

Testing for COVID-19

Briefing and Testing Priorities
Directors of Public Health Humber

(Reproduced with the kind permission of Wakefield Council Director of Public Health and Clare Offer)

Key Messages:

- This is local advice developed by the Humber Directors' of Public Health based on the current evidence. Guidance in relation to COVID-19 is developing rapidly and national guidance may be produced which supersedes this briefing paper.

Public Health advice relating to testing will be kept under review and updated as necessary.

- The rapid expansion of PCR testing is fully supported, in order to increase our understanding of the spread of COVID-19 in our communities and eventually, to support control measures such as isolation and contact tracing.
- The development of reliable antibody tests is also supported. These will greatly increase our understanding of who has had the virus in the population. We urge caution about the concept of 'immunity passports' as a way of resuming social mixing and work, until we have a better understanding of people's immune response to COVID-19, and how long it might last.
- There is a risk of false negatives as no test is 100% accurate. For this reason, **our local advice is that where a key worker has a negative PCR test result, a local risk assessment should be conducted before returning to work. We strongly advise against employees returning to work in patient-facing, high risk roles before the self-isolation period ends.**

If the key worker is self-isolating because of a household member's symptoms and that household member tests negative, we recommend an individual risk assessment is carried out and documented before the key worker returns to work. The risk assessment should consider the household member's clinical symptoms, how likely they are to have been exposed to COVID-19, the nature of the key worker's job and whether any potential risks of false negative results could be mitigated.

If a key worker who has tested positive for COVID-19 during an episode of illness is identified as a close contact of another positive confirmed case of COVID-19, they must self-isolate for a further 14-days. If they become symptomatic, they must be tested for COVID-19 again.

If another person in the household develops symptoms and they have not previously tested positive for coronavirus (COVID-19), then they need to isolate along with all other members of the household except for the individual who previously tested positive for coronavirus (COVID-19).

- Evidence suggests that PCR testing is best done on day 1-3 of symptoms developing, to minimise the chances of a false negative result. We would advise that testing is offered at least 48 hours after symptoms develop, and that people presenting earlier are asked to wait (especially if they are key workers).
- Tests vary greatly in their reliability and we would advise individuals or organisations against purchasing their own tests independently.
- Prioritisation of staff testing is required to ensure business continuity across the system.

Why do we need to test?

Surveillance: To understand where COVID-19 is spreading, how rapidly, and what the levels of infection are in the community. This helps to inform national decisions about control measures (e.g. social distancing and 'lockdown').

Treatment: To identify individuals with COVID-19, particularly with severe symptoms, to support decisions about treatment and infection control.

(Note: This will become more important as effective therapies specific to COVID-19 are developed. Currently treatment for mild to moderate illness does not vary significantly from other severe respiratory illnesses such as flu, and most people will recover on their own.)

Frontline: To confirm whether key workers are at risk of catching or transmitting the virus, with the aim of reducing the number of key workers in self-isolation and increasing health and social care workforce capacity.

Outbreak control: When cases are at a low enough level to make this feasible, controlling outbreaks of COVID-19 by identifying individual cases, tracing and testing their close contacts.

Public Health England (PHE) is currently working with the Department of Health and Social Care on an integrated approach to scale up contact tracing, even in times of sustained community transmission, as a way to potentially ease some of the UK lockdown measures.

Immunity: To understand whether people have had COVID-19, developed immunity, and could safely return to work or school without risking catching or transmitting the virus.

Different types of testing:

1) **PCR Antigen Tests**

"Do I have the virus right now?"

This test determines whether someone is currently infected with COVID-19. It involves taking a swab of the patient's nose or throat, and extracting the genetic material (RNA) of the virus. Polymerase chain reaction (PCR) is the process used to amplify the genetic material.

Once a person has recovered the test can no longer tell whether they have been infected or whether they have immunity.

Accuracy:

The PCR antigen test is very accurate in identifying the virus, so false positives are very unlikely (i.e. it has a high degree of specificity).

