

ASX Announcement

26 November 2020

AnteoTech Freeze Design of COVID-19 Antigen Rapid Test After Showing Saliva Proxy Sample Use Case Effectiveness

Highlights

- ❖ All development processes required to declare design freeze completed on time and on budget.
- ❖ Saliva sampling development work conducted by AnteoTech indicates that the test can detect SARS-CoV-2¹ antigen in artificial mucus.
- ❖ Clinical trial planning discussions with Victorian Infectious Diseases Reference Laboratory (VIDRL) a unit of Doherty Institute underway and on track for December 2020 commencement.
- ❖ Key supply agreements signed, as well as MOU with Operon (Spain) for contract manufacturing to supply overseas markets.
- ❖ Initial discussions for contract manufacturing in Australia via Ellume completed.
- ❖ High Sensitivity² COVID-19 Antigen Rapid Test on track for launch in late Q1 CY2021/ begin Q2/21.
- ❖ Global market outlook and demand remains strong.

AnteoTech Ltd (ASX: ADO) ("AnteoTech" or "the Company") is pleased to announce that all development processes and internal testing procedures for the high sensitivity COVID-19 Antigen Rapid Test (ART) are complete and the Company has declared a "design freeze" for the product³.

Attributes of COVID-19 Antigen Rapid Test final design include:

- Test completion in cassette in under 15 minutes which includes less than 1-minute analysis time in reader.
- High Sensitivity – 0.02 ng/ml antigen concentration and positive sample detection in low viral load samples (Ct value of 30 and above).
- Inhouse experiments have detected antigen in artificial mucus mimicking saliva samples.

To date the development of AnteoTech's ART has focussed on the use of nasopharyngeal swab samples, however recent lab testing conducted by AnteoTech using artificial mucus

¹ The AnteoTech Antigen Rapid Test detects the Sars-Cov-2 active virus that causes the disease called COVID-19.

² Refer to the World Health Organisation "Antigen detection in the diagnosis of SARS-COV-2 infection using rapid immunoassay – Interim Guidance – 11 September 2020" <https://apps.who.int/iris/rest/bitstreams/1302653/retrieve>

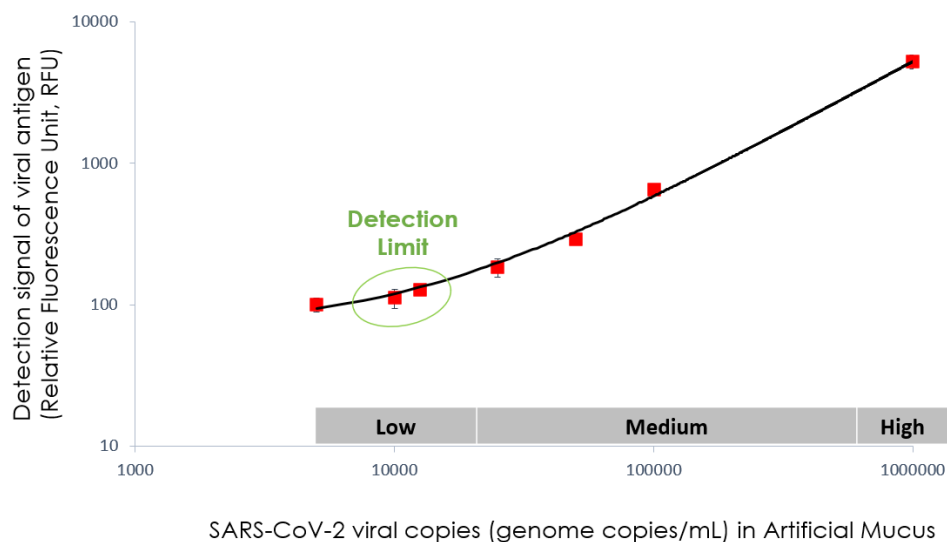
³ Please refer to previous announcements made to ASX on 16 July 2020, 9 September 2020 and 21 October 2020 in relation to COVID-19 Antigen Rapid Test development.

indicates that good detection of SARS-CoV-2 antigen at low viral loads can also be obtained in human saliva, opening the opportunity for integration of a saliva test, once validated independently, into the existing nasopharyngeal test protocol.

