



FDA ADVISORY
No. **2020-483**

30 MAR 2020

TO: THE GENERAL PUBLIC

SUBJECT: List of Approved COVID-19 Rapid Antibody Test Kits

In line with the ongoing response to the increasing number of COVID-19 cases in the Philippines, the Food and Drug Administration (FDA)- Philippines hereby provides an initial list of approved Rapid Antibody Test Kits.

	PRODUCT NAME	MANUFACTURER
1.	NANJING VAZYME 2019-nCoV IgG/IgM DETECTION KIT	Biolidics Limited. – 37 Jalan Pemimpin, #02-07, Mapex, Singapore
2.	NOVEL CORONAVIRUS (2019-NCOV) IgM/IgG ANTIBODY DETECTION KIT (COLLOIDAL GOLD METHOD)	Nanjing Vazyme Medical Technology Co., Ltd – Level 1-3, Bldg. C2, Red Maple Sci-Tech Park, Kechuang Road, Nanjing China
3.	DIAGNOSTIC KIT FOR IgM/IgG ANTIBODY TO CORONAVIRUS (SARS-CoV-2) (COLLOIDAL GOLD)	Zhuhai Livzon Diagnostic Inc. – 1st Building, No. 266, Tongchang Road, Xiangzhou District, Zhuhai, Guangdong Province, People’s Republic of China
4.	2019-nCoV ANTIBODY TEST (COLLOIDAL GOLD)	Innovita (Tangshan) Biological Technology Co., Ltd. – No. 699 Juxin Street, High-Tech Industrial Development Zone, Qian’an 064400, Hebei, China
5.	SARS-CoV-2 ANTIBODY TEST (LATERAL FLOW METHOD)	Guangzhou Wondfo Biotech Co., Ltd. – No. 8 Lizhishan Road, Science City, Luogang District, 510663, Guangzhou, People’s Republic of China



This list shall be regularly updated. For reference please click the link.

<https://drive.google.com/open?id=1Dk8KjbCzk8g92HydWDRvg8K-ATp7gBez>

To report any sale or distribution of COVID-19 rapid test kits not included in the list, you may email us at ereport@fda.gov.ph.


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