As part of PCR antigen test assurance work, PHE's test was compared against nine of the best commercial tests available at the time and the differences in performance were found to be negligible.

In March 2020, further analysis was conducted on 1,144 samples within one laboratory. Of all the samples, 35 were found to have discrepancies between the results from PHE and commercial tests. This fell to 15 discrepant samples after updating a component within the PHE antigen test (which was

found to have degraded as a result of a manufacturing problem). Discordant results between different test systems were at a rate of less than 2%. The steps for testing staff to take to mitigate the issue related to the degraded component have been issued to laboratories.

It has always been the intention to move from the PHE antigen test to commercial test kits once available, as is standard practice for any diagnostic test and this transition is now underway. All PHE laboratories are now switching to CE-marked kits whilst most NHS Trusts are already using commercial kits.

There is a risk of false negatives as no test is 100% accurate. The majority of false negatives are in people with mild symptoms and who are typically less infectious and unlikely to pass the virus onto others.

The likelihood of a false negative is influenced by:

- The type of swab
- Timing of test in relation to onset of symptoms
- How much COVID-19 is circulating in the population
- The use of different assays in laboratory testing
- How swabs are taken (i.e. self-swabbing v staff swabbing)

False negatives are a real possibility and need to be taken into account in deciding whether staff members in self-isolation because of symptoms should return to work 'early'. The current stance is we need to be aware that an unknown proportion (%) of false negative test results are probable and therefore care must be taken in acting upon any negative test results.

A pragmatic approach is advised. For staff testing, we need to think about risk and mitigation requirements.

This presents a particular problem in testing key workers. We know that when we use a test in a population where many people have the illness we are testing for (e.g. health workers with symptoms of COVID-19), a negative result is even less reliable (the 'negative predictive value' is lower). Hence, the chances of a false negative result in key workers who have symptoms and who we know have been exposed to the virus are even higher than in the general population.

This leads to our advice regarding key workers with negative test results:

- Key workers should not return to work until they are completely well (i.e. no longer have symptoms).
- If the key worker is feeling well, a local risk assessment should be conducted. It is strongly recommended the key worker considers completing self-isolation for 7-days as a precaution.

Based on the local risk assessment, the employer may consider it reasonable for the key worker to return to work in low risk settings.

We strongly advise against key workers' returning to patient-facing, high risk roles before the self-isolation period ends.

If we are testing a key worker's household member who has symptoms leading them to self-isolate, the household member may well be from a group of the population where fewer people have or have been exposed to COVID-19. For example, many key workers are currently self-isolating because their child has symptoms of cough or fever. We know that generally we would expect to see these symptoms in young children for a whole range of reasons and that their exposure to COVID-19 will

have been more limited. Thus we would have more confidence in a negative result, and this leads to the recommendation that if a household member tests negative there should be an individual risk assessment before the key worker returns to work.

The test is most accurate on day 1-3 of symptoms developing, so to minimise the likelihood of false negatives it is best conducted at this stage rather than as soon as symptoms are noticed. After 5 days the test becomes less reliable again as patients begin to recover and have less detectable viral material.

Who is this test for?

Ideally, as many people as possible because it will help us to understand how many people have the virus and where it is most prevalent. Once case numbers fall to much lower levels as a result of lockdown, it will also be an essential means of helping to trace the contacts of an infected person and suppress individual outbreaks of the virus.

However, there are global supply challenges, with huge demand for the PCR primers as well as for the positive controls needed to ensure the performance of individual machines. Different machines require different chemicals to make their particular test work, and there are global supply shortages of individual types of reagent.

Testing is being ramped up across the UK with three industrial scale labs being developed in Manchester, Glasgow and Milton Keynes. In the meantime, testing capacity is being prioritised nationally as follows:

- The sickest and most vulnerable patients who are admitted to hospital with severe symptoms of COVID-19
- Increasing capacity to test health and social care workers and other essential staff, or their household members, where they, or a household member, has symptoms consistent with COVID-19. This potentially enables the worker to return to work if the household member tests negative.
- PCR testing capacity will eventually be rolled out to other sectors of the population.

