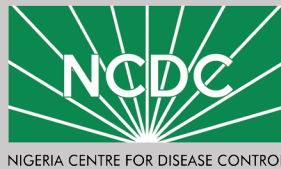


COVID-19



# National Strategy to Scale Up Access to Coronavirus Disease Testing in Nigeria





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# About NCDC

Nigeria Centre for Disease Control (NCDC) is Nigeria's national public health institute with the mandate to protect Nigerians from the impact of communicable diseases of public health significance, amongst other responsibilities. It focuses on this through evidence-based prevention, integrated disease surveillance and response activities, using a One Health approach, guided by research and led by a skilled workforce.

NCDC operations and activities are guided by five key goals to:

- Accurately measure the burden of infectious diseases in Nigeria
- Ensure Nigeria is able to meet its international obligations as a member of the World Health Assembly
- Develop a Public Health laboratory service network to support the detection and prevention of, and response to critical infectious diseases
- Reduce the adverse impact of predictable and unpredicted public health emergencies
- Create an efficiently managed and evidence-based organisation with a clear focus of health promotion and disease prevention.

NCDC currently operates through five directorates: Surveillance and Epidemiology, Public Health Laboratory Services, Health Emergency Preparedness and Response, Prevention and Programmes Coordination, Finance and Accounts and Administration and Human Resources.

# Executive Summary

## Objective

The Federal Ministry of Health through the Nigeria Centre for Disease Control (NCDC) has prioritised testing as one of the key strategies to the COVID-19 response in Nigeria. In order to contain the outbreak, the Government of Nigeria plans to rapidly scale diagnostic testing to cover all 36 States plus the Federal Capital Territory (FCT). This document describes how NCDC will work with donors, partners and the private sector to rapidly scale testing capacity to every state.

## Current Status of COVID-19 Testing in Nigeria

As of April 14 2020, Nigeria has **12 functional testing facilities in eight states**, with a capacity to conduct **a minimum of 1,500 tests per day in Lagos** and **1,000 tests per day in FCT and other states**. As the epidemic intensifies, the NCDC will use a multi-phase approach to scale up testing to all 36 states.

## Strategy for future scale up of testing of COVID-19 in Nigeria

Testing strategy will be adapted based on phases of the epidemic, as defined by WHO.

PHASE	TESTING OBJECTIVE	TESTING STRATEGY
<b>Containment Phase</b>	Identify cases for isolation	<ul style="list-style-type: none"><li>• Test all suspect cases</li></ul>
<b>Transition Phase</b>	Identify cases for isolation	<ul style="list-style-type: none"><li>• Test all hospitalised SARI patients, ill contacts of confirmed patients</li><li>• Pneumonia and Influenza deaths</li></ul>
<b>Localised Community Transmission</b>	Monitor communities with ongoing transmission; identify new areas of community transmission	<ul style="list-style-type: none"><li>• Hospitalised patients in sentinel sites<sup>1</sup> in states with community transmission</li></ul>

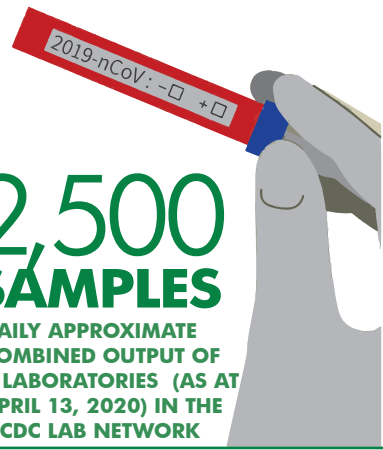
<sup>1</sup> *Sentinel Sites: in states with community transmission, sentinel facilities will be identified for spectrum of disease testing including mild and hospitalised cases as well as deaths in order to understand the severity and proportion of illnesses that are mild/severe/deadly and groups at risk for complications. Sentinel hospitals should have outpatient clinics and OB, Peds and ICU on site. Existing sentinel sites for the Nigerian Influenza Surveillance System are located at Awka, Kano, Abuja and Lagos, they conduct syndromic surveillance for Influenza like illness (ILI) and Severe Acute Respiratory Illnesses (SARI).*

EXECUTIVE SUMMARY

PHASE	TESTING OBJECTIVE	TESTING STRATEGY
<b>Widespread Community Transmission</b>	Monitor trends and burden of disease	<ul style="list-style-type: none"> <li>• Testing of every hospitalised SARI case in sentinel sites</li> <li>• Widespread testing of all phases of cases and of potentially vulnerable groups (e.g. children, pregnant women, etc.) at sentinel facilities</li> </ul>
<b>Waning Transmission</b>	Identify new waves of transmission	<ul style="list-style-type: none"> <li>• Testing of every hospitalised SARI case in sentinel sites</li> <li>• Widespread testing of all phases of cases and of potentially vulnerable groups (e.g. children, pregnant women, etc.) at sentinel facilities</li> </ul>

	CONTAINMENT	TRANSITION	LOCALISED	WIDESPREAD	WANING
<p><b>Expand existing NCDC laboratory network for molecular RT PCR</b></p> <p><i>Expand from 9 to 15 laboratories in a 30-day period.</i></p> <p><b>Increase national capacity to 1500 tests/day nationally</b></p>	✓	✓	✓	✓	✓
<p><b>Leverage capacity within high-throughput HIV molecular testing laboratories</b></p> <p><i>Expand from 0 to 6 Mega-PCR laboratories in Lagos, FCT, Benue, Akwa Ibom, and Anambra states, in a 30-day period.</i></p> <p><b>Increase combined national capacity to a minimum of 5,000 tests per day across the country</b></p>		✓	✓	✓	✓
<p><b>Utilise point of care tuberculosis testing GeneXpert machines for COVID-19 testing</b></p> <p><i>Add 41 new processing sites in 30 days</i></p> <p><b>Increase combined national capacity to a minimum of 7,000 tests per day across the country</b></p>			✓	✓	✓

# Background



**2,500  
SAMPLES**  
DAILY APPROXIMATE  
COMBINED OUTPUT OF  
9 LABORATORIES (AS AT  
APRIL 13, 2020) IN THE  
NCDC LAB NETWORK

Diagnostic testing is an essential response strategy to interrupt the transmission for the COVID-19 pandemic by informing patient management and identifying positive cases, which can then be isolated. The Federal Ministry of Health has prioritised testing as one of the key interventions to the COVID-19 response in Nigeria. In order to rapidly contain the outbreak, the Government of Nigeria plans to rapidly scale diagnostic testing to cover all 36 States plus the FCT.

