Webinar FAQ

Thank you for attending our webinar series and for submitting questions to our speakers. We are grateful to all of you for your contribution to our national effort in diagnostics. While it is not possible for all questions to be addressed during the webinar, we do review all questions and suggestions submitted during each webinar. Please see below a summary of common questions, which have been raised during the first three webinars in this series.

General

1. How can I get in touch?

If you can help boost our testing capacity through technology, supplies or lab capacity, we want to hear from you. There are several ways you can engage.

If you feel that you can help the government increase COVID-19 Testing capacity here is the link to the specific web form to collect information we need: https://www.gov.uk/guidance/help-the-government-increase-coronavirus-covid-19-testing-capacity

You can also email: covid19triageservice@nhsbsa.nhs.uk

Or call:

UK: 0800 915 9965

Outside UK: 0191 264 2321

Additionally, in partnership with Crowdicity, we have launched a **Testing Methods sourcing platform** to collect ideas on a specific challenges, which will be regularly updated. A new challenge regarding COVID Plus: Multiplexing with other pathogens was launched this week. Please post your solutions here. Every solution and comment will be considered by our expert panel.

2. I've submitted an offer to government but haven't heard back - when will I hear?

Thank you for your offer of support. As you can imagine we are currently receiving a very high volume of queries and offers. We have teams of experts reviewing, triaging and evaluating all offers we receive. Please use the forms provided on this link which ensure your offers meet our requirements and can be directed to the right expert group. At this time we are prioritising those offers according to needs and will get in touch with you as soon as possible. However, if your offer doesn't address an immediate priority it may take a bit of time, please bear with us.

3. What is Crowdicity and who should use it?

The Testing Methods Sourcing platform is a partnership between the Department of Health and Social Care, the UK Bioindustry Association, British In Vitro Diagnostics Association and the Royal College of Pathologists to collect ideas on our specific challenges. It is an open platform whereby anyone can offer their ideas and every

solution and comment will be considered by our team of experts. To date we have launched 5 challenges:

i. RNA extraction: New Methods
ii. Desktop PCR equipment for Point Of Care testing
iii. Dry swabs for use in virus detection
iv. Low volume blood collection and sample elution for serology testing

4. Is the Government interested in alternative technologies/ novel solutions to PCR/Ab?

Yes – we want to hear from all companies but our focus is on immediate priorities. Please get in touch in the normal way (see point 1 above).

Swab testing (PCR)

1. What's being done on Point Of Care PCR testing?

Point of Care PCR testing forms an important part of our strategy and is one of the key challenges we have launched though the Crowdicity sourcing platform. Please add your solutions, ideas, comments and any other responses on this platform. Every idea and comment will be considered by our team of experts.

2. What percentage of the population in various geographical regions of the UK need to be have antigen testing to be able to accurately estimate R0 values throughout the UK?

The percentage for a national estimate is tiny. This is because statistical efficiency is reached with relatively small numbers – think for example that an opinion poll of around 1000 people can, roughly, estimate a proportion between say 0.25 and 0.75 with a 95% confidence interval of +/- 0.03. However when the proportions are larger then the confidence interval increases.

3. What is the government doing to improve the process for getting tests to essential workers?

We have expanded eligibility as capacity has increased, everyone who needs a test now has access to one.

The government has improved the process for getting tests to essential workers through several steps:

- We have built strong relationships across private sector, public sector and academic institutions, solved a range of delivery issues and built a national system from scratch in order to do that.
- Improvements include:
    - The launch of a new online portal for those who are eligible to order a test or to be referred for a test by their employer;

    - Establishing 50 drive through testing sites across the UK so that most people should not have to drive more than 45 minutes to get to a testing site;
    - Launching a home delivery route with key industry partners, including Royal Mail and Amazon, so people can receive a test direct to their door;
    - Boosting NHS capability by providing test kits directly to 'satellite' centres at places like hospitals that have a particularly urgent or significant need;
    - Opening three new super labs in Milton Keynes, Cheshire and Glasgow;
    - Establishing a fleet of **mobile testing units**, which can be deployed across the country to meet local demands for testing;
- This is all part of our commitment to boost our testing capacity and to make accessing a test easier, faster and simpler.

4. Have you considered the need for multiple testing of a single individual in your capacity needs analyses?

Testing individuals' multiple times is both expected and a good thing. There are several valid reasons why some individuals may be tested more than once, including regular testing of NHS and social care workers and those participating in a trial to help improve our understanding of the disease.

Our key aim is to ensure that anyone who needs a test in the UK has access to one, and of course this test must be accurate and reliable. Where multiple tests may be required, either to validate a result, or for essential workers, including those on front line in the NHS and care homes, we will ensure that there is sufficient testing capacity available to match demand.

Antibody testing

1. What options is the government considering for collecting blood samples?

We are looking at three blood collection methods, and they will be assessed by PHE in June and July. Those methods are – venous blood via phlebotomy, capillary blood through a finger prick, and a blood spot on paper.

