



FOOD AND DRUG ADMINISTRATION
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FDA CLARIFIES AVAILABILITY OF COVID-19 TEST KITS IN THE COUNTRY

The Food and Drug Administration (FDA) reiterates that there are no registered COVID-19 diagnostic test kits available to the public because no company has complied with the minimum set of requirements. For imported test kits, the FDA only requires a License to Operate (LTO) as a distributor and a Certificate of Product Registration (CPR) from a reliable and mature national regulatory agency (NRA) such as FDA counterparts in the United States, Japan, Singapore, South Korea, Europe among others or a Certificate of Prequalification or Emergency Use Listing from the World Health Organization (WHO). As of today, no company has submitted these.

There is no delay in approval because as soon as proper documents are submitted to the FDA, the certification will be immediately released. This is done to safeguard public interest and ensure that the available test kits for use are safe and will give useful results. Many companies have been marketing test kits since the start of the COVID outbreak, however, the source and reliability of these devices are yet to be verified.

“We cannot vouch for its safety and efficacy by merely accepting the stated claims of a testing kit without the proper regulatory certification from the country of origin and a reliable NRA. These kits may give false positive and false negative results which may affect the response to this pandemic. They may also be counterfeit products that will not test for the novel corona virus at all,” Director General Eric Domingo said.

The only COVID-19 diagnostic test kits used now are PCR based lab kits at the Research Institute of Tropical Medicine (RITM) donated by WHO; and the University of the Philippines National Institutes of Health (UP NIH) and Department of Science and Technology (DOST) developed test kit scheduled to start field testing on Monday, 16 March 2020.

The FDA is committed to staying true to its mandate of safeguarding the public health. “During these difficult times, we strongly request everybody to cooperate and to be vigilant. This is not the time to take advantage of the scarcity of resources by allowing unregulated items into the system. Let us continue to look after each other’s safety.” DG Domingo concluded.