



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



08 OCT 2021

FDA ADVISORY
No. **2021-2452**

TO: ALL HEALTHCARE PROFESSIONALS AND GENERAL PUBLIC

SUBJECT: Caution on the purchase and use of certain COVID-19 Test Kits following the performance validation conducted by the RITM

In the interest of protecting public health and safety, the Food and Drug Administration (FDA) hereby provides the lists of companies with issued Special Certificate and failed performance validation conducted by the RITM as of 13 September 2021:

No.	Product Name	Classification	Cert No.	Name of Company
1	GenBody COVID-19 Ag Mfd by: Genbody Inc	ANTIGEN	SC-COVID19-2020-654	UC BIOSCIENCES INC.
2	FaStep COVID-19 Antigen Rapid Test Device (Nasopharyngeal/ Oropharyngeal Swab) Mfd by: Assure Tech (Hangzhou) Co. Ltd	ANTIGEN	SC-COVID19-2020-597	INFINITE ALLIANCE MARKETING INC.
3	GenSure™ COVID-19 IgG / IgM Rapid Test Mfd by: Hebei Gensure Biotech Inc.	RAPID/ RTK	SC-COVID19-2021-008	NUEVA SUNSHINE PHILS., INC
4	SARS-CoV-2 IgG Screen Mfd by: IMBIAN LAB LLC.	RAPID/ RTK	SC-COVID19-2020-760	KOLONWEL TRADING
5	GA CoV-2 IgG/ IgM Mfd by: GA Generic Assays GmbH	RAPID/ RTK	SC-COVID19-2020-289 SC-COVID19-2020-290	KHRIZ PHARMA TRADING INC.
6	COVID-19 Antigen Test Kit (Dry Fluorescence Immunoassay) Mfd by: Lansion Biotechnology Co., Ltd	ANTIGEN	SC-COVID19-2020-732	ECO APPLICATION SOLUTIONS
7	NADAL COVID-19 Ag Test Mfd by: nal von minden GmbH	ANTIGEN	SC-COVID19-2020-690	DIAGNOSTIKA PILIPINAS, INC
8	SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold) (Specimen: Nasal Swab) Mfd by: JOYSBIO (Tianjin) Biotechnology Co., Ltd.	ANTIGEN	SC-COVID19-2021-103	EHD SOLUTIONS INC
9	SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold) (Specimen: Nasal Swab)	ANTIGEN	SC-COVID19-2020-715	TOUCHSTAR ENTERPRISES

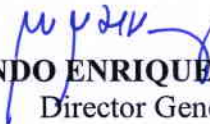


	Mfd by: JOYSBIO (Tianjin) Biotechnology Co., Ltd.			
10	BD Veritor System for Rapid Detection of SARS-CoV-2 Mfd by: Becton, Dickinson and Company-7 Loveton Circle Sparks, MD 21152, USA	ANTIGEN	SC-COVID19-2020-731	REBMANN, INCORPORATED

This FDA Advisory does not cover all the other COVID-19 test kits with similar product name/brand name which are imported/distributed by other companies with valid Special Certificates issued by the FDA.

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 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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