2. What is the Government's strategy for lab-based serology tests?

Lab based serology testing forms a key part of our antibody strategy, under Pillar 3 of the National testing strategy. We believe a national antibody testing programme may provide a critical role in the next phase of this pandemic. However, the science of immunity remains uncertain, though we are making progress every day. There is no strong evidence yet to suggest that those who have been proven to have had the virus are immune. The value of antibody tests is therefore currently limited to answering the question of whether someone has had the virus or not. This is why we are starting the national roll-out in the NHS and care sector where there is a clear need to know who has had the virus.

We are working with the NHS, PHE and industry partners to explore how high-throughput serological tests might facilitate better understanding of sero-prevalence across the country.

3. What specifications are available (MHRA)?

For more information on the required specifications for serology tests please see the most recent guidance from MHRA.

4. Is the government planning to standardise antibody tests?

It is important that tests deployed are effective. Please see the MHRA guidance for further information on the current specifications required for any test.

5. What supply chain issues are expected with antibody testing

DHSC are working closely with the Department for International Trade and the Cabinet Office to investigate multiple channels of supply and delivery to support resilience in supply chains for antibody testing. We are also working with DEFRA to ensure there are no waste disposal issues downstream.

6. Will mass antibody testing ease lockdown measures?

COVID-19 is a new disease and the science around “immunity” to the virus remains uncertain. We do not, for example, know how long an antibody response to the virus lasts nor whether having antibodies means one does not transmit the virus to others. The value of antibody tests therefore is currently limited to answering the question of whether someone has had the virus or not. A positive antibody result it does not mean that you are immune, or that you cannot pass on the virus to others. Social distancing measures and government guidelines continue to apply.

In order to gain answers to these critical scientific questions, the UK Government is conducting some of the biggest seroprevalence surveys in the world – using lab-based tests to monitor the number of people that are presenting an antibody response and how this response changes over time.

7. Why aren’t Public Health England evaluating more antibody kits?

PHE conducts evaluations for its own use and to inform the decisions and recommendations of the cross-government group tasked by DHSC with overseeing the triage process for new tests

Scientific experts at PHE have been evaluating a number of lab-based antibody assays, including those produced by Roche and Abbott, using blood serum samples.

The results are shared with the manufacturers for their information. However, evaluation work is ongoing and the results will be published once all work has been completed and the results have been thoroughly reviewed

PHE is not a regulator and so does not have any role in approvals for tests for use in the UK. The Medicines and Health Products Regulatory Agency is the national regulator for medical tests and any test can legally be marketed and deployed in the UK once it receives a CE mark.

8. What test is being used for seroprevalence testing?

Blood sample surveys (seroprevalence surveys) are widely used to understand immune responses to different pathogens. This is done through laboratory analysis of the levels of different antibodies (IgM and IgG) which can be detected in blood samples. The body makes these antibodies after infection. They are a marker that a person has had the virus, and we hope is now immune and protected against a second infection. It takes two weeks to make IgM and four weeks to make IgG.

Initial seroprevalence testing used EuroImmun. More recently other assays have been used (e.g. In-house and commercial)

9. Will independent labs get access to approved antibody tests?

It very much depends on what the labs have been commissioned to do by government. The lab-based tests that are CE marked are available for purchase by private and government labs.

Testing Supply

1. Are supplies being procured centrally or by individual organisations?

Both. Central contracts are in place for certain supplies to support testing, but NHS and other providers can also procure themselves.

2. Where can we find information on the specific consumables/supply chains needed?

We will be putting out specific calls to industry during our webinars, providing information and detailed specifications for key testing supplies needed. The slides from each webinar, along with the specifications of key consumables will be circulated to all attendees and will be published on the ABPI website. Please see here the published slide decks from all previous webinars.

Further information on how you can help the government to increase testing can be found here: https://www.gov.uk/guidance/help-the-government-increase-coronavirus-covid-19-testing-capacity

3. Are you expecting for tests be manufactured and supplies to be sourced in the UK?

The Government is considering all options to help us grow our testing capacity for COVID-19 including international tests and supplies. That said, there can be logistical and supply chain challenges associated with importing tests and testing supplies and we are certainly keen to source from within the UK where possible.

Looking further to the future, as set out in the National Testing Strategy, we do want to work closely with British diagnostic companies, to build a resilient, diagnostic capability in the UK capable of meeting the testing demands over the coming months and years.

Surveillance

1. What are the geographical and age trends of COVID-19 prevalence in recent weeks?

Data collected from the surveillance work will help scientists working with the UK Government build estimates of the spread and rate of infection across different areas of the UK, different age groups and crucially, how that is changing over time.

The ONS [COVID-19 Infection Survey] findings have been published here: https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/conditionsanddiseases/bulletins/coronaviruscovid19infectionsurveypilot/latest

2. Are we confident that infection results in immunity?

The evidence that infection results in immunity will take time to develop. It is too early in the science of immunity for COVID-19.