FDA GHANA FOOD AND DRUGS AUTHORITY

Your Well-being, Our Priority.

LIST OF FDA REGISTERED COVID-19 ANTIGEN RAPID DIAGNOSTIC TEST KITS

The FDA has approved the attached list of **ANTIGEN-BASED** Rapid Diagnostic Test Kits (RDTs) for screening and diagnosis of Corona virus (SARS-CoV-2) in Ghana, in line with the Ministry of Health's Antigen Testing Guidelines for COVID-19 in Ghana (1st Edition).

These Antigen RDTs for COVID-19 diagnosis have **NOT** been approved for **Home Use or Self-Testing**. These have been approved **solely** for use in **Registered and Certified Medical/Healthcare Facilities** which have been licensed by the Health Facilities Regulatory Agency (HeFRA).

The public is, therefore, being cautioned to refrain from the use of Rapid Diagnostic Test Kits for **Self-Testing** or **Home Use Purposes.** Please note that sample collection, testing and interpretation of test results by untrained persons with no supervision can pose many risks which would impact negatively on the quality of the results attained.

These risks may include false-negative, false positive results or erroneous diagnosis which could result in avoidable quarantine and false reassurances leading to the spread of the COVID-19 infection. Also, the results of such self or home testing would not be captured as part of the National data as it contravenes the National Guidelines for Laboratory Testing and Reporting on Respiratory Infectious Diseases in Health Facilities in Ghana. Consequently, data captured for Policy and other strategic decision making may be compromised which would hinder national efforts targeted to control the spread of the COVID-19.

NO.	PRODUCT NAME	LOCAL AGENT
1.	HEALGEN COVID-19 ANITIGEN RAPID TEST KIT (BN: 2010266)	Dekolgo Enterprise, Accra
2.	HUIHAI 2019 nCoV ANTIGEN RAPID TEST KIT (BN: 20210118)	Enfia Pharmaceuticals Company Limited
3.	BIOPANDA COVID-19 RAPID ANTIGEN TEST KIT (BN: CVA 21032206)	Impact Medical and Diagnostic Centre
4.	LEPU MEDICAL SARS-CoV-2 ANTIGEN RAPID TEST KIT	iCheck Health Solutions Limited
5.	SURE STATUS COVID-19 ANTIGEN TEST CARD (BN: 97K04208)	K. Yalley Company Limited
6.	VERI-Q COVID-19 Ag RAPID TEST KIT	Nilex Corp Company Limited
7.	CELLEX Q SARS-CoV-2 RAPID ANTIGEN TEST (BN: B201109)	PharmaFen Ghana Limited
8.	ABBOTT PANBIO COVID-19 Ag RAPID TEST DEVICE (BN: 41ADF450A)	Codix Healthcare Limited
9.	STANDARD Q COVID-19 ANTIGEN TEST KIT (BN: QC030200054)	Codix Healthcare Limited
10.	GENRUI SARS-CoV-2 ANTIGEN TEST KIT (COLLOIDAL GOLD) (BN: 20201215)	Omni Speciality Products
11.	FLOWFLEX SARS-CoV-2 ANTIGEN RAPID TEST KIT (BN: TC10022021K2255)	Aceline BCNJ
12.	UDXBIO COVID-19 ANTIGEN RAPID TEST KIT (BN: 202107003)	Denzel Logistics
13.	FLUORECARE SARS-COV-2 SPIKE PROTEIN ANTIGEN TEST KIT (BN: 21017)	KrisMed Laboratory Supplies

14.	ANBIO BIOTECH RAPID COVID-19 ANTIGEN TEST KIT (COLLOIDAL GOLD) (BN: 2021361311)	Mangel Klicks Company Limited
15.	GLOW+ COVID-19 ANTIGEN RAPID TEST KIT (BN: 2104131)	Panacyte Scientific Ghana Limited
16.	ORIENT GENE CORONAVIRUS ANTIGEN RAPID TEST CASSETTE (BN: 2105331)	Africa Medical Technologies
17.	SELF-DIAGNOSTICS SARS-CoV-2 ANTIGEN RAPID TEST KIT (BN: COV1020069)	Carlwil Healthcare Limited
18.	NASOCHECK COMFORT SARS-CoV2 ANTIGEN TEST KIT (BN: 21CG2725X)	Medishire Ghana
19.	COVIDENT COVID-19 ANTIGEN TEST KIT (BN: 2021361313)	ACCAD Healthcare Limited
20.	FLOWMEDICS SARS-CoV-2 ANTIGEN TEST KIT (BN: TC10022021K2255)	Flow Living Medicare Limited
21.	EDINBURGH GENETICS ACTIVXPRESS+ COVID-19 ANTIGEN COMPLETE TESTING KIT (BN: 202140302)	mPharma Pharmaceuticals Limited