

Press release

A*STAR, TTSH and MiRXES launch multiplex COVID-19 kit that tests for SARS-CoV-2 and Influenza A and B

- Singapore's Agency for Science, Technology and Research, Tan Tock Seng Hospital and Singapore-based molecular diagnostic company MiRXES expand range of infectious disease testing solutions with the Fortitude SARS-CoV-2 & Flu A/B Test. It combines the RT-PCR Fortitude Kit SARS-CoV-2 test that detects COVID-19, with syndromic panel assays for Influenza A, and Influenza B.
- MiRXES has obtained Provisional Authorisation from Singapore's Health Sciences Authority (HSA) for the deployment of the Fortitude Syndromic Panel Kit. It is also currently applying for CE Mark, Emergency Use Authorisation (EUA) from the United States Food and Drug Administration (FDA), and approval from Japan's Pharmaceuticals and Medical Devices Agency (PMDA).



SINGAPORE – 18 January 2021 – During the winter months, the COVID-19 pandemic coincides with the flu season. Patients with COVID-19 or flu exhibit a set of similar symptoms (flu-like syndrome), making it difficult for healthcare professionals to differentiate them based on symptoms alone. To assist in accurate diagnoses, the Agency for Science, Technology and Research (A*STAR), Tan Tock Seng Hospital (TTSH), and MiRXES, a leading molecular diagnostic company headquartered in Singapore, will launch a multiplex COVID-19 kit that simultaneously tests for SARS-CoV-2 and influenza. This will make a decisive difference as accurate and timely diagnosis is critical during the ongoing third wave of the COVID-19 outbreak in the Northern Hemisphere.

MiRXES has obtained Provisional Authorisation from Singapore’s Health Sciences Authority (HSA) for the deployment of the Fortitude SARS-CoV-2 & Flu A/B Test, and is currently applying for CE Mark, Emergency Use Authorisation (EUA) from the United States Food and Drug Administration (FDA), and approval from Japan’s Pharmaceuticals and Medical Devices Agency (PMDA).

The Fortitude SARS-CoV-2 & Flu A/B Test combines the tested and proven RT-PCR Fortitude Kit with syndromic panel assays for Influenza A, and Influenza B. This multiplex diagnostic detects and differentiates SARS-CoV-2 viruses that cause COVID-19, and other pathogens that cause seasonal epidemics of influenza (flu). This will help healthcare professionals detect and differentiate patients with these infections, and offer more precise treatment options.

The Fortitude SARS-CoV-2 & Flu A/B Test is built on the original Fortitude Kit developed in Singapore by A*STAR and TTSH, which was licensed to MiRXES for mass production and distribution in February 2020. To date, the Fortitude Kit has been deployed in 13 Singapore hospitals and labs and

exported to more than 40 countries worldwide, including the United States, Hong Kong, and Panama.

“Following the deployment of the MiRXES Fortitude Kit worldwide, we continue to monitor and identify global needs in infectious disease testing. We are working in close collaboration with key partners such as A*STAR and TTSH to meet these needs by expanding our Fortitude COVID-19 test range. Hospitals and labs in US, Europe, and Japan have already expressed interest in deploying the Fortitude SARS-CoV-2 & Flu A/B Test,” said Dr Lihan Zhou, Co-founder and Chief Executive Officer of MiRXES.

“Singapore’s Health Sciences Authority’s leadership in regulatory science has been instrumental in supporting innovations from our start-ups and SMEs, enabling them to obtain regulatory approvals in other jurisdictions, such as the European CE and US FDA. The new multiplex Fortitude Syndromic Panel Kit will continue to put Singapore on the map with our innovations in diagnostics,” said Dr Sidney Yee, Chief Executive Officer of the DxD Hub, A*STAR.

“TTSH with collaborators at A*STAR, has been providing novel diagnostic solutions for our patients since the threat of SARS and ‘Bird flu’ in 2003. Our assay for respiratory organisms is a panel designed to simultaneously detect an array of Influenza viruses, with slots specifically reserved to rapidly incorporate a test for any emerging virus with epidemic or pandemic potential, as previously done for Bird flu, Swine flu, and MERS-CoV. The assimilation of SARS-CoV-2 into our influenza panel was a natural progression, planned for since inception. The expanded panel was ready for TTSH deployment as early as March 2020, a testament to the long-term commitment of a small group of medical, science, and technical collaborators,” said Adj A/Prof Timothy Barkham, Senior Consultant, Department of Laboratory Medicine, TTSH.

<ENDS>

About MiRXES

Founded in 2014 as a spin-off from Singapore's Agency for Science, Technology, and Research (A*STAR), MiRXES translates research discoveries to deliver world-leading multi-cancer early detection. With a strong clinical pipeline in cancer early detection and precision medicine, MiRXES is also addressing unmet clinical needs in cardiovascular diseases and infectious diseases. MiRXES has physical presence in Singapore, USA, China and Japan with sales in over 40 countries globally. In 2019, MiRXES launched its flagship product, GASTROClear, the world's first molecular blood test for early detection of gastric cancer. In response to the COVID-19 pandemic, MiRXES licensed and distributed the Fortitude Kit from A*STAR. Since February 2020, millions of Fortitude tests have been deployed globally.

For more information, visit www.mirxes.com.

Follow us on LinkedIn at <https://www.linkedin.com/company/mirxes/>

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

The Agency for Science, Technology and Research (A*STAR) is Singapore's lead public sector R&D agency. Through open innovation, we collaborate with our partners in both the public and private sectors to benefit the economy and 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 improving societal outcomes in healthcare, urban living, and sustainability. A*STAR plays a key role in nurturing scientific talent and leaders for the wider research community and industry. A*STAR's R&D activities span biomedical

sciences to physical sciences and engineering, with research entities primarily located in Biopolis and Fusionopolis. For ongoing news, visit www.a-star.edu.sg.

About Tan Tock Seng Hospital

Tan Tock Seng Hospital (TTSH) is the flagship hospital of the National Healthcare Group and part of Singapore's Public Healthcare System. As a pioneering hospital with strong roots in the community for over 175 years, TTSH is recognised as the People's Hospital, serving a resident population of 1.4 Million living in Central Singapore. Together, with 70 community partners and 80 community health posts, it brings care beyond the hospital into the community as an integrated care organisation – Central Health. As one of the largest multi-disciplinary hospitals in Singapore, TTSH operates more than 1700 beds with centres of excellence including the National Centre for Infectious Diseases (NCID), Institute for Geriatrics & Active Ageing (IGA), NHG Eye Institute (NHGEI), TTSH Rehabilitation Centre, and Ang Mo Kio Specialist Centre (AMKSC). TTSH's 600-bed Integrated Care Hub will be ready in 2022 to provide for subacute care and rehabilitation. As a healthcare leader in population health, systems innovation, health technologies and workforce transformation, TTSH hosts Singapore's largest purpose-built innovation centre for healthcare – the Ng Teng Fong Centre for Healthcare Innovation (CHI) and its Co-Learning Network of 37 local and international partners.

For more information, visit www.ttsh.com.sg.

Forward-Looking Statements

This release may contain forward-looking statements based on current assumptions and forecasts made by the MiRXES management. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation,

development or performance of the company and the estimates given here. The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.