BLiSS Initiative: Regional Priority Assessment of Diagnostics in Africa

PATH Global Diagnostics Program

May 2023
Outline

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• Background on diagnostics
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• Regional diagnostic priorities
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• Local approach to diagnostic supply security
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Introduction: PATH BLiSS Initiative

Vision
Local manufacturing that enables sustainable access to high-quality, appropriate, and affordable diagnostic tools in LMICs to improve global health equity.

Goal
Strengthen the capacity of LMIC diagnostic developers and manufacturers to reliably and sustainably supply high-quality diagnostics that meet local and regional diagnostic needs.

Approach
PATH’s Boosting Local Supply Security (BLiSS) Initiative aims to identify and structure target investments for local, LMIC-based diagnostic companies to support this goal, centering opportunities around the overlapping need for health impact, sustainable market ecosystem, and return on investment. In collaboration with OSF, PATH is moving this initiative forward in the sub-Saharan Africa region to identify and prioritize business cases for local investments, and to socialize and connect these with prospective funders.

Regional priority assessment
To ensure country and regional priorities are driving our process and down-selection of investment opportunities, a regional priority assessment is needed.
Introduction: regional priority assessment

PATH has conducted primary and secondary research to inform a high-level regional priority assessment on diagnostics in sub-Saharan Africa (SSA), including desk research and review of global health publications, as well as direct discussions with subnational, national, and regional global health stakeholders.

These stakeholders include but are not limited to the following:

- African Society for Laboratory Medicine, CEO and Directors
- Africa CDC, Head of Division of Lab Systems and Networks and Project Managers
- WHO, Regional Advisor, Public Health Laboratories
- MOHs, including representatives of Uganda, Senegal, Rwanda, and Ethiopia
- PATH country colleagues across DRC, Tanzania, Uganda, Zambia, Kenya, and Senegal
- Others such as the National Drug Authority in Uganda, national and regional procurement agency in Senegal
Introduction: regional priority assessment

PATH has conducted primary and secondary research to inform a regional priority assessment on diagnostics in sub-Saharan Africa (SSA), including desk research and review of global health publications, as well as direct discussions with subnational, national, and regional global health stakeholders.

Findings from this assessment have been organized into review of SSA diagnostic priorities, as well as SSA supply security landscape. See below.

**Diagnostics priorities landscape**

- Health and disease areas
- Types of diagnostic technology and products
- Existing players in market
- Fit with local health systems

**Supply security landscape**

- Investment and funding of diagnostics
- Operational, infrastructure
- Workforce, training, and education
- Regulatory and quality
- Cost and affordability
- Policy and government support
- Supply chain considerations

*Improved understanding of regional priorities and context to drive our process and inform investment opportunities.*
Background on diagnostics
The need for diagnostics

Diagnostics are critical for the accurate detection and treatment of disease and typically serve at least one of the following purposes in the health care continuum:

- **Confirmation or exclusion** of disease or condition
- **Triaging** patients with suspected conditions to determine whether confirmatory diagnosis is needed
- **Monitoring** efficacy of a treatment or intervention
- **Prognosis** of disease progression or health outcomes to inform disease management
- **Screening** for disease in asymptomatic persons for early detection or to assess risk


Pathology and laboratory medicine (PALM) is a highly complex set of medical subdisciplines that span the breadth of diagnostic testing that is needed to support all health care.

While the expertise of those working in each subdiscipline differ, there may be overlap in the technologies used, sample types required, use settings, and relevant health areas.

