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NATIONAL GUIDELINES for Laboratory Testing and Reporting on Respiratory Infectious Diseases in Health Facilities in Ghana

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National Guidelines for Laboratory Testing and Reporting on Respiratory Infectious Diseases in Health Facilities in Ghana,

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Preface

The unprecedented COVID-19 pandemic in the world tested the limits of medical knowledge, health system infrastructure and capacity, and the international global health response. The pandemic uncovered fatal weaknesses in our health systems severely affecting health systems across the globe regardless of development status. This effect on healthcare recently occurred during the Ebola virus disease outbreak in West African countries - Liberia, Guinea and Sierra Leone inhibiting the response to the epidemic outbreak. With Western, Middle and Central Africa increasingly hosting dangerous ecological risk factors for zoonotic spillover events, the ongoing COVID-19 pandemic which originated in China must be a game-changer for how the global community and Ghana in particular, deals with this deadly respiratory pathogen moving forward.

The COVID-19 pandemic has highlighted the inadequacy of scientific and medical advancements in preventing and managing the global spread of emerging infections. In order to make progress, we need highest-level government commitment to continuously invest in laboratory diagnostic capacities. There must be dynamic policies and timely decisions to resource our laboratories to attain and maintain international standards. There is a great need to support innovation in the medical sciences to enhance respiratory sample collection, processing and testing, data collection and management via improved detection and surveillance protocols. This should be accompanied with sober consideration of the socio-economic drivers of the many ecological risk factors that are facilitating disease spillover.

The constant threat of events of Public Health Emergency of International Concern has called for strengthening of Ghana's systems for identifying public health threats. Ghana's approach to the Covid-19 pandemic has been to adopt a whole of Ghana approach for tracking, testing and treating cases. In line with the overall goal of containing, improving and sustaining laboratory diagnostic testing and reporting in the country as far as the outbreak of respiratory infectious diseases are concerned, the Ministry of Health (MoH) set up a team of experts to develop these National Guidelines for compliance by both public and private institutions.
These guidelines therefore set out the mechanisms to guide the utilization of laboratory facilities to provide diagnosis of infectious respiratory disease outbreaks in the country. It outlines the functions of the laboratory in any infectious respiratory disease response and provides the regulatory requirements for accreditation of public and private laboratories for diagnosis of such pathogens. It also sets out the reporting requirements for laboratories testing for infectious diseases and the role of the Ministry of Health.

The MoH puts a premium on Diagnostic testing and reporting as a key progressive strategy to national response for respiratory infectious diseases in Ghana.

I therefore urge all stakeholders to strictly adhere to these guidelines and ensure that both public and private facilities work collaboratively.
Thank you

KWAKU AGYEMAN-MANU (MP)
MINISTER FOR HEALTH

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Content

SECTION 1: INTRODUCTION

Climate change, habitat destruction, changing land use, biodiversity loss, pollution, and other ecological and human dynamics, have led to increasing risks of disease emergence, re-emergence, spread and persistence. Diagnostic testing for respiratory infectious diseases is critical to understanding epidemiology, informing case management, supporting prevention strategies and eventually overcoming transmission. The current COVID-19 outbreak which was reported by China on 31 December 2019 was declared a public health emergency of international concern (PHEIC) on 31 January 2020 and subsequently a pandemic on 12 March 2020. The disease has affected many countries globally and in the African region. Lessons being learned from COVID-19 and other respiratory infectious outbreaks such as Ebola, Meningitis, Tuberculosis, influenzas (H1N1), SARS, MERS etc. makes it relevant to have seamless and well-coordinated mechanisms for laboratory testing and reporting guidelines for the country.

The COVID-19 pandemic and other recent outbreaks such as Ebola in 2014 and Lassa fever in 2019 have shown the critical need to build national systems and maintain effective multisectoral coordination for appropriate responses to health emergencies. Disease prevention and surveillance has been strengthened by the development of various preparedness plans. There is also a nationwide network of laboratories with varying diagnostic capacities and trained multidisciplinary rapid response teams in place at the district, regional and national levels. Reporting of health events currently occurs in both paper and electronic formats with web-based electronic reporting from the district up to the national level. The district health information management system (DHIMS2) was being implemented in 260 districts as at December 2018. The surveillance systems of the animal and human sectors cover priority zoonotic diseases. There are 3 regional veterinary laboratories (i.e. Accra, Tamale and Takoradi) with biosafety facilities that have capacity to test for some zoonotic diseases. This document describes general guidelines for laboratory diagnosis and reporting of results at all levels in both public and private institutions.

