



PRESS STATEMENT

FDA APPROVES SELF-ADMINISTERED COVID-19 ANTIGEN TEST KITS

25 January 2022

The Food and Drug Administration (FDA) has approved two (2) self-administered COVID-19 antigen test kits in compliance with the application requirements listed in the FDA Advisory No. 2021-0684 entitled “Guidance on the Process for the Issuance of Special Certification for COVID-19 Test Kits Based on FDA Memorandum No. 2020-006 and FDA Memorandum No. 2021-009.” These kits can be used by individuals to detect SARS-CoV-2 antigen from nasal swab of probable COVID-19 patients. Guidelines for the use of these kits shall be released by the Department of Health.

The FDA has updated the list of approved COVID-19 test kits, to include the self administered test kits with Special Certification and is available at the FDA website. This list will be regularly updated.

Link:

<https://docs.google.com/spreadsheets/d/13S12QST9RKlyX1ipUhqhmngwq3rdtbLRnDWPg8-OSqo/edit#gid=0>.

The FDA remains steadfast in ensuring that all related COVID-19 applications are processed upon receipt of the result of performance validation from RITM.

We ask the public and stakeholders to be vigilant in the purchase of these COVID-19 test kits. To ensure safety, efficacy and quality of these health products, you are advised to source your COVID-19 test kits from FDA authorized importers who are holders of the Certification for the COVID-19 test kits or their duly authorized FDA licensed distributors.

