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

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COVID TESTS AT KIA RELIABLE; FDA DISMISSES DR BONNEY'S CLAIMS

The Food and Drugs Authority, the statutory body mandated by Sec 118 4(b) of the Public Health Act 851, 2012 has noted with concern, a media interview granted to Joy News on August 31, 2020 by Dr. Kofi Bonney of Noguchi Memorial Institute for Medical Research, during which inaccurate and unscientific claims were made about the performance of the device intended to be used for testing passengers arriving at the Kotoka International Airport (KIA).

The FDA wishes to state that, testing authorised for detection of the SARS-CoV-2 Virus at KIA is not a rapid diagnostic test kit (RDT) but rather a device which detects the virus in nasopharyngeal (nasal) swabs.

This device detects the **ANTIGEN** (SARS-CoV-2 Virus) by fluorescence technology.
It is worth noting that other matured regulatory authorities like the Ghana FDA have approved this technology and similar products for use in detecting the SARS-CoV-2 Virus.
The FDA in granting market authorisation to this device, compared the specificity and sensitivity to the Gold Standard, PCR and it met the requirements of not less than 99.0% concordance.

In the absence of an International Reference Standard for antigens and antibodies for SARS-CoV-2 virus, all diagnostics for COVID-19 shall continue to be validated (compared head-to-head) against the Gold Standard PCR and approved if they meet the acceptance criteria.
The inaccurate statements made by Dr Bonney are corrected as follows:

- The sensitivity of the device, being not less than 99.0% makes it **statistically improbable** for the claim that more than half of the test results will come out as false negative (people who are carrying the virus and are falsely reported not to be)
- The specificity of the device, being also not less than 99.0% makes it **highly improbable** for test results to come out as false positive (people who are carrying other viruses to be classified as SARS-CoV-2) as being claimed.
- The nasal specimens are not placed on paper but rather onto cartridges which are inserted into the device and the results displayed electronically on an LCD, which can be printed out from a computer.
- The allusion to "tests done over the years" and all statistics given with reference to performance of RDTs in response to the accuracy of the Antigen test cannot be true for SARS-CoV-2, as the disease has not been around for that long for such data to have been gathered on RDT antigen.
- Data available to the FDA on **Antibody and Antigen RDTs** from March 2020 to date shows that their sensitivity ranges from 4% - 62% and not 34%-80%. This is the reason why the FDA has not authorised any **Antibody or Antigen RDT kits** to date.
- The misleading statement alleging that The WHO requires confirmation of a **negative** RDT test by a PCR test is inaccurate. This has also no relevance with respect to the specific antigen testing being done at the KIA as this uses a device which has been validated against PCR and found to be comparable and is **not** an RDT kit.

The Food and Drugs Authority wishes to assure the public that the device approved for use at the KIA is fit for purpose and the Authority shall continue to monitor its performance in accordance with regulatory requirements.

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