In line with the system of health facilities, the country has a network of laboratories with varying diagnostic capacities from district to the national levels. Within the health delivery structure, the apex public health laboratory is the National Public Health Reference Laboratory (NPHRL) in Accra with three others as zonal Public Health Laboratories at Kumasi, Sekondi-Takoradi and Tamale. There are two internationally reputable academic research laboratories; the Noguchi Memorial Institute for Medical Research (NMIMR), University of Ghana and the Kumasi Centre for Collaborative Research into Tropical Medicine (KCCR), Kwame Nkrumah University of Science and Technology, with molecular diagnostic capacity for the 2019 novel coronavirus.

Similarly, there are three research institutions under Ghana Health Service (Kintampo Health Research Centre, Dodowa Health Research Centre and Navrongo Health Research Centre) that also provide support in times of outbreaks investigations. Additionally, there are well-functioning private health facilities, standalone private laboratories, quasi-public health facilities, Centre for Scientific and Industrial Research (CSIR), Teaching Hospitals, Mission Hospitals and academic institutions laboratories that complement efforts in terms of infectious disease outbreaks. The Regional Hospitals Laboratories also help in the diagnoses of infectious agents.

To ensure access to timely laboratory testing and results, it is important that testing is decentralized. Public and private laboratory systems need to collaborate to ensure a wide and robust network of laboratories to produce results during outbreaks of respiratory infectious diseases.
Currently, there are ten human and animal health sector laboratories nationwide, providing testing for COVID-19 with a plan to establish additional centers in each region. For an effective whole-of-society approach, the involvement of private sector facilities to compliment public sector laboratories is critical to address any current and future outbreaks.

1.1 Objectives of the Guidelines

1. To strengthen and harmonize laboratory protocols for diagnosing and reporting of infectious respiratory pathogens.
2. To facilitate the participation of public and private sector laboratories in respiratory infectious disease outbreaks.
3. To ensure adherence to national regulatory requirements by all health facilities and laboratories for an effective response to outbreaks of respiratory infections.

1.2 Guiding Principles

1. Resilience and Rapid Response laboratory systems
2. Quality Assurance for diagnostic testing and reporting
3. Efficiency and Effectiveness of resource mobilization and utilization
4. Collaboration with Development Partners
5. Networking

1.3 Functions of Laboratories During Outbreaks

The functions of the laboratory during outbreaks are to test suspected cases, contacts of confirmed or probable cases, and confirmed cases on treatment requiring repeat testing. Specifically, the laboratory's role is to:

- Establish appropriate, accurate, early confirmation of cases and sustainable diagnostic testing capacities to respond to public health and clinical care needs of the country
- Put in place measures to ensure surge capacity to process a large volume of specimens to cope with the public health response strategies
- Conduct monitoring of the pandemic and ensure timely release of laboratory information for diagnosis and patient care
- Collate, analyze, and report laboratory data to inform public health decision making and response in terms of Antimicrobial susceptibility testing to guide treatment and post outbreak surveillance.
- Track the genetic evolution of the pathogen and contribute to research and development of relevant vaccines by characterization of the pathogen

SECTION 2: GOVERNANCE AND COORDINATION

Effective system of governance and coordination mechanisms shall be the key driving force for the implementation of these guidelines. In times of outbreaks of infectious respiratory diseases, the Ministry of Health (MoH) shall be the fulcrum for leadership, oversight and coordination of all laboratory testing and reporting activities in line with these guidelines.

This role will ensure that all relevant key stakeholders are brought on board to achieve our collective agenda of containing the outbreak. MoH shall also take responsibility in mobilizing the needed resources to ensure that health facilities and laboratory institutions are adequately resourced.
The Ministry of Health shall ensure that all public and private facilities and laboratories acquire an ISO 15189 accreditation to meet international standards.

This general guideline shall be the reference document but other guidelines for specific infectious disease outbreaks should also be used when the need arises. The content shall be revised from time to time to satisfy contextual issues.

SECTION 3: REGULATORY REQUIREMENTS

1. All public and private sector facilities and laboratories MUST have valid registration and accreditation with relevant national and statutory institutions before they operate.
2. Relevant statutory regulatory bodies shall collaborate to ensure health facilities and laboratories adhere to standards and policies according to their legal mandate
3. Relevant laboratory assessment tools shall be used to assess the capacities of facilities and the laboratories.

SECTION 4: HUMAN RESOURCE REQUIREMENTS FOR SAMPLE COLLECTION, PROCESSING AND TESTING

1. All participating health professionals should have biosafety and biosecurity training and certification.
2. Sample collection should be performed by trained and certified health professionals such as doctors, all categories of nurses, laboratory scientists/technicians, disease control officers, pharmacists. Physician assistants Etc.
3. Sample collectors and transporters should be trained and certified.