Examples

- Diagnosis of infectious diseases often requires access to microbiology, virology, or molecular laboratory services.
- Biopsies to diagnose cancer would be conducted in a cytopathology lab.
- Cervical cancer may be screened for by Pap smear (cytopathology) or by testing for HPV (molecular pathology).
Sampling of diagnostic tools & techniques

**Chemistry**
*Measures specific substance, or analyte, in the body.*

Sample: Blood, urine, saliva  
Location: Laboratory, point of care*, at home*  
Examples: Blood glucometer (diabetes management), cholesterol levels (CVD)

**Microbiology**
*Tests for presence of infectious substances in the body or immune response (i.e., antibodies or antigens).*

Sample: Blood, body fluids, swabs  
Location: Laboratory, point of care*, at home*  
Examples: Hepatitis C test, HIV viral load test, antimicrobial susceptibility, malaria test (microscopy or RDT)

**Hematology**
*Measures characteristics or components of blood.*

Sample: Blood, bone marrow  
Location: Laboratory  
Examples: Platelet count, hemoglobin test (anemia)

**Molecular**
*Analyzes and tests for DNA, RNA, or protein expression.*

Sample: Swab, blood  
Location: Laboratory, point of care*  
Examples: COVID-19 PCR test, cystic fibrosis mutation panel, whole genome sequencing

*dependent upon specific technology
The right tools in the right place

Appropriate **technology and diagnostic tools** are needed to address various health area and health systems priorities:

- **Technology landscape** – What tools exist for what health and disease areas?
- **Biological characteristics** – What is the burden of the condition or disease to the individual and population? How urgent is it to diagnose early? Are symptoms common to other conditions?
- **Health system** – Where do patients seek care? What resources (human, infrastructure, etc.) are available at each level of care?

- Each of these must be considered to match technologies to the appropriate use case and settings.

Example: Tiered network of diagnostics services across a health system

Regional health priorities
Research and stakeholder engagement revealed an extensive list of regional health priorities across the region, with context-specific input based on perspective and local country and community needs. Across the SSA region, common health areas of focus include malaria; respiratory infections; maternal, newborn, and child health (MNCH); hepatitis; yellow fever; antimicrobial resistance; HIV and opportunistic infections (OI); Ebola; tuberculosis; diarrheal diseases; and noncommunicable diseases (NCDs).

While multilateral organizations continue to highlight some of these, such as HIV, tuberculosis, malaria, COVID-19, and MNCH, more light can be shed with a view of country-specific needs. A few highlights from this assessment are noted below, with more details about the list of health priorities to follow.

**Democratic Republic of the Congo**
- Cholera and other diarrheal diseases are one of the leading causes of death, prompting multisectoral strategic plan for elimination of cholera (2023–2027), in progress.
- Among top countries impacted by respiratory infections, including pneumonia, which is one of the top three causes of death in children under 5 years old in DRC.
- Advanced HIV disease (AHD) and OI focus is evolving in DRC, including priority on CD4 and cryptococcosis RDTs for managing HIV cases.

**Uganda**
- Priority zoonotic diseases (PZD) are key focus in Uganda as well due to constant and increasing outbreaks, including anthrax, zoonotic influenza, viral hemorrhagic fevers, brucellosis, rabies, and more. This is part of the One Health focus.
- While COVID-19 focus is deprioritized, an integrated disease surveillance approach is still important.

**Senegal**
- Emerging high disease burden areas include respiratory infections such as pneumonia, tuberculosis, heart disease, diabetes, and high blood pressure.
- MNCH is priority given mortality rate for children under 5 years old in Senegal.
- Prioritization of lab-based diagnostics for pregnant women, children under 5 years, and elders.

**Zambia**
- Top causes of death from 2015 to 2019 include malaria, pneumonia, TB, anemia, and diarrheal diseases.
- Noted need for LFA for antimicrobial resistance.

**Tanzania**
- Changing demographics and epidemiological transitions have impact on health priorities, such as higher demand for MNCH as well as NCDs for aging population.
- Priority health areas noted in the Health Sector Strategic Plan from 2021 to 2026 include HIV, TB, malaria, and NCDs.
What are the health area priorities in sub-Saharan Africa?

