# UK COVID-19 device product market: call for evidence

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## Introduction

In this call for evidence, we are seeking evidence and opinions on the following areas:

* costs for individual businesses involved in the domestic COVID-19 test kit sector
* scale and nature of domestic COVID-19 test kit activity, including manufacturing and trading
* scale and nature of activities abroad which are integral to our existing domestic COVID-19 test kit supply and market
* the direction of the COVID-19 test kit market

We welcome all evidence and analysis any stakeholder can provide on these broad topics. We are particularly interested in responses from:

* manufacturers of COVID-19 or other diagnostic tests
* distributors of COVID-19 or other diagnostic tests
* industry bodies
* academics and experts in the diagnostics industry
* think tanks and other research groups with relevant insight
* any others with evidence of potential impacts

We invite you to submit a response to the questions outlined below.

The call for evidence will run for 4 weeks, ending on 16 September 2021.

The results of this call for evidence will help to shape the policy and the resultant analysis will be published in the impact assessment underpinning the policy.

## How to respond

We invite you to submit written responses via email. Fill in your responses and send the form to [validation@dhsc.gov.uk](mailto:validation@dhsc.gov.uk).

For background on the policy and legislation, please see the ‘UK COVID-19 device product market: call for evidence’ document.

## Demographic questions – form for completion

Please answer all questions as far as they are applicable to you. This will help us to understand the make-up of respondents and analyse your responses. For example, if you’re responding on behalf of an individual, please answer questions addressed to organisations where you can (for example, on location and nature of work).

### Are you responding on behalf of an individual or an organisation?

Please enter your responses in a new line after the question.

### What is the name of your organisation?

Please enter your responses in a new line after the question.

### In which country is your headquarters based?

Please enter your responses in a new line after the question.

### If your organisation is part of a group of companies, what is the name and location of the parent organisation?

Please enter your responses in a new line after the question.

### If UK-based, select the nation or region your organisation is based in [delete any that do not apply]

Scotland

Wales

Northern Ireland

North East of England

North West of England

Yorkshire and the Humber

East Midlands

West Midlands

East of England

London

South East of England

South West of England

Other (please state)

### What is the nature of your organisation? [delete any that do not apply]

Manufacturer

Retailer

Distributor

Trade association

Other (please state)

### Does your organisation manufacture COVID-19 detection tests? (If yes, specify the type of tests)

Please enter your responses in a new line after the question.

### Does your organisation distribute or sell COVID-19 detection tests? (If yes, specify if your organisation sells directly to the patient – for example, high street retailer)

Please enter your responses in a new line after the question.

### Does your organisation currently sell COVID-19 detection tests on the UK market?

Please enter your responses in a new line after the question.

### Does your organisation manufacture or distribute other diagnostic tests (not COVID-19 detection tests)? (If yes, please specify)

Please enter your responses in a new line after the question.

### How many employees are in your organisation? [delete any that do not apply]

0 to 4

5 to 9

10 to 19

20 to 49

50 to 99

100 to 249

250 or above

### Can we contact you with follow-up questions?

Please enter your responses in a new line after the question.

### If you’re happy to be contacted, what is your email address?

Please enter your responses in a new line after the question.

### Can we cite you directly in publications such as the impact assessment?

Please enter your responses in a new line after the question.

## Call for evidence questions – form for completion

Below are a number of detailed questions to help guide your responses and highlight the evidence we are most interested in receiving. The answer to these questions will more closely align with our analytical needs and the specific policy issues where we want to build our underlying understanding.

### Costs to business: familiarisation and transition costs

We invite manufacturers and retailers of COVID-19 tests to respond to the questions within this section.

It is important that we understand as much as possible about the impact the legislation introducing mandatory validation for COVID-19 detection tests has on business. Your feedback on the following questions will help us give a more representative estimate and help us to account for the costs associated with different sized businesses.

We are interested in understanding the familiarisation and transition costs for manufacturers and retailers impacted by this legislation. In this case, the familiarisation and transition costs refer to the costs incurred as a result of familiarising and transitioning into the new mandatory validation regime for COVID-19 tests.