4. Specimen processing and laboratory testing should be done by trained and certified health professionals (medical laboratory scientists and technicians
5. Diagnostic testing should be done by trained and certified medical laboratory scientists and any other recognized professionally trained scientists.
6. Ministry of Health shall provide a list of validated and approved testing methods for diagnosis of respiratory infectious diseases in Ghana

SECTION 5: SPECIMEN ARCHIVAL

1. All infectious diseases specimens are a national resource for use in research investigations towards a better understanding and for the development of diagnostic tools. Every effort should be made to archive specimen of infectious respiratory outbreaks.
2. The procedure for archiving of specimen shall include proper documentation on the samples, timeliness for archival, indexing, procedure for retrieval in cases of retesting, access to the archive, maintenance and monitoring of proper storage conditions.
3. Research work on archived samples require the approval of the Ministry of Health, Ghana Health Service Ethical Review Board and Institutional Committees.

SECTION 6: SAMPLE COLLECTION, PROCESSING AND TESTING

6.1 Sample Collection

1. All healthcare workers (HCW) who collect, handle or transport any clinical specimens must adhere strictly to infection prevention and control (IPC) guidelines
2. During sample collection, the safety of HCWs should be assured by providing appropriate personal protective equipment (PPE).
3. There should be timely communication between clinical and laboratory staff in order to enhance appropriate infection prevention and control.
4. Existing protocols for shipment of samples from source to the testing centres shall be upheld unless otherwise revised in the future.

6.2 Processing and Testing

1. The assessment should look at the biosafety level of the lab, disinfection and waste management, safety conditions, use of safety equipment (PPE) and biosafety behavior, and capacities of staff to provide the services.
2. All MOH approved testing laboratories including private sector laboratories will be required to submit 10 % of the positive and 1% of the negative samples tested per month to designated laboratories for quality assurance purposes.

3. All testing laboratories shall use testing methods that have been validated and approved by MoH.
4. All testing laboratories must be enrolled in national and international quality assurance (EQA) programs.
5. A target turnaround time (TAT) from specimen collection to availability of results should **not** go beyond 48 hours to allow for effective clinical management and robust outbreak response.

6.3 Biosafety

It is mandatory for a risk assessment to be conducted to ascertain the state of preparedness of the health facility and laboratories using the relevant laboratory assessment tool. The assessment should assess the biosafety level of the lab, disinfection and waste management, safety conditions, use of PPE and biosafety behavior. All staff performing testing should have received biosafety training. If biosafety standards are not met accreditation of the laboratory would be withheld until the conditions are met.

6.4 Quality Assurance

National laboratory technical team shall be composed to ensure the highest standards of quality assurance and improvement of laboratory testing. Quality assurance will be maintained at all phases of testing. The reliability and reproducibility of the results should be measured through internal and external quality assurance processes, and corrective action taken when the established quality criteria has not been met by the facility. Appropriate corrective measures shall be applied for compliance by the facility. The MoH will seek the support of external quality assurance assessors such as the WHO and other supporting partners to conduct periodic assessments of the laboratories.

All laboratories should commit to establishing robust Quality Management Systems (QMS) and strive to achieve ISO 15189 Accreditation status.

SECTION 7: DATA CAPTURE AND REPORTING RESULTS

As the laboratory is a crucial part of the response process in case of a respiratory infectious disease outbreak, it is important that the right linkages with the other testing sites, surveillance and case management teams are established. All testing sites will be required to provide testing results to the district and region as well as the case management centres in which it is located. This would contribute to the national laboratory data. Where an electronic medical records (EMR) or Laboratory Information Systems is used, entries of results must be made in such a system. The reporting requirements are as follows:

7.1 District Level

The case investigation forms for all cases tested should be shared daily with the District Health Management Team (DHMT) via the District Director of Health Services (DDHS). This will ensure

cases testing positive are promptly and adequately followed up. Clients accessing testing services in private laboratories should be informed that they will be followed up by the District Health Management Teams in the event of a positive test result.

7.2 Regional and National Levels

Test results from the laboratories should be shared daily with the Regional Rapid Response Team via the Regional Director of Health Services (RDHS). All test results, positive or negative, should all be reported to national health authorities through the designated channels of the Ghana Health Service and the Ministry of Health. A national automated data capture electronic system provided by the Ministry of Health shall be used in all laboratories whether public, private or quasi government.

The following shall apply:

1. There shall be a national automated data capture and analysis software procured by the MoH for data capture and reporting. This software shall be available for both public and private health facilities and laboratories involved in testing.
2. Data capture for samples, processing, testing and transmission shall be the responsibilities of participating institutions.
3. The automated system provided by the MoH shall ensure a real time data reporting.
4. All data and information on samples and testing shall be the property of the State.
5. All designated public and private laboratories shall have the MOH automated system installed on their Computers/Laptops and will be required to report as defined by MoH.
6. All health facilities and laboratories must put measures and procedures in place to ensure information security.
7. Mechanisms for internal review of results by the testing institution before release to the District Rapid Response Teams must be in place.

