Telephone: General Lines: 256 - 417-712260
Permanent Secretary's Office: 256 -417- 712221
Toll Free 0800100066

E-mail : ps@health.go.ug
Website: www.health.go.ug

IN ANY CORRESPONDENCE ON
THIS SUBJECT PLEASE QUOTE NO **ADM.214/283/01**

THE REPUBLIC OF UGANDA

Ministry of Health
P. O. Box 7272
Plot 6, Lourdel Road
KAMPALA
UGANDA

2nd November 2020

The Director,
Uganda Virus Research Institute
ENTEBBE

DESIGNATION AS SARS-Cov-2 COVID-19 NATIONAL DIAGNOSTIC REFERENCE LABORATORY.

As part of the National Response for COVID-19 Public Health Emergency, I am pleased on behalf of the Ministry of Health (MOH) to designate Uganda Virus Research Institute (UVRI) as the Uganda SARS-Cov-2/COVID-19 National Diagnostic Reference Laboratory. The designation is based on the historical role and expertise played by UVRI in previous outbreaks of viral infections in Uganda and acknowledgement of UVRI by national and international partners in responding to several outbreaks associated with viral infections including viral hemorrhagic fevers over several years.

In accordance with this role, UVRI as a National Reference lab is expected to provide leadership in building and supporting the necessary laboratory and diagnostic capacity for adequate detection of and response to COVID-19 for the country. This role will be periodically reviewed by MOH with a view to ensuring UVRI's optimum effectiveness in providing the anticipated leadership particularly for supporting efficient response to COVID19.

In performance of this role, UVRI will be guided by the following Terms of Reference as the COVID-19 Reference Laboratory:

Uganda Virus Research Institute (UVRI) will:

1. Provide COVID-19-related virological expertise and laboratory support, including training, to all national COVID testing laboratories

2. Support capacity building of COVID-19 testing laboratories in the country including supporting decentralization of COVID-19 testing to optimize the capacity across the country in collaboration with CPHL

3. Develop and implement state-of-the art methods for COVID-19 testing

4. Act as the national center for validation of COVID-19 diagnostic assays before they are licensed for use in the country and provide to MOH and relevant government agencies, technical details of diagnostic assays developed and/or evaluated by UVRI for the detection of COVID-19 virus;

5. Provide a national reference resource of well-characterized proficiency panels and materials for ensuring quality assurance for COVID-testing in thecountry

6. Characterize viruses including through whole genome sequencing and provide such sequence data to a publicly-accessible data base; and provide MOH updates of the evolution of the virus and its relevant to epidemic response

7. Track the evolution of the virus causing COVID-19 and identify changes that may be relevant to diagnostic tests, vaccine development and/or antiviral treatment;

8. Depending on the further evolution of the COVID-19 epidemic, provide technical guidance towards
   i. development or refinement of diagnostic assays
   ii. development of protocols for antiviral resistance testing;
   iii. antigenic characterization of the circulating SARS-CoV-2 viruses;
   iv. development/assessment of specific tests for diagnostic humoral immune responses; and
   v. development of tests for infectivity of recovering patients.

9. To the best of your capacity and through harnessing other diagnostic capabilities in the country, provide confirmatory testing of virus materials and other clinical samples from suspected cases of COVID-19

10. Support improvement of biosafety procedures across all testing facilities

11. Working with other partners and MOH, support the development and maintenance of an updated SARS-Cov-2/COVID-19 testing algorithm for the country

12. Meet agreed timeframes and deadlines for testing and reporting results to the referring sites across the country;

13. Support maintain and demonstrate a high level of technical proficiency and capacity in all matters pertaining to COVID-19 testing, including through proficiency testing of viral detection methods;

14. Assist MOH to develop and evaluate its strategy and recommend methods for the national surveillance and diagnosis of COVID-19, including by assisting MOH through the development and revision of relevant methods, and by contributing to the development of recommendations, guidelines and other documents.

15. Treat all virus materials and clinical samples, together with all data and information relating thereto, which are obtained by the laboratory through its role as the reference laboratory as confidential and proprietary to the provider and ensure that materials are not transferred or provided to any third party unless MOH has expressly requested in writing that UVRI provide the materials to such recipient laboratory; and the recipient laboratory uses the materials solely for the Purpose as approved by MOH under specific material transfer agreements

16. In connection with all of the foregoing, the laboratory must implement and maintain appropriate technical and organizational measures to protect the confidentiality and security of the materials, and to protect the materials from unauthorized access, theft, damage, loss, destruction or misuse;

17. UVRI shall only use provided materials for the purposes of:
    i. detection, identification, and characterization (including through whole genome sequencing) of the COVID-19 pathogen, including the inclusion of resulting sequence data in a publicly accessible data base,
    ii. non-commercial assay development;
    iii. and validation of assays, and
    iv. the performance of any other work as explicitly foreseen in these Terms of Reference (all of the foregoing, collectively, the "Purpose");

18. Except as may explicitly otherwise be provided in these Terms of Reference, does not use, and does not provide and permit others to use, the materials for any purpose other than the Purpose, unless a separate written agreement has first

been established with the Provider covering such other use; any such separate agreement will be provided to MOH.

19. UVRI shall ensure that results of the use of the materials for the Purpose are only reported to MOH or other labs that provided the materials (hereinafter, the Provider")

20. UVRI will, subject to agreement with MOH and/or Provider, as applicable, be entitled to publish the results of the use of the materials for the Purpose;

21. Adhere to and comply with:
    i. all applicable laws, statutes, rules, regulations and other legal or ethical requirements;
    ii. all relevant national and/or international biosafety standards for work with high-threat pathogens; and
    iii. all national and international regulations relating to the receipt of dangerous goods;

22. Obtain and maintain in effect any applicable national and/or international licenses, permits, authorizations, accreditations, documentation and/or other recognition which are necessary or required for the laboratory to perform its tasks

Dr. Henry G. Mwebesa
DIRECTOR GENERAL HEALTH SERVICES

cc. Hon. Minister of Health
Hon. Minister of State for Health (GD)
Hon. Minister of State for Health (PHC)
Permanent Secretary
WHO Country Representative
CDC Country Director
Directors / MOH
The Incident Commander COVID-19
Commissioner Laboratory and Diagnostic Services