2) Antibody Test

“Have I had the virus and am I now immune?”

This is a blood test which will identify whether a person has had the virus and is now immune. It is likely to be able to identify antibodies produced in response to a current or very recent infection (IgM) and longer term antibodies which develop after about 28 days (IgG).

At present we believe that immunity to COVID-19 develops after about 28 days, but it is important to stress that we don't know how long lasting that immunity will be. Evidence is conflicting: experience of some other coronaviruses suggests that immunity can be relatively short term, while some studies of SARS-COV-1 have found immunity to last several years.

This test may be helpful in the future in determining how many people have had mild or asymptomatic cases of COVID-19, and in clearing individuals with immunity to return to work or school.

Given that the test can't assess long term immunity before 28 days, it is unlikely to offer any advantage over PCR testing for determining whether a key worker with symptoms could safely return to work.

Pillar 4 serology testing was launched by the UK Government on 21 May 2020. On the 28 May, antibody tests were made available to NHS and care staff, eligible patients and care residents in England to see if they have had coronavirus as part of a new national antibody testing programme. Public Health England independently evaluated the Roche Elecsys Anti-SARS-CoV-2 serology assay for the detection of anti-SARS-CoV-2 in serum samples. The assessment involved 93 serum samples from individuals who had recovered from COVID-19 and 472 negative samples assessment (i.e. individuals who had not previously had COVID-19 infection). All negative samples tested negative by the assay (i.e. specificity of 100%) and overall sensitivity was 83.9%.

These testing kits are newly developed and further research is required to understand the long-term immunity to COVID-19. There is currently no evidence that people who have recovered from COVID-19 and have antibodies are protected from a second infection. As such, we recommend those who have tested positive for COVID-19 antibodies (anti-SARS-CoV-2) comply with self-isolation guidance if they experience COVID-19 symptoms or are identified as a positive case's close contact.

3) Combination Testing

A recent paper showed that the combination of IgM ELISA (testing for recent antibodies), plus PCR detected 98.6% of cases versus 51.9% with a single PCR.

Early results are promising but lots more work is needed to roll this out as a national test.

Public Health England Role

Public Health England (PHE) are not directly delivering this programme of testing.

The PHE role is to help people understand what testing is available, how testing is being nationally prioritised, and how testing will develop in the future.

PHE are working alongside the Department of Health and Social Care to scale up contact tracing. The NHS Test and Trace contact tracing programme was launched on the 28 May 2020 across England. The service aims to help identify, contain and control coronavirus transmission, reducing the spread and impact of the virus. PHE and DHSC are working with the Local Authorities to manage COVID-19 outbreaks.

Mass testing and contact tracing: will these reduce lockdown measures and social distancing?

An expansion of PCR testing will greatly help our understanding of how many mild or asymptomatic cases there are in the community at any one time. Antibody testing would help us to understand how many people may have already had the virus in a mild or asymptomatic form. Both may help to inform decisions about the level at which the virus is circulating within the community, levels of population immunity, and how long we need to maintain social distancing or 'lockdown' measures for.

Contact tracing is a key tool in managing outbreaks but it is very resource-intensive and usually applied to tens or in severe outbreaks hundreds of cases. In the UK people have tested positive for COVID-19, and we expect there to be many more cases with mild symptoms.

Public Health England is currently working with the Department of Health and Social Care and Local Authorities on an integrated approach to scale up contact tracing, even in times of sustained community transmission, as a way to potentially ease some of the UK lockdown measures.

Contact tracing is important for managing outbreaks in confined settings e.g. care homes, prisons.

Lockdown and social distancing remain crucial for suppressing new cases, until we reach a level where we can realistically undertake contact tracing to manage individual cases and emerging pockets of infection.

It is unlikely to be possible to come out of lockdown until we have greatly expanded our capacity for testing and contact tracing. Even when we have emerged from the most severe version of 'lockdown', handwashing, respiratory hygiene and social distancing will still be massively important in keeping the virus under control.

