

## CONTRIBUTORS

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## INTRODUCTION

Functioning laboratories are a key component of effective and sustainable health systems and have played a crucial role in the global COVID-19 response. They are an essential part of rapid detection and confirmation of the virus, which is key both to optimized treatment and isolation of infected patients to prevent disease spread. Laboratories are needed for the diagnosis, prevention, control, and surveillance of diseases while supporting governments and policy makers to implement data-driven policies.

Unfortunately, in many low-and middle-income countries (LMICs), increased COVID-19 testing has put a strain on the already limited infrastructure and capacity of laboratory services, further overwhelming labs that are overburdened, understaffed and under equipped. Increased capacity in laboratory diagnostic response is needed both to continue to curb the spread of COVID-19 and simultaneously detect and curb increasing rates of HIV, TB, and Malaria.

In order to continue to efficiently respond to the pandemic, the gaps and challenges faced when providing laboratory services and diagnostics must be addressed. Resources must be allocated towards training staff and building long-term capacity to ensure resilient systems for future pandemics. Investments in equipment, including lab supplies and reagents, as well as quality control and preventative maintenance, are critical to ensuring staff have the tools needed to carry out their work. Lab infrastructure must be assessed and improved so that labs are appropriately designed, safe, and have access to a reliable source of electricity. Finally, testing supplies, lab standard operating procedures, and testing and lab systems need to be strengthened to build stronger links to clinical care and improve sample transportation and faster result turn-around times. These steps are key to ensuring that results are timely, relevant, and accurate.

**GOAL:** Improve resiliency in core laboratory and diagnostic infrastructure to allow for timely, accurate detection and reporting and response to COVID-19 and future pandemics.

## ACRONYMS

<b>Ag-RDT</b>	Antigen-RDT
<b>RT-PCR</b>	Reverse transcription polymerase chain reaction
<b>FDA</b>	Food and Drug Administration
<b>CE</b>	Conformité Européenne
<b>WHO</b>	World Health Organization
<b>UPS</b>	Uninterruptible power supplies
<b>HVAC</b>	Heating, ventilation, and air conditioning.
<b>IDSR</b>	Integrated Disease Surveillance and Response

## OBJECTIVE 1: Strengthen integrated laboratory systems to increase COVID-19 antigen and molecular testing, and support longer term laboratory capacity.

### Strategy 1.1 Procure Antigen-RDT (Ag-RDT) and molecular tests for COVID-19 diagnosis, screening, and surveillance.

The choice of test depends on the reason for testing: diagnosis (identify current infection), screening (to identify infected persons who are asymptomatic) or surveillance (to monitor population-level infection and disease). Other factors to take into account include test capacity (point-of care, or high throughput), turn-around time and disease prevalence.

- Intervention If necessary, conduct an in-depth needs assessment and gap analysis of the laboratories using the tool developed by WHO for developing plans to strengthen laboratories: [Laboratory assessment tool for laboratories implementing SARS-CoV-2 testing \(who.int\)](#)
  - Intervention Ag-RDT: Select tests that are approved by FDA, CE or WHO (Emergency Use Listing) and have demonstrated performance >80% Sensitivity and >97% Specificity. Select tests that are user friendly, affordable, offer good quality and shelf life, and vendors with good distribution and technical support.
  - Intervention Molecular Tests: Choose those tests that are approved by FDA or CE or WHO (Emergency Use Listing).
  - Intervention Request quality certification documents and studies, ideally validated by a third party. New products have come to market rapidly during the pandemic, underlining the importance of quality assurance.
- ➔ See PIH Supply Chain toolkit for more information on procurement and distribution of diagnostic tests
- Intervention Roll out initial and refresher training of end users at all levels of the health system, both laboratory and clinical staff. Consider resources developed by [ASLM-African Society for Laboratory Medicine](#).
- More resources on COVID-19 diagnosis and clinical management can be found at: [COVID Testing - COVID-19 Protocols \(covidprotocols.org\)](#)

### Strategy 1.2 Strengthen specimen transport networks for molecular testing

- Intervention Building upon any networks established and maintained by corresponding MOHs and National Labs, conduct mapping of laboratory network. Identify available in-country molecular and specialized testing to serve as referral labs.
- Intervention Decentralize sample collection by training teams of lower-level staff in the health system.
- Intervention If logistics networks are not already established, conduct mapping of private sector transportation providers with capabilities for safe specimen transport. Consider contracting a range of transport options at different levels, scaled to the anticipated volume of samples, including motorcycle, car, and truck transport.
- Intervention Provide training to sample collectors on proper collection and handling of clinical samples.
- Intervention Provide sample collectors and drivers with adequate PPE and plan for surge staffing as needed

### Strategy 1.3: Strengthen building blocks of the laboratory information system to respond to COVID-19 and future pandemics

Laboratory information systems should be developed to include COVID-19 results reporting while strengthening results reporting for other disease areas.

