keep under review whether any compliant business faces enforcement costs.

Education

202. Manufacturers and third parties will need educating about this policy as retailers will be liable if found selling tests that have not passed independent validation once the transition period ends in 2021.

203. We are contacting key stakeholders in advance to help disseminate knowledge of the policy and regulations across the system, as well as to gain support for the new policy. In addition, we are working closely with key stakeholders to ensure they support us privately but also make public comment to highlight the benefits of this new policy for consumers specifically.

204. As the secondary legislation is laid in the House, and throughout its passage, DHSC press office will produce a GOV.UK press notice to be issued to all national media alongside any potential Written Ministerial Statement or laying in the House of Commons Library. This will also include publication of the government's response to both consultations and new regulations on GOV.UK.

205. Alongside published products, DHSC communications officials will work with supportive consumer journalists and digital colleagues to ensure digital content is created to highlight the benefits of this to consumers who will want to understand which testing products have been validated. A full communications handling plan has been developed outlining handling in further detail, with a total cost of £15,098.

Direct costs and benefits to business calculations

206. As discussed above

Risks and assumptions

207. As discussed above

Impact on small and micro businesses

208. The policy intent is to impose a minimum floor for COVID-19 testing in order to maintain public confidence in tests and compliance with their role in government strategy to control the prevalence of COVID-19. Exemption of any size of manufacturer would undermine the policy objective and so has not been considered for SMBs. The Private COVID-19 Testing Validation Consultation which ran from 8 April 2021 to 5 May 2021 has provided feedback that has prompted consideration of a reduced charge for small and medium enterprises for the programme of work.

209. Analysis of the ONS' UK Business Workbook suggests that:

- 93% of businesses involved in the manufacture of basic pharmaceutical products are micro[23] or small[24] (76% and 17% respectively)
- 85% of businesses involved in the manufacture of pharmaceutical preparations are micro or small (68% and 16% respectively)
- 95% of businesses involved in the wholesale of pharmaceutical goods are micro or small (72% and 24% respectively)
- Across all 3 groups, 94% of businesses are micro or small (71% and 22% respectively)
- Across all businesses, 99% of businesses are micro or small (90% and 10% respectively)

210. On this basis, businesses affected by this legislation are 5% less likely to be SMBs than businesses overall. Further, SMBs affected are disproportionately likely to be micro than small.

211. During the public consultation, small and micro businesses and trade associations highlighted that a high fee could present a barrier for SMEs entering the market. For the purposes of the first stage (desktop validation) there is an adjustment in fees to account for the differential impact on small and micro businesses. Where a company meets the definition of a small or medium-sized enterprise (under 250 employees) this represents a reduction of 55% for the fees associated with this stage. At present the fee schedule for the second laboratory validation stage (to follow through an additional SI in Autumn 2021) has not been finalised, but will feature a similar proportional reduction (assumed also to be 55% for the purpose of this IA) for small or medium-sized enterprises.

212. In real terms, this reduces the per-product cost for both stages from £65,000 to £30,000. The response we have had from engagement with small and medium sized enterprise with regards to this pricing adjustment has been very positive in terms of mitigating any disproportionate impacts that the cost of validation could have on SMEs.

[23] 0 to 9 employees
[24] 10 to 99 employees

213. Taking an average number of products per business of one for SMEs and 3 for larger entities,[25] and assuming that employee numbers are commensurate with revenues, validation fees represent around 7% of 2021's revenues from COVID-19 test products[16] for a micro business, 0.6% of revenues for a small business and around 0.1% for a medium or large entity. The reduction in fees takes this down to 3.0% for micro businesses and 0.3% for small businesses, at a cost to government of around 46% of programme costs (NPV £29.4m over the appraisal period). Achieving parity between micro, small and other businesses would require a 98% to 74% subsidy of programme costs for micro/small businesses (respectively) at a cost to government of 77% of programme costs (NPV £49.3.3m).

UK internal market

214. Goods regulations such as those for *in vitro* diagnostic devices of which COVID-19 antigen and molecular tests are a subset are a reserved matter. We have recognised that these particular goods have a close connection to devolved matters around public health and have engaged closely with the devolved administrations.

215. In the initial period of operation, the regulatory regime will apply uniformly throughout all regions of the UK. There is no evidence of specific regional issues regarding supply of the COVID-19 tests or their market at this stage. Though differing approaches to public health policy may affect the demand for testing there is no evidence that such policies would negatively interact with this regulatory regime to give rise to any issues.

216. One medium term cause of variance is the different approaches to travel and events passes planned in Scotland and Wales.

217. In Wales the COVID Pass is not required for under 18s so the work has focussed on adults and considered vaccination levels at 80% and the number of large events that will take place over the next 2 months (football, rugby matches and large concerts). What is difficult to quantify is numbers that will use lateral flow tests to access nightclubs and will this result in extra demand.

218. In Wales the expectation is that around 80% will use vaccination status. Forecast is that it may create an additional demand of 156k of tests a week (2.5 million by end of December 2021) from pharmacies collect and direct. Welsh Government have seen an increase in demand in these channels but difficult to assess how much of this is COVID Pass related.

219. However the retention of PCR testing for returning travellers does mean their could be lower demand LFD from the travel sector. Though it could see a shift in Welsh travellers

[25] Based on consultation responses and market research.

returning via English airports rather than those in Wales for example flights going through Bristol Airport rather than Cardiff.

220. We will monitor the situation in partnership with the devolved administrations to ensure they can deliver their local policies, avoid supply issues and to manage any risks to the UK Internal Market.

221. In the longer term, divergence will occur with Northern Ireland under the current terms of the Ireland/Northern Ireland Protocol. As Northern Ireland remains within the EU acquis for goods, the new medical devices regulations will come into force in Northern Ireland next May. Northern Ireland will therefore need to follow this new EU regulatory regime which differs substantially from the current EU regime; the current EU regime is closely aligned with the UK regime prior to the implementation of the preferred policy option. However the new EU regime still relies on third party conformity assessment which is a less rigorous approach than that implemented through our amended regulations may result in more bad tests making it through to market.

222. Evidence to date doesn't suggest this presents a threat that companies would try to circumvent UK regulations by moving production to, or landing goods via, Northern Ireland. Interviews with academics, companies and other private sector stakeholders suggest the logistical costs of doing so would outweigh the potential savings of having to comply with a less rigorous regulatory regime, even for large companies well established in the Republic of Ireland.

223. The UK market in medical devices is highly integrated (including for COVID-19 tests) and the Northern Ireland market is dependent on supplies from England. Our research to date suggests that many companies focus on one country or regulatory regime. Those companies we have interviewed suggest that it would not be economical to seek 2 regulatory clearances for the sake of just accessing the small Northern Ireland Market. However, where companies have already sought access to another EU market such as France or Germany and thus gained the appropriate approvals this would likely become less of an issue. We recognised this presents a potential risk of supply constraint after the divergence. We are continuing to monitor this situation and will consider appropriate action, including reactivating the currently dormant medical devices Common Framework (which would include the Northern Ireland Executive as a party) to manage regulatory coherence.

Monitoring and evaluation

224. Introducing a regulatory regime is a strong intervention in the market, it is required to address the public health priority caused by the COVID-19 pandemic. We recognise the fast-paced approach to regulation we are taking is unique as is the underlining cause of this particular market failure. However, we also recognise that the market conditions and

the risks to public health may evolve rapidly. As such we intend to keep the regulatory regime under continuous review and engage with stakeholders to ensure its efficiency and effectiveness.

225. Although this regulatory regime is focused on COVID-19 related tests, COVID-19 will not be the last pandemic or other serious public health issue that requires rapid market intervention. As such it will be important to retain the learning from this regime's functioning to apply to future regimes.

226. To this end we have committed in the regulation itself to formally evaluate the regulatory regime set out in the first SI in a report published no later than 31 December 2022. This evaluation will then be published in a report for Parliament. Given any drastic change in the market should occur relatively quickly, the outcomes of the intervention should also become apparent more quickly. As such our current planning is to review in May 2022 particularly as we are aware international partners will be bringing in their own regulations at this time they will provide useful counterpoints to assess the effectiveness of our approach.

227. To assess the ex post costs and benefits of the policy in an evaluation, there are certain impacts we would want to monitor in order to be robust in this assessment. The main themes to this evaluation will be supply, test performance, affordability, wider impacts, enforcement and unintended consequences.

    1. Supply: to understand how the number of products in the market is impacted by the policy we will monitor the number of products applying for validation compared to what we expect. We will continue to engage with stakeholders, including NHS officials, to assess the impact upon supply, as well as engaging with stakeholders to review whether familiarisation and transition costs in this IA remain accurate. Furthermore, we will monitor the number of products passing and failing at each stage and for what reason, as well as the number that reapply.
    2. Test performance: to understand the impact on test performance we will compare the difference in performance of tests on the UK market before and after the policy comes into force. This will provide evidence to assess whether this regulation is effective in achieving the policy objective.
    3. Affordability: carrying out market research will allow us to better understand the impact of the policy on affordability by monitoring changes in unit cost of producing tests and any corresponding price rises on consumers.
    4. Wider impacts: engage with the both the upstream and downstream supply chain to recognise the impact of the policy on raw material providers, distributors and retailers. Additionally, compare the nationality of products in the market compared to our current assessment to understand the impact on trade flows.
    5. Enforcement: monitor the number of investigations carried out by MHRA and the outcome, to ensure we are not imposing unnecessary burden to compliant business.

6. Unintended consequences: we will also engage with stakeholders to understand any unintended consequences of the policy that haven't been anticipated in this impact assessment.
7. Public health: monitor the performance of devices that pass and devices that fail validation. It is reasonable to expect that this legislation will improve the average quality of test devices sold in the UK, by virtue of excluding lower performing devices from the market, but it will not be possible to quantify this without detailed knowledge of the performance and market share of devices that never present for validation or do not proceed beyond the desktop stage. We do not consider the cost of identifying and testing these products to be proportionate to the benefit of accurately evaluating the benefit of the removal of those products from the market. Beyond this, we can assert qualitatively that improvements in average test quality will result in the benefits described in paragraphs 18 and 19 [and critically will reduce the proportion of tests falsely suggesting that COVID-19 carriers are free from infection, and so will reduce the opportunity for onward infections] but any claim around average impacts will be highly sensitive to assumed average performance improvements and behavioural responses of individuals receiving test results. Given the dependency on assumptions around performance improvements, we do not consider it to be proportionate to estimate these with sufficient confidence to include in our evaluation.

