



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



FDA ADVISORY
No. **2021-0684**

15 APR 2021

TO: ALL MEDICAL DEVICE MANUFACTURERS, IMPORTERS, TRADERS, DISTRIBUTORS AND OTHER CONCERNED PARTIES

SUBJECT: 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

In the interest of service, the Food and Drug Administration hereby informs all medical device manufacturers, importers, traders, distributors and all concerned about the process for the issuance of Special Certification for COVID-19 Test Kits pursuant to the provisions of FDA Memorandum 2020-006 entitled "Issuance of Special Certification for Imported Test Kits of COVID-19" and FDA Memorandum 2021-009 entitled "Minimum Performance Requirements for COVID-19 Test Kits Used for SARS-CoV-2 Infection":

1. The requirements to be submitted for the application for Special Certification for COVID-19 Test Kits are the requirements indicated in FDA Memorandum 2020-006 and the copy of the product profile indicating the specificity and sensitivity of the COVID-19 test kit as stipulated in Section III (B) (Paragraph 1) of FDA Memorandum 2021-009.
2. All applications that comply with the requirements shall be endorsed to the Research Institute for Tropical Medicine (RITM) for performance validation, otherwise, the applications shall be disapproved. Fees for the conduct of the performance validation shall be settled with the RITM.
3. Upon receipt of the results of the performance validation from the RITM, all applications that comply with the specificity and sensitivity as set forth in FDA Memorandum 2021-009 shall be issued a Special Certification, otherwise, the application shall be disapproved.
4. 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 CDC
 - d. US FDA



- e. Other counterpart reference laboratories
- f. Other international regulatory agencies

The filing of application shall be guided by FDA Circular 2020-026 entitled "Food and Drug Action Center (FDAC) New Normal Operational Guidelines of the Food and Drug Administration (FDA)".

Dissemination of this Advisory to all concerned is hereby requested.


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