



03 APR 2020

FDA ADVISORY
No. **2020-513**

TO: The General Public

SUBJECT: FDA Approves the First Locally Manufactured Test Kit for COVID-19 for Commercial Use

The Food and Drug Administration (FDA) has now approved the Real-Time PCR for the detection of COVID-19 manufactured by the Manila HealthTek, Inc. for commercial use.

The test kit was previously approved by the FDA for field trial. with gene sequencing on 10 March 2020. Upon the company's submission of necessary requirements today, the FDA issued a certification for this COVID-19 test kit to be allowed for commercial use.

This is the first locally made PCR based COVID-19 test kit approved by the FDA which was developed in collaboration with the University of the Philippines-National Institute of Health (UP-NIH), funded by the Department of Science and Technology (DOST).

Aside from this PCR based test kit, the FDA has approved one additional rapid test kit today, which brings the total number of COVID-19 approved test kits to 30. The FDA will continue to update the public on COVID-19 testing kits approval.


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