The Nigeria Centre for Disease Control (NCDC) implementing this directive and following best practice, recommends and implements COVID-19 diagnosis by molecular RT-PCR testing. Currently (as at 13 April 2020), nine laboratories provide national testing capacity with an approximate combined testing output of about 2,500 samples daily.

As global shortages of diagnostic kits and laboratory consumables increasingly impacts the optimal functionality of the laboratory system in Nigeria and across the world, an adaptive testing strategy will be adopted to ensure the most vulnerable persons, those at elevated risk, and those with super spreading potential have access to testing.

## Objective

This document proposes a strategic approach to increasing accessibility to testing as new testing modalities are available, and as NCDC works with donors, partners and the private sector to rapidly scale testing capacity to every state.

## Key Results

This is an evolving strategy to put in place the testing we need to fight this battle against COVID-19:

1. From April 2020, NCDC will work with existing laboratories to ensure that everyone who meets the case definition gets tested.
2. In the next one month, NCDC will expand testing capacity to six more molecular laboratories in the country, resulting in a total of 14 laboratories.
3. In May 2020, we will begin testing for COVID-19 in existing HIV/TB laboratories (which will also enable routine and systematic testing of health workers).
4. Between May and September 2020; we will roll out mass testing to survey the population, to learn more about this virus and contribute to research and development.



# Current Status of COVID-19 Testing

Since the release of the first SARS-CoV-2 genomic sequence from Hubei province in January 2020, the global diagnostic product pipeline has made available several molecular diagnostic tests developed for both open and closed systems<sup>2</sup>.

The availability of the technical resources and infrastructure developed by the national HIV/AIDS and TB control programs with the support of their major partners (The United States Government and The Global Fund for HIV, TB and Malaria) for the country has been recognised as a critical resource which can be leveraged to support the COVID-19 response.

The NCDC, in collaboration with the national stakeholders, has developed this strategy to optimise the high-throughput machines available at USG-supported laboratories and the near point of care platforms provided through the GeneXpert machines available at TB DOTS sites across the country.

To ensure long-term sustainability and enhancing the public health laboratory network, primary focus will be given to developing RT PCR capacity within existing laboratories either in academic, Federal and State facilities and then phasing testing to other platforms as new diagnostic tests become available in Nigeria.

<sup>2</sup> See Annex 1

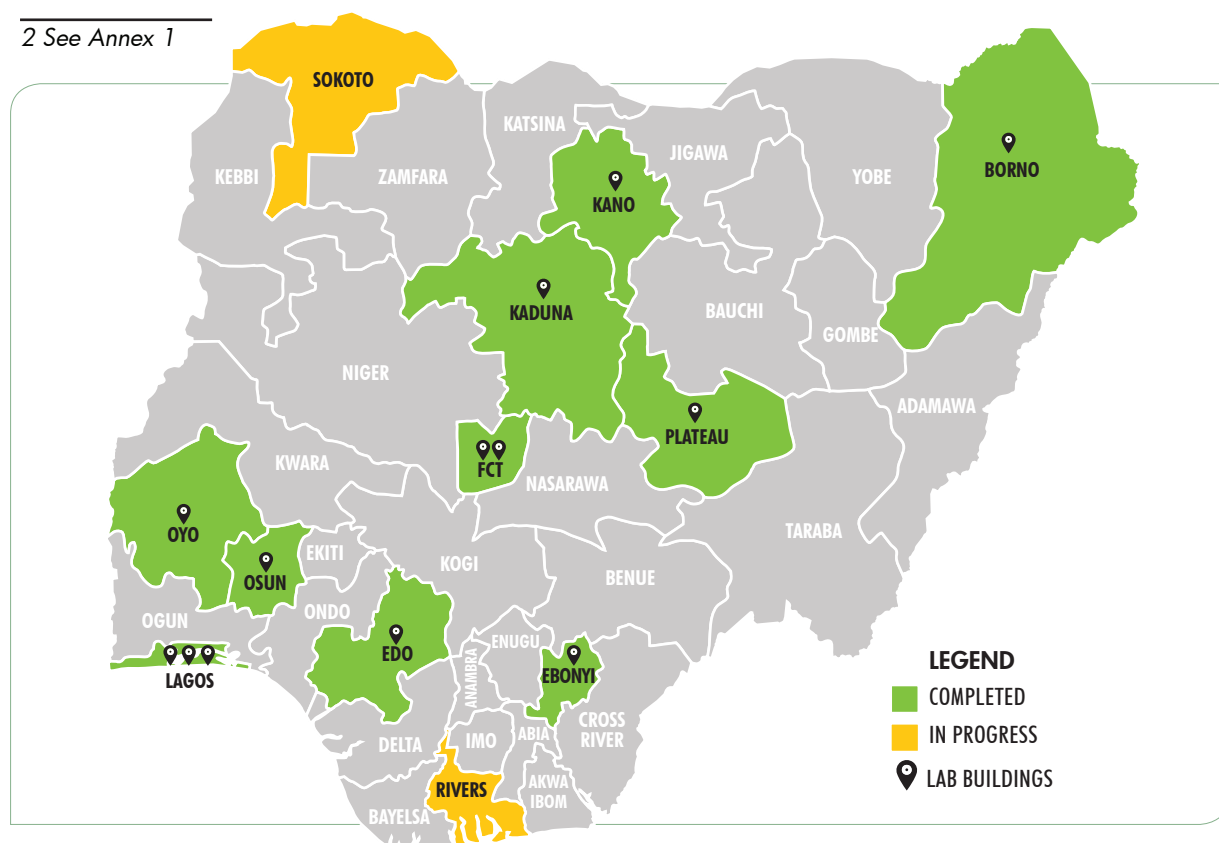


Figure 1: Laboratory Testing Capacity for COVID-19 as of April 15, 2020

# The National Testing Strategy

The national testing strategy as outlined provides guidance to clinicians, laboratories and epidemiologists on the prioritisation of testing during the various phases of the pandemic i.e. community transmission versus widespread transmission (*Table 1 below*).