228. The evaluation will be commissioned according to the principles described in The Magenta Book, ensuring impartiality and robustness.

Annexe 1: Programme costs (option 1)

Breakdown of programme costs			
	Low	**High**	**Best**
Tests in circulation	329	329	329
Apply for validation	146	146	146
Pass to technical	72.05731	21.77844	32.36779
Pass overall	71.53755	21.51454	32.009
Pass rate (Pass overall/Tests in circulation)	22%	7%	10%
Programme costs	£11.5m	£9.0m	£9.5m
Optimism bias	£4.7m	£3.7m	£3.9m
Total (year 1)	£16.2m	£12.6m	£13.4m
Per device	£111,000	£87,000	£91,000
Annual churn	33%	100%	50%
Total (year 2+)	£5.39m	£12.65m	£6.68m
Average annual cost	£6.47m	£12.65m	£7.34m
NPV	£57.20m	£108.85m	£64.14m
Government Mitigation	46%		
Cost to business	£8.8m	£6.8m	£7.2m
UK Market share %	33%		
2021	**£2.9m**	**£2.2m**	**£2.4m**
Each year from 2022 to 2030	£1.0m	£2.2m	£1.2m
Average annual	£1.1m	£2.2m	£1.3m
NPV	£10.1m	£19.2m	£11.3m

Annexe 2: Annual UK COVID-19 diagnostic market valuation, profits and loss of profits (option 1)

	Market Valuation (bn)	UK Based Profits (m)			UK Based Profit Loss (m)		
		Low	High	Best	Low	High	Best
2021	£3.7	£121	£364	£243	£95	£340	£219
2022	£2.2	£73	£218	£146	£57	£204	£131
2023	£1.4	£45	£134	£89	£35	£125	£80
2024	£0.8	£24	£73	£49	£19	£69	£44
2025	£0.4	£13	£39	£26	£10	£37	£24
2026	£0.2	£7	£20	£13	£5	£18	£12
2027	£0.2	£6	£17	£12	£5	£16	£10
2028	£0.2	£5	£16	£10	£4	£15	£9
2029	£0.1	£5	£14	£9	£4	£13	£8
2030	£0.1	£4	£12	£8	£3	£11	£7
Average annual		£30	£91	£60	£24	£85	£55
NPV		£288	£863	£575	£225	£806	£519

Annexe 3: Stakeholder feedback on profit margins in the UK COVID-19 Diagnostic Market (anonymised due to commercial sensitivity)

Profit margins in the UK COVID-19 Diagnostic Market	
Stakeholder	**Gross Profit Margin (%)**
1	20
2	20
3	30+
4	10 to 25
5	11

Annexe 4: Manufacturers familiarisation costs

			Familiarisation Costs					
			Best		High		Low	
Desktop Validation	Tests applying for validation			146		146		146
	Total familiarisation per test			£28,800		£28,800		£28,800
Laboratory Validation		Tests in circulation	329		329		329	
		Pass overall	32		22		72	
		Pass rate (Pass overall / Tests in circulation)	9.73%		6.54%		21.74%	
	Tests in lab review (Tests applying for validation x Pass rate)			15		10		32
	Total familiarisation per test			£320,000		£320,000		£320,000
UK Market Volume %				32.6%		32.6%		32.6%
Total Costs (Desktop + Lab validation) x UK Market %				**£2.9m**		**£2.4m**		**£4.7m**

Annexe 5: Manufacturers transition costs

			Transition Costs					
			Best		High		Low	
	Tests applying for validation			146		146		146
		Cost of addressing performance requirements	£190,000		£190,000		£190,000	
		Need to pay for performance requirements	75%		75%		75%	
Desktop Validation	Total transition cost per test			£142,500		£142,500		£142,500
		Tests in circulation	329		329		329	
		Pass overall	32		22		72	
		Pass rate (Pass overall / Tests in circulation)	9.73%		6.54%		21.74%	
Laboratory Validation	Tests applying for validation (Tests applying for validation x Pass rate)			15		10		32
	Total transition cost per test			£0		£0		£0
UK Market Volume %				32.6%		32.6%		32.6%
Total Costs (Desktop + Lab validation) x UK Market %				**£6.8m**		**£6.8m**		**£6.8m**

Annexe 6: Retailers familiarisation costs

Type of Validation	Activity	Familiarisation Costs	
		Best=High=Low	
	Desktop Exercise	41	
	UKAS	1,262	
	Retailers in scope		1,303
Desktop Validation	Total familiarisation per test		134
	Desktop Exercise	41	
	UKAS	1,262	
Laboratory Validation	Retailers in scope		1,303
	Total familiarisation per test		£122
Total Costs (Desktop + Lab validation)			**£0.3m**

Annexe 7: Retailers transition costs

Type of Validation	Activity	Hours Taken and Price Per Hour	Transition Costs			
			Best=High=Low			
Desktop Validation	Desktop Exercise				41	
	UKAS				1,262	
	Retailers in scope					1,303
		Hours taken	5			
		Price per hour	10 x £1.22			
	Cross reference current test portfolio against GOV.UK list			£61		
		Hours taken	1			
		Price per hour	10 x £1.22			
	Assess stock depletion timelines and future procurement			£12		
	Total transition cost per test					£73
Laboratory Validation	Desktop Exercise				41	
	UKAS				1,262	
	Retailers in scope					1,303
		Hours taken	1			
		Price per hour	10 x £1.22			
	Cross reference current test portfolio against GOV.UK list			£12		
		Hours taken	2			
		Price per hour	10 x £1.22			
	Assess stock depletion timelines and future procurement			£24		

Type of Validation	Activity	Hours Taken and Price Per Hour	Transition Costs			
			Best=High=Low			
	Total transition cost per test					£37
Total Costs (Desktop + Lab validation)*UK Market %						**£0.1m**

Annexe 8: NPV over the 10 years

	Direct cost to business																				
	Manufacturers												Retailers						Total costs		
	Loss of profits			Programme costs			Familiarisation Costs			Transition Costs			Familiarisation Costs			Transition Costs					
	Low	High	Best	Low	High	Best	Low	High	Best	Low	High	Best	Low	High	Best	Low	High	Best	Low	High	Best
2021	£95.0m	£340.4m	£219.2m	£2.9m	£2.2m	£2.4m	£4.7m	£2.4m	£2.9m	£6.8m	£6.8m	£6.8m	£0.3m	£0.3m	£0.3m	£0.1m	£0.1m	£0.1m	£109.9m	£352.4m	£231.8m
2022	£56.9m	£204.0m	£131.4m	£1.0m	£2.2m	£1.2m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£57.9m	£206.3m	£132.6m
2023	£34.9m	£124.9m	£80.4m	£1.0m	£2.2m	£1.2m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£35.8m	£127.1m	£81.6m
2024	£19.2m	£68.7m	£44.2m	£1.0m	£2.2m	£1.2m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£20.1m	£70.9m	£45.4m
2025	£10.2m	£36.7m	£23.6m	£1.0m	£2.2m	£1.2m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£11.2m	£38.9m	£24.8m
2026	£5.1m	£18.2m	£11.7m	£1.0m	£2.2m	£1.2m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£6.0m	£20.5m	£12.9m
2027	£4.5m	£16.3m	£10.5m	£1.0m	£2.2m	£1.2m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£5.5m	£18.5m	£11.7m
2028	£4.0m	£14.5m	£9.3m	£1.0m	£2.2m	£1.2m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£5.0m	£16.7m	£10.5m
2029	£3.6m	£12.9m	£8.3m	£1.0m	£2.2m	£1.2m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£4.6m	£15.2m	£9.5m
2030	£3.2m	£11.5m	£7.4m	£1.0m	£2.2m	£1.2m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£4.2m	£13.7m	£8.6m
Average annual	£23.7m	£84.8m	£54.6m	£1.1m	£2.2m	£1.3m	£0.5m	£0.2m	£0.3m	£0.7m	£0.7m	£0.7m	£0.03m	£0.03m	£0.03m	£0.01m	£0.01m	£0.01m	£26.0m	£88.0m	£56.9m
NPV	£225.0m	£806.2m	£519.1m	£10.1m	£19.2m	£11.3m	£4.7m	£2.4m	£2.9m	£6.8m	£6.8m	£6.8m	£0.3m	£0.3m	£0.3m	£0.1m	£0.1m	£0.1m	£247.2m	£835.2m	£540.7m

Annexe 9: Full list of evidence gathered and stakeholder engagement activity

1. Known DHSC models for programme costs given testing demand.
2. Publicly available data from the national technical validation process for manufacturers of COVID-19 tests.
3. Orion Market Research[16] on the UK COVID-19 diagnostic market.
4. Data and evidence gathered from interviews with suppliers and manufacturers of COVID-19 tests on the costs, transition and familiarisation costs, supply chain impacts and profit margins of different test types. In particular, several Small and Micro Businesses.
5. Discussions with experts, trade bodies and officials across UK Government and the devolved administrations.
6. Commissioned research from research consultancy Efficio UK to understand UK trade flows.
7. Data on the importation of COVID-19 Tests to the UK from UK Trade Info (HMRC data).
8. University of Cambridge and University of Sussex research commissioned by DHSC in August 2021 on the COVID-19 testing market.
9. Public consultations:
    - on the validation policy (including 43 respondents including large and small manufacturers, chemists, retailers, trade associations, professional bodies, local authorities, universities and individual experts) between May to June 2021
    - on the laboratory validation policy live between 2 to 30 September 2021
10. Call for evidence, live on GOV.UK between 19 August and 16 September. Questions focussed on gathering evidence on a number of areas, including but not limited to:
    - familiarisation and transition costs
    - insights on industry business planning assumptions for the future
    - profit margins
    - size and volume of the UK COVID-19 market
    - the life cycle of a COVID-19 test product
11. Five roundtables with over 75 industry stakeholders, including academics, manufacturers, retailers, consumer groups and distributors held between April and September 2021.
12. Interviews with stakeholders: we reached out to over 30 external stakeholders and held interviews with manufacturers (including Small and Medium Enterprises and Small and Micro Businesses), retailers, trade associations and enforcement agencies.
13. Questionnaire of retailers conducted by a retail trade association.
14. Examination and comparison with other countries regulatory regimes.
15. Oyewole, A. and others. 'COVID-19 Impact on Diagnostic Innovations: Emerging Trends and Implications' Diagnostics 2021, 11, page 182.

