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FDA ADVISES ON THE USE OF UNREGISTERED RAPID DIAGNOSTIC TEST KITS (RDT) FOR CORONAVIRUS

There have been concerns and calls from sections of the public for the use of Rapid Diagnostic Test (RDT) Kits to test for Coronavirus disease.
These test kits are based on the detection of antibodies, in blood or serum, in people who are believed to have been infected with coronavirus.

The Food and Drugs Authority (FDA) wishes to caution the public who are using and any persons importing these test kits, that RDT Kits must be validated **within the appropriate settings and target population,** that is, Ghana, before they can be approved for use.
This validation process is guided by independently evaluating the diagnostics for assurance of quality and performance through collaboration with Research laboratories and Public Health laboratories and the expert Technical Advisory Committee for Medical Devices.

Commercially marketed test kits that pass the evaluation/validation process, will be granted Emergency Use Authorization (EUA) for use during this pandemic. The list of all registered products including authorized test kits is maintained on the FDA website.

Currently Ministry of Health's approved method for screening and clinical diagnosis of the Coronavirus in Ghana is the Polymerase Chain Reaction (PCR) Test.

The public is therefore being cautioned to desist from the importation and use of unauthorized antibody-based RDTs either for self-test, screening or diagnosis. The use of unvalidated and unauthorized test kits may result in false positive or false negative results. The consequence of unnecessary quarantine and contact tracing or spread of infection by persons with the disease. These results if used for policy decision-making, could undermine public confidence and hamper national efforts being put in place to control the disease.

As evidence accumulates, based on rigorous data, the FDA will update and/or amend this information brief in the interest of public health and patient protection.
The public is assured that as and when any antibody RDTs are independently validated and authorized for use in Ghana through the FDA's Emergency Use Authorization Process, the existing communication channels would be used to make this information public.

All concerns regarding coronavirus antibody RDTs being offered for sale or questions about any other FDA regulated products should be directed to the following contacts:

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