UTILITY OF THE WONDFO SARS-CoV-2 TEST

Understanding the antibody status of the population will be key for public health agencies and the Government when deciding to relax social distancing rules and allowing a return to normality. As PCR based tests do not inform on an individual's immune response to the virus, Wondfo's SARS-CoV-2 POCT is ideal and essential tool for this surveillance.

The Wondfo Biotech manufactured SARS-CoV-2 point of care test (Wondfo POCT) detects antibodies to the SARS-CoV-2 virus, which causes the COVID-19 disease. The presence of antibodies to SARS-CoV-2 may convey a level of immunity to COVID-19 and will be invaluable in the management of the COVID-19 pandemic.

Manufactured to the highest standards
The Cellmid sponsored Wondfo SARS-CoV-2 kit is manufactured to the highest standards in a facility certified by the Australian Therapeutic Goods Administration (TGA), the US Food and Drug Administration (FDA) and the Chinese National Medical Products Administration (NMPA) under the Medical Device Single Audit Program (MDSAP). Wondfo's facility has a current export certificate.

Strong clinical performance
The clinical dataset and technical validation remains one of the strongest in the industry with 596 people tested for antibodies against the SARS-CoV-2 virus including some at an early stage of symptoms. The Wondfo POCT showed 94% concurrence with the Polymerase Chain Reaction (PCR) method, which detects the virus itself, over the study. It has a specificity of 99.6% (false positives) and sensitivity of 83.4% ove the first 3-7 days of symptoms (false negatives). Sensitivity improves significantly as the disease progresses.

Utility in exposure and immunity detection
The Wondfo POCT provides important information on the antibody response to SARS-CoV-2 and thus potential immunity to the virus, which allows for implementing surveillance programmes in the population; sampling for herd immunity and detecting an individual's immune system status to help ensure that people return to work safely. It may also be used in the management of the COVID-19 pandemic by improving detection rates in combination with PCR method.

PCR sampling error is high – room for improvement
While PCR is used as the current gold standard method in the diagnosis of acute disease, it is reliant on accuracy of sampling. If there is virus in the collected sample PCR is highly accurate, however the success of sampling depends on the person taking the sample, the patient's stage in the disease and their individual manifestation. As the virus moves through the respiratory system, from the nose to the throat and then deep in the lungs, sampling efficiency changes, with nasal swabs with PCR showing only 63% success rate, and oropharyngeal swabs detecting virus only 30% of the time (Wang et al JAMA 2020). This may lead to missed cases, and PCR is often repeated multiple times before a positive is seen.

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Improving detection of COVID-19 with antibody POCT in combination with PCR
A recent study by Zhao et al, funded by the Bill and Melinda Gates Foundation and published in the journal Clinical Infectious Diseases, 2020, showed that RNA based sampling only detected the virus successfully 67% of the time in the first week after onset of symptoms, falling to 46% in week 2. Importantly, Zhao showed that by combining antibody-based screening methods with PCR, detection rates of COVID-19 were improved ($p<0.001$), even in very early disease in days 0-7 ($p=0.007$).

Investigating the immune status of the population
Our understanding of the SARS-CoV-2 virus dynamics in the population is limited, particularly as many of those infected may only experience very mild symptoms or none at all. The danger in emerging viruses like SARS-CoV-2 is that there is no underlying immunity in the unexposed population, leading to high infection rates, serious illnes and fast spread. Social distancing rules have been brought in to "flatten the curve", reducing the rate of spread, so that the number of new cases per day does not get too high and overburden our health systems, particularly critical care. It is also thought that herd immunity might slowly develop over time.

Governments recognise the importance of POCT antibody tests
The German goverment has recently announced that from the end of April they will start mass testing of the population with antibody tests to monitor immunity levels and issue cerificates to those who are safe to return to work. The US government called for the development of antibody tests in a POCT format to facilitate widespread testing for immunity. India, Spain and Argentina are using antibody POCT tests in acute diagnosis in the absence of adequate PCR infrastructure.

Utility in research
There is a strong global momentum to rapidly develop an effective vaccine against SARS-CoV-2. Clinical studies will require monitoring subjects for developing immunity, which can be done only by monitoring antibodies against the virus. Cellmid will continue to collect and report data and collaborate with research groups.

The Wondfo POCT was designed to be used by medical professionals only and it is not suitable for 'at home' use. The POCT does not replace PCR based tests that detect viral material in swabs and it does not diagnose infectious state. The Wondfo POCT detects the body's own response to the virus in the form of IgM and IgG antibodies. Both tests are important in disease management; PCR informs on infectious state, the Wondfo POCT on exposure and immunity.

Note
Please note the above information reflects our current understanding of the COVID-19 pandemic, testing and utility of various testing methodologies. This is not meant to be a comprehensive review or a form of advice. If you are concerned that you are experiencing COVID-19 symptoms, you need to contact your doctor who will be able to refer you to the appropriate testing facility.

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