



FDA ADVISORY
No. 2020-409

119 MAR 2020

TO: **THE GENERAL PUBLIC**

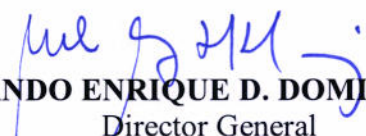
SUBJECT: **List of Approved COVID-19 Test Kits for Commercial Use**

As the Philippine Government continues to exhaust all efforts to respond to the current COVID-19 pandemic, the Food and Drug Administration (FDA) - Philippines hereby provides an initial list of approved COVID-19 Test Kits for commercial use. The kits in the list below have complied with the requirements as per FDA Memorandum No. 2020-006 entitled, "Issuance of Special Certification for Imported Test Kits of COVID-19." These are PCR based kits used in laboratories, and not point-of-care kits.

PRODUCT NAME	MANUFACTURER	DISTRIBUTOR
Nucleic acid detection kit for 2019 ncov	Shanghai GenoeDx Biotech Co., LTD- Shanghai, China.	S & S Enterprise
Novel coronavirus 2019-ncov nucleic acid detection kit (fluorescence PCR method)	Beijing Applied Biological Technologies Co., Ltd- Changping District 102206 Beijing P.R	Sahar International
Allplex™ 2019-nCoV Assay	Seegene Inc. -Seoul, Republic of Korea	Endure Medical, Inc
SOLGENT DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit	Solgent Co., Ltd-3F, 32, Techno 6-ro, Yuseong-gu, Daejeon, South Korea	Wellness Pro Incorporated

This list shall be regularly updated. For reference please click the link.
<https://drive.google.com/open?id=1Dk8KjbCzk8g92HydWDRvvg8K-ATp7gBez>.

To report any sale or distribution of COVID-19 test kits not included in the list, you may utilize our online reporting facility, **eReport** at www.fda.gov.ph/report, or email us via report@fda.gov.ph.


ROLANDO ENRIQUE D. DOMINGO, MD
Director General