We have assessed the tasks we believe that manufacturers and retailers will need to take in order to transition into the new system.

We would like to ask you to provide your assessment or estimate (or both) on the questions below.

For each activity, please estimate the time taken and cost per hour. You should take into account the level of seniority and level of pay of the employee who would take responsibility for these tasks. If there are multiple employees undertaking a task, please reflect this in the hours taken.

Please also identify whether you would undertake these activities in house or contract these services out.

To answer these questions, please enter this information as far as possible with your best estimates.

Please skip the section that is not relevant to you.

### Manufacturer: desktop review

For each activity, please estimate:

* hours taken to carry out activity
* cost per hour (hourly wage of internal or external employee, excluding non-wage cost uplifts such as National Insurance contributions)

#### 1. Assessing guidance documentation

Hours taken:

Cost per hour:

#### 2. Engagement with government communications highlighting guidance or new regulations

Hours taken:

Cost per hour:

#### 3. Assessing portfolio of tests in need of assessment

Hours taken:

Cost per hour:

#### 4. Develop and disseminate communications across relevant areas of business

Hours taken:

Cost per hour:

#### 5. Collating information for application

Hours taken:

Cost per hour:

#### 6. Submitting application through GOV.UK portal

Hours taken:

Cost per hour:

### Manufacturer: laboratory validation

For each activity, please estimate:

* hours taken to carry out activity
* cost per hour (hourly wage of internal or external employee, excluding non-wage cost uplifts such as National Insurance contributions)

#### 1. Assessing guidance documentation

Hours taken:

Cost per hour:

#### 2. Engagement with government communications highlighting guidance or new regulations

Hours taken:

Cost per hour:

#### 3. Assessing portfolio of tests in need of assessment

Hours taken:

Cost per hour:

#### 4. Develop and disseminate communications across relevant areas of business

Hours taken:

Cost per hour:

#### 5. Logistical costs of transporting of test kits to a UK-based laboratory

Hours taken:

Cost per hour:

#### 6. Collating information for application

Hours taken:

Cost per hour:

#### 7. Process application through GOV.UK portal

Hours taken:

Cost per hour:

#### Do you agree that the activities above accurately reflect the steps required to familiarise and transition into the new regulatory system?

Please enter your responses in a new line after the question.

#### Are there any additional activities you would identify as necessary for familiarisation and transition to the new system?

Please enter your responses in a new line after the question.

### Retailer: desktop review

For each activity, please estimate:

* hours taken to carry out activity
* cost per hour (hourly wage of internal or external employee, excluding non-wage cost uplifts such as National Insurance contributions)

#### 1. Assessing guidance documentation

Hours taken:

Cost per hour:

#### 2. Engagement with government communications highlighting guidance or new regulations

Hours taken:

Cost per hour:

#### 3. Cross reference current test portfolio against GOV.UK list

Hours taken:

Cost per hour:

#### 4. Assess stock depletion timelines and future procurement

Hours taken:

Cost per hour:

#### 5. Develop and disseminate communications across relevant areas of business

Hours taken:

Cost per hour:

### Retailer: laboratory validation

For each activity, please estimate:

* hours taken to carry out activity
* cost per hour (hourly wage of internal or external employee, excluding non-wage cost uplifts such as National Insurance contributions)

#### 1. Assessing guidance documentation

Hours taken:

Cost per hour:

#### 2. Engagement with government communications highlighting guidance or new regulations

Hours taken:

Cost per hour:

#### 3. Cross reference current test portfolio against GOV.UK list

Hours taken:

Cost per hour:

#### 4. Assess stock depletion timelines and future procurement

Hours taken:

Cost per hour:

#### 5. Develop and disseminate communications across relevant areas of business

Hours taken:

Cost per hour:

#### Do you agree that the activities above accurately reflect the steps required to familiarise and transition into the new regulatory system?

Please enter your responses in a new line after the question.

#### Are there any additional activities you would identify as necessary for familiarisation and transition to the new system?

Please enter your responses in a new line after the question.

### Future business planning and horizon scanning

We invite manufacturers and distributors of COVID-19 tests to respond to the following questions.