Annexe 10: Policy research paper on Canada’s approach to regulating COVID-19 detection tests

Background

The coronavirus (COVID-19) pandemic has created an unprecedented demand on Canada's health care system and has led to an urgent need for access to health products. As of February 17, 2021, the number of confirmed cases in Canada has exceeded 800,000.

From the outset, the COVID-19 pandemic created global supply chain challenges. Shortages of health products are a growing global problem with particular implications for smaller markets like Canada.

Approximately 83% of drug manufacturing activity is conducted outside of Canada and roughly 68% of drugs in final dosage form are imported. As well, imports account for nearly 75% of Canada’s medical device market.

Many of these imports are from single suppliers, making Canada particularly vulnerable to unforeseen events that disrupt manufacturing and distribution.

The COVID-19 pandemic has made this situation worse. It has disrupted supply chains and caused an increase in demand for certain health products used to prevent, treat and manage COVID-19.

‘COVID-19 medical device’ means a medical device that is manufactured, sold or represented for use in relation to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Medical devices play an important role in diagnosing, treating, mitigating or preventing COVID-19.

Since March 2020, Health Canada has responded to over 400 medical device shortage reports received as of February 17, 2021. Health Canada was made aware of only 27 medical device shortages from 2015 to February 2020. At that time, there were no mandatory requirements to report medical device shortages in Canada.

Interim Orders

An Interim Order (IO) is one of the fastest mechanisms available to the federal government to help make health products available to address larger-scale public health emergencies.

As part of Health Canada's efforts to prevent and alleviate shortages of key products, they have been expediting access to medical devices through the Interim Order Respecting the Prevention and Alleviation of Shortages of Drugs in Relation to COVID-19. This permitted the exceptional importation of specified health products that may not fully meet Canadian regulatory requirements, but are manufactured to comparable standards, to help alleviate a shortage.

As of March 1, 2021, IO No. 2 replaces IO 1, allowing the Department to continue to issue expedited authorizations for the sale or import of medical devices to deal with the current significant risk of COVID-19 to the health and safety of Canadians.

The second IO maintains the flexibilities and regulatory oversight of the first IO until at least fall 2021 so that devices can continue to be sold and imported into Canada. Both IOs cover medical devices such as: testing devices.

Importantly, an authorization under IO No. 2 will be granted only if Health Canada determines that there is an urgent public health need for the importation or sale of the COVID-19 medical device.

As of February 17, 2021, 265 medical devices were permitted for exceptional importation and sale under this IO.

Health Canada intends to maintain the flexibilities and regulatory oversight provided by the IO until at least the fall of 2021.

Health Canada also intend to bring forward regulatory amendments that would allow many of the flexibilities under the IOs to continue after the fall of 2021.

Expedited Review

The IO provides an expedited authorization pathway for:

- new COVID-19 medical devices that are not yet licensed in Canada
- COVID-19 related uses for existing devices licensed under the 'Medical Devices Regulations' or IO No. 2 and
- COVID-19 medical devices that leverage an authorization of a device from a trusted foreign regulatory authority, whereby the Minister would maintain the ability to request additional information on a case-by-case basis

One of Health Canada's stated priorities is to review diagnostic tests using nucleic acid technology. This helped to increase the number of testing devices available in Canada to diagnose active and early-stage infections of COVID-19.

Canada are also reviewing and authorizing serological tests that detect previous exposure to COVID-19. In May 2020, Canada authorized the first serological testing device to help improve our understanding of the immune status of people infected and provided guidance on serological tests.

Health Canada continue to collaborate with the Public Health Agency of Canada's National Microbiology Laboratory (NML) and with provincial public health and laboratory partners as they:

- review and engage in their own studies of serological technologies
- develop tests
- assess commercial tests

When making regulatory decisions, the Canadian Government considers the data provided by the NML and provincial public health and laboratory partners.

This expedited authorization for sale or import does not apply to medical device licences which are currently suspended on the grounds of safety or effectiveness concerns. It is not intended to permit sale or import of previously licensed medical devices with identified safety or effectiveness concerns.

How are they regulated?

One of Health Canada's roles is to regulate and authorize health products that 'improve and maintain the health and well-being of Canadians'. To that end, only testing devices authorized by Health Canada can be imported or sold in Canada.

As part of the Canadian Government's broad response to the pandemic, Health Canada introduced regulatory measures. These measures aimed to expedite the regulatory review of COVID-19 health testing devices without compromising safety, efficacy and quality standards.

Unauthorized tests may not produce accurate results, leading to potential misdiagnosis. Health Canada's regulatory system aims to corroborate that authorized COVID-19 tests are well supported by evidence, indicating they will provide accurate and reliable results.

The COVID-19 pandemic has created an unprecedented demand for medical devices. New mechanisms are in place to enable expedited access to medical devices, including 2 IOs signed by the Minister of Health. These IOs:

- speed up the review of these medical devices
- allow certain medical devices that may not fully meet regulatory requirements to be imported and sold in Canada
- enable timely scientific review of submissions for medical devices
- leverage authorization of trusted regulators, such as the United States Food and Drink Administration (FDA)

In Canada, medical devices are classified into 1 of 4 classes. Class I represents the lowest risk and Class IV the highest. To determine the appropriate classification for their device, manufacturers are encouraged to refer to the classification rules for medical devices in the 'Medical Devices Regulations'.

The following are examples of COVID-19 medical devices that fit within each class.

1. Class I: masks, respirators, gowns, face shields.
2. Class II: infrared thermometers, gloves, personal protective equipment (PPE) decontamination devices, syringes.
3. Class III: ventilators.
4. Class IV: SARS-CoV-2 testing devices.

Medical Device Establishment Licence

IO No. 2 introduces new requirements for importers and distributors of COVID-19 medical devices to hold a Medical Device Establishment Licence (MDEL)

Health Canada have expedited the review and issuance of thousands of MDELs. These have been issued for companies asking to manufacture (Class I), import or distribute medical devices in relation to COVID-19 that meet similar high quality and manufacturing standards as Canadian-approved devices.

In general, any person who imports into or sells a COVID-19 medical device authorized under this IO for human use in Canada requires an MDEL.

List of authorized testing devices

The list of authorized testing devices includes testing devices authorized under 'Interim Order No. 1 for importing and selling medical devices for COVID-19' (March 18, 2020, to March 1, 2021) and devices authorized under 'Interim Order No. 2 for importing and selling medical devices for COVID-19' (enacted March 1, 2021).

The performance of authorized COVID-19 testing devices has not been assessed in people who are vaccinated against COVID-19. However, Health Canada does not expect intramuscular COVID-19 vaccinations to interfere with the performance of authorized nucleic-acid or antigen-based testing devices.

Tests that identify antibodies to the spike protein of the SARS-CoV-2 virus, however, will be unable to distinguish between people who have been infected and those who are vaccinated.

Manufacturers of authorized tests will be asked to change their product labelling to reflect the impacts of vaccination on the performance of COVID-19 testing devices.

Testing devices for COVID-19 contains more information on the types testing devices that Health Canada is authorizing. There is information on nucleic acid-based and serological testing devices, as well as guidance on the requirements for applications for serological testing devices.

Health Canada maintains the list of medical devices for exceptional importation and sale, and will update it as required.

Table 1.1: List of authorised testing devices	
Number of authorised testing devices	
Device Type	**Number authorized**
Authorized testing devices intended for point-of-care use (often referred to as rapid tests)	20
Self-testing devices	1
Antigen Testing Devices	12
Nucleic Acid Testing Devices (often referred to as PCR)	44
Serological Testing Devices	22
Total number of authorized COVID-19 testing devices	78
Notes: The total number of authorized COVID-19 testing device applications is updated every day at 5:00pm. At 11 August 2021, 228 applications had been made. Point-of-care testing devices (rapid tests) and Self-testing devices totals include antigen, nucleic acid (PCR) and serological testing devices.	

1. Lab-based tests are conducted in a lab environment by a trained laboratory technician.
2. Point-of-care testing devices are used by an approved operator (often a health care professional) in a near-patient environment.
3. Self-testing devices are those that can be purchased and used by the general public.

Access to testing devices for COVID-19

Early diagnosis is critical to slowing and reducing the spread of COVID-19 in Canada. Health Canada regulates the sale and import of medical devices, including commercial testing devices related to COVID-19.

As part of the government's broad response to the pandemic, Health Canada introduced a number of agile regulatory measures to expedite the regulatory review of COVID-19 health products without compromising safety, efficacy and quality standards.

Only testing devices authorized by Health Canada can be imported or sold in Canada. Unauthorized tests may not produce accurate results. This can lead to potential misdiagnosis. Health Canada confirms that authorized COVID-19 tests are well supported by evidence that indicates they will provide accurate and reliable results.

Any testing devices that were first authorized under IO No. 1 are deemed as authorized under IO No. 2.

COVID-19 ‘for research use only’

Labelling a product ‘For Research Use Only’ applies only to a medical device in the research phase of development. A commercial medical device is not considered to be in the ‘research phase’ of development if it:

- has validated performance characteristics
- has instructions-for-use documents citing performance claims or
- is under review for regulatory approval by Health Canada (or another regulatory jurisdiction)

During the course of scientific evaluation, Health Canada considers exceptions:

- for the purposes of validating use of the test in a lab environment prior to procurement and/or
- as a direct result of a request we make for samples

In these cases, the device can be imported and distributed to the public health laboratory using ‘For Research Use Only’ labelling.

Oversight of lab-developed tests

Health Canada doesn't regulate lab-developed tests. These tests are different from commercial lab tests. The labs create lab-developed tests themselves. Manufacturers make commercial tests and then sell them to public and private labs to use.