Advice for the public and professionals on other tests:

Some manufacturers are selling products for the diagnosis of coronavirus (COVID-19) infection in community settings, such as pharmacies.

The current view of Public Health England is that use of these products is not advised.

We can confirm that there are no CE-marked tests for home use, and it is illegal to supply such products.

There are many uncertainties as to how well any of these tests work, particularly antibody tests, and we would not advise that individual health or social care settings (e.g. GP practices or care homes) make use of them.

Testing prioritisation across staff groups:

Staff testing is required to get staff out of self-isolation and back to work as quickly and safely as possible. Staff testing priorities are required to ensure business continuity across the system. Testing capacity will be split and allocated across the system partners as follows:

- Acute Trust (incl. ICU, A&E and paramedic staff)
- Acute Trust (incl. all other hospital staff)
- Community Trust
- Adult Social Care
- Children's Services (incl. all children's social care and nursing)
- Mental Health Trust
- Primary Care
- Care Services (incl. residential, domiciliary and hospice care)

As testing capacity becomes available and increases, there will be flexibility in the Humber to offer testing to other key workers, such as Police, Fire and Rescue, Prison staff etc.

NB: Allocations are guides only. The number of tests available to staff will be flexible to ensure a proportionate response.

References and further reading:

Department of Health and Social Care, 2020. Coronavirus (COVID-19): Scaling up our testing programmes. Available here:

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/878121/coronavirus-covid-19-testing-strategy.pdf

Public Health England, 2020. COVID-19: management of exposed healthcare workers and patients in hospital settings. Available here: <https://www.gov.uk/government/publications/covid-19-management-of-exposed-healthcare-workers-and-patients-in-hospital-settings/covid-19-management-of-exposed-healthcare-workers-and-patients-in-hospital-settings>

Public Health England, 2020. Evaluation of Roche Elecsys Anti-SARS-CoV-2 serology assay for the detection of anti-SARS-CoV-2 antibodies. Available here:

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/887222/PHE_Evaluation_of_Roche_Elecsys_anti_SARS_CoV_2.pdf

Public Health England, 2020. Stay at home: guidance for households with possible coronavirus (COVID-19) infection. Available here: <https://www.gov.uk/government/publications/covid-19-stay-at-home-guidance/stay-at-home-guidance-for-households-with-possible-coronavirus-covid-19-infection#ending-isolation>

Gleave, R. 2020. Contact tracing: letter to Directors of Public Health. Available here:

https://www.gov.uk/government/publications/contact-tracing-letter-to-directors-of-public-health?utm_source=7b644133-8de5-44b8-a10d-1d0cef430e26&utm_medium=email&utm_campaign=govuk-notifications&utm_content=immediate

Science Media Centre, 2020. Expert comments on different types of test for COVID-19. Available here: <https://www.sciencemediacentre.org/expert-comments-on-different-types-of-test-for-covid-19/>

Wilson, M.E (2020). Serologic tests for SARS-CoV-2: First steps on a long road. Available here: <https://www.jwatch.org/na51255/2020/03/31/serologic-tests-sars-cov-2-first-steps-long-road>

Petherick, A. 2020. Developing antibody tests for SARS-CoV-2. Available here:

[https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(20\)30788-1/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)30788-1/fulltext)

Wilson *et al.*, 2020. Testing for COVID-19 in New Zealand to Achieve the Elimination Goal. Available here:

<https://blogs.otago.ac.nz/pubhealthexpert/2020/04/06/testing-for-covid-19-in-nz-to-achieve-the-elimination-goal/>

Acknowledgements

The following people and organisations have contributed to this document:

Mike McDermott – Associate Director of Public Health, East Riding of Yorkshire Council

Megan Doran – Public Health Senior Officer (Health Protection), East Riding of Yorkshire Council

Clare Offer – Public Health Registrar, Wakefield Council

Wakefield Council Public Health

East Riding of Yorkshire Public Health

Hull City Council Public Health

North East Lincolnshire Public Health

North Lincolnshire Public Health

Public Health England

Humber Local Resilience Forum (LRF) through the Testing Cell