

Advanced MedTech

PRESS RELEASE

ADVANCED MEDTECH COMMERCIALISES INDUSTRY-FIRST SARS-CoV-2 DIRECT MULTIPLEX RT-PCR ASSAY CO-DEVELOPED BY A*STAR AND DSO

- RESOLUTE 2.0 DIRECT MULTIPLEX RT-PCR COVID-19 DIAGNOSTIC TEST ELIMINATES NEED
 FOR EXTRACTION OF VIRAL RNA FROM TEST SAMPLES, CUTS DOWN TEST DELIVERY TIME
 BY HALF WHEN COMPARED TO OTHER APPROVED RT-PCR TESTS.
- INDUSTRY-TOPPING THROUGHPUT OF CLOSE TO 4,000 SAMPLES A DAY ACHIEVED WITH **RAVE**, A COMPLEMENTARY AUTOMATED AND ROBOTICS LAB SYSTEM DEVELOPED BY A*STAR'S ARTC, SIMTECH, AND DXD HUB.
- ADVANCED MEDTECH (AMTH) GRANTED HSA PROVISIONAL AUTHORISATION TO MANUFACTURE AND SUPPLY RESOLUTE 2.0 TESTS, AVAILABLE IMMEDIATELY FOR USE IN HEALTHCARE INSTITUTIONS AND LABORATORIES THROUGHOUT SINGAPORE.
- AMTH IS ONE OF THE LARGEST COVID-19 DIAGNOSTIC TEST MANUFACTURERS IN SINGAPORE WITH ABILITY TO RAMP PRODUCTION CAPACITY TO 2 MILLION TESTS A MONTH

Singapore, 20 July 2020 – RESOLUTE 2.0, an industry-first SARS-CoV-2 direct multiplex Reverse-Transcription Polymerase-Chain-Reaction (RT-PCR) assay kit co-developed by Singapore's Agency for Science Technology and Research (A*STAR) and DSO National Laboratories (DSO), has been made available for clinical use in Singapore by Advanced MedTech Holdings (AMTH), a global medical technology leader. The kit detects SARS-CoV-2, the virus that causes COVID-19.

AMTH licensed the RESOLUTE 2.0 technology from A*STAR and DSO and has been granted Provisional Authorisation from Singapore's Health Sciences Authority (HSA) to manufacture and supply the test. The pilot production of the RESOLUTE test kit was conducted in close collaboration with, and validated by, the Diagnostics Development (DxD) Hub, a national platform hosted by A*STAR.

RESOLUTE 2.0 eliminates the need for extraction of viral RNA from patient test samples, thus minimising potential human errors and halving the test delivery time when compared to other approved RT-PCR kits which are considered the gold standard in SARS-CoV-2 detection. A multiplex RT-PCR, RESOLUTE 2.0 also allows for simultaneous detection of multiple SARS-CoV-2 targets and human control target in one single reaction.

To further expedite the RESOLUTE 2.0 testing process, A*STAR's Advanced Remanufacturing and Technology Centre (ARTC), the Singapore Institute of Manufacturing Technology (SIMTech) and DxD Hub co-developed the complementary Rapid Automated Volume Enhancer (RAVE) robotics lab system. The made-in-Singapore automated system will also be distributed by AMTH. It minimises the manual steps in the preparation of a test assay (uncapping of tubes, pipetting etc.), shortening the time to results. Two sets of RAVE and thermal cyclers can process an industry-topping throughput of close to 4,000 samples a day. RAVE also reduces test contamination and infection risks for laboratory workers. For more information on RAVE, please refer to Annex A (Fact Sheet on RAVE).

To support Singapore's efforts to significantly expand its nationwide COVID-19 testing capability, AMTH set up one of the largest automated in-vitro diagnostics manufacturing facilities in the country in just 6 weeks. The site is fully operational and can ramp up capacity to produce 2 million tests per month.

With the support of DxD Hub, AMTH intends to file for regulatory approval for the RESOLUTE 2.0 test with the US FDA and will file additional regulatory submissions around the world.

Abel Ang, Group Chief Executive of Advanced MedTech, said: "We are proud to have worked with A*STAR, DxD Hub, DSO National Laboratories and other agencies to rapidly bring world-class multi-disciplinary research done in Singapore to the global stage. The speed, accuracy, and scale of the combined RESOLUTE 2.0 test kit and RAVE automation will make it an indispensable part of the overall toolkit of leading COVID-19 testing centers around the world. I am proud of how our team was able to complete technology transfer and scale up our manufacturing capability in a matter of weeks."

Mr Frederick Chew, Chief Executive Officer, A*STAR, said: "This cutting-edge diagnostics innovation is a result of triple-helix public-private collaboration between A*STAR, DSO and Advanced MedTech. The integrated RESOLUTE 2.0 + RAVE system combines strong engineering capabilities with deep biomedical science to create value. Separately, the range of COVID-19 technology innovations emanating from the entire local ecosystem over the past few months has been very heartening. I am particularly pleased to see public sector technologies being licensed to local companies to address Singapore's COVID-19 public health needs. At the same time, our local companies can commercialise and export these technologies."

Dr Beh Swan Gin, Chairman, Singapore Economic Development Board (EDB), said: "I am heartened that Advanced MedTech stepped forward to support Singapore's efforts to expand testing for COVID-19. The speed at which it has scaled up its test-kit manufacturing capacity is testament to the capabilities of our MedTech sector, and to the strength of private-public partnerships in Singapore. EDB will continue working closely with Advanced MedTech and other industry partners, to contribute to the fight against COVID-19 in Singapore and globally."

For more information on the RESOLUTE 2.0 test, please visit www.advancedcovidtest.com

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About the Agency for Science, Technology and Research (A*STAR)

A*STAR is Singapore's lead public sector R&D agency, spearheading economic-oriented research to advance scientific discovery and develop innovative technology. Through open innovation, we collaborate with our partners in both the public and private sectors to benefit society.

As a Science and Technology Organisation, A*STAR bridges the gap between academia and industry. Our research creates economic growth and jobs for Singapore, and enhances lives by contributing to societal benefits such as improving outcomes in healthcare, urban living, and sustainability.

We play a key role in nurturing and developing a diversity of talent and leaders in our Agency and research entities, the wider research community and industry. A*STAR's R&D activities span biomedical sciences and physical sciences and engineering, with research entities primarily located in Biopolis and Fusionopolis. For ongoing news, visit www.a-star.edu.sg.

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About Advanced MedTech Holdings

Advanced MedTech Holdings is a global medical technology leader with a core focus in urology devices and services. Headquartered in Singapore, with operations in US, Germany, Spain, France, Italy, China, Malaysia and Japan, the Company serves millions of patients and physicians in 100 countries worldwide. Advanced MedTech Holdings makes strategic investments in disruptive medical technology companies, strengthening its portfolio of healthcare solutions for customers around the world. Advanced MedTech Holdings is a wholly-owned subsidiary of Temasek. For more information on Advanced MedTech Holdings, please visit https://www.advanced-medtech.com/.

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