We are interested in understanding how agents in the market for private COVID-19 testing are currently planning for the future, how they are thinking about the market and what opportunities they see.

We would value evidence or feedback on the following questions:

#### What horizon period are you currently planning for within your business planning? [delete all that do not apply]

0 to 6 months

7 months to 1 year

1 to 2 years

2 to 3 years

3 to 5 years

5 to 10 years

More than 10 years

#### What opportunities have you identified and what demand do you expect over the next year for testing provided by the private sector?

Please enter your responses in a new line after the question.

#### Are there any dependencies or risks attached to this? Where possible break this down by technology type. (For example, do you anticipate greater demand for polymerase chain reaction (PCR) versus lateral flow testing or vice versa?)

Please enter your responses in a new line after the question.

#### If you are currently selling in the COVID-19 diagnostics market, do you expect to expand into the wider diagnostics market, or continue solely with COVID-19 diagnostics?

Please enter your responses in a new line after the question.

### Interaction with epidemiological pattern, universal free testing and the vaccine programme for COVID-19

#### How is the free provision of lateral flow tests (the government’s universal free testing offer) impacting your business planning decisions? (Or, if you are not a business, how do you predict that the free provision of lateral flow tests will impact business planning decisions?)

Please enter your responses in a new line after the question.

#### How is the government’s free provision of PCR tests impacting your business planning decisions?

Please enter your responses in a new line after the question.

#### How is the free provision of tests (the government’s universal free testing offer) impacting the value and profitability of the private COVID-19 diagnostic market?

Please enter your responses in a new line after the question.

#### How is the COVID-19 vaccine programme impacting your business planning?

Please enter your responses in a new line after the question.

#### How is the vaccine programme impacting the value of the private COVID-19 diagnostics market?

Please enter your responses in a new line after the question.

#### How do you think the epidemiological pattern of this pandemic will affect the market for test devices over the next 10 years?

Please enter your responses in a new line after the question.

#### How is the uncertainty of the future of the pandemic impacting your business planning decisions? For example, external variables such as the potential for the emergence of new variants. (Or, if you are not a business, how do you predict these will impact these decisions?)

Please enter your responses in a new line after the question.

#### To what extent do you believe consumer behaviour regarding illness and diagnostics has changed due to the pandemic?

Please enter your responses in a new line after the question.

#### Will businesses want to test staff or customers (or both) in the absence of government requirements to do so?

Please enter your responses in a new line after the question.

#### If new variants begin to spread, will businesses and individuals take it upon themselves to use privately bought tests to manage their own risks?

Please enter your responses in a new line after the question.

#### Outside of medical diagnostics over the next 10 years, what activities, business areas or type of consumers will make regular use of COVID-19 testing?

Please enter your responses in a new line after the question.

### Understanding the market

We invite stakeholders involved in the manufacture or distribution of COVID-19 or other diagnostic tests, academics and experts in the diagnostics industry to respond to the questions within this section.

#### What is the average life cycle for your product or products or a COVID-19 diagnostic device?

Please enter your responses in a new line after the question.

#### How would this vary by technology type? For instance, how long would a device last for before manufacturers decide to update or make substantive changes to their product (for example due to innovation, market competition or new variants)?

Please enter your responses in a new line after the question.

#### Can you estimate how much it would cost, on average, to modify a COVID-19 detection test in the following 3 scenarios:

#### Re-work of manufacturing process or packaging that does not have regulatory impact

Please enter your responses in a new line after the question.

#### Re-work of manufacturing process or packaging that does have regulatory impact

Please enter your responses in a new line after the question.

#### Change to the test construction (for example chemistry or packaging)

Please enter your responses in a new line after the question.

#### What would be the most likely scenario if a COVID-19 test product failed validation? [delete all that do not apply]

Product is discontinued and exit the market

Redesign and resubmit for validation

Seek alternative international markets

Other (please specify)

#### How would this vary by:

#### Technology type

Please enter your responses in a new line after the question.

#### Country of origin

Please enter your responses in a new line after the question.

#### Size of revenue

Please enter your responses in a new line after the question.