The following **health areas** have been noted of specific diagnostic importance across SSA as reflected by subnational, national, and global public health stakeholders:

<table>
<thead>
<tr>
<th>Health Area</th>
<th>Diagnostic methods</th>
<th>Importance of diagnosis</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Diabetes</strong></td>
<td>Blood tests (e.g., fasting glucose, HbA1c), oral glucose tolerance test, random blood glucose test.</td>
<td>Diagnosis allows for proper management, treatment, and prevention of complications.</td>
</tr>
<tr>
<td><strong>Cardiovascular disease (CVD)</strong></td>
<td>Electrocardiogram (ECG), echocardiogram, stress tests, lipid profile.</td>
<td>Early diagnosis helps prevent complications, guides treatment, and promotes heart health awareness.</td>
</tr>
<tr>
<td><strong>Tuberculosis (TB)</strong></td>
<td>Tuberculin skin test, interferon-gamma release assay (IGRA), chest X-ray, sputum tests.</td>
<td>Early diagnosis enables prompt treatment, reduces transmission, and prevents severe complications.</td>
</tr>
<tr>
<td><strong>Human immunodeficiency virus (HIV)</strong></td>
<td>HIV antibody/antigen tests, viral load tests, CD4 count test.</td>
<td>Early diagnosis allows for timely antiretroviral therapy (ART), improves outcomes, and prevents HIV transmission.</td>
</tr>
<tr>
<td>[other] Sexually transmitted infections (STIs)</td>
<td>Nucleic acid amplification tests (NAATs), serological tests, urine/blood tests.</td>
<td>Diagnosis is vital for appropriate treatment, partner notification, and prevention of complications and transmission.</td>
</tr>
<tr>
<td><strong>Hepatitis</strong></td>
<td>Blood tests (e.g., hepatitis B surface antigen, hepatitis C antibody), liver function tests, viral load tests.</td>
<td>Diagnosis helps guide treatment, prevent liver damage, and prevent transmission to others.</td>
</tr>
<tr>
<td><strong>Malaria</strong></td>
<td>Blood smear microscopy, rapid diagnostic tests (RDTs).</td>
<td>Accurate diagnosis allows for timely treatment, reduces severe complications, and prevents deaths.</td>
</tr>
<tr>
<td>Maternal, newborn, and child health (MNCH)</td>
<td>Prenatal care assessments, ultrasound, blood tests (e.g., hemoglobin), clinical examination.</td>
<td>Diagnosis helps ensure appropriate maternal care during pregnancy and childbirth and newborn care, reducing maternal and neonatal mortality and morbidity rates.</td>
</tr>
<tr>
<td><strong>Respiratory infections</strong></td>
<td>Chest X-ray, throat/nasal swabs, blood tests.</td>
<td>Early diagnosis guides appropriate treatment, prevents complications, and helps with outbreak control.</td>
</tr>
<tr>
<td><strong>Hemorrhagic fever</strong></td>
<td>Reverse transcription-polymerase chain reaction (RT-PCR), antibody tests.</td>
<td>Early diagnosis allows for prompt isolation, treatment, and containment of outbreaks.</td>
</tr>
<tr>
<td><strong>Diarrheal disease</strong></td>
<td>Stool culture, polymerase chain reaction (PCR), rapid antigen tests.</td>
<td>Diagnosis guides appropriate treatment, prevents dehydration, and helps identify outbreaks and potential interventions.</td>
</tr>
<tr>
<td><strong>Antimicrobial resistance (AMR)</strong></td>
<td>Culture and sensitivity testing, molecular diagnostics, environmental surveillance.</td>
<td>Diagnosis helps identify resistant strains, guides appropriate treatment, and supports antimicrobial stewardship efforts.</td>
</tr>
</tbody>
</table>

Sources: priorities identified through interviews with stakeholders and consultations from PATH country staff
What are metrics of public health impact?

**Diagnostic and treatment gaps**
Each disease area has a varied and complex continuum of care process, which can be generalized to the following process:

- **Prevention**
- **Screening**
- **Diagnosis**
- **Treatment**
- **Monitoring**
- **Continuing support**

At each step of this process, significant gaps can be observed where patients may be lost to the system and unable to receive the proper care to support their well-being.

- **The diagnostic gap** is the difference between the number of people who have a particular health condition and the number of people who have received an accurate diagnosis for that condition.

- **The treatment gap** is the difference between the actual need for treatment and the availability and accessibility of treatment services.