Provinces and territories are responsible for the delivery and administration of health care services, including public and private lab-developed tests. They can develop their own sample collection and testing methods for COVID-19. They are responsible for ensuring that these tests provide accurate and reliable results, which includes making sure that both the tests and collection methods are safe and effective.

Lab-developed testing is how all initial diagnostic testing for COVID-19 in Canada was accomplished. Canada's NML developed a nucleic acid-based testing method and then validated that the test would produce reliable and accurate results.

Lab-developed nucleic-acid tests make use of machines (called thermocyclers) that are commercially available. Health Canada doesn't regulate the use of those machines in lab-developed tests. Labs that use these machines for diagnosis are responsible for validating their results in accordance with the requirements of their jurisdiction.

Types of testing devices for COVID-19

Most submissions to Health Canada are for 3 types of commercial testing devices.

1. Nucleic acid-based testing
2. Antigen-based testing
3. Serology-based testing

Health Canada doesn't regulate who can collect a sample from a patient. Provinces and territories are responsible for delivering and administering health care services, including the collection of samples from patients.

In the case of a lab-based or point-of-care test, Health Canada receives evidence showing that the test performs adequately after an appropriate sample has been collected. We generally do not assess the process involved in collecting samples.

This also applies to point-of-care devices that are authorized for use by trained operators. In such instances, Health Canada has not necessarily received evidence that a trained operator can collect the sample.

Health Canada does not assess the collection of nose or throat swabs by individuals other than trained health care professionals.

Each testing device must indicate in the instructions for use the type(s) of sample collection that can be used with the device. Manufacturers must provide evidence in their submission to demonstrate the device can provide accurate results with the specified sample collection method(s).

Similarly, the instructions for use must indicate the intended user (for example, lab staff, health care professional, general public), which also determines the intended settings (for example, lab, doctor's office, pharmacy, bedside, home).

List of applications under evaluation

Health Canada publishes a list of applications for testing devices that are currently under evaluation. This list provides information on the products that have been submitted to Health Canada for authorization. These applications for testing devices are complete and ready for scientific review. The applicant has agreed they can be made public.

Being on the list of applications does not guarantee that Health Canada will authorize a product.

Details of an application are only discussed with an authorized representative of the applicant.

How to get authorization

Health Canada is open to reviewing all testing device submissions and encourages applications for innovative testing technologies, prioritizing the review of:

- tests that can be used at point of care to provide rapid diagnostic or monitoring results, including nucleic acid-based and antigen-based tests
- saliva tests (tests that use spit as the sample instead of a sample from the nose or throat)

Other technologies that are a priority include:

- point-of-care antigen tests that do not use only nasopharyngeal (NP) swab samples, or may be used in asymptomatic people or may be administered by trained operators
- point-of-care molecular tests that do not use only NP swab samples, or may be used in asymptomatic people or may be administered by trained operators
- tests designed to address emerging variants
- novel diagnostic technologies that may use alternative samples, such as breath, or a different analytical approach

Manufacturers are required to submit an application to Health Canada for the purpose of obtaining authorization to sell or import a COVID-19 medical device under the Interim Order No. 2 for importing and selling medical devices related to COVID-19. This is the most

effective pathway for manufacturers wanting to apply for authorization for COVID-19 test devices. As part of the application, manufacturers are required to explain the safety, effectiveness and quality of their medical device.

Active authorizations issued under IO No. 1 are deemed as active authorizations under IO No. 2 without any action required from the manufacturer.

A device that meets the definition of a COVID-19 medical device as defined in IO No. 2, must clearly indicate its use in relation to the SARS-CoV-2 virus, including the active role the device plays in the diagnosis, treatment, mitigation or prevention of COVID-19, the disease caused by the virus.

Health Canada are waiving the fees for these applications.

To submit an application for authorization, follow these 4 steps.

1. Review the guidance document on how to apply for medical devices for use in relation to COVID-19, under the IO.
2. If you are submitting an application for one of the following test-related devices, make sure to review the specific information provided for each of these devices:
   - nucleic acid testing
   - antigen testing
   - serological testing
   - test swabs
3. Prepare your submission package. Each submission must include enough information, including relevant data and device labelling, so that Health Canada can authorize the device. Applicants should provide direct evidence or scientific justification if appropriate. Scientific justification could include scientific articles on the performance of an applicant's device or highly similar device by trained operators, or in sample asymptomatic populations.
4. Submit your application to the Medical Devices Directorate at hc.devicelicensing-homologationinstruments.sc@canada.ca.

Administrative and regulatory screening stage

Health Canada validates the application for administrative completeness and to examine the regulatory information within the application.

Within 15 days of submission, Health Canada will either ask for more information or indicate the application is complete.

If Health Canada considers the application is complete, the application passes to the review stage.

Review stage

Health Canada does a scientific assessment of the application 40 calendar days from acceptance of a complete application.

Independent scientific evaluation

Health Canada may ask the NML to conduct an independent scientific evaluation of some COVID-19 testing devices to support decision-making. The evaluations will include an assessment of the sensitivity and specificity of the testing devices. The results of these evaluations will be shared with Health Canada to support decision making. The manufacturer is notified if its testing device is referred to the NML.

The evaluation by Public Health Agency of Canada's National Microbiology Laboratory (PHAC-NML) provides independent information to:

- support pre-market review
- confirm or refute manufacturer claims
- support decision making for devices already on the market

The devices referred to PHAC-NML for scientific evaluation by Health Canada include test devices with potentially good performance (such as data to support good sensitivity or specificity) and:

- that are fundamentally different from others in its class
- from manufacturers that are new to the Canadian regulatory environment for medical devices
- from manufacturers that provided sufficient but limited information to support an authorization or licence

PHAC-NML may also evaluate testing devices requested by manufacturers on a case-by-case basis provided that it has the capacity as well as the scientific and public health mandate to do so. PHAC-NML will provide the results of these evaluations to:

- the manufacturer
- Health Canada, to help make licensing and post-market regulatory decisions

The manufacturer is still obligated to provide Health Canada with enough information about the quality, safety and effectiveness of the testing device to determine whether to authorize or license the device.

Fees related to the submission of an application for a COVID-19 medical device authorization

To remove impediments for manufacturers in this time of public health need, Health Canada waives all application fees for COVID-19 medical device authorizations

Quality Management System requirements related to the submission of an application for a COVID-19 medical device

To remove impediments for manufacturers in this time of urgent public health need, Health Canada does not require manufacturers to provide a Medical Device Single Audit Program (MDSAP) certificate with their application for a COVID-19 medical device subject to IO No. 2.

Manufacturers will be required to share information to demonstrate that their products are of consistent quality and effectiveness. This can be demonstrated by either providing a copy of the manufacturer's Quality Management System certificate to ISO 13485:2016, or by submitting evidence of Good Manufacturing Practices and its proper implementation.

Submitting an amendment

Section 6 of IO No. 2 states that no person can import or sell a COVID-19 medical device if there are significant differences in the device from that which was initially submitted to Health Canada for approval under either io No. 1 or IO No. 2, unless the Minister has issued an amended authorization.

The onus is on the authorization holder (the manufacturer) to identify and communicate these significant differences to Health Canada. A summary of the changes, compared to that which was initially approved, must be submitted by the authorization holder to Health Canada

Application

1. The name of the device.
2. The class of the device.
3. The identifier of the device, including the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or medical device group family.
4. The name and address of the manufacturer as it appears on the device label.
5. the address where the device is manufactured, if different from the one referred to in Step 4.
6. The diagnosis, treatment, mitigation or prevention for which the device is required.

7. The known information in relation to the quality, safety and effectiveness of the device.
8. The directions for use, unless directions are not required, for the device to be used safely and effectively.
9. An attestation by the applicant that documented procedures are in place in respect of distribution records, complaint handling, incident reporting and recalls.
10. A copy of the label of the device.

Class III and IV devices

An application in respect of a Class III or IV COVID-19 medical device must contain, in addition to the information and material referred to in subsection (1), the following:

1. A description of the materials used in the manufacture and packaging of the device.
2. A list of the countries, other than Canada, where the device has been sold, the total number of units sold in those countries and a summary of any reported problems with the device and any recalls of the device in those countries.

Labelling

A person must not import or sell a COVID-19 medical device unless the device has a label that sets out the following information.

1. The name of the device.
2. The name and address of the manufacturer.
3. The identifier of the device, including the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or device group family.
4. In the case of a Class III or IV device, the control number.
5. If the contents are not readily apparent, an indication of what the package contains, expressed in terms appropriate to the device, such as the size, net weight, length, volume or number of units.
6. An indication that the device is sterile, if the manufacturer intends the device to be sold in a sterile condition.
7. The expiry date of the device, if the device has one, to be determined by the manufacturer on the basis of the component that has the shortest projected useful life.
8. Unless self-evident to the intended user, the medical conditions, purposes and uses for which the device is manufactured, sold or represented, as well as the performance specifications of the device if those specifications are necessary for proper use.
9. The directions for use, unless directions are not required, for the device to be used safely and effectively.
10. Any special storage conditions applicable to the device.

Expanded use

Part 1 of the Regulations does not apply to the importation or sale of a medical device or a COVID-19 medical device that is set out in column 1 of the 'List of Medical Devices for Expanded Use' [published by the Government of Canada on its website, as amended from time to time] for the expanded use set out in column 2 if the following conditions are met.

1. The Minister determines that there is an urgent public health need for the expanded use of the medical device or the COVID-19 medical device.
2. The Minister has evidence to support the conclusion that the benefits associated with the expanded use outweigh the risks, having regard to the uncertainties relating to the benefits and risks and the urgent public health need.
3. The Minister determines that the health or safety of patients, users or other persons will not be unduly affected.