#### Who would typically bear the cost of a reinvestment? (For example, manufacturers in reduced profits or through cost cutting, equity holders in reduced dividends or further investment, or customers in prices?)

Please enter your responses in a new line after the question.

#### How much would you estimate that it costs to bring a new product to market? Please outline financial cost and amount of time taken to bring a product to market.

Please enter your responses in a new line after the question.

#### How would this vary by technology type?

Please enter your responses in a new line after the question.

### Estimate of profit margins

#### For each of the following COVID-19 test technology types, please provide an accurate assessment of your current and target gross profit margins. (Gross profit margin is the product revenue minus the cost of sales divided by revenue.) [use one of the following choices for each type]

Negative gross profit margin

0% to 10%

11% to 20%

21% to 30%

31% to 40%

41% to 50%

51% to 60%

61% to 70%

71% to 80%

81% to 90%

91% to 100%

#### 1. Polymerase chain reaction (PCR)

Current gross profit margin:

Target gross profit margin:

#### 2. Lateral flow devices

Current gross profit margin:

Target gross profit margin:

#### 3. LAMP (loop mediated isothermal amplification)

Current gross profit margin:

Target gross profit margin:

#### 4. Other (please specify)

Current gross profit margin:

Target gross profit margin:

#### In calculating the gross profit margin above, what elements have you included in the cost of sales? (For example, fixed costs, research and development spending, branding)

Please enter your responses in a new line after the question.

#### What proportion of devices currently available on the market would you anticipate presenting to the scheme for validation, rather than being excluded from the market?

Please enter your responses in a new line after the question.

#### How would this vary by technology type?

Please enter your responses in a new line after the question.

#### How would this vary by country of origin?

Please enter your responses in a new line after the question.

#### How would this vary by size of revenue?

Please enter your responses in a new line after the question.

#### Are you aware of any research which you believe accurately represents the volume of tests available on the private market in the UK? Please provide the title and source, and brief summary.

Please enter your responses in a new line after the question.

#### In terms of volume of test devices, what estimate of the market share of the UK COVID-19 diagnostic market is supplied by non-UK business?

Please enter your responses in a new line after the question.

#### Are you aware of any research that best represents the size of the UK’s diagnostics market, or market for COVID-19 tests?

Please enter your responses in a new line after the question.

#### Are you aware of any research that estimates the value of the UK diagnostics market, or market for COVID-19 tests?

Please enter your responses in a new line after the question.

#### Do you expect to see a reduction in the number of COVID-19 detection products on the market or of those imported into the UK?

Please enter your responses in a new line after the question.

#### What would be the most likely impact on the supply chain if a COVID-19 test product failed validation?

Please enter your responses in a new line after the question.

#### How would this vary by technology type, country of origin and size of revenue? (For example, a company could find new work to replace the contract lost)

Please enter your responses in a new line after the question.

#### What proportion of your supply chain is UK-based?

Please enter your responses in a new line after the question.

## Next steps

We will analyse the responses we receive to this call for evidence and this will directly feed into the development of the impact assessment for the policy introducing validation for COVID-19 tests. When we are satisfied that we have collated the best evidence, we will submit a full impact assessment to the Regulatory Policy Committee for their review.

In addition, we will shortly launch a full public consultation which seeks views on the government’s policy proposals to introduce a second statutory instrument in the autumn to introduce mandatory laboratory validation for COVID-19 detection tests.

The full public consultation will provide individuals and organisations with the opportunity to feedback on the government’s proposals and the potential to shape the policy. This is separate from the call for evidence, which seeks specific evidence to support the impact assessment.

Thank you for responding to this call for evidence.

## Privacy notice

The questions forming part of this review include requests for information which may be commercially sensitive. Such information will be used by the Department of Health and Social Care for the purposes of this impact assessment only. However, no commercially sensitive information will be published in the impact assessment itself. Any personal data (for example, names and email addresses) provided to the Department of Health and Social Care as a result of responding to the questions below will be processed in accordance with [DHSC’s privacy notice](https://www.gov.uk/government/publications/dhsc-privacy-notice).