- Intervention Involve both clinical and laboratory teams in design or improvement of COVID-19 reporting systems- including forms and work flow- to ensure that results can be utilized for clinical management. Results must follow the patient and reach the correct facility or care team. This is particularly important when digital results systems do not exist. For example, if samples are collected in a hospital intake area, but patients are quickly moved to one of several wards, there

- Intervention must be associated workflow to ensure results make their way to the patient’s new ward and care team.
- Intervention Create test order forms for end users and result reporting forms for laboratory staff, in both digital and paper formats.
- Intervention Ensure that lab communication is adapted to minimize turnaround time in reporting of results, leveraging shared data systems and electronic notification when possible.
- Intervention Create COVID-19 modules in any existing clinical or epidemiologic platforms such as Electronic Health Records, Electronic Medical Records, and mHealth outreach tools. Where possible, link laboratory information systems to clinical information management systems and ensure care providers can act upon laboratory results.
- Intervention Increase data analysis and epidemiological capacity locally. Consider training or hiring additional staff to address surges in data analysis and epidemiological surveillance needs.

**Strategy 1.4 Enhance laboratory equipment management systems.**

- Intervention Adapt or develop programs for equipment use and maintenance following international guidelines with training for operation and maintenance for their use, and develop an annual plan for any equipment requiring certification.
  - Intervention Provide all relevant equipment documentation to end users and biomedical technicians: user manual, service manual, parts manual, spare parts vendor contact information, and technical support contact information (phone & email).
  - Intervention When selecting new equipment for purchase, consider the availability of qualified local and regional service providers. Consider service contracts for complex lab equipment where available.
  - Intervention Install uninterruptible power supplies (UPSs) for sensitive equipment to improve power quality, provide some surge protection, and provide backup power in case of power failure.
  - Intervention Provide training to facilities and laboratory staff on the maintenance of HVAC and refrigeration equipment. Purchase the necessary tools for service and repair of this equipment.
  - Intervention Purchase adequate equipment to ensure redundancy of critical systems in case of equipment breakdown (e.g. cold chain, ventilation, air conditioning)
  - Intervention Strengthen or develop an annual plan for equipment in the lab that includes daily, monthly, and annual servicing, maintenance, and warranty extensions as applicable.
- ➔ See PIH Infrastructure toolkit for more information on equipment management

**OBJECTIVE 2: Strengthen laboratory human resources by training and supporting existing staff and incorporating temporary staff**

**Strategy 2.1 Proactively support the health and performance of all laboratory staff.**

- Intervention Forecast, procure, and distribute adequate PPE for all laboratory staff. Train laboratory staff on proper PPE allocation and usage.
- Intervention Consider staggering laboratory personnel with different hours to minimize risk of infection and contact in the context of COVID-19.
- Intervention Consider hiring and training new laboratory staff to allow for greater volume of services and adequate breaks for all staff. Recruit key trained personnel including but not limited to laboratory technicians and microbiologists. This will help retain staff, reduce risk, and reduce errors. Anticipate that periods of high demand will require additional staffing and may lead to higher turnover of staff.
- Intervention For laboratory personnel who are exposed to COVID-19, provide social support such as assistance to isolate, access to food, and psychosocial support.

