

Health

Medical technology & services



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Holista Colltech receives maiden order for SARS-CoV-2 test kits from Malaysia

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Holista CollTech Limited ([ASX:HCT](#)) has received permission from the Medical Devices Authority (MDA) of Malaysia to import and distribute an antigen-based SARS-CoV-2 rapid test kit (RTK-AG) developed and manufactured by Guangdong Hecin Scientific Inc. of China.

The company will distribute the kit in Malaysia through its long-term partner, Zuellig Pharma, with strict adherence to conditions imposed by the MDA.

With the approval, the company has already secured an initial order for 15,000 units worth \$95,000 in Malaysia.

Special access to import kits

MDA has stipulated that Holista can import up to 45,000 units of the antigen rapid test kits to Malaysia within the first three months of the permission for importing medical devices under the Medical Device (Exemption) Order dated June 14, 2021.

The first 15,000 units will be shipped by the end of June 2021, and the order marks the first commercial transaction of SARS-CoV-2 test kits by the company.

These test kits will be used to detect the presence of the SARS-CoV-2 viral antigen from nasal swabs within 15 minutes.

It is for screening purposes by healthcare professionals and not the sole basis for diagnosis and exclusion decisions.

The maiden order was from Klinik Mutiara, part of Amegajaya Sdn Bhd, a medical consultancy that works closely with Malaysia's Ministry of Health and related agencies.

Approval for other countries

Apart from Malaysia, Holista has the rights to distribute the two Hecin products in Brunei, Thailand, Indonesia, Philippines, Taiwan, Vietnam, Cambodia, Laos, Myanmar, Singapore and the UK.

The sales and distribution of the said test kits are also subject to securing the respective country's regulatory approvals.

Hecin has granted exclusivity to Holista until December 31, 2021, subject to Holista achieving sales performance in the respective countries by July 2021.

Due to the current pandemic, it is taking time to obtain regulatory approvals from the respective country's regulatory bodies.

However, Holista is in the process of negotiating with the Chinese company for a further extension following the Malaysian MDA approval.

Guangzhou-based Hecin has developed diagnostic products for nucleic acid, immunofluorescence, flow cytometry, as well as medical reagents, amongst others.

Hecin has conducted clinical trials for the antigen test kits in Daye City Centre for Disease Control and Prevention within China.