The test used an artificial mucus developed from natural mucin and electrolyte to produce a liquid which replicates the viscosity and elements of saliva to mimic saliva and mucus produced by the salivary glands in the mouth. The artificial mucus was spiked with inactivated SARS-CoV-2 virus simulating varying viral loads from real world examples. Saliva and mucus from the mouth is naturally expected to carry lower amounts of antigen when compared with nasopharyngeal swab samples obtained from the same patient. Seven different viral load levels were produced, the lowest level simulating a viral load typically seen in patients' early stage of infection (pre symptom onset) or late stage of infection. Each viral load level was tested 6 times result being recorded for each iteration of the test. This was repeated for all seven viral levels.

The ability to detect signals from artificial mucus samples spiked with low antigen load again confirms the sensitivity of AnteoTech's ART test.⁴ These internal results are subject to external validation and clinical trial.

Detection of Inactivated SARS-CoV-2 Virus in Artificial Mucus



Design Freeze a critical milestone – On track for market launch



All development work required to declare a 'design freeze', the point at which the technical work and inputs are locked in, has now occurred in line with our development schedule and budget. This includes finalisation of key contracts for the procurement of antibodies and Europium particles. The design freeze incorporates both artificial mucus and nasopharyngeal swab sample protocols.

⁴ Refer to the World Health Organisation "Antigen detection in the diagnosis of SARS-COV-2 infection using rapid immunoassay – Interim Guidance – 11 September 2020" <https://apps.who.int/iris/rest/bitstreams/1302653/retrieve>

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We are planning to contract manufacture at multiple sites. In order to supply overseas markets we have signed an MOU with Operon (Spain) to allow detailed planning for manufacturing processes to be undertaken in line with regulatory approval requirements. These processes will also provide the basis for a detailed manufacturing contract with Operon to be signed in the new year. Separately, we have conducted preliminary discussions with Ellume with a view to manufacturing in Australia utilising Ellume's newly commissioned production facilities in Richlands, Brisbane. These discussions will continue into the new year and we will leverage the work completed with Operon to feed into detailed planning with Ellume.

The Company remains on track to commence clinical trials for the COVID-19 ART test in December. As previously announced the clinical trial procedure has been approved by the Therapeutic Goods Administration (TGA), and discussions with Victorian Infectious Diseases Reference Laboratory (VIDRL) a unit of Doherty Institute, the laboratory undertaking the trial, are well advanced.

Market outlook

The global need for rapid and accurate testing for COVID-19 has not eased despite promising signals from the vaccine industry. Even with a COVID-19 vaccine, testing will continue to be a key tool in clinical decision making, supporting treatment response and directives on isolation, as we globally seek to return to a status of normality and learn to exist in a COVID-19 world.

While a vaccine may be available to mass populations in the next 12 to 24 months, whether the vaccine prevents transmission of SARS-CoV-2 or mainly just protects against illness is largely unknown. If the latter, achieving herd immunity through immunisation becomes a difficult prospect. Similarly, the nature and length of immune responses, and the characteristics of the virus and possibilities of reinfection are also unknown. With availability of vaccine doses also likely to be restricted many millions of people at high risk of disease will not be immunised any time soon.⁵ All these factors in our opinion indicate that there will be a need for continued testing as part of the response to the ongoing pandemic.

Not only does AnteoTech see a strong opportunity in the provision of rapid point of care testing in clinical settings we also believe that population screening in commercial and social settings will become popular if not mandatory. Testing will likely form the corner stone of any large scale COVID safe plans that will need to be developed to enable the movements of people across global borders and for corporations and businesses to protect their employees and clients.

AnteoTech's CEO Derek Thomson commented: "This is an exciting and timely development in the rollout of our COVID-19 Antigen Rapid Test. A saliva test is a less invasive and more comfortable test for patients, and only a few have been successfully developed and commercialised. The next phase is to validate our results in a clinical trial, and we are now seeking trial sites and collaboration partners for this step. If the results of the saliva trial are favourable and available in time, we are aiming to submit an approval application to the Therapeutic Goods Administration for a COVID-19 ART test capable of using either/or saliva and nasopharyngeal swab samples."

"Our development project for the COVID-19 Antigen Rapid Test is making excellent progress and we look forward to fulfilling an ongoing need for COVID-19 high sensitivity rapid testing in key global markets in 2021".

⁵ [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(20\)32472-7/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)32472-7/fulltext)

This announcement has been approved by the Board.

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ABOUT ANTEO GROUP – AnteoTech Ltd (ASX:ADO)

Anteo is a surface chemistry company with Intellectual Property ("IP") in its core technology product groups AnteoCoat™, AnteoBind™ and AnteoRelease™. The Company's purpose is to create shareholder value by identifying and solving important global industry problems by providing unique value-add solutions for its customers. Customers operate in the life sciences, diagnostics, energy and medical devices markets.

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