



23 OCT 2020

**FDA ADVISORY
NO. 2020-1928**

T O : ALL CONCERNED STAKEHOLDERS AND GENERAL PUBLIC

SUBJECT : Delisted Companies with Issued Special Certification for COVID-19 Rapid Antibody 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 Rapid Antibody Test Kits have voluntarily surrendered their authorization to market the product:

	Company's Name	Product Name	SC CONTROL NUMBER
1	SAFEGUARD DNA DIAGNOSTICS INC.	Cellex qSARS-CoV-2 IgG/IgM Cassette Rapid Test – Cellex, Inc.,	SC-COVID19-2020-092
2	MEDICAL CENTER TRADING CORPORATION	SARS-CoV-2 Antibody Test (Lateral Flow Method) – Guangzhou Wondfo Biotech Co., Ltd.	SC-COVID19-2020-098
3	PHARMALLY PHARMACEUTICAL CORPORATION	SARS-CoV-2 Antibody Test (Lateral Flow Method) – Guangzhou Wondfo Biotech Co., Ltd.	SC-COVID19-2020-062
4	PHARMALLY PHARMACEUTICAL CORPORATION	DIAGNOSTIC KIT FOR IgM/IgG ANTIBODY TO CORONAVIRUS (SARS-CoV-2) (COLLOIDAL GOLD – Zhuhai Livzon Diagnostic Inc.	SC- COVID19-2020-071
5	MARSMAN DRYSDALE MEDICAL PRODUCTS, INC.	Cellex qSARS-CoV-2 IgG/IgM Cassette Rapid Test	SC- COVID19-2020-425
6	MARSMAN DRYSDALE MEDICAL PRODUCTS, INC.	2019-nCoV Antibody Test (Colloidal Gold) – Innovita (Tangshan) Biological Technology Co., Ltd.	SC-COVID19-2020-266
7	VALUE- RX, INC	2019-nCoV Antibody Test (Colloidal Gold) – Innovita (Tangshan) Biological Technology Co., Ltd.	SC-COVID19-2020-236
8	PHILIPPINE UNITED TECHNIC CORPORATION	DIAGNOSTIC KIT FOR IgM/IgG ANTIBODY TO CORONAVIRUS (SARS-CoV-2) (COLLOIDAL GOLD) – Zhuhai Livzon Diagnostic Inc	SC-COVID19-2020-229
9	PHILIPPINE UNITED TECHNIC CORPORATION	SARS-CoV-2 Antibody Test (Lateral Flow Method) – Guangzhou Wondfo Biotech Co., Ltd.	SC-COVID19-2020-230

10	ETIHEALTH PHILIPPINES INC	DiagnoSure COVID-19 IgG/ IgM Rapid Test Cassette	SC- COVID19-2020-194
11	ADP PHARMA CORPORATION	DIAGNOSTIC KIT FOR IgM/IgG ANTIBODY TO CORONAVIRUS (SARS-CoV-2) (COLLOIDAL GOLD) – Zhuhai Livzon Diagnostic Inc	SC-COVID19-2020-175
12	A-Z MARKET ENTERPRISE DEVELOPERS INC	SARS-CoV-2 Antibody Test (Lateral Flow Method) – Guangzhou Wondfo Biotech Co., Ltd.	SC-COVID19-2020-117
13	GETZ BROS. PHILIPPINES, INC	LOGIX SMART CORONAVIRUS DISEASE 2019 (COVID-19) KIT – Co-Diagnostics, Inc	SC-COVID19-2020-165
14	ZUELLIG PHARMA CORPORATION	A*STAR FORTITUDE KIT 2.0 (COVID-19 Real-Time RT-PCR TEST) – Accelerate Technologies Pte. Ltd.	SC-COVID19-2020-007
15	ROCHE (PHILIPPINES), INC	TIB MOLBIOL LIGHTMIX® MODULAR WUHAN CoV RdRP-GENE	SC-COVID19-2020-011
16	ROCHE (PHILIPPINES), INC	TIB MOLBIOL LIGHTMIX® MODULAR SARS AND WUHAN COV E-GENE	SC-COVID19-2020-010
17	IMPEXCOS CO.	VivaDiag™ COVID-19 IgM/IgG Rapid Test	SC-COVID19-2020-164
18	GETZ BROS. PHILIPPINES, INC.	Qiastat-Dx Respiratory SARS-CoV-2 Panel	SC-COVID19-2020-495
19	BIOSITE MEDICAL INSTRUMENTS	Anti-SARS-CoV-2 Rapid Test	SC-COVID19-2020-232

For more information and inquiries, kindly contact the FDA-Center for Device Regulation, Radiation Health, and Research through email address cdrrhr@fda.gov.ph.

Dissemination of this advisory to all concerned is hereby requested.


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