

## ASX Announcement

9th September 2020

### AnteoTech Progress High Sensitivity COVID-19 Antigen Rapid Test Toward Full Commercialisation

- **Proof of Concept and Design Verification phases complete**
- **Very high sensitivity achieved in internal Design Verification - COVID-19 antigen rapid test detects virus at just 0.02ng/ml significantly exceeding target test detection of 0.1ng/ml**
- **Virus swab sample internal validation trials complete and successful**
- **Clinical trials for regulatory approval to be conducted very soon**
- **Manufacturing discussions underway**
- **International media campaign instigates discussions with multiple industry participants**

AnteoTech Ltd (ASX: ADO) ("AnteoTech" or "the Company") is pleased to announce that it has progressed the development of the COVID-19 high sensitivity antigen test (see 16 July 2020 announcement) to the end of the second phase - Design Verification sooner than expected and is progressing to the third phase - Design Validation which includes clinical trials for regulatory approval.

#### Roll Out Approach and Timelines

To meet immediate market demand AnteoTech have made the decision to roll out the COVID-19 antigen test and the COVID-19 Flu A/ Flu B multiplex test in two stages. The COVID-19 stand alone test will be rolled out first and development processes for the more complex multiplex test will start in late 2020.

For the COVID-19 stand alone test, if clinical trials are successful, we will be applying for regulatory approval in Australia (for Australian Register of Therapeutic Goods registration) and the U.S. (for Emergency Use Authorisation), simultaneously. Regulatory approvals for other markets will follow quickly, based on the establishment and confirmation of distribution arrangements.

We estimate that development of the COVID-19 antigen test including regulatory approval will be complete in 5 to 8 months from now.

#### AnteoTech COVID-19 Antigen Product Development Overview

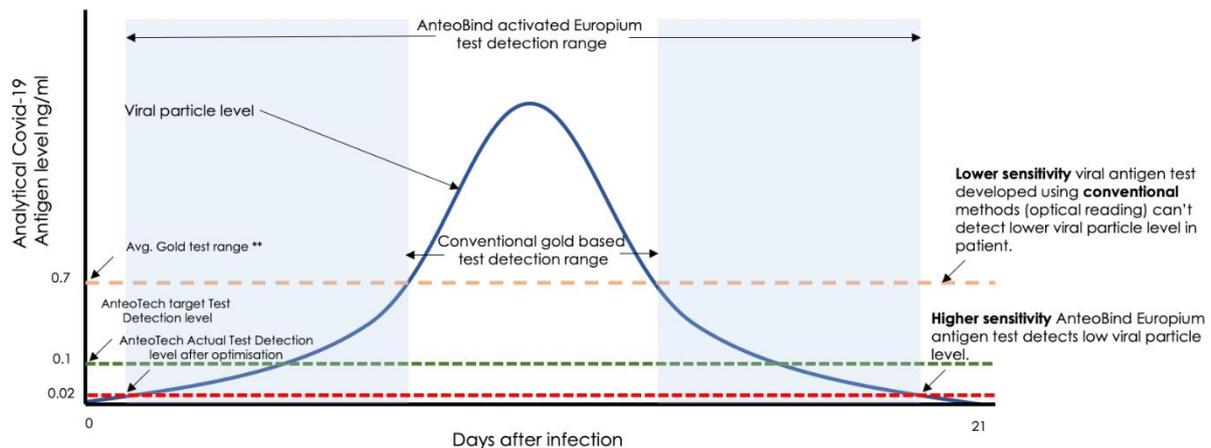


## Development

Internal development testing work on the COVID-19 antigen test including screening of antibody pairs has continued and we have been very pleased with the results. Our original sensitivity target was 0.1ng/ml.

We are pleased to announce that we have achieved significantly higher sensitivity detecting COVID-19 antigen at just 0.02ng/ml consistently through 3 different batch experiments using recombinant samples procured from multiple suppliers.