**Burden of disease**
To understand a snapshot comparison of how these prioritized diseases affect populations across Africa, we look at the **burden of disease** as a percentage of total disability-adjusted life years (DALYs) caused by the disease within a population.

DALYs denote the overall impact of a disease or health condition by considering the **years of life lost and the years lived with a disability due to that disease**. Though this is not a perfect measure, it is a common public health standard.
What are metrics of public health impact?

### Burden of disease

These diseases create significant burden of disease across SSA according to DALYs, based on the following reasons:

- As neonatal diseases occur earlier in life and have higher mortality rates, they increase the years of life lost.
- As malaria, cardiovascular diseases, and HIV/AIDS can affect people over a longer period of time, they may increase both years of life lost and years lived with a disability.

### Diagnostic and treatment gaps

<table>
<thead>
<tr>
<th>Disease</th>
<th>Diagnostic gap of all patients</th>
<th>Treatment gap of diagnosed patients</th>
<th>Population*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Across Africa</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diabetes</td>
<td>56%</td>
<td>6%</td>
<td>Across 28 LMICs</td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>61%</td>
<td>9%</td>
<td>Across 44 LMICs</td>
</tr>
<tr>
<td>Tuberculosis</td>
<td>35%</td>
<td>5%</td>
<td>Across 183 high-burden and 24 non-high burden TB countries</td>
</tr>
<tr>
<td>HIV/AIDS and other STDs</td>
<td>46%</td>
<td>13%</td>
<td>Global</td>
</tr>
<tr>
<td>Malaria</td>
<td>62%</td>
<td>20%</td>
<td>Across 25 LMICs</td>
</tr>
<tr>
<td>Maternal</td>
<td>62%</td>
<td>10%</td>
<td>Across 9 LMICs</td>
</tr>
<tr>
<td>Neonatal</td>
<td>62%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The diagnostic and treatment gaps combined lead to inadequate care provision for patients. It is critical to note that patients lost due to the diagnostic gap will not receive care and treatment, nor are they likely to know that they are living with a certain disease.

Sources: Multiple, Multiple, Multiple, Multiple, Multiple, Multiple, TB, CVD, CVD, HIV, HIV, STIs, Malaria, Malaria, MNCH, Hepatitis, Hepatitis, RTIs, Hemorrhagic fever, Hemorrhagic fever, Diarrheal disease, AMR
Regional diagnostics priorities
Prioritization of different diagnostic technologies is often driven by health area and disease burden, with various applications influenced by innovation and ongoing R&D. As a result, these priorities continue to shift with local needs and current technologies. Research and stakeholder engagement provided further understanding of the diagnostic technology priorities and nuances across the SSA region, which include diagnostics at the point of care, those with multiplexing capability, centralized lab capacity, and digital health technologies.

A few highlights are noted below, with further detail on the priority diagnostic technologies and how they may fit into appropriate health systems to follow.

**Summary: diagnostic technology priorities**

**Tanzania**
- In addition to point-of-care (POC) tests that are needed at the primary health care level, mobile technology application in health is of particular interest in Tanzania and could support through virtual care and remote diagnostics. Tanzania has a very strong eHealth program, showcasing their continued commitment to digital health.

**Senegal**
- Point-of-care diagnostics can help decentralize access and link better to primary health care systems for improved patient care, with applications for diabetes, high blood pressure, and other noncommunicable diseases, for example.
- Centralized lab diagnostics are also critical, with need to strengthen and prioritize for key health areas such as viral hemorrhagic fevers and MNCH.

**Democratic Republic of the Congo**
- In addition to POC tests, combination tests, equipment required for viral load and hematology, and X-rays are needed to support public health in DRC.

**CHAI**
- Lateral flow assays (LFAs) that are low-cost, simple, and device-free can improve essential diagnostic access in low- and middle-income countries, which is part of the reason that ongoing LFA research is important for global health.
What are diagnostic technology priorities in sub-Saharan Africa?

