

Head Office

Mail: P.O. Box CT 2783, Cantoments-Accra, Ghana

Fax: +233 - 302 - 229794 (+233)-302-233200/235100 (+233)-0299802932/3 (Hotline)

0800151000 (Toll free)

Email: fda@fdaghana.gov.gh

FDA/CPED/20/0002

23RD March 2020

PUBLIC HEALTH ALERT - RAPID DIAGNOSTIC TEST (RDT) KIT FOR CORONA **VIRUS**

The Food and Drugs Authority (FDA) wishes to inform the general public that it has not registered any Rapid Diagnostic Test Kits (RDTs) for screening and diagnosis of CORONA VIRUS (SARS-CoV-2) in Ghana.

The current tests for screening and diagnosis of the Coronavirus in Ghana, approved by the Ministry of Health is the Polymerase Chain Reaction (PCR) tests.

The FDA, guided by current global practices and advise from eminent Ghanaian scientists, is also not registering any such RDTs (based on serology; antigen-antibody reaction) for self-test.

This process will be guided by independently evaluated diagnostics as an assurance of quality. As evidence accumulates based on rigorous data, the FDA will update and/or amend this guidance as appropriate and necessary in the interest of public health and patient protection.

The FDA wishes to informall prospective applicants to be guided appropriately.

All concerns regarding the use of rapid test kits for coronavirus and any other FDA regulated products should be directed to the following contacts;

0299802932



www.fdaghana.gov.gh



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To ensure your safety and protection against Covid-19, you are all reminded to strictly comply with the safety measures put out by His Excellency the President of the Republic of Ghana (including handwashing, sanitizing, social distance, avoiding handshake and touching of face).

FDA...Your Well-being, Our Priority

Signed DELESE A. A. DARKO (MRS) Chief Executive Officer

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