



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



FDA ADVISORY
No. 2021-3604

29 DEC 2021

TO: IMPORTERS, DISTRIBUTORS AND TRADERS OF MEDICAL DEVICES AND OTHER CONCERNED PARTIES

SUBJECT: Acceptance of Application for Special Certification for COVID-19 Self-Test Kits

In the interest of service, the Food and Drug Administration hereby informs all concerned stakeholders that the FDA shall start the acceptance of applications for Special Certification of COVID-19 self-test kits effective 16 January 2022 in accordance to the following issuances:

1. FDA Memorandum No. 2020-006 entitled "Issuance of Special Certification for Imported Test Kits of COVID-19"
2. FDA Memorandum No. 2021-009 entitled "Minimum Performance Requirements for COVID-19 Test Kits Used for SARS-CoV-2 Infection".

Moreover, companies with failed performance validation can request for re-testing. However, endorsement to RITM for re-testing shall be made only if the company can provide the positive results of the performance validation conducted by following international agencies/organizations, otherwise, recall procedure shall be implemented:

- a. World Health Organization (WHO)
- b. Foundation for Innovative Diagnostics (FIND)
- c. US - Centers for Disease Control and Prevention (CDC)
- d. US - Food and Drug Administration (FDA)
- e. Other counterpart reference laboratories
- f. Other international regulatory agencies

The filing of application shall be guided by latest FDA issuance on receiving and processing of applications for authorizations at the Food and Drug Administration.

This kit shall be acquired through a prescription from authorized establishments. The DOH shall release guidelines on the use of those self-administered test kits.

Dissemination of this Advisory to all concerned is hereby requested.


ROLANDO ENRIQUE D. DOMINGO, MD
Director General

DTN: 20211215075753

