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Singapore sets stringent regulations for COVID-19 test kits for professional use

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16 COVID-19 diagnostic tests have been authorised for Professional Use by HSA under PSAR

With effect from 1 January 2022, only COVID-19 tests that have received full-fledged registration with Singapore's Health Sciences Authority (HSA) or have been authorised under the Pandemic Special Access Route (PSAR) shall be supplied in Singapore.

The COVID-19 tests that have received full-fledged registration with HSA are listed on the Singapore Medical Device Register (SMDR).

These 16 kits are being distributed by SDT Molecular, Veredus Laboratories, PerkinElmer Singapore, JN Medsys, bioMérieux Singapore, SPD Scientific, Abbott Laboratories (Singapore), MiRXES, All Eights (S), Life Technologies Holdings, Acumen Research Laboratories and Qiagen Singapore.

Where there are tests that have not been registered on SMDR as yet, and the Ministry of Health (MOH) determines that there is a clinical need for the use of these tests, MOH designates these tests as “emergency medical devices”. Only these tests would qualify for authorisation under the PSAR. HSA evaluates to determine if these tests meet the essential standards of safety, quality, and efficacy as appropriate prior to granting authorisation under PSAR.