FOOD AND DRUGS AUTHORITY

GUIDELINES FOR THE AUTHORISATION OF EMERGENCY USE ANTIGEN/ANTIBODY RAPID DIAGNOSTICS TEST KITS FOR SARS-CoV-2 VIRUS

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1.0 INTRODUCTION

This Guideline outlines the policies of the Food and Drug Authority (FDA) for authorizing the emergency use of Rapid Diagnostic Test kit, which is classified as a Class IV medical device (High Risk).

In executing its mandate, the FDA takes cognizance of the powers granted the Minister of Health by Sections 169 – 173 of the Public Health Act, 2012 (Act 851) in the event of a public health emergency and provides this Guidance for the purposes of those emergency situations in which the Authority would not object to the use of a potentially life-saving medical device for a use for which the device ordinarily is required to have, but does not have FDA approval.

The Emergency Use Authorization (E.U.A) Guideline (FDA/SMC/BPD/GL-EUM/2019/08) will allow the expedited approval of medical products in emergency situations for the diagnosis, treatment, or prevention of serious or life-threatening diseases or conditions caused by such agents, when there are no adequate, approved, and available alternatives.

2.0 BACKGROUND

Molecular testing is still currently the recommended and most specific method for the identification of infectious cases and Polymerase Chain Reaction (PCR) remains the gold standard testing platform for testing SARS-CoV-2.

The average detection time for the nucleic acid testing takes two to three hours with strong specificity and relatively high sensitivity. Serology may play a role in post-infection research especially if sensitive and specific tests are developed and in surveillance and mass screening but is not recommended for case detection for COVID-19. An antibody testing method can screen individuals with results within 15 minutes.

Currently, there are no prequalified Rapid Diagnostic Test Kits (RDTs) for the detection of SARS-CoV-2 Virus prequalified by the World Health Organisation (WHO).

In the USA, CDC has so far only given Emergency Use Authorisation for molecular rapid near patient tests for detection of the 2019 novel coronavirus that causes COVID-19 but is working to develop a new laboratory test to assist with efforts to determine how much of the U.S. population has been exposed to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes COVID-19. In order to develop the test, CDC needs blood samples from people who had COVID-19 at least 21 days after their symptoms first started.

Researchers are currently working to develop the basic parameters for the test, which will be refined as more samples become available. Once the test is developed, CDC will need additional samples to evaluate whether the test works as intended.

The USFDA does not intend to object to the development and distribution by commercial manufacturers of serology tests to identify antibodies to SARS-CoV-2 and where the test has been validated, notification is provided to USFDA for use by laboratories.

The CDC has pointed out, however, that

- Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
- Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
- Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.

Singapore has used a serology test kit to aid in contact tracing, but the test has not been broadly validated for clinical use. The results from this test are not to be used for confirmatory testing or as sole basis for diagnosis.

In China, a number of nucleic acid testing kits and antibody testing kits for COVID-19 have gained approval for clinical use by China's National Medical Products Administration for clinical use.

Nucleic acid testing, however, currently remains the primary detection method for the novel coronavirus in China and antibody testing cannot replace nucleic acid testing but can provide an auxiliary diagnosis for those negative cases detected by nucleic acid testing.

In Ghana, Rapid Diagnostic Test (RDTs) kits for antibody/antigen detection for SARS-CoV-2 can play a role in the general screening of the population and in contact tracing of confirmed cases. However, these kits need to be scientifically evaluated and validated to verify whether they are suitable for use before being deployed for field-testing and screening. This is also critical in view of numerous recent alerts on

substandard and falsified rapid diagnostic test kits in circulation including one confirmed alert issued by the W.H.O.

Ghana has established an evaluation protocol for COVID 19 antibody/antigen RDTs in line with global standards. The suitability of COVID-19 antigen/antibody RDTs is being investigated to inform recommendations on their use in Ghana. This Guideline is not for the use of COVID-19 RDTs for home testing.

3.0 PURPOSE

This policy provides guidance to applicants on the requirements for evaluation of COVID19 antigen/antibody RDTs in Ghana. It has been developed in the absence of WHO prequalified Rapid Diagnostic Test Kits (RDTs) for the detection of SARS-CoV-2 Virus. The Ghana FDA will grant an Emergency Use Authorisation to COVID-19 test kits that pass the evaluation process.

The validity of authorisation for Emergency Use will be 12 months from the date of authorisation after which the standard Medical Device Registration Requirements shall apply.

4.0 SCOPE

This policy applies to all SARS-CoV-2 Rapid Diagnostic Test Kits submitted to FDA for evaluation in accordance with Section 118 of the Public Health Act, 2012, Act 851.

5.0 PROCEDURE

The test kit shall be evaluated by the FDA and subjected to the evaluation protocol by the University of Ghana Noguchi Memorial Institute for Research and The West African Centre for Cell Biology of Infectious Pathogens – WACBIP; and the Public Health Reference Laboratory (PHRL, Korle-Bu) as per Section 127 (5), Part 7, of the Public Health Act, 2012 (Act 851).

6.0 REQUIREMENTS

6.1.1 Documentation

- Complete pages 3 - 4 of the Application Form for Classes II-IV Medical Devices (available online at the FDA website www.fdaghana.gov.gh)
- Source of starting material and characterisation of Antibody/Antigen used
- Manufacturing license and free sale cert
- Antibody/antigen being detected

- Certificate of Analysis
- Testing protocol
- Instruction for the use of the test kit (IFU)
- Data on the calibration of the reference standard (Positive control) used to establish the final concentration, as well as the readouts.
- Assay methods used; the validation protocol and report.

6.1.2 Fees

- FDA Application Fee - GHC equivalent of USD160 per annum
- UGNMIMR Evaluation Fee - GH¢10,000.00
- Public Health Reference Laboratory (PHRL, Korle-Bu) Evaluation Fee - GH¢10,000.00

6.1.3 Samples

- Tests – 300 pieces (commercial presentation equivalent to 300 tests)
- Antigen/Antibody standards (specific for SARS-CoV-2) from the manufacturer**
- Negative control standards (specific for SARS-CoV-2) from the manufacturer**

Note

- **Applicant to submit adequate quantities of each standard to conduct 25 tests.
- In order to ensure lot-to-lot consistency, applicants would be required to submit, to the FDA, samples of each lot (at least 100 tests) imported after the authorisation of the product.