As the COVID19 situation evolves and the characteristics of the outbreak changes, new disease epicentres will emerge thus elevating the importance of a state level response. Various states are at different levels of the outbreak, therefore a tailored approach suited to the context is required recognising the need to prepare for potential subsequent phases.

In order to characterise the outbreak and understand the transmission dynamics of the COVID-19 pandemic in Nigeria, more people need to be tested. To achieve scale, an integrated approach to testing is required, leveraging capacities and assets from other national disease programs for efficiency

The World Health Organization (WHO) has defined four transmission scenarios<sup>3</sup>:

1. Countries with no cases
2. Countries with 1 or more cases, imported or locally detected (**Sporadic Cases**)
3. Countries experiencing clusters of cases related in time, geographic location, or common exposure (**Clusters of cases**)
4. Countries experiencing larger outbreaks or sustained and pervasive local transmission (**Community transmission**)

As the transition from sporadic cases to community transmission can be extremely rapid, the testing strategies outlined will be pursued nationally, while implementation of the testing modalities will be implemented in phases as the resources become available.

It is possible that these scenarios may be occurring at the state level and various states will be at various stages of the pandemic. The success of this strategy is dependent on the ability to leverage existing molecular diagnostics resources in the country to support the COVID-19 response.

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<sup>3</sup> Laboratory testing strategy recommendations for COVID-19: Interim guidance 21 March, 2020

Table 1: Proposed testing strategy to be adopted by phase of transmission

	CONTAINMENT PHASE	TRANSITION PHASE (SPORADIC CLUSTERS)	LOCALISED COMMUNITY TRANSMISSION	WIDESPREAD COMMUNITY TRANSMISSION	WANING TRANSMISSION
Testing Capacity	<b>Testing capacity available</b>	<b>Testing capacity available</b>	<b>Testing capacity strained</b>	<b>Testing extremely strained</b>	<b>Increasing testing capacity</b>
Objective	Identify cases and isolate	Identify cases and isolate	<ul style="list-style-type: none"> <li>Monitor trends in communities with transmission</li> <li>Focus on identifying new clusters/communities</li> </ul>	Monitor trends and disease burden	Identify second wave of transmission
Testing Criteria	Cases meeting suspected case definition	<ul style="list-style-type: none"> <li>Hospitalised SARI<sup>4</sup> patients</li> <li>Contacts of confirmed patients who are ill</li> <li>Pneumonia and Influenza deaths</li> </ul>	Hospitalised patients in sentinel sites <sup>5</sup> in states with community transmission	<ul style="list-style-type: none"> <li>Testing of every hospitalised SARI case in sentinel sites</li> <li>Widespread testing of all phases of cases and of potentially vulnerable groups (e.g. children, pregnant women, etc.) at sentinel facilities:</li> </ul>	<ul style="list-style-type: none"> <li>Testing of every hospitalised SARI case in sentinel sites</li> <li>Widespread testing of all phases of cases and of potentially vulnerable groups (e.g. children, pregnant women, etc.) at sentinel facilities:</li> </ul>
Testing Capacity Required	<ul style="list-style-type: none"> <li>NCDC network of public health laboratories</li> </ul>	<ul style="list-style-type: none"> <li>NCDC network of public health laboratories</li> <li>HIV laboratories with PCR capacity</li> <li>Private laboratories</li> </ul>	<ul style="list-style-type: none"> <li>NCDC network of public health laboratories</li> <li>HIV laboratories with PCR capacity</li> <li>Private laboratories</li> </ul>	<ul style="list-style-type: none"> <li>NCDC network of public health laboratories</li> <li>HIV laboratories with PCR capacity</li> <li>Private laboratories,</li> <li>GeneXpert laboratories</li> </ul>	<ul style="list-style-type: none"> <li>NCDC network of public health laboratories</li> <li>HIV laboratories with PCR capacity</li> <li>Private laboratories,</li> <li>GeneXpert laboratories</li> </ul>

4 SARI- Severe Acute Respiratory Illness

5. Sentinel Sites: in states with community transmission, sentinel facilities will be identified for spectrum of disease testing including mild and hospitalised cases as well as deaths in order to understand the severity and proportion of illnesses that are mild/severe/deadly and groups at risk for complications. Sentinel hospitals should have outpatient clinics and OB, Peds and ICU on site.

# PRONG 1: Expand Existing NCDC Laboratory Network With Molecular RT-PCR

Currently, molecular tests are largely delivered through NCDC's VHF laboratory network and other national laboratories that have molecular diagnostic equipment.

## Objectives

- i. **Increase testing capacity** from 9 laboratories in 6 states to **at least 15 laboratories in 12 states and the FCT**
- ii. **Increase national testing output** from 2,500 tests a day to **at least 3,500 tests per day across the country**

PERFORMANCE FRAMEWORK: PRONG 1			
Item	Baseline	Target	Timeline
RT PCR Laboratories	9 Laboratories in 6 states	15 Laboratories in 12 States and FCT <sup>6</sup>	30 Days
National Testing capacity	2,500 tests per day	3,000 tests per day	30 days

<sup>6</sup> See Annex 2

## Efforts to ensure effective delivery of this prong are outlined below:

- NCDC is currently working with State governments and other tertiary health facilities to identify other laboratories with required capacities such as existing PCR capacity and biosafety level 2 cabinets to roll out testing, leveraging on existing laboratories for Viral Haemorrhagic Fevers and polio. These laboratories can be activated with minimal training and/or equipment.
- The NCDC is funding sample transportation from state capitals to testing laboratories using a private courier company (TRANEX).
- The NCDC is expanding the availability of trained state personnel on sample collection. This activity began in February 2020.
- The digital tool for surveillance- SORMAS is being rolled out in all testing laboratories to implement real time data reporting. Data clerks have been assigned to each facility to assist with data management.
- Validated diagnostic test kits have been procured through multiple sources to ensure availability of reagents given the global shortages and restriction of flights.

