ASX Announcement

21st October 2020

Independent Validation Study Confirms Targeted Sensitivity of AnteoTech COVID-19* Antigen Rapid Test

- **Operon study results demonstrate high sensitivity of AnteoTech COVID-19 Antigen Rapid Test**
- **9 of 25 positive samples in the study PRC tested above Ct 30**
- **Next steps include continued work with Operon to finalise lower limit of detection**

AnteoTech Ltd (ASX: ADO) ("AnteoTech" or "the Company") is pleased to announce that it has received the results of an independent validation study of the AnteoTech COVID-19 Antigen Rapid Test using stored patient swab samples. The independent study was conducted by Spanish lateral flow developer and manufacturer Operon, S.A., https://operon.es/ at their research facilities in Zaragoza, Spain using locally acquired positive COVID-19 patient samples and a range of local negative samples. All the samples were PCR tested prior to the study enabling a direct head to head comparison of the performance of the AnteoTech COVID-19 Antigen Rapid Test against this lab-based testing process that is widely accepted as a very reliable measure of test sensitivity**.

Validation Testing Method

- RT-PCR confirmed COVID-19 nasopharyngeal swab samples were collected into a 3mL viral transport media (VTM) or universal transport media (UTM) with known PCR cycle threshold (Ct) values
- 0.05mL VTM was mixed 1:1 with 0.05mL of AnteoTech's Lysis Buffer
- 0.1mL of the mixture was added to the AnteoTech COVID-19 Antigen Test cassette
- After 15 minutes, cassette was read by the reader (< 1 minute)
- The RT-PCR-confirmed positive samples (n=25) were evaluated and plotted. (see below)

Interpreting PCR testing – Ct Values

PCR testing is a lab-based process that analyses a sample via amplification techniques. For COVID-19 the PCR test seeks to detect the viral DNA associated with the virus to confirm a positive sample. To ensure the sample has been thoroughly analysed the test cycles through amplification stages with each amplification stage doubling the intensity of detection for the viral DNA from the previous cycle. The test completes on the amplification cycle in which the viral DNA is detected or when the test process exhausts all available amplification cycles without detecting the viral DNA (which is deemed a negative sample). For positive samples, the amplification cycle in which the viral antigen is detected is labelled with the specific cycle number. This is the sequential amplification cycle number or Ct value.

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

**https://www.tga.gov.au/covid-19-testing-australia-information-health-professionals#:~:text=PCR%20tests%20are%20generally%20considered,laboratory%20equipment%20and%20trained%20technicians

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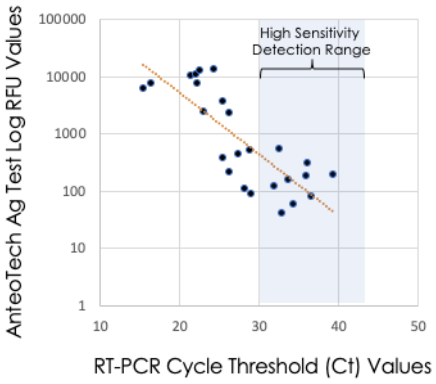
Therefore, the higher the Ct value the lower the viral load in the sample i.e. the higher the Ct value the greater the sensitivity required to detect the viral antigen via point of care testing techniques.

Point of care tests that detect viral antigen in samples with a PCR test Ct value above 30 are generally considered to be highly sensitive***. Most point of care tests can detect viral antigen in samples with a Ct value of 25 or lower as these samples are usually characterised by high viral load***.

Operon Validation Study Results

The figures below are the results of the current Operon validation trial of AnteoTech's Covd-19 Antigen Rapid Test.

Figure 1. Performance of PCR-confirmed positive samples in VTM/UTM



RT-PCR confirmed positive COVID-19 nasopharyngeal swab samples were evaluated by the reader-based AnteoTech COVID-19 Antigen Rapid lateral flow test.

Figure 2. Confirmed viral load range detection against Ct value

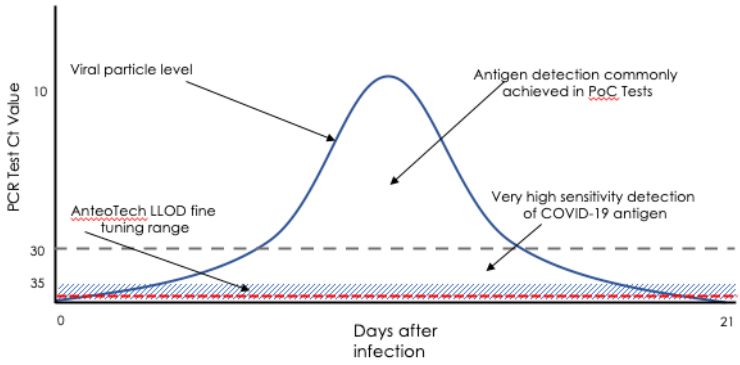


Figure 1 plots all of the 25 positive samples that were clearly detected by the AnteoTech COVID-19 Antigen Rapid Test in the tested sample set against confirmed Ct value (x axis) and the AnteoTech reader detection result (y-axis). 9 of those samples were confirmed PCR tested at above Ct value of 30. In order that the finalised test captures these low viral level samples accurately and differentiates them from negative samples, the lower limit of detection cut off is required to be determined. The determination of this setting will require further development work and validation testing. Finalisation of the lower limit of detection and subsequent clinical trial will produce final sensitivity and specificity statistics.

Figure 2 portrays the viral load ranges demonstrated in the results. This result using stored swab samples aligns to our in-house laboratory results using recombinant samples that the test detects COVID-19 in the range of Ct 30 to Ct 35. This PCR level is typically recorded from patients who are at very early onset or recovery stages of the disease cycle and have very low levels of viral load.

***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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Next Steps – Lower Limit of Detection (LLOD)

We are continuing to work with Operon to generate more data that will enable us to accurately determine the lower limit of detection settings that will finalise our design freeze and enable us to progress to clinical trial. This process will require further analysis of background readings of negative samples and collection of readings from more positive samples to provide a broader set of results on which to base our calculations. This is a very important process as it will determine the settings which will be used in the upcoming clinical trial for regulatory approval.

Further announcements on validation study results from Operon and other collaborators will be announced as they are completed.

AnteoTech's CEO Derek Thomson commented: "We are very pleased to have reached this key milestone in our development of the AnteoTech COVID-19 Antigen Rapid Test. The control of COVID-19 requires highly sensitive testing to ensure all positive patients are identified and isolated at the point of care to ensure they don't continue to spread the disease. We believe we are making an important contribution to the control of the disease and we look forward to entering clinical trials following the final stages of our validation phase which we believe will lead to making our test available to global markets very soon."

This announcement has been approved by the Board.

ABOUT OPERON, S.A.

OPERON, S.A. is a reference company contributing quality and innovative solutions to the "in vitro" diagnostics field, aiming to improve the quality of life in the community.
Operon aims to be a leading company in technology and "in vitro" diagnostic products, with a solid reputation and a diversified offer with presence in all continents relying on high quality products and services:

- Immunochromatography Tests.
- Molecular Biology Tests.
- Raw Materials: Monoclonal Antibodies and Recombinant Antigens.
- Customized services: contract-manufacturing.

ABOUT ANTEOTECH GROUP – AnteoTech Limited (ADO:ASX)

AnteoTech (formerly Anteo Diagnostics Ltd) 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 and energy markets.

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