The following diagnostic technologies have been noted to be of specific diagnostic importance across SSA, as reflected by subnational, national, and global public health stakeholders:

- **Point-of-care (POC) tests**, including rapid diagnostic tests (RDTs), are needed at the primary health care level to support timely diagnosis and treatment of communicable and noncommunicable diseases.

- **Multiplex diagnostics** allow for the detection of multiple biomarkers and pathogens with one sample, decreasing burden on health care and laboratory workers.

- **Laboratory diagnostic capacity** is still critical, as many health conditions do not have readily available POC tests or require confirmatory lab testing.

- **Digital health technologies**, including mobile applications and accompanying diagnostics have potential to guide patient care and improve data management.

Sources: priorities identified through interviews with stakeholders and consultations from PATH country staff
Rapid diagnostic tests (RDTs)
Easy to use, may be usable by minimally trained health care workers or laypersons.
Provide quick results – often less than 20 minutes.
Appropriate for multiple settings, including rural health posts and home testing.
Encompass self-tests and some point-of-care tests.
Often used for triage or screening testing to guide clinical next steps.
Common sample types: nasal or oral swabs, oral fluid and saliva, blood, and urine.
Examples: Antigen or antibody rapid tests; urinary dipsticks.

Laboratory diagnostics
Required for diagnosis of conditions that require equipment or trained laboratorians not available at the primary care level.
Often used for confirmatory diagnosis and for diseases that do not have POC tests.
Central or regional reference labs, or private-sector labs, often offer these services in LMICs.
Time to results may be weeks to months.
Examples: blood, stool, tissue, or urine cultures; comprehensive panel tests; ELISAs.

Point-of-care (POC) and near POC diagnostics
Essential at the primary health care level.
Minimizes time from seeking care to diagnosis and treatment.
Product types include RDTs and other tests that may require skilled health care workers, such as molecular tests.
Time to result may be minutes to hours.
Examples: Some molecular tests; antigen or antibody rapid tests; urine dipsticks.

Multiplex diagnostics systems
Allow for testing one sample for multiple biomarkers or pathogens.
Differentiate infections with similar symptoms.
Guide effective treatment options.
Examples: Combo rapid tests; handheld biomarker analyzers; some molecular tests and ELISAs.

Digital health technologies, including mobile applications, accompanying diagnostics have potential to guide patient care and improve data management. Digital health technologies include electronic medical records (EMRs), data collection applications, laboratory surveillance networks, and handheld diagnostic devices with internet connectivity.
Where are the diagnostic technologies needed?

Understanding of the existing **diagnostic ecosystem and health systems** in sub-Saharan Africa is important to assess appropriate development and commercialization of diagnostic tool(s) to a specific health need, but this is often very context-specific.

Services offered at different levels of the health system are dependent upon **cost, infrastructure, population, burden of disease**, and many other factors.

Where someone seeks care and the tools available may be location-dependent (**urban vs. rural**) and/or cost-dependent (**private vs. public sector**).

Example: Three-tier Ethiopian health care system
Source: Abraha A et al. Social determinants of under-5 child health: A qualitative study in Wolkayit Woreda, Tigray Region, Ethiopia *PLOS One*. 2019. https://doi.org/10.1371/journal.pone.0218101.g001
How do the diagnostic technologies get there?

Public, private, and development sector organizations involved in the diagnostics supply chain often have several tiers, layers, and intermediaries.

Public health facilities may source diagnostics through a centralized government agency, whereas private or academic hospitals might work directly with distributors.

Government agencies may post tender requests to solicit bids or work with global agencies, such as The Global Fund or UNICEF, to submit orders for necessary tools.

Example: Sénégal Pharmacie Nationale d’Approvisionnement (National Supply Pharmacy) distribution circuit. Pathway in green represents the public sector, and the pathway in orange represents the private sector. Both sectors must source from the central medical store.
https://www.pna.sn/circuit.php
Supply security landscape
Regional supply security landscape

Across the SSA region, supply security challenges exist for diagnostic companies seeking to develop and manufacture products locally and for patients seeking to access diagnostics services. Select examples of supply security threats across seven areas can be found below.