# PRONG 2: Leverage Capacity within the High-Throughput HIV Molecular Testing Laboratories

There are about 37 molecular laboratory equipment platforms currently deployed and in use within the PEPFAR-supported National PCR Network for HIV viral load and Early Infant Diagnosis (EID) testing. These include 6 Mega-PCR labs with very-high throughput machines which can be leveraged to expand COVID-19 testing. In response to global demand for rapid testing, Roche and Abbot technologies have developed and validated the SARS-CoV2 assay on the Corbas 6800/8800 and the M2000 platforms respectively. These kits have received the U.S. Emergency Use Authorization (EUA) for the use of these platforms for SARS COV2 testing<sup>7</sup>.

These **Mega-PCR laboratories** have a combined minimum testing capacity of **7,000 tests per day**, about half of which will be dedicated to COVID-19 testing. This will enable the bulk testing of COVID-19 suspected cases to be implemented in Abuja and Lagos using Roche Cobas 6800/8800; as well as Benue, Akwa Ibom and Anambra, using Abbott M2000. Implementation of the test will **increase the national output by at least additional 3500 tests per day**.

EXISTING HIGH THROUGHPUT MACHINES AVAILABLE WITHIN THE HIV VL/EID NETWORK: - LABORATORY	LOCATION	MANUFACTURER AND MODEL	NUMBER
<b>NCDC National Reference Laboratory</b>	Gaduwa, Abuja, FCT	ROCHE C8800	2
<b>Defense Reference Laboratory</b>	Asokoro, Abuja, FCT	ROCHE C8800	2
<b>Federal Medical Centre</b>	Makurdi, Benue State	Abbott M2000	4
<b>Uyo University Teaching Hospital</b>	Uyo, Akwa-Ibom State	Abbott M2000	4
<b>Dim Odumegu Ojukwu Teaching Hospital</b>	Awka, Anambra State	Abbott M2000	4
<b>Nigeria Institute of Medical Research</b>	Lagos, Lagos State	Roche C8800	1
		Roche C6800	1
<b>TOTAL</b>			<b>18</b>

**It is proposed that one instrument in each of the laboratories will be dedicated exclusively to COVID-19 testing.**

<sup>7</sup> See Appendix

## Objectives

- i. Increase testing capacity at the epicentres of the pandemic by integrating additional 3 Mega PCR laboratories for COVID-19 testing in Lagos, and FCT
- ii. Increasing testing capacity in Benue, Akwa Ibom and Anambra where the M2000 platforms are available
- iii. Increase national testing output from **3,000** tests a day to at least **5,000** tests per day

PERFORMANCE FRAMEWORK: PRONG 2			
Item	Baseline	Target	Timeline
Mega PCR Laboratories	Nil	<b>6</b> Laboratories in Lagos and FCT <sup>6</sup>	30 Days
National testing capacity	<b>3,000</b> tests per day	<b>5,000</b> tests per day	30 days

### Other useful information to note regarding implementation of this phase are:

- NCDC will work with the partners to train existing facility staff in the six designated laboratories and identify additional surge staff
- Biosafety and Biosecurity as well as appropriate waste management interventions will be instituted
- Careful planning will be required to prevent any disruption to the routine HIV workflow while the laboratories are providing diagnostic services for COVID-19.
- The national integrated sample referral network (NISRN) will be activated at State level to support ongoing transportation mechanism of TRANEX to ensure rapid sample referral to Abuja and Lagos, as well as Benue, Akwa Ibom and Anambra.

# PRONG 3: Repurpose Point of Care Tuberculosis Testing GeneXpert Machines for COVID-19 Testing

The country currently has 407 GeneXpert instruments (manufactured by Cepheid) deployed in 399 health facilities across the country for use as first line testing for TB diagnosis. The Cepheid has also been granted the U.S FDA EUA for the use of the instrument and specially designed cartridge for COVID-19 testing. As part of this strategy therefore and given that every state of the Federation including the FCT has at least 5 GeneXpert sites, at least one GeneXpert site in each state will be repurposed for COVID-19 testing, to decentralise testing to all states.

Each of the GeneXpert instruments in-country has 4-testing modules<sup>8</sup> with testing capacity of about 24 samples per day. There are also available in-country **two mobile laboratories equipped with 2 GeneXpert instruments each**. These will be deployed as needed to support COVID-19 testing surge in target states.

The planned decentralised testing using GeneXpert will enable states to test low volume samples (1–24samples daily) with same day return of results, while bulk samples will be referred to the Central/Regional PCR Laboratories as elucidated above. This will increase the country’s testing capacity by **additional 1,300 tests per day**.

## Objectives

- i. Decentralise testing to state level and improve equitable access to testing for all Nigerians
- ii. Improve turnaround time for testing and results reporting at the state level by 50%
- iii. Support surveillance in severe acute respiratory illness cases (SARI) as per IDSR definition

PERFORMANCE FRAMEWORK: PRONG 3			
Item	Baseline	Target	Timeline
GeneXpert Laboratories	Nil	<ul style="list-style-type: none"> <li>• <b>37</b> Laboratories (at least 1 per state)</li> <li>• <b>2</b> mobile testing laboratories</li> </ul>	30 Days
National testing capacity	<b>5,000</b> tests per day	<b>6,300</b> tests per day	45 days

<sup>8</sup> The four (4) module machines can process 4 tests per run

**Other useful information to note regarding implementation of this phase are:**

- There are **400 GeneXpert machines** across all the states of the federation with a daily testing capacity of 24. The opportunity exists to bring some of these machines on board and in addition procure the 16-module model to expand capacity – in the long-term.
- There are 14 TB reference laboratories across the country with the expertise in GeneXpert and have BSL 2 capacity – and can be prioritised to provide testing.
- It is planned at least 1 GeneXpert laboratory per state can be repurposed to support COVID-19 testing.
- These platforms can be placed at facilities to provide near point of care testing.
- Additional investment will be needed to provide required BSL-2 facilities in significant number of the GeneXpert sites that currently do not meet this biosafety standard.
- Careful planning is required to ensure TB testing is sustained un-impeded while expanding COVID-19 testing at the state levels
- The currently existing GX-Alert system could be interfaced with the SORMAS for lab data uploading



# PRONG 4: Private Sector Engagement

In addition to including existing laboratories from academia, federal and state hospitals, several private facilities<sup>9</sup> have shown interest to provide facilities, technical capacity, and resources to the national response. Such laboratories with molecular testing capability will be engaged and supported to provide COVID-19 testing.

