

Original link: <https://www.mda.gov.my/announcement/595-import-dan-bekalan-kit-ujian-covid-19-semasa-penularan-pandemik-covid-19.html>

IMPORT AND SUPPLY OF COVID-19 TEST KIT DURING COVID-19 PANDEMIC DISEASE

The Medical Device Authority (MDA) would like to inform that all test kits for COVID-19 are medical devices regulated under the Medical Devices Act 2012 (Act 737). In an emergency situation such as the current COVID-19 pandemic, the COVID-19 test kit is exempted from registration through the Medical Devices (Exemption) Order 2016. However, any party wishing to import or supply this COVID-19 test kit must be notified to the MDA to obtain permission to import or supply it for use in Malaysia.

Upon receipt of notification from the applicant, the test kits to be imported and supplied will go through the evaluation process by the COVID-19 Test Kit Evaluation Specialist Committee. This committee was established to assist the MDA in setting criteria and conducting safety and performance assessments of the test kits. After the assessment is made, the Committee will recommend whether a test kit can be used for the purpose of COVID-19 detection based on the criteria and evaluation conducted. Any test kit that does not get permission from MDA does not go through the evaluation process and thus its safety and performance cannot be guaranteed.

MDA would like to inform that only test kits that have passed the assessment based on the set criteria will receive a recommended for use recommendation from the COVID-19 Test Kit Evaluation Specialist Committee and given permission through a "no restriction letter" to be imported or supplied for use in Malaysia. Those who do not have permission to import or distribute the COVID-19 test kit from MDA are not allowed to import and distribute it in Malaysia.

The MDA would also like to inform that the permission granted is only for the use of medical professionals and it cannot be sold or distributed to the public. In this regard, MDA would like to remind those who have obtained permission to import and distribute this test kit to only distribute it to the health premises that have been listed in the "no restriction letter" issued by MDA. The distribution of the COVID-19 test kit to any party other than those listed in the "letter of no obstruction" is a violation of the conditions of authorization which may result in the "letter of no obstruction" being withdrawn and may be subject to action under subsection 5 (2) of the Act 737. Any person convicted of an offense under this subsection shall be liable to a fine not exceeding two hundred thousand ringgit or to imprisonment for a term not exceeding three years or to both.

In addition, the MDA would also like to inform that the advertising of the COVID-19 test kit in any media is not allowed at all. The display of these test kit advertisements can encourage purchases among the general public and this situation is feared to increase the risk of infection as the general public does not have sufficient knowledge to interpret the test results obtained and handle the situation after obtaining the test results. COVID-19 infection detection tests should be performed by qualified and trained health staff in health-recognized health facilities at the Ministry of Health to ensure that patient treatment is performed in accordance with established procedures and thus can curb the spread of the epidemic. Any person convicted of an offense in connection with the advertising of a medical device shall be liable to a fine not exceeding three hundred thousand ringgit or to imprisonment for a term not exceeding three years or to both under subsection 44 (3) of Act 737.

MDA will continue to monitor the advertising, distribution and sale of COVID-19 test kits in the market including the sale and distribution through online platforms to ensure that the COVID-19 test kits on the market are safe and effective.

The public is advised not to be easily influenced by any advertisement related to the COVID-19 test kit and always take infection prevention measures as recommended by the MOH. If there is a need to conduct a COVID-19 test, the public is advised to obtain the test from a MOH-recognized health facility. The purchase, sale and use of COVID-19 test kits among the public is feared to increase the spread of the COVID-19 epidemic as test kits sold to the public may not go through the evaluation process by the COVID-19 Test Kit Evaluation Specialist Committee. In addition, the public does not have sufficient knowledge to interpret the test results obtained and handle the situation after obtaining the test results.

Medical Device Authority (MDA),

Cyberjaya,

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