SECTION 8: RESOURCE MOBILIZATION

1. The MoH shall mobilize resources for effective implementation of these guideline and also provide adequate logistics for sample collection, processing, testing and reporting.
2. Testing for public institutions will be conducted at no cost to the patient. In case of private facilities, patients will be charged for testing at a reasonable cost.
3. In case there are challenges with the private sector the Ministry of Health would make itself available for consultation and necessary support.

SECTION 9: MONITORING

1. Regular supportive supervision visits will be conducted by the national laboratory technical team to testing sites to ensure compliance with testing and reporting requirements and also identify and support with identification and management of gaps.
2. Regular monitoring by regulatory bodies should be instituted to ensure that the public have confidence in the processes and controls of testing by both private and public laboratory facilities.
3. NMIMR and KCCR with support from the National Public Health and Reference Laboratory (NPHRL) shall be responsible for coordinating the administration of proficiency panel that ensures the quality of testing for the response to the outbreak.

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APPENDICES

Appendix I: Summarized checklist for assessment of laboratories capacity for COVID-19 testing

I. General laboratory information

Name of laboratory	
Location: GPS Coordinates	
Type of lab: *Private, NGO	
Laboratory Manager/Contact Person	
Region	
District	
How many hours does this lab operate? (hours)	

II. Biosafety check

Are there separate and dedicated working areas for all diagnostic testing processes; sample handling, nucleic acid extraction, master mix preparation and amplification?	□ Yes □ No
Are the rooms in a unidirectional flow?	□ Yes □ No
How many certified biosafety Level 2 cabinets are available?	□ Yes □ No
Are any other types/classes of biosafety cabinets available? If 'Yes', provide details: _____	□ Yes □ No
Is there Dead- air/ PCR work station or UV box for PCR?	□ Yes □ No
Biosafety training of laboratory staff	□ Yes □ No

III. PPEs available

PPE	Available	Quantities
Gloves	□ Yes □ No	
Disposable gowns/aprons	□ Yes □ No	
Tyvek suits	□ Yes □ No	
Surgical face mask	□ Yes □ No	
N95 respirator	□ Yes □ No	
Face shield	□ Yes □ No	
Shoe cover	□ Yes □ No	
Lab shoe	□ Yes □ No	

IV. Waste management plan

Does the facility have an autoclave?	□ Yes □ No
Does the facility have an incinerator?	□ Yes □ No
If there is no incinerator where does the facility dispose of medical waste?	

V. Human resource strength

No.	Name	Qualification	Title	Telephone number	Email

VI. Basic equipment list for COVID-19 testing

No.	Equipment	Make/ Model	Quantity	Present condition	Last maintenance /calibration	Comments
1	Glove box					
2	Biosafety cabinet 1, 2 or 3					
3	Real-Time PCR machine: e.g. ABI–7500, ABI–Quantstudio 5, MIC, CFX-96, Roche Lightcycler 480, Stratagene MX3000p, Rotorgene Q, etc.					
4	Computer for data					
5	Dead air/PCR work station					
6	Automated nucleic acid extractor					
7	Pipettes 2-10ul					
8	Pipettes 100ul					
9	Pipettes 200ul					
10	Pipettes 1000ul					
11	Fridge					
12	Freezer (-20°C)					
13	Freezer					

No.	Equipment	Make/ Model	Quantity	Present condition	Last maintenance /calibration	Comments
	(-40°C to -70°C)					
14	Vortex					
15	Thermo-mixers/heating blocks					
16	Micro centrifuge (1.5–2 mL)					
17	Racks for 1.5 mL micro centrifuge tubes					
18	2 x 96-well -20°C cold blocks					
19	PPE					
20	Autoclave					
21	Incinerator					
22	Backup UPS					
23	Backup generator					

VII. Stock management

No.	Reagent	Manufacturer	Quantity available in lab	Comments
1	Nucleic Acid Extraction kit			
2	Superscript Kit			
3	SARS-CoV-2 RT PCR assay			
4	10% bleach			
5	99% Ethanol (molecular grade)			
6	BSA			
7	Tris (10 mM)			
8	RT PCR microwell plates and tubes			
9	Pipettes tips			
10	Tubes and cryovials			

Appendix II: Indicators for monitoring

The following should be reported daily to the region and national level daily. Weekly summaries should also be sent.

1. Number of samples received
2. Number of samples tested
3. Number of samples pending
4. Number positive
5. Number rejected

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