



FDA ADVISORY
No. **2021-1338**

18 JUN 2021

TO: ALL CONCERNED STAKEHOLDERS AND GENERAL PUBLIC

SUBJECT: Delisted Companies with Issued FDA - Special Certification for COVID-19 Test Kits

The Food and Drug Administration (FDA) informs all concerned stakeholders and the general public that the following companies with issued Special Certification for COVID-19 Test Kits have voluntarily surrendered their authorization to market the product:

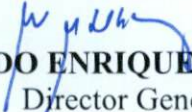
	Company's Name	Product Name	SC Control Number	Classification
1	BIOTECNICA DIAGNOSTICS INC	HIGHTOP SARS-CoV-2 IgM/IgG ANTIBODY RAPID TEST	SC-COVID19-2020-082	RAPID
2	SCIENTIFIC BIOTECH SPECIALTIES INC	DIAGNOSTIC KIT FOR NOVEL CORONAVIRUS (2019-nCoV) IgG ANTIBODY (MAGNETIC PARTICLE CLIA)	SC-COVID19-2021-003	RAPID
3	SCIENTIFIC BIOTECH SPECIALTIES INC	DIAGNOSTIC KIT FOR NOVEL CORONAVIRUS (2019-nCoV) IgM ANTIBODY (MAGNETIC PARTICLE CLIA) (Specimens: Human Serum)	SC-COVID19-2021-070	RAPID
4	NINGBO UNIMED PHILIPPINES INC	SARS-CoV-2 Antibody Test (COLLOIDAL GOLD IMMUNOCHROMATOGRAPHY)	SC-COVID19-2020-176	RAPID
5	INDOPLAS PHILIPPINES, INC	Novel coronavirus (2019-nCoV) antigen detection kit (colloidal gold method)	SC-COVID19-2021-012	ANTIGEN
6	MDX NETHERLANDS DIAGNOSTICS, INC	SAVANT™ New Coronavirus (SARS-CoV-2) N Protein Detection Kit (Fluorescence Immunochromatography)	SC-COVID19-2020-667	ANTIGEN
7	ULIVACCINES, INC	AFIAS COVID-19 Ab	SC-COVID19-2020-315	RAPID
8	MARSMAN DRYSDALE MEDICAL PRODUCTS, INC.	ACON SARS-CoV-2 IgG/IgM Rapid Test	SC-COVID19-2020-499	RAPID



9	WORLDWIDELINK TRADING CORPORATION	ichroma COVID-19 Ag	SC-COVID19-2020-704	ANTIGEN
10	WORLDWIDELINK TRADING CORPORATION	STANDARD™ Q COVID-19 IgG/IgM DUO TEST	SC-COVID19-2020-304	RAPID
11	WORLDWIDELINK TRADING CORPORATION	STANDARD Q COVID-19 IgM/IgG COMBO KIT	SC-COVID19-2020-326	RAPID
12	WORLDWIDELINK TRADING CORPORATION	STANDARD™ Q COVID-19 Ag TEST	SC-COVID19-2020-314	ANTIGEN
13	TRULABORATORIE S CORPORATION	2019-nCoV ANTIBODY TEST (COLLOIDAL GOLD)	SC-COVID19-2020-277	RAPID
14	JUNIPER 3 PROCUREMENT CORPORATION	A Rapid IgM-IgG Combined Antibody Test Kit for SARS-CoV-2 (ICA)	SC-COVID19-2020-809	RAPID
15	JUNIPER 3 PROCUREMENT CORPORATION	Novel Coronavirus(2019-nCoV) Antibody (IgG/IgM) Combined Test Kit (Immunochromatographic method)	SC-COVID19-2020-538	RAPID
16	JUNIPER 3 PROCUREMENT CORPORATION	Novel Coronavirus(2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing)	SC-COVID19-2020-572	RT-PCR
17	MDX NETHERLANDS DIAGNOSTICS, INC.	Anti-SARS-CoV-2 S Protein Antibody Test Card -	SC-COVID19-2021-092	RAPID
18	MDX NETHERLANDS DIAGNOSTICS, INC.	Neutralizing Antibody of SARS-CoV-2 Test (Fluorescence Immunochromatographic Assay)	SC-COVID19-2021-091	RAPID
19	MDX NETHERLANDS DIAGNOSTICS, INC.	COVID-19 Neutralizing Antibody Detection Kit	SC-COVID19-2021-105	RAPID

For more information and inquiries, kindly contact the FDA – Center for Device Regulation, Radiation Health, and Research through e-mail address at cdrrhr@fda.gov.ph or call (02) 8857-1900 loc. 8301.

Dissemination of this advisory to all concerned is hereby requested.


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 Director General

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