Manufacturing/production

Documented procedures and work instructions for:

- all manufacturing activities
- all in-process inspections and tests
- maintaining traceability, including results of tests and inspections and environmental conditions as necessary (for example, preparation of Device Master Record (DMR))
- identification of product status (for example, in-process, under review, nonconforming, released, among others)
- final review of production records and final product release;
- identification and calibration of test equipment, fixtures, jigs, among others
- inventory control
- service and installation activities (as required) and
- handling, storage, and distribution including record keeping

Corrective actions and post-market activities

Documented procedures and work instructions (as appropriate) for:

- identification, analysis, and monitoring or data sources to identify nonconformities or potential nonconformities
- handling/disposition of in-process nonconformities (for example, Material Review Board (MRB), Out of Spec (OOS) procedure, among others)
- receiving, evaluating, and investigating feedback (that is, complaints handling)
- detecting, evaluating, and investigating nonconformities

- corrections and actions to prevent the recurrence of nonconformities including verification of effectiveness
- reporting adverse events to Health Canada (that is, mandatory problem reporting) and
- conducting and reporting advisory notices, corrections, and removals to Health Canada (that is, recall procedures)

Quality, safety and effectiveness information

4(1)(g) of the IO requires that the applicant provide the known information in relation to the quality, safety and effectiveness of the device. To clarify the type of information that should be submitted, the following non-exhaustive list is provided as a guide to inform a submission. The Minister, under section 9 of the IO, may request any additional information, if the information provided is deemed insufficient to render a decision whether to grant an authorization under this IO.

1. A clear description of the device, including how it works, any accessories to be used with it, and diagrams/photos of the device.
2. A copy of the manufacturer's Quality Manufacturing System Certificate, evidence of Good Manufacturing Practices, or other.
3. A discussion of whether any components are manufactured using additive manufacturing (3D printing, laser sintering, bioprinting, among others).
4. If this device is manufactured from or incorporates animal or human tissue or their derivative, evidence of biological safety of the device.
5. A summary of any mechanical/bench testing data performed for the device.
6. A summary of any animal testing and clinical investigations carried out with the device.
7. A summary of any biocompatibility testing performed with the device (if applicable).
8. A summary of the evidence of shelf-life and packaging validation testing (if applicable)
9. A summary of electrical safety and electromagnetic compatibility (EMC) testing (if applicable).
10. If the device is intended to be used at point of care or sold directly to a consumer, marketing materials for the device.
11. If the device is intended to be sold in a sterile condition, a description of the sterilization method and a summary of sterilization validation testing performed.
12. A list of applicable standards used in the design/manufacture of the device.
13. Incidents with a discussion of each event and response from the manufacturer.
14. A comparison table outlining technological differences between this device and predecessors that are or were licensed in Canada (if applicable).
15. A comparison table outlining technological differences between the proposed COVID-19 medical device and any available (authorized) comparators, to the applicant's knowledge.
16. If the COVID-19 medical device is, or includes software, a discussion of the software validation testing performed.
17. If the COVID-19 medical device is, or includes an *in vitro* diagnostic device, analytical validation studies including but not limited to:
    - specimen validation testing

- sample preparation validation
- the limit of detection, when applicable
- inclusivity
- cross reactivity (in silico analysis and cross reactivity testing)
- preliminary precision results, if applicable
- stability of samples
- preliminary reagent stability and
- clinical validity studies

Technologies that are not prioritized for review

To ensure that the number and types of authorized testing technologies is aligned with the public health need, Health Canada has been prioritizing certain tests. Given the number of tests already authorized, as well as current public health needs, the following testing technologies are now considered to be of less priority:

- lab-based molecular tests that do not use saliva samples or otherwise offer new or unique advantages
- point-of-care antigen or molecular tests that use only NP swab samples
- lab-based and point-of-care serology tests

Enforcement

Health Canada actively monitors the post-market safety and effectiveness of health products related to COVID-19 through:

- proactively monitoring major online retailers to identify authorized/unauthorized products making false and misleading COVID-19 claims
- managing risk communications for COVID-19 public advisories, information updates, health care professional communications and shortages
- taking a proactive approach to identifying false and misleading ads for health products related to COVID-19
- taking part in international discussions on the real-world safety and effectiveness of COVID-19 treatments

Enforcement of IO No. 2 takes place through inspection, compliance promotion, monitoring and verification. Health Canada will continue to conduct compliance promotion sessions with regulated parties to increase their understanding of their new obligations and to minimize non-compliance.

Health Canada inspectors verify that the MDEL holder has the ability to conduct rapid, effective recalls of problematic devices when necessary.

Health Canada is conducting remote assessments of MDEL holders who import, distribute or manufacture COVID-related devices. Immediate suspensions of MDELs will occur when establishments do not respond to Health Canada inspectors, or are unable to produce procedures pertaining to recalls, distribution records, or complaint handling.

Health Canada has a number of enforcement powers available to address non-compliance with the 'Food and Drugs Act' or an issue of public health and safety. Actions that could be taken against regulated parties violating the terms of the IO include:

- requesting a plan for corrective measures
- issuing public advisories or other forms of communication
- suspending or cancelling of the regulated party's establishment licence or product licence

Any decision must align with the compliance and enforcement policy framework and the compliance and enforcement policy for health products (POL-0001).

Industry engagement

Domestic

As part of the Canadian Government's measures to regulate COVID-19 tests, a whole-of-government approach, has been established with a range of organizations and stakeholders. These include other government departments, including the Public Health Agency of Canada, as well as provinces and territories, international partners, companies and health care professionals.

1. Connecting companies with government decision makers who play important roles in delivering health products to Canadians.
2. Share information with provincial/territorial health partners about regulatory guidance.
3. Continue to engage and share information with health system partners, such as health technology assessment agencies, to support efficiencies and alignment.
4. Inform health professional networks of activities and seek their perspectives on health care system priorities and challenges.
5. Maintaining a centralized COVID-19 website with relevant information for industry and health professionals.

International

The Canadian Government's international engagement on this issue comprises discussing, collaborating and leveraging resources on issues related to:

- clinical trials and investigational testing
- drug and medical device market authorizations

- health product risk assessments
- potential drug and medical device shortages

This is to ensure that health products are effective and quickly available to Canadians. The Canadian Government also regularly engages with international medical device regulators to exchange best practices and published guidance on regulatory pathways for medical device authorization.

1. International Coalition for Medicines Regulatory Authorities as an executive committee member and playing a leadership role in helping to align policy approaches and regulatory agility in response to the COVID-19 pandemic.
2. World Health Organization's research and development (R and D) blueprint vaccines plan to develop a COVID-19 vaccine.
3. Pan American Health Organization as a member of its COVID-19 task group.

Consultations

Health Canada received comments on IO No. 1 through ongoing discussions with stakeholders, industry conferences and 2 focused stakeholder engagement sessions on June 4, 2020, and September 3, 2020. These comments were generally supportive. Stakeholders understood the need to continue the frameworks and authorities put in place through IO No. 1. The department sought to accommodate stakeholder feedback on IO No. 2 where possible.

In January and February 2021, Health Canada consulted on IO No. 2 with a range of stakeholders, including:

- health stakeholders
- the pharmacy community
- manufacturers and importers of foods for a special dietary purpose, and foods for a special dietary purpose health stakeholders
- medical device licence (MDL) holders
- MDEL holders
- industry associations representing drug market authorization holders
- industry associations representing manufacturers and importers of biocides

Sessions focused on how IO No. 2 differs from IO No. 1 and how the authorities will be used in the future.

Health Canada also accepted written comments from stakeholders between January 22, 2021, and February 11, 2021. Stakeholders were largely supportive of IO No. 2 and the proposed changes from IO No.1.

In general, stakeholders indicated that the tools in IO No. 2 were effective in helping to address shortages. They did not raise significant concerns.

Private sector uptake

1. A total of 92 applications are currently under evaluation week beginning 9 August 2021.
2. A total of 52 manufacturers have already had tests authorised, 44 of which are overseas.
3. The majority of manufacturers are from the United States – 22.
4. Two authorised manufacturers are from Great Britain.
5. The average amount of testing devices Health Canada authorises per month is 5.
6. As of February 17, 2021, 265 medical devices overall were permitted for exceptional importation and sale under the interim orders.

Annexe 11: Research paper on Ireland's COVID-19 testing regulatory regime

Introduction

This paper will look at the testing regime in the Republic of Ireland, looking especially at the regime for travel alongside looking at the role of the private market within the Republic of Ireland (ROI) Sources for the document fall largely on internet resources and the Irish Health Service website.

Travel regulations (last updated 25 September 2021)

Travelling to Ireland

1. Travellers must have appropriate valid proof of vaccination or recovery, or to present evidence of a negative Reverse Transcriptase Polymerase Chain Reaction (RT-PCR) result from a test taken within 72 hours prior to arrival into the country.

2. Ireland is now a part of the EU Digital COVID Certificate for travel originating within the EU/EEA. The Digital COVID Certificate will make it easier to travel to and from these countries and will be accepted as proof of vaccination, recovery or negative test.

3. A relevant EU Digital COVID Certificate based on vaccination, recovery or a negative RT-PCR test constitutes valid proof.

4. Non RT-PCR tests are not accepted when travelling to Ireland and passengers with a Digital COVID Certificate based on a non RT-PCR test (for example, antigen tests) require proof of an additional negative RT-PCR test taken no more than 72 hours before arrival.

5. In situations where a person is required to present evidence of a negative/'not detected' RT-PCR test prior to travel, and is unable to do so due to persistently positive RT-PCR test after recovery, then a positive RT-PCR result will be acceptable which was taken no less than 11 days and no more than 180 days prior to arrival to the State.

Proof of vaccination

A non-Digital COVID Certificate proof of vaccination means a record or evidence in written or electronic form in English or Irish or an official translation into Irish or English which contains the following:

- confirmation that the person to whom the record or evidence refers is a vaccinated person
- the date or dates on which the person was vaccinated
- the body in the state concerned implementing the vaccination programme (howsoever described) on behalf of the state that administered or caused to be administered the vaccination to the person concerned
- the Health Services Eire (HSE) Vaccination Card is an example of acceptable non-Digital COVID Certificate proof of vaccination

Proof of recovery: recovery certificates

A non-Digital COVID Certificate 'proof of recovery' means a record or evidence in written or electronic form in English or Irish or an official translation into Irish or English which contains the following:

- name
- date of birth
- disease from which holder has recovered
- date of holder's first positive Nucleic Acid Amplification Test (NAAT) test result
- Member State or third country in which test was carried out
- certificate issuer
- dates the certificate is valid from and valid until (not more than 180 days after the date of first positive NAAT test result)

Approved vaccines

For the purposes of travel, passengers are considered vaccinated if they have been vaccinated with a vaccine approved by the European Medicines Agency with recommended number of days after the final dose, see table below.

