

MEDIA RELEASE:

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AUSTRALIAN COVID-19 TESTS APPROVED FOR USE IN EUROPE

Australian biotech company Microbio has broken into the international market following the approval of its COVID-19 tests for sale and use in Europe. The company has been granted a CE Mark following extensive testing of its product across three continents.

Now based at Queensland's Translational Research Institute, Microbio says that this approval will enable the privately held scale-up to move into additional international markets, including India (and the subcontinent), North America, Africa, and Asia.

The approval follows comprehensive testing in Australia, the United States, the United Kingdom, Italy, and India and comes at a time when the company is seeking to establish advanced manufacturing in Australia to produce its patented reagents.

Microbio Chief Scientific Officer Dr Flavia Huygens said that when COVID-19 began to spread across the world, the company pivoted to adapt the core Microbio technology to develop two distinct versions of InfectID-COVID-19 tests — Detection and Replicating tests. Microbio's InfectID-COVID-19 tests have been designed to specifically target unchanging regions of the SARS-CoV-2 genome and are unlikely to have their accuracy reduced as new variants of SARS-CoV-2 emerge. This successful detection of all variants includes the Mu variant.

The InfectID-COVID-19 tests have been compared to other real-time Polymerase Chain Reaction (PCR) tests that claim to detect all variants, and it had a 100% success rate.

In addition to the Detection test, Microbio's InfectID-COVID-19-Replication test is a novel real-time PCR test designed to detect the SARS-COV-2 virus while it is in its early replicating phase.

"We know that this is one of the biggest limitations of the current PCR-based tests – they can't tell if the virus they're picking up is replicating and infectious, or simply inactive pieces of the virus that the body sheds as it fights the virus," Dr Huygens said.

"The good thing about our tests, is that they use standard laboratory real-time PCR equipment. There's no need for labs to buy expensive new equipment or retrain their staff. The reagent has been tested in a National Association of Testing Authorities, Australia (NATA) accredited lab on existing equipment."

Microbio's Chief Executive Officer Paul Carboon said that the company has the immediate capacity to deliver 500,000 tests a week from a manufacturing facility in Canada. He added that the company expects to manufacture in Australia and is seeking government support to make its technology available to the health system in Australia and key export markets.

"This is a breakthrough. As the world looks to open safely, having testing that detects the presence of SARS-CoV-2 in the early stages of the infection, when the virus is actively replicating (and is likely most infectious) is vitally important and it is exciting that an Australian company has been able to develop this technology."

"We have had considerable interest from overseas including the United States and India, and gaining the CE Mark opens up the world to us," Mr Carboon said.



For more information, visit microbio.com.au.

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For media enquiries or interview requests with Microbio's Chief Scientific Officer, Dr Flavia Huygens or Chief Executive Officer, Paul Carboon, contact:

Nicole Panoutsos | Wrights | + 61 423 506 714 | npanoutsos@wrights.com.au

About Microbio

Microbio is an Australian biotechnology company based in Brisbane. The team at Microbio has brought together the latest advances in bioinformatics, genomics and molecular microbiology to develop a unique and revolutionary pathogen detection test. The Microbio team is working tirelessly to deliver their game-changing new test to the millions of patients who will benefit from better pathogen diagnosis. Microbio is actively seeking partners worldwide, especially in population health and virology, who will integrate this new information into their proactive regional and corporate testing protocols. Additionally, Microbio is looking to work with pathology laboratory partners who can help deliver these highly specific results faster and to remote locations to improve health, regardless of a patient's location.

About InfectID®

InfectID® is a diagnostic technology that detects and identifies bacterial, fungal and viral targets. The test targets Single Nucleotide Polymorphisms (SNPs), the pathogen's DNA 'fingerprint', found at a specific point in each pathogen's genetic code. By focusing on SNPs rather than the whole genome, the process is fast, inexpensive, highly sensitive and can be adapted to target different pathogens. The technology was refined and became the foundation of Microbio's core product InfectID®-Blood Stream Infection (which is currently in development) InfectID®-Blood Stream Infection uses real-time Polymerase Chain Reaction (PCR) to identify Sepsis-causing pathogen species directly from whole blood without the need for pre-culture. Because the technology is suitable for detecting viruses, the company pivoted in 2020 to develop SARS-CoV-2 detection tests.

Microbio Founders

Dr Flavia Huygens | Executive Director, Founder and Chief Scientific Officer

Flavia's 30-year teaching and research career has focused on molecular microbiology, with a particular focus on human pathogens. Flavia's expertise and exceptional ability to bring together emerging technology in molecular microbiology, genomics, proteomics and bioinformatics have culminated in the creation of InfectID. Flavia recently received a DMTC Ltd 2020 Excellence Award in recognition of exemplary professional conduct in support of DMTC's objectives.

Paul Carboon | Executive Director, Founder and Chief Executive Officer

Paul has 25 years of commercialisation experience. In the technology sector, Paul brings deep understanding of commercial and product management as well as product development. Paul is a leader in biotechnology innovation. He currently serves on the AusMedtech national advisory group and is a founding adviser with the BridgeTech Program. Paul is also an Honorary Fellow of Biotechnology at Melbourne University and has been a judge for the prestigious Eureka awards.