Largest home antibody testing programme for COVID-19 publishes findings

- Over 100,000 volunteers have taken part in the world's largest home antibody testing programme for coronavirus.
- A further 2 studies showed some antibody finger prick tests were both easy to use at home and accurate enough for use in mass surveillance studies.

The first report from the world's largest home antibody testing programme tracking who has been infected by COVID-19 in England has today been published.

The study tracked the spread of infection across England following the first peak of the pandemic.

Over 100,000 volunteers tested themselves at home using a finger prick test between 20 June and 13 July to check if they have antibodies against the virus which causes COVID-19.

The findings indicate that 3.4 million people – 6% of the population – had already been infected by COVID-19 by 13 July 2020, with variations across the country.

People living in London were most likely to have been infected, as were those working in care homes and health care, and people from Black, Asian and other minority ethnic groups and people living in larger households.

It is the first mass antibody surveillance study to be rolled out across the country using a finger prick test that can be used by individuals at home if given approval in the future. Mass surveillance of antibodies in the population is vital to track the extent of infection across the country and identify differences between areas and different groups of the population.

While research showed several finger prick tests were accurate enough for large-scale surveillance studies to monitor the spread of COVID-19, no antibody fingerpick test has yet met MHRA criteria for individual use, which means none are currently approved for use outside of surveillance studies.

Health Minister Edward Argar said:

> Large scale antibody surveillance studies are crucial to helping us understand how the virus has spread across the country and whether there are specific groups who are more vulnerable, as we continue our work to drive down the spread of the disease.
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> We don't yet know that antibodies provide immunity to

> coronavirus, but the more information we can gather on this virus, and the easier we can make it for people to participate in these studies, the better equipped we will be to respond.
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> The British public have already played a massive part in helping to keep the country safe and I'd urge them to consider signing up to one of the many vital surveillance studies taking place over the coming months as part of our national testing effort.

Key findings of the report on the national home testing study include:

- In London, 13% of people had antibodies while in the South West of England it was less than 3%.
- The study showed high rates in those with people-facing jobs in care homes (16%) and health care (12%), compared to 5% of people who were not key workers.
- There were far higher rates in people from Black (17%), Asian (12%) and other (12%) than white (5%) ethnicity. Work is underway between the Department of Health, local Directors of Public Health and local authorities to understand and mitigate risks of transmission for BAME communities at a local level.
- Almost everyone with a confirmed case of COVID was found to have antibodies (96%).
- Those aged 18 to 34 were most likely to have antibodies (8%) with the lowest prevalence in those over 65 (3%).
- People living in the most deprived areas had higher antibody levels than those in the wealthiest areas (7% compared with 5%).
- People living in households of more than 6 or 7 people (12%, 13%) were more likely to have had the virus compared to those living alone or with one other (5%)
- People who smoked were less likely to have antibodies than non-smokers (3% compared to 5%).
- 32% of people reported no symptoms, and this was more common in people over 65 (49%).

This surveillance study will be repeated in autumn and will test a further 200,000 people for antibodies.

While some antibody tests require a larger sample of blood and for the sample to be sent back to a lab, these home antibody tests can be used at home, providing results in under 15 minutes and are more practical for use in large scale antibody surveillance studies. However, no LFIA are yet approved for home use outside of a research study.

Testing positive for antibodies does not mean you are immune to COVID-19. Currently, there is no firm evidence that the presence of antibodies means someone cannot be re-infected with the virus.

If someone tests positive for antibodies, they still need to follow national guidelines including social distancing measures, getting a swab test if they have symptoms and wearing face coverings where required.

Professor Graham Cooke, NIHR Research Professor of Infectious Diseases and research lead at Imperial, said:

> There are still many unknowns with this new virus, including the extent to which the presence of antibodies offers protection against future infections.
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> Using the finger-prick tests suitable for large scale home testing has given us clearest insight yet into the spread of the virus in the country and who has been at greatest risk.
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> These data will have important implications as decisions to ease lockdown restrictions in England.

Published today are 2 peer-reviewed papers from the REACT 2 team reporting the findings of studies carried out in May and June that led to the design of the study testing 100,000 people for antibodies.