However, careful planning is required with the private sector to ensure they align to the best practises adopted during a public health emergency; daily report of data to NCDC, ensuring patient confidentiality is maintained, and no additional research is performed on the samples collected without prior agreement at both the Federal and State levels and appropriate ethical approval.

PERFORMANCE FRAMEWORK: PRONG 4			
Item	Baseline	Target	Timeline
Private Laboratories currently testing	Nil	<b>100- 500</b> samples daily across laboratories	60 Days

<sup>9</sup> The following laboratories offer molecular diagnostics services (Demyhealth Laboratories Apo Abuja; Body Affairs Laboratory Garki Abuja; LifeBridge Diagnostics Garki Abuja; DNA Laboratories Kaduna, Kaduna State; Everright Laboratories, Owerri Imo State; SYNLAB Nigeria Wuse Abuja; Zankli Medical Centre Utako Abuja), 54gene in Lagos State).

# PRONG 5: Future Use of Antigen and Antibody Tests to Learn More about the Disease

The NCDC will explore the role of antigen and antibody tests in the future. This is essential to understand the rate of infection, and how the virus is spreading across the country. This will enable an assessment of the impact of measures taken so far to contain the virus, to inform current and future actions.

# Risks, Challenges and Mitigating Actions

## 1. Accuracy and reliability of tests

Due to the global shortages of reagents and laboratory consumables occurring as well as the rapid distribution of falsified products, careful selection of diagnostic kits is required to ensure any diagnostic kit procured meets national regulatory standards as well as appropriate sensitivity and specificity.

Measures are in place to ensure a rigorous process of checking every step for accuracy and reliability. Both NAFDAC and the Medical Laboratory Science Council of Nigeria are working with several companies to evaluate tests and all new PCR kits will undergo validation. We will also be guided by approved technology from WHO.

## 2. Getting the right supply of people, lab space, equipment and chemicals

Specialist laboratories are needed to analyse each sample with the right diagnostic machines and skilled professionals. Currently, Nigeria has approximately 30 public laboratories with highly specialised machines (extraction and PCR) across the country.

The challenge is the global shortage of materials needed to run the end-to-end testing process at full capacity, particularly the reagents that help to ensure high levels of sensitivity and specificity for these tests. There is also the challenge of trained human resource. NCDC needs to develop a robust human resource management strategy and plan to ensure optimal utilisation of available capacity in-country.

We are working in partnership with coordinating institutions such as WHO, Africa CDC as well as directly with some manufacturers, to ensure supply of these reagents. We are also rapidly investigating how to bring on board the capacity and skills available to us in universities, research institutes and private laboratories, particularly where their testing platforms are open. Private laboratories who have already indicated to test, will be assessed and trained as their supply of reagents and other materials matches their capacity and following validation by NCDC.

### **3. Logistics**

With a highly contagious virus it is important to put in place robust plans for safe access to testing facilities, storage and transportation of clinical samples. We want everyone who is tested to find out their results as quickly as possible. We will continue to harness traditional logistical capabilities alongside new digital solutions, for example to maintain a supply chain of reagents and communicate results, whilst providing people with clear information about what is happening throughout the process.

### **4. Laboratory Consumables and Personal Protective Equipment**

Ensuring availability and use of appropriate PPE is also a challenge given the global demand for these items. Procurement and distribution of PPEs to laboratories and to sample collectors is a priority focus in the testing expansion strategy as part of the overall infection control measures. A robust logistics management system will be put in place to ensure uninterrupted supply of PPEs to health care professionals at the laboratories and health facilities.

# Long Term Strategy for Molecular Laboratories in States in Nigeria – A Hub and Spoke Model

Prior to 2016, despite an increase in infectious diseases, there was no laboratory with the expertise for the diagnosis of many diseases. Many disease programmes developed their own diagnostic approach, leading to several poorly funded disease specific laboratories for measles, yellow fever, tuberculosis, HIV, polio, influenza etc.

In November 2018, President Muhammadu Buhari signed into law the Act establishing NCDC. This Act mandates the agency to lead the prevention, detection and response to infectious disease outbreaks and public health threats. Specifically, Section 3(d) states that NCDC shall 'develop and maintain a network of specialised and reference laboratories for pathogen detection, disease surveillance and outbreak response' (NCDC Act, 2018).

In May 2017, the NCDC National Reference Laboratory was operationalised and currently serves as the apex Public Health Reference Laboratory for Nigeria. Over the last three years, the laboratory has developed the capacity for molecular diagnosis of Lassa fever, monkeypox, yellow fever, measles, rubella, meningitis, cholera, onchocerciasis etc. and highly pathogenic infections such as Ebola. It has progressed towards full accreditation for yellow fever and measles as a reference laboratory and is going through the Strengthening Laboratory Management Toward Accreditation (SLMTA) process.

In addition to its diagnostic capacity, the National Reference Laboratory also provides genetic sequencing and other advanced services for research and surveys. In 2018, the National Reference Laboratory served as the central laboratory for the National AIDS Indicator and Impact Survey (NAIIS) and is well positioned to provide similar support to other disease surveys.

In the last three months, NCDC has established capacity for COVID-19 testing in its National Reference Laboratory and 11 other molecular laboratories in states as at the 14th of April 2020.