<table>
<thead>
<tr>
<th>Funding and investment</th>
<th>Operations and infrastructure</th>
<th>Workforce, training, and education</th>
<th>Regulatory and quality</th>
<th>Cost and affordability</th>
<th>Politics and government</th>
<th>Supply chain</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Product development and commercialization: Lack of funding to support QMS implementation and commercialization.</td>
<td>• Product development and commercialization: Limited infrastructure for manufacturing of diagnostics.</td>
<td>• Product development and commercialization: Disincentivizing environments for biomedical researchers.</td>
<td>• Product development and commercialization: WHO PQ processes are time-consuming and costly, and a lack of harmonized national regulatory pathways makes securing registration in multiple counties difficult.</td>
<td>• Product development and commercialization: High import taxes on raw materials. R&amp;D is expensive, with uncertain returns.</td>
<td>• Product development and commercialization: Minimal government focus on supporting diagnostics development and manufacturing (with some exceptions).</td>
<td>• Product development and commercialization: Difficulty sourcing raw materials for diagnostics production.</td>
</tr>
<tr>
<td>• Service delivery: Minimal budget to support scale-up of diagnostics services.</td>
<td>• Service delivery: Inaccurate forecasting of inventory needs. Limited infrastructure at some health facilities to support diagnostics services (e.g., cold storage, continuous power).</td>
<td>• Service delivery: Limited capacity development opportunities for laboratorians. Health care and laboratorian workforce shortages.</td>
<td>• Service delivery: Poor-quality RDTs on the market decrease end-user trust.</td>
<td>• Service delivery: High costs from diagnostics production trickle down to health facility and/or patient.</td>
<td>• Service delivery: Low political attention to diagnostics needs in national health budgets.</td>
<td>• Service delivery: Limited infrastructure to distribute to rural areas. Long distances between health center and central lab.</td>
</tr>
</tbody>
</table>

Sources: Priorities identified through interviews with stakeholders and consultations from PATH country staff, as well as desk research for further investigation into areas identified.
Funding and investment

A lack of funding available to diagnostics researchers and developers hinders the development of the overall industry.

- Diagnostics are often left out of national health strategies, limiting political justification for funding allocations.

- High costs associated with diagnostics R&D and uncertain returns due to risky nature of R&D disincentivize private investment.

- Minimal funding for diagnostics development disincentivizes biomedical researchers from pursuing local innovation of diagnostics.

- Lack of investments for infrastructure and operational improvements make it difficult for local diagnostics developers and producers to scale up manufacturing, implement QMS, and seek regulatory approvals.

Funding for biomedical research is often siloed to specific health areas, with little flexibility to use funds for neglected disease areas or business operations, such as QMS implementation or product registration.
Operations and infrastructure

Infrastructure for the development, manufacturing, and service delivery of diagnostics compounded with operational inefficiencies at each of these stages all limit supply security.

- Public, private, and development-sector organizations involved in the diagnostics supply chain often have several tiers, layers, and intermediaries. These tend to work as separate functions, leading to poor and irregular communication, information silos, and a lack of accountability.

- Inaccurate forecasting due to limited quantity and quality of data leads to stockouts or products expiring.

- Available utilities and infrastructure at health facilities impact what services can be provided.

**Operational and infrastructural considerations**

- **Utilities**: water, gas, electricity, waste management, internet/cellular connectivity.
- **Equipment and materials**: cold storage, laboratory equipment, reagents, PPE, general lab supplies.
- **Processes**: data management, communications, procurement and distribution policies.
- **Location**: road conditions, available routes, proximity of patients to health centers, proximity of health centers to centralized labs/distribution centers.

**Example**

In DRC, a key barrier to cholera diagnosis is related to the lack of equipment and screening tools (culture kits, sample collection tools, rapid screening tests, etc.). In addition, there are only three laboratories in the DRC that analyze cholera samples (Goma, Lubumbashi, and Kinshasa).

Source: PATH DRC office
Supply chain considerations

The diagnostics supply chain starts with procurement of raw materials needed for R&D and ends once the patient receives their test result and connection to care.

