



Malaysia Granted Permission for COVID-19 Test Kit from China for Emergency Use

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Homegrown Holista Colltech Receives Initial Order for 15,000 Units for Deployment



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Amid rising concerns about the threat and economic impact of COVID-19, Holista Colltech Limited has been granted permission for Special access under the Medical Device (Exemption) Order 2016, from the Medical Devices Authority ("MDA") of Malaysia's Ministry of Health ("MOH") to import and distribute for an antigen rapid test kit (RTK-AG) developed and manufactured by Guangdong Hecin Scientific Inc. ("Hecin") of China. With this approval, the Company has secured an initial order for 15,000 units in Malaysia.

Holista Colltech Limited ("Holista"), a natural wellness and health products specialist headquartered in Petaling Jaya and listed on the Australian Securities Exchange ("ASX: HCT"), said the Hecin(TM) 2019-nCoV diagnostic test kits will be used to detect the presence of the SARS-CoV-2 viral antigen from nasal swabs within 15 minutes.

Antigen tests look for the coating or proteins of the virus while Polymerase Chain Reaction ("PCR") tests detect its nucleic acid, or genetic material (also known as RNA). The former can deliver results within minutes and generally cost less; the latter, while more accurate, can take up to several days and are generally more expensive.

The 15,000 units will be shipped by the end of this month to Klinik Mutiara, part of Amegajaya Sdn Bhd, a medical consultancy that works closely with MOH and related organizations. The maiden order secured by Holista's wholly owned Holista Biotech Sdn. Bhd. is worth approximately A\$95,000 (US\$73,000). The kits will be used by registered professionals at Klinik Mutiara for screening purposes.

MOH's Medical Devices Authority ("MDA") has granted Holista permission to import and distribute up to 45,000 units of the Hecin antigen test kit for emergency use within three months from the date of approval on 14th June 2021.

The clinical performance of Hecin RTK-Antigen test kit against PCR Comparator method using nasopharyngeal swabs specimens has obtained a sensitivity of 96.23% and specificity 99.07%. The trial was carried out in Daye City Center for Disease Control and Prevention within China. The results serve as the basis for obtaining the CE mark in Europe. The MDA also conducted its own clinical trials in Malaysia prior to this approval.

The MDA has also granted Holista similar import and distribution approval for Hecin Antibody Test kit which can test human serum, plasma or whole blood for levels of antibodies to assess immunity after vaccination.

Holista has rights to distribute the Hecin COVID-19 test kits in Brunei, Thailand, Indonesia, Philippines, Taiwan, Vietnam, Cambodia, Laos, Myanmar, Singapore and the United Kingdom.

The channel distribution will be handled by Holista's long-time partner, Zuellig Pharma.

Holista will build upon the approvals and commercial arrangements for these test kits to extend distribution rights and partnerships worldwide for pandemic-related infection control, testing and related healthcare solutions.

"The pandemic has impacted Malaysia severely with rising infections, deaths and prolonged movement controls which have disrupted business, education, social interaction and many other activities. Rapid testing is the key to controlling the spread of infection and revive economic activity with confidence," said Holista's CEO, Dato' Dr Rajen Manicka.

"An infected person can spread the virus for several days without showing symptoms. To counter this, regular antigen RTK testing can curb infections control in a very affordable manner. High frequency mass testing has been hugely successful in curbing infections in China, South Korea, Slovakia, Switzerland and the United Kingdom. We are glad that they are being introduced in Malaysia," he said.

"The Slovakia approach of testing brought infections down by more than 50%. Its success has been reported by British Medical Journal, The Lancet, Science and Scientific American earlier this year," Dato' Dr Rajen added.

Holista has also developed a mobile application that allows efficient tracking and tracing based on the 'Traffic Light' model that has been successfully deployed by the National Health Service in the United Kingdom.