



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



PRESS STATEMENT
26 March 2020

UNREGISTERED COVID-19 TEST KITS

The Food and Drug Administration (FDA) has approved twelve (12) COVID-19 test kits for commercial use as of today, March 26, 2020. These test kits are Real Time Polymerase Chain Reaction (RT-PCR) based, which is the current recommended testing kit for COVID-19. As stated in the Department of Health (DOH) Circular No. 2020-0143, there is currently no clear evidence to support the use of point-of-care tests (lateral flow rapid tests) in the diagnosis of COVID-19.

“The FDA continuously reviews all applications on COVID-19 test kits, and expedites processes. We are streamlining procedures to efficiently facilitate COVID-19 associated health commodities. We understand the urgency of the situation, but we cannot compromise the quality and safety of these kits without scientific evidence and proper documentary basis,” Director General Eric Domingo said.

Currently, the FDA does not require clearance of foreign donated COVID-19 health products prior to customs release. In fact, the DOH already received around 108,000 donated test kits from Korea, China and Singapore. There are no reports that DOH donated or registered commercial products have difficulty with the Bureau of Customs (BOC).

“Test kits for commercial use that did not go through FDA approval are probably brought into the country by importers without proper permits, and therefore not released by the BOC. Businessmen should not import these products before they are certified by the FDA. An application for product certification of a diagnostic kit is not equal to an approval to sell or distribute,” DG Domingo stated.

During this time of crisis, FDA maximizes all measures to combat the effects of the COVID-19 pandemic. “Rest assured that we are continuously evaluating these products. Products of good quality with clear indications for use shall be approved,” DG Domingo concluded.