**Access to raw materials and equipment** is a common pain point for local manufacturers, specifically for enzymes, antibodies, nitrocellulose, quality management system equipment, and secondary packaging equipment, hindering local development and production of diagnostics.

**Procurement processes** are often driven by governments and global agencies in LMICs:

- Government processes, budget cycles, and bureaucracy often cause funding disbursement delays, impacting the working capital available for distributors.
- Reliance on donor or global agency funding sometimes requires products to meet predetermined specifications, limiting options.

**Limited infrastructure** to deliver diagnostics to rural areas or health outposts or transport samples back to centralized lab inhibits patient access to these technologies.

**Example**

“The issue here [in DRC] is that there is a poor availability of tests for respiratory diseases rather than a complete shortage, which makes access slightly more difficult for a portion of the population. These tests are extremely useful for early patient management and should be extended to all General Hospitals of Reference to bring them closer to those who need them.”

Source: PATH DRC office
Workforce, training, and education

Challenges related to the development and sustainability of a well-educated and trained workforce impacts supply security of diagnostics from R&D through service delivery.

- There is **significant inequity noted in LMICs with respect to the number of experts and professionals** across biomedical research and health care in Africa, which is further exacerbated by **limited training and retention** from local systems within which they work. This directly impacts the upstream development of customized health technologies for the region, as well as the downstream implementation of health technologies for case management and health systems in their communities.

- The **public’s education** and awareness of available technologies and local products is also needed, as there has historically been mistrust in these.

- **Continued support for professionals** in local health care systems as well as those in upstream development of these technologies is required, with capacity building and economic incentives central to this effort.

**Example:**

Africa constitutes 15% of the world’s population but bears 25% of the global disease burden and produces only 2% of the world’s research output. Significant challenges that contribute to this include a lack of well-trained researchers despite existing pockets of excellence, limited career progression pathways, and poor research infrastructure, including a lack of access to scholarly tools such as scientific literature.

Source: Kasprowicz 2020.

**High-income countries have 73 times as many health researchers per million inhabitants as low-income countries.**

Sources: Ciocca & Delgado 2017, WHO 2022.
Regulatory and quality

Addressing regulatory and quality management challenges is crucial to improve access to diagnostics and medical diagnostics in LMICs.

- **Inefficient and fragmented regulatory and quality systems** create barriers for local manufacturers to enter and scale diagnostic markets. For example, GMP and WHO PQ processes can act as a barrier to local manufacturers with respect to procurement limitations, overwhelming associated costs, and long processes that can stifle innovation.

- There is a need to **strengthen regulatory mechanisms**, like support for African Medical Agency, and to ensure coverage for appropriate diagnostic health areas (e.g., limited rigorous authorizations for bacterial/viral pneumonia tests to date).

- **Inconsistencies** across authorization processes across countries and certain health areas can also create challenges for local manufacturing of products. For example, DRC is now working to address this limitation for bacterial and viral pneumonia tests.

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**Example**

The ZaZiBoNa collaborative medicines registration initiative was established in 2013 by Zambia, Zimbabwe, Botswana, and Namibia, but any southern African country may voluntarily participate. The initiative was formed to address regulatory challenges, such as huge backlogs of product applications, high staff turnover, long registration times, inadequate financial resources, and limited capacity to assess certain products. Manufacturers apply to register their product in countries individually and request assessment by ZaZiBoNa, which assigns countries to conduct reviews. WHO is responsible for quality assurance of the final reports. Post assessment, ZaZiBoNa makes a recommendation to the countries, who make the final decision to register or reject products based on country-specific requirements. This regional harmonization helps reduce regulatory workload, accelerate registrations of required products, build mutual trust and confidence in regulatory collaboration, and improve information sharing and networking.

Source: Sithole 2020.
Cost and affordability

Costs to manufacturers, procurers, and end users impact each stage of the diagnostic development and commercialization lifecycle.

- Manufacturers face significant taxes and expenses when importing key materials for diagnostic development and production, which can contribute to the overall cost of locally manufactured diagnostics in Africa.