A full course of any one of the following vaccines	**Regarded as vaccinated after (days)**
2 doses of Pfizer-BioNtech Vaccine: BNT162b2 (Comirnaty®)	7
2 doses of Moderna Vaccine: CX-024414 (Moderna®)	14
2 doses of Oxford-AstraZeneca Vaccine: ChAdOx1-SARS-COV-2 (Vaxzevria® or Covishield)	15
1 dose of Johnson and Johnson/Janssen Vaccine: Ad26.COV2-S [recombinant] (Janssen®)	14

Travelling with children

1. Children between the ages of 12 and 17 will be required to have a negative RT-PCR test taken within 72 hours prior to arrival to travel into the country, unless they have valid proof of vaccination or recovery.
2. Children of any age, travelling with accompanying vaccinated or recovered adults will not be required to self-quarantine post arrival. However, where one accompanying adult needs to self-quarantine, then all children must also self-quarantine.

Passengers arriving into Ireland who have not travelled outside the EU + Iceland, Liechtenstein, Norway, Switzerland within 14 days of arrival

1. Ireland is now a part of the EU Digital COVID Certificate for travel originating within the EU/EEA.
2. If you have valid proof of vaccination, no travel-related testing or quarantine will be necessary.
3. If you have valid proof that you have recovered from COVID-19 in the past 180 days, no travel-related testing or quarantine will be necessary.
4. If you do not have valid proof of vaccination or recovery, you will need to present evidence of a negative RT-PCR result from a test taken within 72 hours prior to arrival into the country. No further travel-related testing or quarantine will be necessary.

Travel restrictions for passengers arriving into Ireland from outside EU + Iceland, Liechtenstein, Norway, Switzerland

Please note: This includes those arriving from Great Britain.

1. If you are travelling to Ireland from abroad you must fill out a Passenger Locator Form before departure.
2. If you have valid proof of vaccination (see above), no travel-related testing or quarantine will be necessary.
3. If you have valid proof of recovery from COVID-19 in the past 180 days (see above), no travel-related testing or quarantine will be necessary.
4. If you do not have valid proof of vaccination or recovery, you will need to:
    - present evidence of a negative result from a RT-PCR test taken within 72 hours prior to arrival into the country

- self-quarantine for 14 days

If you receive a negative result from a RT-PCR test taken from day 5 onwards after arrival into Ireland, you will be able to leave quarantine.

Arriving from Northern Ireland

1. Travellers whose journey originated in Northern Ireland and have not been overseas in the past 14-days are not obliged to complete a Passenger Locator Form or provide proof of vaccination, recovery or test results upon arrival into Ireland.
2. However, travellers who have been overseas in the past 14 days are subject to the requirements based on their travel history, and according to their health status.

Exemptions

Full or partial exemptions for passengers from home quarantine (where applicable)
There are some limited exemptions from the requirement to complete home quarantine (where applicable).

1. A person arriving in the State in the course of their duty and who hold a valid Annexe 3 certificate (ensuring the availability of goods and essential services).
2. Drivers of a heavy goods vehicle arriving in the State in the course of their duty.
3. Airline pilots, aircrew, maritime master or maritime crew and who arrive in the State in the course of performing their duties.
4. A person travelling to the State pursuant to an arrest warrant, extradition proceedings or other mandatory legal obligation.
5. A member of An Garda Síochána or Defence Forces travelling to the State in course of their duty.
6. A person travelling to the State for unavoidable, imperative and time-sensitive medical reasons and these reasons are certified by a registered medical practitioner or person with equivalent qualifications outside the State.
7. A person having been outside of the State to provide services to or perform the functions of an office holder (under any enactment or the Constitution) or a member of either house of the Oireachtas or the European Parliament.
8. Diplomats and certain other categories of persons entitled to privileges and immunities in the State.

Passengers who do not need to provide evidence of a pre-departure RT-PCR test (where applicable)

1. Passengers with a valid EU Digital COVID Certificate based on a vaccination or recovery certificate (or accepted alternative documents) who are travelling from the EU.
2. People who are travelling in the course of their duties and are an international transport worker in possession of an Annexe 3 certificate, the driver of a heavy goods vehicle or are aviation crew or maritime crew.
3. Patients travelling to Ireland for urgent medical reasons, and that reason is certified by registered (children aged 11 and under).
4. Passengers whose journey originated in Northern Ireland and have not been overseas in the 14-day prior to arrival.
5. A member of the Gardaí or Defence Forces personnel travelling to the State in the course of performing his or her duties.
6. A person who travels to the State pursuant to an arrest warrant, extradition proceedings or other mandatory legal obligation.
7. Travel to perform the function of or provide services to an office holder or elected representative, where such travel to Ireland is required to continue providing such services or performing such functions.
8. If a citizen has a genuine humanitarian emergency requiring urgent travel, and might not be able to obtain the result of a pre-departure RT-PCR test in time, they should contact the nearest embassy or consulate immediately for advice and consular assistance before commencing their journey.

International travel from Ireland

A HSE COVID-19 test result cannot be used for the purposes for international travel from Ireland. A negative PCR test from a private company is required.

Testing Regime

The testing regime in Ireland is different to the UK in the types of test used and the situations for tests. The types used and offered by the Irish Government are primarily PCR tests and are done on a symptomatic basis. There seems to be little to no mass asymptomatic testing in the Republic of Ireland. If someone has symptoms of COVID-19 they are advised to self-isolate and get a free HSE COVID-19 test which is a PCR test and sent to a lab for testing. This then feeds into the contact tracing system as COVID-19 is notifiable under the infectious diseases legislation. The tracing service receives both positive and negative test results as a way to monitor cases.

If someone shows symptoms, they are advised to contact a GP or go to a free test centre for a PCR test to be conducted.

HSE only uses LFD Antigen tests in the following scenarios:

- hospitals
- places where there is an outbreak of COVID-19
- education and early years facilities - as part of a pilot project

Therefore LFDs are not widely used in Ireland as part of state provided testing for COVID-19.

1. You can get a free PCR test in a HSE COVID-19 test centre without a GP referral, if you have not had a positive COVID-19 PCR test in the last 9 months.
2. Children under 16 must have an adult with them if they are getting a test. A parent or guardian must give consent for a child under 16 to have a test.

An online Recovery Certificate portal has been launched to allow members of the public request a certificate of recovery.

You can request this certificate if you had a positive RT-PCR test more than 11 days ago and less than 6 months (180 days) ago.

This certificate proves that you've had COVID-19 in the last 6 months (180 days) and is considered another form of the EU Digital COVID Certificate.

Healthcare workers in Ireland are referred for testing to Occupational Health if they meet one of the following criteria:

- acute respiratory infection (sudden onset of at least one of the following: cough, fever, shortness of breath)
- sudden onset of anosmia (loss of sense of smell), ageusia (loss of sense of taste) or dysgeusia (distortion of sense of taste) with no known medical reason for these symptoms
- any acute respiratory illness who has also been in contact with a confirmed or probable COVID-19 case in the last 14 days prior to symptom onset

Private market

The following providers can now generate a Digital COVID Certificate that can be used for travel after a negative test and the list located on the gov.ie site is updated regularly:

1. GeoMed Diagnostics
2. Complete Laboratory Solutions (CLS)
3. Enfer
4. Eurofins Biomnis
5. PlusVital
6. Randox

7. Diagnostix
8. Beacon Hospital
9. Bon Secours Hospital

There is also a separate, and more substantial, list on the Irish Government website for LFD Antigen test providers. This is for countries who do not need to see a RT-PCR test as part of the entry requirements. This list is broken down by area and provides the name, address, and contact details. It seems that these providers are currently restricted (or greatly dominated) to pharmacies and medical practices.

The private market in Ireland seems to be limited to the travel industry with many larger firms and websites advertising primarily under the travel testing sector.

Ireland is a member of the EU and therefore the CE marking on IVDs for C-19 detection will be sufficient for any manufacturer of test devices to market their product on the Irish market. The Irish state has not decided to add additional conformity assessments to the CE marking requirements. The basis of the Irish testing regime is predominantly symptomatic and the state provides free PCR tests for those with symptoms of COVID-19 and therefore the reliance on additional conformity assessments was not considered appropriate by the Irish Government.

Irish vaccination programme

The Irish vaccine programme is currently open to anyone over the age of 12. The Irish state has predominantly used the Pfizer vaccine for their vaccination programme and has conducted 3.4 million second dose vaccinations to date (28 September 2021). The Irish population is just over 5 million so the percentage of people obtaining the second dose vaccination is approximately 69% of the population having their second vaccination. This is a strong vaccination programme for a small population and reduces the need for the Irish state to conduct asymptomatic testing.

Summary

1. Ireland has a symptomatic testing regime which relies on state-provided PCR tests. LFD tests are rarely used and only used if quick non-lab based diagnosis is needed.
2. The private market is largely restricted to the travel testing corner currently with several big players. The Irish Government has a list of approved PCR and LFD test providers which the public can access. Testing for travel is privately operated and comes with a cost to the consumer.
3. The travel restrictions for coming into Ireland depend on previous travel history, however, if someone is fully vaccinated or has a negative PCR test (at least 72 hours before arrival) they are ok to not isolate on entry to Ireland.

Annexe 12: An analysis of UK organisations and their COVID-19 testing approaches

Introduction

The stated purpose of this paper is to research the role of the private testing market for COVID-19 test devices for large organisations, in order to determine where the private market is supporting the government provision of tests.

The content of this research has been made through the latest publicly available data which, by its nature, might be out of date. Where possible we have tried to highlight the date of the published information.

Organisations have been analysed across a multitude of sectors such as sport, media, film, broadcasters, finance, education, retail and food manufacturing and tried to obtain information regarding their testing.

Any relevant information has been compiled into tables to illustrate clear comparisons.
As of 13 March 2021, over 48,000 businesses had signed up to the free workplace testing scheme which closed on 17 July 2021.

Travel Industry

Research has been undertaken to analyse testing approaches across the travel industry and organisations within the sector.