NCDC has shown capacity to develop a well-functioning national public health laboratory that is robust, IHR compliant and progressively working in response to national and global health security threats.

# Current Model for Diagnosis of Epidemic Prone Disease in Nigeria

In addition to the capacity at the National Reference Laboratory, NCDC leads the coordination and supports a network of public health laboratories across the country. These laboratories are located within Federal Teaching Hospitals and are directly managed and funded by the hospitals, with support from NCDC and international partners.

These laboratories are responsible for the diagnosis of epidemic prone diseases including:

1. Lassa fever/Ebola/VHFs (5)
2. Antimicrobial Resistance (12)
3. Yellow fever/measles/rubella (6)
4. Influenza (1 laboratory, 4 sentinel sites)
5. Meningitis/cholera (17)
6. Monkeypox (1)
7. Onchocerciasis (1)
8. Hepatitis E/rotavirus (1 laboratory, 4 sentinel sites)

In this role, NCDC carries out the following:

1. Provides leadership for the standardisation of diagnostic methods across laboratories
2. Ensures a centralised supply chain system for the provision of reagents and other supplies to maintain operations
3. Supports capacity development for laboratory scientists and other laboratory personnel
4. Coordinates regular quality assurance control activities
5. Ensures communication and learning across laboratories
6. Provides surge capacity when there is increased demands on the laboratories as a result of outbreaks
7. Organises the laboratories into a network based on interests to enable communication, mutual support and learning
8. Provides preventive and routine maintenance support to laboratories

The HIV/AIDS and Tuberculosis programmes have the highest number of public health laboratories outside of NCDC's network of laboratories. These are located in Federal and State hospitals. Most of the funding to support these laboratories come from international partners. The two reference laboratories for polio are located in the University of Ibadan Teaching Hospital and the University of Maiduguri Teaching Hospital. The National Tuberculosis, Buruli Ulcer and Leprosy Control Programme (NTBLCP), National AIDS and STI Control Programme (NASCAP) and the National Primary Health Care Development Agency currently provides some support but only from a vertical disease specific perspective.

All these laboratories are supported by the US Centers for Disease Control, USAID, Global Fund, US President's Emergency Plan for AIDS Relief (PEPFAR) and others.

# Developing a Hub and Spoke Model for Public Health Laboratories in Nigeria

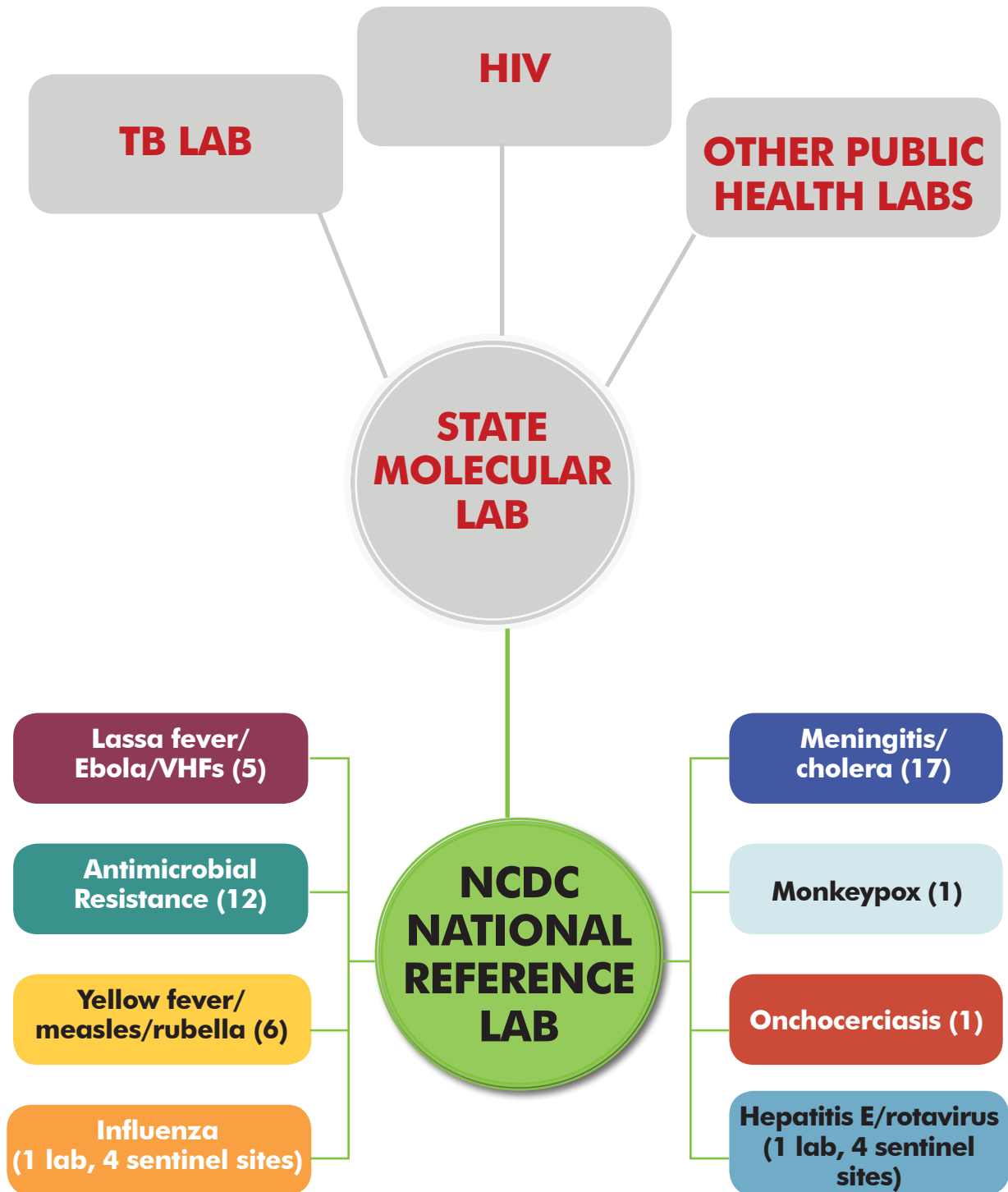
The rapid investment in establishing molecular laboratories in Nigeria following the COVID-19 pandemic, highlights the critical need for a well-defined hub and spoke model for public health laboratories in Nigeria. The goal is to ensure that all states in Nigeria establish a molecular laboratory, which will be linked to the NCDC National Reference Laboratory in a hub and spoke model.

