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Occupational Health Briefing Note Covid-19 Testing 23rd April 2020 By Dr Bernard Yew Consultant Occupational Health Physician PAM Group Medical Director

There has been a significant push by the government on testing and PAM Group are aware that there are an increasing number of suppliers offering rapid antibody testing kits for sale. This note informs clients on the limitations and facts that employers should consider as part of any testing programme.

There are two types of Covid-19 tests

Test Type	Purpose	Current Status
Antigen	Detects the genetic structure of Covid-19 and indicates if a person has Covid-19. Used to treat infected people.	Being used by the NHS to test patients and key workers in the UK
Antibody	Detects the blood structure of a person is used more to assess if a person has the Covid-19 antibodies and has had the virus. Used to trace infection and levels of immunity.	None currently approved in the UK, may be the likely test used as part tracing the virus and implementing any lockdown restrictions

What about antigen testing?

This is mostly being used by the NHS for patients and key workers. It is used to diagnose if the virus is present and allow treatment to be provided. It should be used where there is a suspicion that a person may have the virus or to provide surveillance on key workers to detect and protect them.

Can PAM provide antigen testing?

Yes, in exceptional circumstances testing can be provided however, there is currently capacity in the UK government testing programme for key workers therefore we would only consider testing for non-key workers in exceptional circumstances. We would advise that if there is a requirement for antigen testing then the person should be referred to the NHS either as a key worker or a patient

What does the antigen test involve?

When obtaining a sample, a swab which resembles an extra-long cotton bud is pushed deep inside the nose or to the back of the throat. The swab is then sent off to a lab

How long does it take to get a result?

Most labs use a method called the polymerase chain reaction (PCR), which takes several hours. It can take about 48 hours for labs to run the tests and tell people their result. Several groups around the world, are developing faster genetic tests, typically based on a method called loop mediated isothermal amplification (LAMP). This method takes less than half an hour. Handheld LAMP tests that could be used in homes and airports and this method may start to become available within weeks.

How accurate are antigen tests?

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Genetic testing to identify the presence of the virus should be accurate and reliable if done properly. However, data from China has shown that false negatives and false positives can occur. This may be because the swabbing wasn't done correctly, or because overworked lab technicians were making mistakes

What about antibody testing?

The World Health Organisation has advised that widespread testing will be a key factor in reducing lockdown restrictions and allowing societies to get back to normal living. It is likely that if an Antibody test is approved it would be an appropriate test to assess if a person was a risk and could be released from restrictions e.g. be safe at work.

What is the delay in approving antibody testing?

Medical Science! There is a lot that we do not know about Covid-19, the UK government has not approved an antibody test yet because the tests have limitations and the range of results from testing is not straight forward. There are two types of antibody tests are being worked on;

- 1. A rapid test device that can produce results there and then in around 15 minutes
- 2. A laboratory analysed blood test this can take 3 working days for results to be provided.

Whilst the rapid test is the most desirable for speed, none are approved and their results are unreliable; at this time the laboratory blood test is more accurate.

What are the limitations of antibody tests?

Antibody testing cannot detect infections in the first two weeks or so, when people are most contagious. However, our bodies normally keep making antibodies even after we have recovered from an infection, so testing the blood of individuals for antibodies against this coronavirus should reveal how many of us have been infected so far. This will help in the calculation of the infection fatality rate.

Due to the rapid outbreak of Covid-19, the level of trialling this test is nowhere near what we would expect and therefore the quality of the test is very much in question. The Spanish government sent 640,000 rapid device tests back to a Chinese manufacturer as the test were only 30% accurate.

Every person is different. Therefore the test may produce wrong results and lead to a false sense of security, resulting in faster spread of the outbreak.

Can antibody testing assist in providing an indication if a person is fit for work?

Yes, this is possible. It could take one or more tests at intervals and there may be some occasions where genetic testing for the virus would help as well. It is unlikely that antibody testing will lead to an earlier return to work, compared to current UK government guidelines on when a person can go back to work, if suspected of having COVID-19.

Can antibody tests distinguish between people who have recovered and those who are still infected?

Yes. Individuals should start producing antibodies against COVID-19 around 10 days after showing symptoms (perhaps 15 days after infection). After another two days, their bodies should start making a



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new type of antibodies. Most people will recover fully as soon as the new antibody levels peak around a month after the onset of the disease.

How accurate are these 15 minute rapid antibody?

Numerous companies are marketing and selling these kits. To date, there is no convincing evidence that these mass-produced testing kits are sufficiently accurate. Professor Sir John Bell of Oxford University indicated that the most promising rapid antibody test kits have been evaluated but unfortunately, none of them performed satisfactorily. There were many false negative results (virus is present when result indicates that it is not) and unacceptable false positive results (virus not present but result indicates that it is) as well. Professor Bell indicated that none of the tests validated would have met the criteria of a good test, as agreed with the MHRA (Medicines and Healthcare products Regulatory Agency). We are aware that organisations are being approached by suppliers of rapid device antibody testing kits. Suppliers are making spurious claims or simply misleading buyers.

At this time there is no such rapid testing kit which has been validated by MHRA/PHE.

Having a reliable and accurate antibody test kit may still be some weeks away. Having no test is better than having insufficiently accurate tests. Therefore, PAM Group would advise employers against purchasing such products. The supplier may indicate that the product has been registered with the MHRA but that does not mean that it has been validated by the regulatory body. There are still significant steps between registration and validation of the product.

What about antibody blood testing?

The accuracy of these tests is currently better than the rapid device a test, the downside is that they require laboratory analysis therefore results are provided in 2-3 working days.

Can PAM provide antibody blood tests?

Yes. Our laboratory is currently providing this service and we would advise that if an organisation feels that it must start antibody testing, we would recommend that the safest practice is a nurse review and an antibody blood test is conducted.

We recognise these are difficult times and we remain determined to support all our clients where ever possible. It is comforting to know that technologies are being constantly developed and we are regularly reviewing the situation. As soon as there is a validated product available, we will update our advice.

Should you have any further questions or need help please do not hesitate to get in touch.

Your Sincerely,

Dr Bernard Yew

PAM Group Medical Director