Twenty UK airports were analysed, and it was found that:

- 100% offer private testing
- there are10 different private providers across the sector

Airport	Do they offer private testing?	Private testing providers	Target customers
Aberdeen	Yes	ICTS UK and Ireland and TAC Healthcare Group Ltd	General Population
Belfast	Yes	Belfast International Airport works in collaboration with	General Population

Airport	Do they offer private testing?	Private testing providers	Target customers
		diagnostics firm Randox to supply PCR, Antigen and LFDs	
Birmingham	Yes	**ExpressTest** runs 2 sites at Birmingham Airport offering PCR Fit to Fly and LFD	General Population
Bournemouth	Yes	GP Delivered Quickly (GPDQ) provides a range of COVID-19 testing options. Clinician-led testing is on offer for both pre-departure tests and UK re-entry. Pre-departure Lateral Flow and PCR.	General Population
Bristol	Yes	Testing provided by Nuffield Health for travellers before departure through PCR and Lateral Flow Antigen testing services	General Population
Cardiff	Yes	Testing provided by Nuffield Health for travellers before departure through PCR and Lateral Flow Antigen testing services	General Population
City	Yes	The airport's testing centre is delivered in partnership with Collinsons	General Population
East Midlands	Yes	Testing provided by Collinsons for travellers before departure through PCR and Lateral Flow Antigen testing services	General Population

Airport	Do they offer private testing?	Private testing providers	Target customers
Edinburgh	Yes	ExpressTest runs 2 sites offering PCR Fit to Fly and LFD	General Population
Exeter	Yes	GPDQ provides a range of COVID-19 testing options. Clinician-led testing is on offer for both pre-departure tests and UK re-entry. Pre-departure Lateral Flow and PCR.	General Population
Gatwick	Yes	Cignpost supply Lateral Flow / Rapid Antigen and PCR (pre-departure) Boots offer a private PCR swab test service Collinsons offers a range of tests including PCR, antigen and Lamp The Hilton London Gatwick offers a Test and Rest Package. It includes a PCR self-testing swab kit and overnight accommodation at the hotel. The Sofitel London Gatwick offers a Test and Rest package. It includes a PCR self-testing swab kit and overnight accommodation at the hotel.	General Population
Glasgow	Yes	Partnered with ICTS UK and Ireland and the TAC Healthcare Group Ltd to	General Population

Airport	Do they offer private testing?	Private testing providers	Target customers
		offer pre-departure PCR Park and Test facilities to passengers	
Heathrow	Yes	Cignpost supply Lateral Flow / Rapid Antigen (pre-departure) Qured supply Lateral Flow / Rapid Antigen (pre-departure) and PCR	General Population
Leeds Bradford	Yes	Working in collaboration with NPH Group to provide pre-departure and UK re-entry PCR testing, carried out by qualified clinicians.	General Population
London Stansted	Yes	Collinsons and Randox are offering a number of COVID-19 testing options at London Stansted Airport - RT PCR, Reverse Transcription Loop-Mediated Isothermal Amplification (RT LAMP), Rapid Antigen, Antibody	General Population
Luton	Yes	Collinsons offers a range of tests including PCR, antigen and LAMP	General Population
Manchester	Yes	Collinsons and Randox supply tests at Manchester Airport, including RT PCR, Rapid Antigen, Antibody and RT LAMP	General Population
Newcastle	Yes	Working in collaboration with NPH Group to provide pre-departure and UK re-entry PCR testing, carried out by qualified clinicians.	General Population

Airport	Do they offer private testing?	Private testing providers	Target customers
Norwich	Yes	Working in collaboration with NPH Group to provide pre-departure and UK re-entry PCR testing, carried out by qualified clinicians.	General Population

Sports industry

Research has been undertaken to analyse testing approaches across a wide array of sports and their respective organisations underpinning their governance.

Eight organisations were analysed, and it was found that:

- 4 organisations have private testing regimes in place
- 40% highlight the universal testing offer

Organisation	Private Testing	Private Testing Provider	Further Info
Premier League	Yes	Prenetics	**September 2021** Two RT-PCR tests weekly, at 20 sites in the UK (football teams), 80 participants per team The Premier League successfully kicked off on June 17, 2020. To date over 20,000 tests have been processed with results delivered in 24 hours to team officials.
The Football Association (F.A.)	No	N/A	**July 2021** Users are signposted to universal free testing offer on GOV.UK “Free NHS lateral flow testing is available to clubs and F.A. encouraging clubs to take this up, applies to all youth and adult football and Futsal, including all formats of the game, both indoors and outdoors.”

Organisation	Private Testing	Private Testing Provider	Further Info
English Football League (EFL)	Yes	Yes	**January 2021** Twice-weekly COVID-19 testing for all 72 Clubs from Monday 11 January 2021. The tests have initially been procured from the private sector and will be fully funded by the PFA following discussions that have taken place with the EFL across the past 72-hour period. Private testing provider not disclosed.
British Horseracing Authority	No	N/A	**July 2021** No racecourse attendees will be asked to complete specific pre-entry medical screening, but will instead be encouraged to complete lateral flow tests in advance of raceday and check in using the NHS COVID-19 App on arrival.
Wimbledon	No	N/A	**June 2021** Required to show proof of COVID status upon entry in the form of: Full vaccination (first and second dose), and

Organisation	Private Testing	Private Testing Provider	Further Info
			with the second dose administered at least 14 days before your visit, OR A negative lateral flow test taken within 48 hours of your visit (for those aged 11 and over),
Team GB	Yes	Randox	**June 2021** Two-year partnership for Team GB's COVID-19 testing for the Tokyo 2020 Olympic Games, in 2021 and Beijing 2022 Olympic Winter Games. Randox has created a bespoke dashboard for Team GB to register its samples, which will be taken by the Team GB Clinical Team and then transported to the company's laboratory in Northern Ireland. Randox will test over 1,000 Olympians, coaches and support staff. Randox will provide each member of Team GB with 3 rounds of pre-departure tests – 14 days, 96 hours and 72 hours prior to departure – plus Day 2, Day 5 (if

Organisation	Private Testing	Private Testing Provider	Further Info
			required) and Day 8 testing once back in the UK.
RFU	No	N/A	**July 2021** Encouraged to use government's universal testing offer. "Clubs may consider the use of lateral flow testing, asking participants to take a COVID-19 test before participating, where this is practical and possible. Rapid lateral flow tests help to find cases in people who may have no symptoms but are still infectious and can give the virus to others. Free Rapid Flow Lateral Tests are distributed by the government and can be sent to an individual's home address."
Great North Run	Yes	Cignpost	**September 2021** Cignpost ExpressTest has partnered with the Great North Run, representing the firm's ongoing commitment to the health and wellbeing of the UK population. This partnership also expands Cignpost Express Test's

Organisation	Private Testing	Private Testing Provider	Further Info
			presence further across sport, having already partnered with the Scottish FA, the PGA European tour and Sail GP amongst others. The Great North Run is the largest half marathon in the world, boasting nearly 60,000 participants each year. The firm operates at more than 30 screening facilities across the UK.

Retail and service industries

Research has been undertaken to analyse testing approaches across numerous organisations within the retail and service industry sector.

Five organisations were analysed, and it was found that:

- 2 organisations
- 20% have private testing regimes

Organisation	Private Testing	Private Testing Provider	Further Info
Waitrose / John Lewis	Unknown	N/A	**December 2020** John Lewis offered free almost-instant COVID-19 tests to its workers at 40 of its sites. Up to 16,000 workers voluntarily tested every week up to 3 times a week. This information is likely out-of-date, no further info was publicly available.
Amazon	Yes	Not disclosed	**June 2021** Amazon has a private workplace testing programme, using PCR testing that was rolled out in autumn 2020. It has hired lab technicians and conducts tens of thousands of tests a

Organisation	Private Testing	Private Testing Provider	Further Info
			day across hundreds of its sites worldwide. The lab in Manchester has processed 900,000 test samples to date (3 June). The test results are anonymous and will be shared with UK Health Security Agency once the lab is approved for sequencing.
BAE Systems	Yes	Circular 1 and Duradiamond	**June 2021** Engineering giant BAE Systems has used a private lab to do in-house mass testing of its 8,000 employees at its shipyard in Barrow-in-Furness, Cumbria Employees are required to submit a RT-LAMP test roughly every 7 days on a rotation basis.
Food and Drink Federation	No	N/A	**October 2021** Users are encouraged to use universal free offer scheme:

Organisation	Private Testing	Private Testing Provider	Further Info
			Testing is currently available via the NHS for symptomatic individuals through home-testing kits, drive-through centres and a number of NHS facilities. In addition, employers are being encouraged to use asymptomatic onsite or home testing for their employees to provide confidence to employees and customers and help to protect and enable business continuity.
Confederation Of British Industry (CBI)	Unknown	N/A	**July 2021** Government-funded asymptomatic workplace testing is no longer available, but firms can invest in private testing or encourage employees to get tests through community routes.

Arts and media industries

Research has been undertaken to analyse testing approaches across numerous organisations within the arts and media industries.

Four organisations were analysed, and it was found that:

- 100% do not have a private testing regime in place

Organisation	Private Testing	Private Testing Provider	Further Info
BT	No	N/A	N/A
BBC	No	N/A	**Guidance dated from July 2021** BBC guidance stated employees should follow the GOV scheme where available and order lateral flow tests (testing twice a week).
Arts Council England	No	N/A	N/A
British Film Industry	Unknown	N/A	**Guidance dated from July 2021** An appropriate testing regime should be in place for cast and crew, and for those with whom they will work in close contact. From 22 September 2021, cast and crew travelling from amber list countries who do not qualify for the Quarantine

Organisation	Private Testing	Private Testing Provider	Further Info
			Exemption for Fully Vaccinated Individuals may still qualify for the Quarantine Exemption for Film and HETV. The individual must complete a pre-departure test before arrival, alongside a PCR test on or before day 2 after arrival.

Education

Research has been undertaken to analyse testing approaches across numerous organisations within the higher education industry.

