



Republic of the Philippines  
Department of Health  
FOOD AND DRUG ADMINISTRATION



FDA ADVISORY  
No. **2021-0520**

08 MAR 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	MDX NETHERLANDS DIAGNOSTICS, INC.	FOSUN COVID-19 RT-PCR DETECTION KIT	SC-COVID19-2020-183	PCR
2	MDX NETHERLANDS DIAGNOSTICS, INC.	Real-Time Fluorescent RT-PCR Kit for Detecting SARS-2019 nCoV	SC-COVID19-2020-148	PCR
3	CLEARBRIDGE MEDICAL PHILIPPINE	NANJING VAZYME 2019-nCoV IgG/IgM DETECTION KIT	SC-COVID19-2020-029	RAPID
4	UC BIOSCIENCES INC.	ORIGHT COVID-19 IgG/IgM RAPID TEST KIT	SC-COVID19-2020-250	RAPID
5	UC BIOSCIENCES INC.	Cellex qSARS-CoV-2 IgG/IgM Cassette Rapid Test	SC-COVID19-2020-104	RAPID
6	UC BIOSCIENCES INC.	2019-nCoV ANTIBODY TEST (COLLOIDAL GOLD)	SC-COVID19-2020-102	RAPID
7	BIOPHARMA MEDICAL SOLUTIONS, INC.	SARS-CoV-2 FLUORESCENT PCR	SC-COVID19-2020-079	PCR
8	BIOPHARMA MEDICAL SOLUTIONS, INC.	SOLGENT DiaPlexQ™ NOVEL CORONAVIRUS (2019-nCoV) DETECTION KIT	SC-COVID19-2020-090	PCR
9	CLEARBRIDGE MEDICAL PHILIPPINES, INC	SAVANT™ New Coronavirus (SARS-CoV-2) N Protein Detection Kit (Fluorescence Immunochromatography)	SC-COVID19-2020-657	ANTIGEN
10	INDOPLAS PHILIPPINES, INC.	SARS-CoV-2 Antibody Test (Lateral Flow Method) – Guangzhou Wondfo Biotech Co., Ltd.	SC-COVID19-2020-091	RAPID
11	CRESTLINE SCIENTIFIC CORPORATION	Cellex qSARS-CoV-2 IgG/IgM Cassette Rapid Test	SC-COVID19-2020-161	RAPID
12	MUREX DIAGNOSTIC PRODUCTS SPECIALISTS	SARS-CoV-2 Fluorescent PCR	SC-COVID19-2020-182	PCR



13	ADAMSON MEDTEX INTERNATIONAL CORP	DIAGNOSTIC KIT FOR IgM/IgG ANTIBODY TO CORONAVIRUS (SARS-CoV-2) (COLLOIDAL GOLD) – Zhuhai Livzon Diagnostic Inc	SC-COVID19-2020-032	RAPID
14	AGLOBAL CARE, INC	2019-nCoV ANTIBODY TEST (COLLOIDAL GOLD)-INNOVITA	SC-COVID19-2020-099	RAPID
15	ST. TYKE, INC	PCL COVID19 IgG/IgM RAPID GOLD	SC-COVID19-2020-396	RAPID
16	BIOPHARMA MEDICAL SOLUTIONS, INC.	2019-nCoV Antibody Test (Colloidal Gold) – Innovita (Tangshan) Biological Technology Co., Ltd.	SC-COVID19-2020-157	RAPID
17	BIOSITE MEDICAL INSTRUMENTS	MAGLUMI 2019-nCoV IgM/IgG	SC-COVID19-2020-739	RAPID
18	MGV SCIECHEM CORPORATION	2019 n-CoV IgG/IgM RAPID TEST CASSETTE	SC-COVID19-2020-613	RAPID
19	HEALTHSOLUTIONS ENTERPRISES, INC	DIAGNOSTIC KIT FOR IgM/IgG ANTIBODY TO CORONAVIRUS (SARS-CoV-2) (COLLOIDAL GOLD) - Zhuhai Livzon Diagnostic Inc.	SC-COVID19-2020-394	RAPID
20	HEALTHSOLUTIONS ENTERPRISES, INC	LabGun COVID-19 RT-PCR Kit	SC-COVID19-2020-214	PCR
21	HEALTHSOLUTIONS ENTERPRISES, INC	Real-Time Fluorescent RT-PCR Kit for Detecting SARS-2019 nCoV	SC-COVID19-2020-211	PCR
22	HEALTHSOLUTIONS ENTERPRISES, INC	2019-nCoV NUCLEIC ACID TESTING KIT (FLUORESCENCE PCR METHOD)	SC-COVID19-2020-220	PCR
23	HEALTHSOLUTIONS ENTERPRISES, INC	SOLGENT DiaPlexQ™ NOVEL CORONAVIRUS (2019-nCoV) DETECTION KIT	SC-COVID19-2020-213	PCR
24	HEALTHSOLUTIONS ENTERPRISES, INC	NOVEL CORONAVIRUS (2019-NCOV) NUCLEIC ACID DETECTION KIT (FLUORESCENCE PCR)	SC-COVID19-2020-222	PCR

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

Dissemination of this advisory to all concerned is hereby requested.

  
**ROLANDO ENRIQUE D. DOMINGO, MD**  
 Director General

DTN 20210222153610