The first study, published in the journal Thorax, is the biggest and most robust study on finger prick antibody tests. It analysed 11 finger prick antibody tests to evaluate their accuracy and ease of use among NHS workers, comparing them to gold standard lab-based antibody tests. The research team found the 4 best performing self-tests were able to accurately identify individuals with antibodies over 80% of the time, while also correctly ruling out those who don't in more than 98% of tested individuals. None of these tests met MHRA criteria for use outside of surveillance studies.

The second study, published today in Clinical Infectious Diseases, is one of the largest studies of the usability of home testing to date. With over 14,000 participants, 2 finger prick tests were used by members of the public who gave feedback to improve the process for testing in the larger study of 100,000 volunteers. The study found that over 97% of people were able to successfully perform the test on their own, and up to 94% had a valid result. Importantly, participants ability to read their test results on their own was very similar to that read by a clinician.

Taken together these 2 studies provide one of the most comprehensive assessments of home antibody self-testing to date and underpin the major findings reported today.

Professor Helen Ward, lead author for the study of population prevalence, said:

> Thanks to the contribution of tens of thousands of members of the public, we have shown that the pandemic of SARS-CoV-2 infection in England has spread very unevenly. It has fallen particularly heavily on ethnic minority groups and key workers, particularly in care homes and healthcare. Those in deprived and densely populated areas are most likely to have been exposed to the virus, and we need to do far more to protect people from any future waves of

infection.

Kelly Beaver, Managing Director – Public Affairs, Ipsos MORI said:

> The thorough and rigorous work carried out by Imperial College London has allowed us to find a robust at home finger prick test for COVID-19 antibodies. This is the springboard for developing a far greater understanding of COVID-19 antibodies and how prevalent they are in the population through our large-scale antibody study, conducted with over 100,000 members of the public.

The REACT programme, which has been commissioned by the Department of Health and Social Care, is being carried out in partnership with Imperial College Healthcare NHS Trust and Ipsos MORI.

The MHRA is the national regulator for medical devices and verifies all tests. For finger prick antibody tests to be suitable for wider use outside of academic surveillance studies, it recommends a sensitivity of at least 98%, correctly identifying those who have had coronavirus infection, and specificity of at least 98%, correctly identifying those who have not had coronavirus infection. None of these 11 tests evaluated during the first REACT 2 study met all criteria, and no other tests have met these criteria yet.

REACT 2 Study 1: The research team assessed 11 tests on just under 300 NHS workers who had recovered from COVID-19 at least 21 days previously and participants were asked to fill out a survey on how easy the tests were to use. Each device was assessed according to the manufacturer's instructions and performed first by the NHS worker followed by a technician. The tests were then compared against the accuracy of a lab test. Researchers also evaluated the tests on a batch of 500 blood samples from before the pandemic. The tests were evaluated on people with mild infection, who had not been hospitalised. Individuals who have had a mild infection are less likely to have launched a strong immune response to the infection, meaning they may only have low levels of coronavirus antibodies. Testing on these individuals will therefore give a good indication of whether the tests are suitable for large-scale community testing on the general population, outside the hospital setting, where cases are less severe.

Sensitivity of the 11 tests was variable, ranging from 21% to 96%, and in all cases was lower than what manufacturers reported. Tests which were more than 80% sensitive underwent further specificity testing.

On specificity, the finger prick tests were found to correctly identify the absence of antibodies 97% of the time and were therefore deemed suitable for use in national-scale antibody studies. Six had specificity over 98%, which the UK Medicines and Healthcare products Regulatory Agency recommends as the minimum level for use in clinical settings. This means they are reliable enough for use as a healthcare test at individual level as they provide a low number of false negatives.

There are 2 types of antibodies produced called IgG and IgM. Some lateral flow antibody tests are looking for the presence of both and some just for one.

This study looked at the sensitivity and specificity rates for detecting IgG antibodies to the coronavirus. These are typically long-lasting antibodies produced in response to infection.

REACT 2 Study 2 and 3: A major public involvement exercise and usability study was carried out with members of the public to assess how easily people can use the antibody tests at home without supervision. Feedback from an initial pilot study involving 315 people was used to guide the design of the antibody testing pack and instruction guides. The findings of this study were also used to inform a large-scale survey of adults in England, involving 14,400 volunteers, who took one of two different antibody tests and provided feedback. This work under-pinned the launch of REACT 2 Study 5, the population study of 100,000 volunteers.

Devices with lower sensitivity can still play an important role in surveillance studies as long as the specificity is high enough and the results are not used to guide behaviour.

The reports published for pre-print can be found here