GHANA ASSOCIATION OF MEDICAL LABORATORY SCIENTISTS

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COVID-19 UPDATE: THE FOOD AND DRUGS AUTHORITY AND PARTNERS ARE ADVISED TO REVIEW THE METHOD USED TO VALIDATE COVID-19 ANTIBODY RAPID DIAGNOSTIC TEST (RDTs) KITS IN GHANA

The Ghana Association of Medical Laboratory Scientists (GAMLS) is deeply concerned about the criteria being currently used for the validation of antibody rapid diagnostics test kits (RDTs) for COVID -19 testing in Ghana.

The continuous use of Real Time Polymerase Chain Reaction (RT-PCR), the so called "gold standards", as a yardstick for antibody RDTs validation makes it almost impossible for any COVID-19 antibody RDTs to get approval from the regulator, as the method being used amounts to comparing oranges to apples instead of apples to apples.

Scientifically, methods evaluation or validation of a test method, test kit/reagent among others, is done using the so-called "gold standard" within the same class of the item being evaluated. In method validation, the first principle is to always compare like to like: ie, molecular to molecular detection methods (RT-PCR to RT-PCR) and serological to serological (RDT to RDT). The second consideration, is where methods or test kits/reagents of different classes are evaluated, the highest and most superior gold standard available is used.
We strongly advise that the Food and Drugs Authority (FDA) and its partners review and use the appropriate method to evaluate and validate antibody RTDs for COVID-19 testing in order not deny Ghanaians the benefits of using RDTs for screening and diagnostic of the disease.

It will be recalled that, on July 28th 2020, the Food and Drugs Authority (FDA) updated Ghanaians on the status of COVID-19 antibody rapid diagnostic test (RDT) kits submitted by various vendors for evaluation and approval for COVID-19 testing in Ghana. In the briefing, addressed by the Chief Executive Officer (CEO), Mrs. Delese Mimi Darko, the regulatory body indicated that all 34 RDTs received failed to meet the sensitivity requirement of 99% when compared to the "gold standard.
The CEO further explained that due to the unavailability of a "gold standard" for antibody tests, the RT-PCR "gold standard" was used to validate the COVID-19 antibody RDTs.

Whiles the professional body appreciates and commends the FDA's efforts in ensuring that test kits, reagents, equipment and other related consumables approved for use in Ghana are of high quality and

meet the required standards, it is our professional opinion that the current method being used in the evaluation of COVID-19 antibody RDTs is flawed and should be reviewed to ensure that Ghana takes advantage of the many benefits that RDTs offer in screening and diagnoses of COVID-19.

Though the World Health Organization (WHO) and Center for Diseases Control (CDC) have not recommended the use of any particular RDT for COVID-19 testing, countries' are advised to evaluate available RDTs and develop testing algorithms that best suits their need.

As of August 6, 2020, the USA FDA had provided emergency use authorization (EUA) for 12 COVID-19 RDTs. The Foundation for Innovative New Diagnostics (FIND) has also validated 26 RDTs whiles 10 RDTs have been validated by the COVID-19 Testing Project.

As a professional body, we strongly believe that COVID-19 antibody RDTs have their place in the screening of persons exposed to the virus and can provide the country a more accurate estimate of the true burden of the pandemic in Ghana.

We are therefore encouraging the FDA to consider reviewing its current validation methodology. Reputable international organizations such as FIND and others have recommended the use of a **comparator gold standard** -- an intermediate method used to bridge the gap between RT-PCR and RDT for the validation of COVID-19 RDTs.

There is a misleading misconception that Ghana is using the highest standards to validate COVID-19 RDTs because they are been compared to RT-PCR. This in reality is counterproductive and results in falsely skewed results that creates the impression that the RDTs are of lower quality. The current results obtained may simply be due to the fact that the RDTs are compared to a far superior test methodology and not that the RDTs are necessarily not meeting the standard. One may ask why at least one of these RDTs have been validated with acceptable performance in other jurisdictions but are not meeting the sensitivity requirements in Ghana (Table 1). What might be the problem? We strongly encourage the FDA to review its validation methodology.

Table 1: List of Countries and the antibody RDT validation report received

Country	Sensitivity (%)	Specificity (%)
Russia	100	100
France	100	98
Nigeria	93	100
Malaysia	90	100
Colombia	100	96
Japan	88.1	97.6

We will like to use this opportunity to again urge government, the Ministry of Health and the Ghana Heath Service to speed up processes to use the 130 GeneXpert testing devices to expand testing to other parts of the country as has been previously promised.

We continue to encourage the general public to respect the directives by the authorities and to strictly adhere to all the safety protocols and maintain good personal hygiene practices to protect themselves and their families, and to protect frontline workers and their families.

Laboratory regards,

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GAMLS, PUBLIC RELATIONS, 13th August 2020