Seven organisations were analysed, and it was found that:

- 90% have a private testing regime in place
- 100% also signposting to universal testing offer

Organisation	Private Testing	Private Testing Provider	Further Info
Imperial College London	PCR – Yes LFD – No	Imperial College London	**Current Guidance** Imperial offers 2 different asymptomatic testing options which are both free for students and staff – PCR Testing Scheme and LFD Collect The PCR testing scheme is available to all Imperial students and staff, with one test being taken per week, as long as: LFD Collect is a collection service for testing at home, with 2 tests per week. This collection service is used as part of a scheme organised by the government's DHSC.

Organisation	Private Testing	Private Testing Provider	Further Info
University College London	No	N/A	**Current Guidance** The current policy is to sign-post students and staff to universal free testing offer of regular rapid lateral flow tests (LFT) to check for COVID-19. Results are reported through the NHS and Connect to Protect UCL is providing free COVID-19 tests for symptom-free students and staff as part of the national testing programme for universities. Visitors cannot access UCL's testing service.
Cambridge	Both	Cambridge University	**Current Guidance** You can book a test via the NHS or you can take a University test. We strongly encourage all members of staff, and students who are not eligible for the asymptomatic screening programme, to

Organisation	Private Testing	Private Testing Provider	Further Info
			take twice-weekly LFTs. Free lateral flow home testing kits are available to all adults in England through the NHS. Weekly asymptomatic screening programme for COVID-19 at the University of Cambridge. Weekly PCR test. Participation in the programme is voluntary.
Oxford	Both	Oxford University	**Current Guidance** The University's in-house COVID-19 testing service is open to all staff and students of the University and colleges, providing rapid access to free PCR testing for those with suspected COVID-19.
Liverpool	Both	Liverpool University	**Current Guidance** On-campus PCR We are not able to offer testing to members of the

Organisation	Private Testing	Private Testing Provider	Further Info
			general public or anybody who is not part of our university community.
Loughborough	Yes	Loughborough	**Current Guidance** “It is a requirement that all students returning to the University take an asymptomatic Lateral Flow Test the day before they travel.” “You must also take a Lateral Flow Test at our on-site Test Centre on the day of your arrival and/or before accessing accommodation or any facilities, and take another test 3 days after your arrival.” “You will then be required to take weekly Lateral Flow Tests at our onsite testing centre throughout the autumn term.” “If any of your lateral flow tests is positive, you will need to take a confirmatory PCR

Organisation	Private Testing	Private Testing Provider	Further Info
			test, bookable through the Connect and Protect service." "Compliance with the University's Covid testing requirements will be monitored and the University may not allow students" access to University facilities if they have not complied with our testing regime.
Russell Group	Unknown	N/A	**Current Guidance** Our universities have worked hard to make campuses Covid-secure, with twice-weekly testing and very low overall infection rates on campus.

Banking

Both organisations analysed had instituted private testing regimes, however the latest publicly available information is dated from many months ago.

Organisation	Private Testing	Private Testing Provider	Further Info
Goldman Sachs	Yes, but currently unknown	Not Disclosed	Free mass testing for members of its 6,000-strong London workforce who choose to return to the office. Eligible colleagues who have returned or are planning to return to a Goldman Sachs office will be offered one-time PCR and antibody tests.
CitiGroup	Yes	Not disclosed	**April 2021** COVID-19 testing programme for its Canary Wharf headquarters in a bid to get more employees back in the office, as City investment banks gradually reopen after the latest UK lockdown. More UK staff will return to Citi's Canary Wharf headquarters from 12 April as the bank expands a pilot

Organisation	Private Testing	Private Testing Provider	Further Info
			COVID-19 testing from around 1,000 eligible employees Required to take a LFD test 3 times a week.

Conclusion

This research sought to analyse the role of the private testing market for COVID-19 test devices in large organisations across various industries, specifically in evaluating where the private market is supporting government provision of tests.

Our key findings are summarised below.

1. Out of a total of 46 organisations analysed 79% (34 organisations) have private testing regimes (however this information is based on publicly available data and may not be reflective of current practices within researched companies).
2. The highest rate of private testing regime was in the travel sector – 100%.
3. The lowest was in the arts and media industries – 0%.
4. The vast majority of organisations highlight the universal testing offer.

List of private providers

‘Project Screen’ by Prenetics

Stated capacity of 40,000 tests a day with 120 live sites across UK.

1. Premier League
2. British Boxing Board of Control
3. At the England and Wales Cricket organisation, over 450 players, staff, match officials and broadcasters were successfully screened using RT-PCR on-site testing
4. At the BAFTAS, Project Screen provided home PCR testing delivered by trained medical professionals in the run up to the event. For crew, Lateral Flow Antigen testing was set up for everyone on-site. Those with a positive test result would be confirmed via on-site PCR testing in a purpose-built Prenetics lab. Over 400 COVID-19 tests were conducted to support the event.
5. Pinewood Studios
6. Sky Entertainment
7. IWG
8. IBM developed the Digital Health Pass to allow employees to return safely to the workplace and other locations. Built on IBM Blockchain technology, the solution is designed to enable organisations to verify health credentials for employees, customers and visitors entering their site based on various health criteria. Project Screen by Prenetics acted as an integrated LAMP testing laboratory using anonymised QR code scanning of health passes and the upload of COVID-19 test results. Able to test around 53 employees and validate the trial of the Digital Health Pass system.
9. At Heathrow Airport, rapid pre-departure LAMP tests are offered for international travellers with over 880 tests on average conducted per day
10. At the charity event Soccer Aid, 4 RT-PCR tests were conducted per participant and 728 tests conducted over a 4-week period, including 438 home collections.
11. At London Southend Airport, rapid pre-departure LAMP testing is offered for international travel.
12. At Mustard Foods, 200 LFDs tests were offered to staff
13. New Pictured LTD
14. At the World Snooker Championships, attendees were required to have taken an LFD. The scheme was part of the Event Research Programme (ERP)
15. At the Home Office, testing was offered for children seeking asylum before going into care.
16. Manchester Airport works in partnership with Collinson to provide RT-LAMP testing for passengers departing from Manchester, and offering RNA-extracted LAMP for Test To Release (Day 5). Daily testing capacity stands at over 2000
17. At Matchroom boxing, 19,000 COVID-19 tests were conducted at over 40 designated testing bays, across 10 boxing events
18. At London Stansted Airport, pre-departure LAMP testing is offered for travellers.

19. Within the OFSTED organisation, home COVID-19 testing arrangement are in place for OFSTED inspectors before school visits.
20. At London Luton Airport, rapid LAMP testing on departure is offered for international travellers.
21. At Gatwick London Airport, pre-departure tests are offered to travellers using rapid Direct LAMP technology, with a stated testing capacity of over 500 per day.
22. At the O2 Arena, Test To Release tests are offered using RNA-extracted LAMP technology.
23. Within UKAD, home testing is offered for staff to visit sports leagues and players.

Boots

1. In-store PCR, rapid antigen, test to release testing services.
2. At-home PCR for both general use and travel.
3. Day 2 and Day 8 travel testing service.
4. The free rapid NHS Lateral Flow Tests that are being made available by the government are for England only and available from selected Boots pharmacies to collect.
5. You can order and pay for tests for up to 6 people using the Group Booking facility.
6. There is an ongoing partnership through EasyJet, in which customers will be able to book all the required tests needed both before and after their holiday through Boots.

Well Pharmacy

1. In-pharmacy testing service pre-departure, day 2 and day 8 PCR test.
2. Rapid lateral flow COVID-19 tests are now available at 570 Well pharmacies across the UK.
3. People without symptoms are able to visit their local Well pharmacy and collect a box of 7 rapid COVID-19 test kits to use twice a week at home, free of charge, and then enter their results online as part of the NHS Pharmacy Collect service.

Chronomics

1. Partnered with TUI to offer testing packages for all TUI package holiday customers for the rest of 2021.
2. Tests that are offered include Fit to Fly (PCR), Fit To Fly (Rapid Antigen), Day 2 COVID-19 Test (and vaccinated), Day 2 and Day 8, Test To Release, Test To Return, Self-test Rapid Antigen.
3. Supported by Newmarket Holidays and Superdrug.

Circular 1 Health

1. Partnered with Superdrug to offer Fit to Fly (PCR), Fit To Fly (Rapid Antigen), Day 2 COVID-19 Test (and vaccinated), Day 2 / Day 8, Test To Release.

Klarity

1. Partnered with TUI and First Choice to provide self-administered PCR COVID-19 testing and antigen (rapid flow) COVID-19 testing, for a discounted rate to customers.
2. Klarity provide 3 different rapid antigen test packages: (1) Basic antigen: Antigen (rapid flow) self-test; (2) Standard antigen: Antigen (rapid flow) assisted self-test; (3) Premium antigen: Antigen (rapid flow) fully guided self-test.
3. Standard PCR and Premium PCR.

Screen 4

1. Partnered with TUI to provide kits for self-administered PCR COVID-19 testing, for a discounted rate.
2. Pre-travel PCR testing both via self-test and in-clinic appointment.
3. Fully Vaccinated Day 2 Day RT-PCR Test, both via self-test and in-clinic appointment.
4. Non Vaccinated Day 2 and 8 COVID-19 Self-Test and clinician test.
5. Test to Release Day 5.
6. COVID-19 Antibody Home Test.
7. Test capacity stands at 20,000.

GPDQ

1. Pre-departure PCR, Day 2 and Day 8, lateral flow testing at Norwich, Bournemouth, Exeter airports.
2. Antibody and PCR testing at clinic sites across UK.
3. Self-tests available via post.

Nuffield Health

1. Offer in-clinic testing at Covent Garden, Moorgate, Cannon Street Station sites.
2. Private testing available for anyone without symptoms including tests for travel, government-approved Gold Standard PCR and Lateral Flow Antigen testing services.
3. Approved Fit-to-Fly Test Certificates.
4. Partnered with Cardiff and Bristol airports.
5. At-home COVID-19 Rapid Antigen Test available to purchase online from a unit of 25 to a maximum of 500.

Tac Healthcare

1. Private testing at Glasgow and Southampton airports.

NPH Group

1. COVID Fit to Fly, Test to Release, Day 2, Day 8, Rapid Antigen testing services provided at Newcastle, Leeds and Bradford airports.