



PRESS STATEMENT
March 19, 2020

LIST OF FDA APPROVED COVID-19 TEST KITS FOR COMMERCIAL USE

The Food and Drug Administration (FDA) has released today a list of approved COVID-19 test kits for commercial use. These are PCR based reagent kits used in laboratories and not point-of-care or do-it-yourself kits. The companies have complied with the requirements as stated in the FDA Memorandum No. 2020-006 entitled, "Issuance of Special Certification for Imported Test Kits of COVID-19."

"FDA has released an initial list of approved kits with Special Certification. There are still pending applications that are due for evaluation. The list shall be regularly updated." Director General Eric Domingo said.

The list is made available to the public through this site,
<https://drive.google.com/open?id=1Dk8KjbCzk8g92HydWDRvg8K-ATp7gBez>

"FDA is hard at work in processing COVID-19 related applications during this time. We ask the public and stakeholders to be analytical of COVID-19 test kits that they may encounter as we have identified some applications which appear to be suspicious and unauthorized. During this period of emergency, safety is still of utmost priority. We need to be vigilant of the entry of counterfeit products and be watchful of those who try to take advantage of the current situation. FDA remains faithful to its mandate of protecting the public health against unregulated health commodities", DG Domingo assured.