The molecular lab in each state will also serve as a state-level hub, to ensure that every state has a well-coordinated structure for other disease specific laboratories such as for HIV and Tuberculosis.

The benefits of this model are:

1. NCDC will provide strategic leadership and coordination on behalf of the Federal Ministry of Health to public health laboratories
2. Optimise the use of human, financial and material resources across public health labs
3. NCDC will work with the Medical Laboratory Science Council of Nigeria and other stakeholders to ensure the development and maintenance of diagnostic, biosafety and biosecurity standards
4. NCDC will support the development of supply chain for reagents and sample transportation mechanisms and information management systems
5. NCDC will work with other stakeholders on the implementation of disease surveys and surveillance activities





# Indicators





According to the global recommendations NCDC will endeavour to reporting the following indicators to tracking testing.

- The number of SARI/ILI cases reported (compared with previous years in same month/week)
- The number of patients tested for COVID-19
- The number of patients who test positive for COVID-19
- The number of tested suspected cases per 100,000 population

The Government of Nigeria would provide these reports to WHO, Africa Centres for Disease Control as agreed.

# ANNEX 1: Consumables and Platforms Required for Testing (Credit CHAI, Nigeria 2020)

In order to run SRS-CoV2 Nat tests,  
3 types of consumables need to be procured from suppliers

				
	<b>Sample Collection Device 8: Medium</b>	<b>Additional Reagents (RNA Extraction Kits, Master Mix, etc.)</b>	<b>Non-Proprietary Lab Items and Decontamination</b>	<b>Proprietary Lab items (Reagents and consumables)</b>
<b>Products</b>	Swabs for collection of nasopharyngeal or oropharyngeal samples Collection medium required to transport/store/prepare the sample	RNA extraction kits for isolating viral RNA prior to testing	Nonproprietary (generic) laboratory consumables such as: gloves, pipette tips, lab gowns, DNA/RNA degrading agent, bleach, etc.	Test reagents + any controls/calibrators
<b>Suppliers</b>	<ul style="list-style-type: none"> <li>• Copan</li> <li>• Puritan</li> <li>• BD etc.</li> </ul>	<ul style="list-style-type: none"> <li>• Qiagen</li> <li>• Roche</li> <li>• Thermo Fisher</li> </ul>	<ul style="list-style-type: none"> <li>• Roche</li> <li>• Abbott</li> <li>• LASEC</li> </ul>	<ul style="list-style-type: none"> <li>• Roche</li> <li>• Abbott</li> <li>• Hologic</li> <li>• Cepheid</li> <li>• BD</li> <li>• Qiagen</li> </ul>

	<b>Equipment</b> <b>Automated Tested Kits</b> <b>Proprietary automated testing platform</b> <b>(m2000, 68/8800, GeneXpert, etc)</b>	<b>Additional Equipment</b> <ul style="list-style-type: none"> <li>• Biosafety cabinet</li> <li>• Micropipettes</li> <li>• Vortex</li> <li>• Cold blocks</li> </ul>
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## ANNEX 2:

# Additional Facilities Identified per State to Expand Diagnostic Testing in the Next One Month

STATE	FACILITY	qRT PCR CAPACITY	BSL2	STATUS
Abuja	<ul style="list-style-type: none"> <li>• NRL</li> <li>• IHVN</li> <li>• Defence Reference Lab</li> </ul>	MIC, Quant Studio 5 Corbas Corbas	Yes Yes Yes	ACTIVATED
Lagos	<ul style="list-style-type: none"> <li>• NIMR</li> <li>• LUTH</li> <li>• Biobank</li> <li>• CPHL</li> <li>• 54gene</li> </ul>	Quant Studio 3 MIC, Rotor- Gene Light cycler None qPCR ABI7900	Yes Yes Yes Yes Yes	ACTIVATED
Borno	• UMTH	ABI 7500	Yes	ACTIVATED
Kano	• AKTH	MIC		ACTIVATED
Enugu	• UNTH	ABI 7300	Yes	TBD
Ebonyi	• AU-FETHA	MIC	Yes	ACTIVATED
Edo	• Irrua Specialist Teaching Hospital	Rotor-Gene	Yes	ACTIVATED
Port Harcourt	• University of Port Harcourt Teaching Hospital	ABI 7300	No	TBD <sup>10</sup>
Jos	• NVRI	Rotor-Gene	Yes	ACTIVATED
Ibadan	• UCH	ABI 7500	Yes	ACTIVATED
Sokoto	<ul style="list-style-type: none"> <li>• TAMRED</li> <li>• UDUTH</li> </ul>	Rotor-Gene ABI 7300	Yes	TBD
Owo	• FMC, Owo	Rotor-Gene	Yes	TBD
Kaduna	• DNA labs	Rotor-Gene		ACTIVATED
Anambra	• NAUTH (Accunalysis Diagnostic Centre)	MIC	Yes	TBD