**Strategy 2.2 Deploy a cyclical training strategy in order to train new hires and continually reinforce and refresh skills of existing staff.**

Intervention	As part of the national COVID-19 strategy, convene national, district, and major hospital laboratory and clinical representatives to update the tools and systems for diagnostic testing and lab operations. This may include lab manuals, Standard Operations Procedures (SOPs), algorithms, and training materials following national and international standards in alignment with new and innovative technologies.
Intervention	Identify highly competent and motivated members of the laboratory workforce to serve as lead trainers. Engage lead trainers to carry out virtual trainings for COVID-19 procedures at all levels of the lab system, enhancing their leadership skills for future projects.
Intervention	Provide laboratory personnel with opportunities for continued learning, expanding their knowledge and skills. Key topics include: rapid diagnostic testing, molecular testing, microbiology procedures, operation of lab equipment, workflow management, biosafety practices, and quality assurance.
Intervention	Provide regular refresher trainings and tools for self-evaluation of skills to allow laboratory staff to identify their gaps in knowledge or skills and continue building key competencies.
Intervention	Train clinical teams on how to interpret test results and ensure rapid test results are built into clinical care algorithms.
Intervention	Provide additional training to select laboratory personnel on integrated disease surveillance (IDSR) strategy, using the IDSR training curriculum modules.

**COST CONSIDERATIONS**

**Objective 1:**

- FA, CE or WHO approved Ag-RDT tests
- FDA, CE or WHO approved molecular tests
- Third party documentation for quality assurance
- Refresher training for all staff and end users on COVID-19 Ag-RDT and molecular test use
- Contract costs for transportation of specimens
- Purchase of vehicles for transport (motorcycle, cars, trucks, etc)  
Fuel for specimen transfer
- PPE for sample collectors and drivers
- Validation and printing of test order forms and reporting forms
- Costs for consultant if needed for integration of COVID-19 modules into digital health platforms
- Training costs for data analysis and epidemiological surveillance
- Hiring of data analysis and/or epidemiological surveillance staff as needed
- Costs for purchase and installation of UPS
- Training on maintenance of HVAC and refrigeration equipment
- Purchase of tools for maintenance of HVAC and refrigeration equipment
- Purchase of backup equipment (cold chain, ventilation, HVAC)

**Objective 2:**

- Procurement costs for PPE
- Distribution costs for PPE
- Training on PPE allocation and usage

- Hiring and training of new laboratory staff during times of surge
- Costs for convening stakeholders for tool, procedure, and training material updates
- Incentives for training of trainers
- Trainings for laboratory personnel on rapid diagnostic testing, molecular testing, microbiology procedures, operation of lab equipment, workflow management, biosafety practices, quality assurance
- Refresher trainings for laboratory staff
- Trainings for clinical teams on interpretation of test results
- Trainings for laboratory staff on integrated disease surveillance strategy

**RESOURCES:**

[ASLM-African Society for Laboratory Medicine](#)

[Assessment tool for laboratories implementing COVID-19 virus testing: Interim Guidance \(who.int\)](#)

[COVID-19 Strategic Preparedness and Response Plan Operational Planning Guideline \(who.int\)](#)

[COVID-19 Target product profiles for priority diagnostics to support response to the COVID-19 pandemic v.1.0 \(who.int\)](#)

[Diagnostic testing for SARS-CoV-2 \(who.int\)](#)

[Genomic sequencing of SARS-CoV-2: a guide to implementation for maximum impact on public health \(who.int\)](#)

[Global Fund COVID-19 Response Mechanism Informational Note](#)

[Guidance for laboratories shipping specimens to WHO reference laboratories that provide confirmatory testing for COVID-19 virus: interim guidance, 2 March 2020](#)

[https://www.who.int/publications/i/item/antigen-detection-in-the-diagnosis-of-sars-cov-2infection-using-rapid-immunoassays](#)

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[Laboratory assessment tool for laboratories implementing SARS-CoV-2 testing \(who.int\)](#)

[Laboratory assessment tool for laboratories implementing SARS-CoV-2 testing \(who.int\)](#)

[Laboratory biosafety guidance related to coronavirus disease \(COVID-19\) \(who.int\)](#)

[Laboratory testing strategy recommendations for COVID-19: interim guidance, 21 March 2020 \(who.int\)](#)

[SARS-CoV-2 antigen-detecting rapid diagnostic tests: an implementation guide \(who.int\)](#)

[SARS-CoV-2 genomic sequencing for public health goals: Interim guidance, 8 January 2021 \(who.int\)](#)

[WHO reference laboratories providing confirmatory testing for COVID-19](#)

[WHO | Quality assurance](#)

[SLMTA | Strengthening Laboratory Management Toward Accreditation](#)