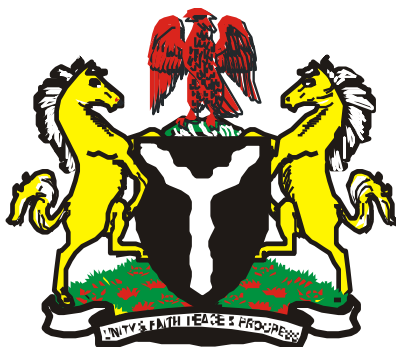


GUIDANCE FOR PRIVATE SECTOR MEDICAL LABORATORIES THAT SEEK TO PROVIDE TESTING THROUGH COMPLETELY PRIVATE ARRANGEMENTS

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INTRODUCTION

The COVID-19 pandemic has rapidly spread throughout the world, leading to significant impacts on healthcare systems and causing societal disruption. To respond effectively to the COVID-19 outbreak, rapid detection of cases and contacts, appropriate clinical management and implementation of community mitigation efforts are critical.

A key response strategy to reducing the impact of the COVID-19 pandemic is to safely expand diagnostic testing to ensure a larger number of people can access testing during the public health emergency ¹. During the course of the COVID-19 pandemic globally, medical laboratories from the private sector have been an important resource to assist with increasing the scale of testing through the provision of resources either through financial support or leveraging existing infrastructure and technical expertise. The Nigeria Centres for Disease Control (NCDC) has developed a national testing strategy that aims to harness the public and private sectors to rapidly expand diagnostic testing

This guidance document has been developed to guide engagement with the private sector medical laboratories to help accelerate the availability of COVID-19 diagnostic testing for the duration of the public health emergency. Throughout the following document, 'private sector' will refer to laboratory facilities which are for-profit or not-for-profit.

In the national strategy, there are private medical laboratories that are being supported to provide testing to the public sector. This has been agreed with the State Governments in the states where they operate. For these private medical laboratories, providing a public sector function, NCDC and its partners will continue to support the provision of reagents and consumables so that testing is conducted at no cost to the patient.

To further expand testing, we are now providing this guidance for private sector medical laboratories that seek to provide testing through completely private arrangements.

Principles of engagement with the private sector medical laboratories:

1. All private sector medical laboratories should have valid registration with the statutory national and state level authorities to perform diagnostic testing.
2. Further to Regulation 1 of Medical laboratories Regulations for Inspection, Approval, Monitoring and Accreditation which empowers the MLSCN: " to inspect, monitor, evaluate and accredit Medical laboratories to ensure the maintenance of good standard of Medical Laboratory practice, international best practices, improving and strengthening the capacity and quality of services of the Medical laboratories", all such private sector medical laboratories to be used for this purpose will be evaluated and coordinated under the MLSCN, who will provide details of status of any private sector laboratory to NCDC for appropriate reporting.
3. All staff working within the facilities should be appropriately trained and registered with appropriate national bodies.

¹ https://covid19.ncdc.gov.ng/media/files/COVID19TestingStrategy_2ZWBQwh.pdf

4. The medical laboratories will provide evidence of implementation of quality management system to demonstrate the ability to produce accurate results. Such evidence includes accreditation, certification or on-going efforts to achieve accreditation or certification.
5. Medical laboratories that are working towards accreditation or certification will meet the following criteria
 - a) The laboratory should be participating in Proficiency testing or inter-laboratory comparison for a minimum of two laboratory tests of their choice.
 - b) Have QMS documentations such as quality manual and documented procedures.
 - c) The laboratory shall provide current validation/verification reports of the RT PCR equipment that will be used for the test.
 - d) Risk management and waste management plan of the laboratory.
6. The currently approved mode of diagnosis at the moment (as at 21/05/20) is via Real time Polymerase Chain Reaction (RT PCR). A test kit with at least two gene target assay should be used with analytical performance data of 100% clinical sensitivity and 100% clinical specificity. It is recommended that kits which have undergone independent evaluations should be used ².
7. The laboratory test should be only offered when prescribed as per NCDC national guidance on case definition.
8. Priority for testing should always be provided to symptomatic patients.
9. Appropriate biosafety and infection prevention and control precautions should be taken when collecting the sample. Samples should be collected in a room or setting with appropriate airflow and use of appropriate PPEs (N95 respirator, face shield, gloves, lab gowns) and in appropriate sample medium e.g Viral Transport medium, normal saline (see national SOP on COVID sample collection).
10. Appropriate biosafety and bio-security precautions should be ensured while performing diagnostic testing. RNA extraction should be conducted in a biosafety level 2 or equivalent facility. Use of the appropriate level PPE is also recommended; disposable gown, gloves, face shield, respirator mask.
11. ALL results from such tests MUST be communicated daily to NCDC via established communication channels for the national COVID testing laboratory network and using the standardized reporting templates. Download the NCDC lab daily reporting linelist [HERE](#).
12. Positive results are also to be immediately communicated to state authorities where the cases reside, with adequate information to inform a public health response.
13. Private medical laboratories are responsible for bearing all their operational costs to provide diagnostic testing services.
14. Medical laboratories that meet requirements nos 1 - 13 above, should apply and obtain ***special approval** to offer COVID-19 testing services from MLSCN by clicking or copying this link to your

² <https://www.finddx.org/covid-19/sarscov2-eval-molecular/molecular-eval-results/>

browser

https://docs.google.com/forms/d/e/1FAIpQLSfH_ietMS0NeRDoTJoSW_MxEwE2zk4IXZASJPff-T_91PHYA/viewform

15. Use MLSCN approval letter to engage state accreditation body e.g HEFAMAA, PHERMC (find out which agency is responsible for this in the state your laboratory is located). Please note that some states will require the laboratory to sign an MoU in this regard
16. Download and fill NCDC laboratory assessment checklist [HERE](#) and email to celestina.obiekea@ncdc.gov.ng, ncdclabnetwork@ncdc.gov.ng, requesting for an on-site validation of the laboratory, for inclusion into the national network

***Medical laboratories not granted this special approval and who act contrary to Regulation 1 of the Medical Laboratories Regulations for Inspection, Approval, Monitoring and Accreditation will be sanctioned in accordance with the provisions of the said Regulation.**

*This guidance document is published in collaboration with the **Nigeria Centre for Disease Control (NCDC)***

