



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



FDA ADVISORY
NO. 2020-2183

23 DEC 2020

TO : ALL CONCERNED STAKEHOLDERS AND GENERAL PUBLIC

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

The Food and Drug Administrative (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-2 ANTIBODY TEST (COLLOIDAL GOLD)	SC-COVID19-2020-102	RAPID
7.	Biopharma Medical Solutions, Inc.	SARS-CoV-2 FLOURESCENT 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	SC-COVID19-2020-657	RAPID
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) – Zhuhau 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

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

Dissemination of this advisory to all concerned is hereby requested.


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