### AnteoTech COVID-19 Antigen Test Design Locked In After Achieving 0.02ng/ml Detection During Optimisation Phase

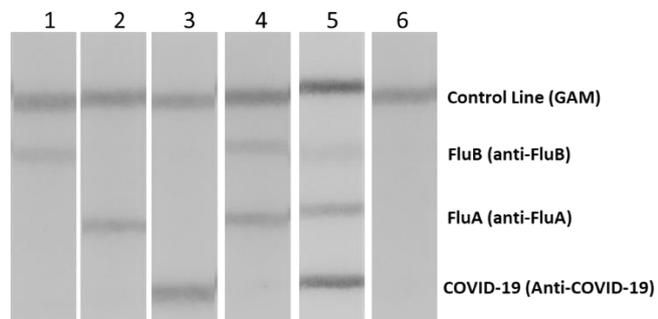


\*\*<https://doi.org/10.1021/acs.analchem.0c01975>

Separately we have produced and tested the first half strip edition of the COVID-19 FluA/FluB multiplex with very good initial results. Clear signal was observed across all combinations of potential detection with no observed cross reactivity consistently through 3 different batch experiments using recombinant samples procured from multiple suppliers. This gives us high confidence that the multiplex test will be developed on the foundation of the existing individual tests with similar results.

### COVID-19, FluA and FluB – Multiplexed Lateral Flow Assay

- Three antibodies (anti-FluA, anti-FluB and anti-COVID-19 antibody) coated on the nitrocellulose membranes as test lines.
- Three monoclonal antibody conjugated europium particles (FluA, FluB and COVID-19 antibody) were pre-mixed as detection.
- Good signal/noise ratio observed for the multiplexed assay
- No cross-reactivity observed between three antibody pairs for respective antigens
- Replicate experiments repeated to confirm the observation



1. FluB antigen (Inactivated) only
2. FluA antigen (Inactivated) only
3. COVID-19 antigen (recombinant) only
4. FluA + FluB mixed antigens
5. FluA+FluB+COVID-19 mixed antigens
6. Lysis buffer only, with no antigens

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## COVID-19 Antigen Test Validation

### Initial Internal Validation Testing

A key milestone for any assay development designed to detect viral particles is the transition from development using recombinant samples (inactivated virus or purified antigens) and clinical validation with virus active samples (nasal swab samples).

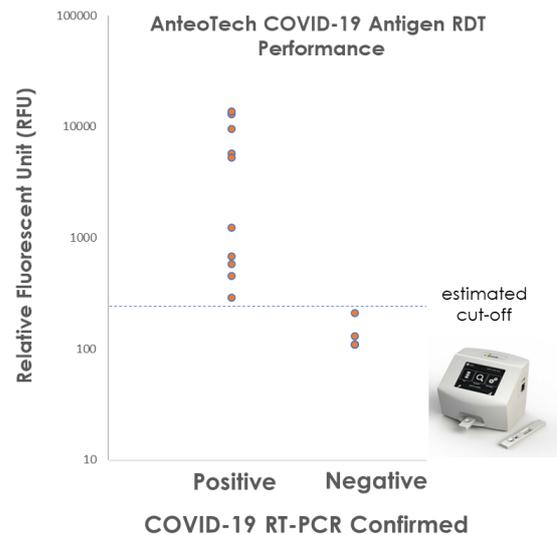
For our first swab sample test we chose a very small sample set that was PCR tested to identify positive and negative samples accurately. The samples were stored in viral transfer medium which diluted the samples about 1:5 or higher ratio. Further, we took the samples and added them to a lysis buffer further diluting the samples in a 1:5 ratio. The total dilution for the test was around 1:25, which is a much higher dilution setting than we would expect in a point of care clinical trial or real world use of the test.