<sup>10</sup> To be done

## ANNEX 3:

# List and Distribution of Existing HIV Focused Molecular Laboratories

FACILITY	STATE	FUNDING SOURCE	GEO-POLITICAL ZONE
<b>Usman Dan Fodio University Teaching Hospital</b>	<b>Sokoto</b>	Global Fund	<b>NW</b>
<b>University of Maiduguri Teaching Hospital</b>	<b>Borno State</b>	Global Fund	<b>NE</b>
<b>Lagos State University Teaching Hospital</b>	<b>Lagos State</b>	Global Fund/ Lagos State Government	<b>SW</b>
<b>Nnamdi Azikiwe University Teaching Hospital</b>	<b>Anambra State</b>	Global Fund	<b>SE</b>
<b>Federal Medical Centre, Jalingo</b>	<b>Taraba State</b>	GON	<b>NC</b>
<b>Defense Reference Hospital, Abuja</b>	<b>Federal Capital Territory</b>	PEPFAR	<b>NC</b>
<b>National Reference Laboratory, Abuja</b>	<b>Federal Capital Territory</b>	PEPFAR	<b>NC</b>
<b>Federal Medical Centre, Makurdi</b>	<b>Benue State</b>	PEPFAR	<b>NC</b>
<b>Federal Teaching Hospital, Gombe</b>	<b>Gombe State</b>	PEPFAR	<b>NE</b>
<b>Ahmadu Bello University Teaching Hospital, Zaria</b>	<b>Kaduna State</b>	PEPFAR	<b>NW</b>
<b>Jos University Teaching Hospital</b>	<b>Plateau State</b>	PEPFAR	<b>NC</b>
<b>Obafemi Awolowo University Teaching Hospital, Ife</b>	<b>Osun State</b>	PEPFAR	<b>SW</b>
<b>Anambra State University Teaching Hospital</b>	<b>Anambra State</b>	PEPFAR	<b>SE</b>
<b>University of Uyo Teaching Hospital</b>	<b>Akwa Ibom</b>	PEPFAR	<b>SS</b>
<b>Braithwaite Memorial State Hospital, Port Harcourt</b>	<b>Rivers State</b>	PEPFAR	<b>SS</b>

# ANNEX 4:

## Strategic Approach to Scaling Up Laboratory Testing for COVID-19 in Nigeria

STRATEGIC APPROACH TO SCALING UP LABORATORY TESTING FOR COVID-19 IN NIGERIA			
STRATEGY	DESCRIPTION/RATIONALE	DELIVERABLE	TIMELINE
<p><b>PRONG 1:</b> <b>Expand existing NCDC laboratory network</b></p> <p>AIM: <b>To provide immediate access to testing</b></p>	<p>There are several laboratories within the NCDC network that have worked on molecular diagnosis of epidemic prone diseases.</p> <p>The laboratories are conversant with the biosafety and biosecurity requirements for testing dangerous pathogens</p> <p>These laboratories can be activated with minimal training and/or equipment repairs and/or replacement as necessary</p> <p>These are 'open' systems; therefore, reagents and kits are available.</p>	<ul style="list-style-type: none"> <li>• Increase testing from 9 laboratories in 6 states to 14 laboratories in 14 states + FCT</li> <li>• Increase total national testing capacity from 2,500 tests a day to 3,000 tests per day</li> </ul>	4–6 weeks
<p><b>PRONG 2:</b> <b>Leverage capacity within high throughput HIV molecular testing laboratories</b></p> <p><b>Aim: to scale up volume of testing</b></p>	<p>There are three laboratories where high throughput machines have been installed to test HIV viral load/early infant diagnosis</p> <p>These laboratories have the combined capacity to conduct a minimum of 6,000 tests daily (1,000 – 2,000 test per machine per day).</p> <p>Locations of the high through put ROCHE machines (kits for Abbott machines are not yet available).</p> <p>National Reference laboratory Abuja (supported by IHVN)</p> <p>Defence Reference laboratory, Abuja (supported by US DOD)</p> <p>Nigeria Institute of Medical Research (supported by FHI)</p> <p>COVID-19 Test kits for these machines have been ordered and are likely to be readily available, dependent on global supply</p>	<ul style="list-style-type: none"> <li>• Increase testing capacity from thousands to tens of thousands of tests daily (based on availability of test kits, efficiency of sample transportation, support for power and optimal staffing)</li> <li>• Increase testing at the major epicentres of the outbreak-Lagos and Abuja</li> </ul>	6–8 weeks

STRATEGIC APPROACH TO SCALING UP LABORATORY TESTING FOR COVID-19 IN NIGERIA			
STRATEGY	DESCRIPTION/RATIONALE	DELIVERABLE	TIMELINE
<p><b>PRONG 3:</b> <b>Deploy point of care tuberculosis testing capacity</b></p> <p>AIM: <b>To decentralise testing and speed up testing across the country and to strengthen national surveillance for COVID-19</b></p>	<p>There are about 400 GeneXpert machines across all the states of the federation. Virtually all the machines are 4 modules (can do about 4 –8 tests day); the opportunity exists to bring some of these machines on board and procure addition 16 module machines.</p> <p>There are 14 TB reference laboratories across the country with the expertise in GeneXpert and have BSL 2 capacity – and can be prioritised to provide testing. Eventually, at least 2 laboratories per state that have GeneXpert machines can be repurposed to support testing</p>	<ul style="list-style-type: none"> <li>Decentralise testing to state level and improve turnaround time for testing in states with low numbers of cases</li> <li>Support surveillance in severe acute respiratory illness cases (SARI) as per IDSR definition</li> </ul>	12–20 weeks
<p><b>PRONG 4:</b> <b>Support private sector laboratories with molecular testing capacity</b></p> <p>AIM: <b>Introduce redundancy, resilience and choice</b></p>	<p>Several private laboratories currently have molecular diagnostic equipment and expertise; many have shown interest in supporting the scale up of testing (short list available).</p> <p>A shared cost model, with quality control and obligatory reporting to NCDC can be established</p> <p>Has the potential to introduce slack into the current testing approaches</p>	<ul style="list-style-type: none"> <li>Private laboratories with molecular diagnostic expertise are in Kano, Kaduna, Lagos and Port Harcourt</li> </ul>	4–8 weeks
<p><b>PRONG 5:</b> <b>Future use of antigen and antibody tests to learn more about the Disease</b></p>	<p>Use of antigen and antibody tests for research and surveillance purpose</p>	<ul style="list-style-type: none"> <li>Evidence of rate of infection and spread in Nigeria</li> </ul>	Based on availability of validated antibody and antigen kits



**NIGERIA CENTRE FOR DISEASE CONTROL**  
**NATIONAL STRATEGY TO SCALE UP ACCESS TO**  
**CORONAVIRUS DISEASE TESTING IN NIGERIA**

**NIGERIA CENTRE FOR DISEASE CONTROL**

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