Results of this test are below:

### AnteoTech COVID-19 Antigen RDT – Nasal Swab Sample Initial Lab Evaluation

- AnteoTech's iteration 2 design (estimated LLoD 20pg/mL) was used to evaluate the actual COVID-19 patient nasal swab samples confirmed by RT-PCR in VTM (viral transfer media), diluted 1:5 with AnteoTech's Lysis Buffer
- 100 ul mixture (sample + Lysis Buffer) was added to the sample well, 15 minutes incubation on the bench, then <30 seconds reading by reader to obtain result

Sample #	Reading Test line Signal (RFU)	RT-PCR Confirmed
1	580	Positive
2	12960	Positive
3	1230	Positive
4	5740	Positive
5	680	Positive
6	290	Positive
7	9560	Positive
8	450	Positive
9	5240	Positive
10	13800	Positive
11	110	Negative
12	110	Negative
13	110	Negative
14	210	Negative
15	130	Negative



The AnteoTech COVID-19 antigen test detected strong positive signal from 10 of the samples and very low signal from 5 of the samples with estimated positive/negative cut-off set at 230 RFU.

In essence, the AnteoTech COVID-19 antigen test worked perfectly first time.

Further, the sample set was very highly diluted and this appears to confirm that the AnteoTech COVID-19 antigen test is operating at very high sensitivity.

**We stress that the testing protocol described was an initial validation taken on a very small sample size and will not be used for clinical evidence in regulatory approval.**

It does however, confirm the test has in our view very successfully made the transition from recombinant sample research to operation using virus active samples. This confirms that our product has met our design validation criteria and operates at high sensitivity. It provides us with confidence to move forward to clinical trial.

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### Further Validation Testing

This week we will begin 2 more external validation testing exercises with our partner organisations GeneoDx <http://www.geneodx.com> and Operon, in Spain <https://operon.es>. These validations will be closed IP and will use pre prepared strips made in the AnteoTech labs and an encrypted Axxin reader sent from AnteoTech. The tests will harness COVID-19 samples collected by the partners and will be an independent assessment of the effectiveness of the test.

These two independent studies are expected to provide further validation of the test and indicate the versatility of the test using patient samples from different geographies and different strains of the virus.

For continued development work in our lab we have secured gamma irradiated (recombinant) samples from VIDRL <https://www.vidrl.org.au> in Victoria and further collaboration work with this organisation is in progress.

### Regulatory Approval

We are currently in dialogue with the Therapeutic Goods Administration (TGA) to determine the exact requirements of clinical trial for the Australian market in light of their articulated priority on COVID-19. Once we have determined the exact requirements for clinical trial we will move to conduct that trial during the current phase of activity.

We have investigated the requirements for clinical trial for emergency use regulatory authorisation (EUA) in the U.S. and at this stage we believe the expected requirements of the TGA will be able to be used for a duplicate process for the FDA in the U.S. i.e. one clinical trial process for the two markets.

### Manufacturing

Preliminary supply chain and manufacturing development work has been undertaken. Key contracts for antibody and Europium particle supply are in the process of being negotiated and will be finalised shortly. Other raw material contracts will be developed as extensions of existing commercial arrangements.

We are currently in discussion with our key reader partner, Axxin, to finalise development agreements and supply arrangements. These discussions are progressing well and we are collaborating on immediate areas of need including supply of readers for clinical validation and manufacture of cassettes.

In terms of assay manufacturing we are focussing on procuring outsourced manufacturing capability for the Australian market from local organisations. For overseas markets we expect to procure additional manufacturing capability and we have identified organisations in the U.S., Europe and China as potential candidates. Some of the required discussions have been undertaken and we will continue our focus on this area in the coming weeks. Finalisation of manufacturing arrangements will be made during the Production Validation phase.

### Business Development and Market Operations

During August we launched an international media campaign focused on industry publications. As a result of the exercise AnteoTech's COVID-19 Antigen FluA/FluB development was covered in many tier 1 industry publications.

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Simultaneously we posted an industry information focused page on our website inviting industry participants to express interest in development and/ or distribution of the COVID-19 Antigen FluA/FluB test.

Since that time we have received responses from the industry organisations, some with global reach requesting distribution and development partnership dialogue.

**AnteoTech's CEO Derek Thomson commented:** "We are very pleased with the progress we are making on the COVID-19 antigen FluA/FluB test development. We believe we have a proven working COVID-19 test with sensitivity far higher than we originally anticipated and this provides us with confidence that we can make a significant contribution to the fight against COVID-19. Our development program is on track and I thank the Life Sciences team for their continued commitment to this very important project."

This announcement has been approved by the Board.

**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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