- The evaluation process for developed diagnostic products is complex and expensive, especially with limited harmonization across the region.

- Fragmented market and procurement mechanisms at country and regional levels make purchasing and development of commercialization strategies challenging.

- Ability to forecast and secure institutional demand for locally manufactured products is very important and top of mind for manufacturers.

- Costs, including varying coverage, to end users also impact demand of diagnostic products.

**Example**

With a large population at risk of infection from multiple communicable diseases like malaria and COVID-19, South Africa has considerable market potential. It also has the strongest economy in southern Africa, but local in vitro diagnostics manufacturing capacity is still restricted to simple diagnostic technologies for malaria, HIV, schistosomiasis, hCG, hepatitis B surface antigen (HBsAg), syphilis, CD4 S/P, bilharzias, and some pregnancy tests and urine dipsticks. Most of the other diagnostics equipment is imported due to little domestic production at heightened procurement costs.

Source: WHO 2011.
Policy and government

Country and regional policies and governance impact the availability and adoption of diagnostic products.

- Clarity on priority **diagnostic product use cases** from governance structures and appropriate stakeholders is important for diagnostic development and manufacturing.

- Generally, there is **limited government support and funding for diagnostic** development and manufacturing specifically (with some exceptions like South Africa). Instead, focus on local vaccine manufacturing seen in policy and government is much more common and can serve as a proxy to translate into the diagnostics space.

- Policies that require significant and **unique regulatory evaluations** for diagnostic products often limit product adoption downstream.

- **Buy-local policies** and **intraregional trade initiatives** can have significant impact on local diagnostic manufacturing and are, not surprisingly, a high priority for local manufacturers for this reason.

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**Example**

A study of regulations of medical diagnostics and devices across Partner States of the East African Community found that, in some countries, more than one agency is mandated for diagnostic regulations. Requiring buy-in from multiple stakeholder agencies or organizations prior to obtaining regulatory approval adds to the costs associated to obtain approval and causes delays in getting product to market and realizing revenue.

Source: Rugera SP et al. 2014.
Local approach to diagnostic supply security
Starting local to address global inequities

PATH tackles supply security challenges by centering local priorities and existing capacities in a target region. More specifically, the BLiSS Initiative works to identify existing local strengths and capabilities that can help address the regional health and diagnostic priorities with financial support and technical assistance, as needed.

One challenge of this approach is the limited evidence and quantitative data available to support the case and clear value proposition of local manufacturing for improved supply security of diagnostics. This is an area that we hope to support in this body of work and continue to learn from our collaborators to improve access to high-quality and appropriate health technologies.

Regional manufacturing of pharmaceuticals and other health products in Africa can play an important role in the global health agenda for improved access to affordable, high-quality medicines.

- Julia Kaufman, Center for Global Development

Manufacturing diagnostics locally may not deliver more affordable tests initially but should increase sustainability in access and create a local industry with important indirect benefits, such as employment and infrastructure development, and potential for cost savings in the longer term.

- Medicins Sans Frontières

The African Union and the Africa CDC’s Partnerships for African Vaccine Manufacturing Framework for Action offer a blueprint for how to accelerate local manufacturing in a coordinated way. This model could be replicated for diagnostics and therapeutics … [and] must begin with an understanding of the existing capacity to then map a way forward for developing different types of products.

- Dr. Nanthalie Mugala, World Economic Forum

Examples:

- The establishment of QMS can help ease the transition of a diagnostic developer from R&D to manufacturing capability.
- Investment in raw materials production can help address limited access to these key resources for developers and manufacturers in a specific region.
Application to the BLiSS Initiative
Regional priorities to inform investment opportunities

PATH utilized the learnings from this Regional Priority Assessment of Diagnostics in Africa to support the OSF-supported BLiSS project in its review and due diligence of local diagnostic companies. For example, questions posed to companies allowed mapping of their product portfolio and strategy to the local priorities with respect to key health areas, technologies, and supply security challenges.

These priorities also informed the value proposition of each investment opportunity across the following areas:

- **Health impact**: review of relevant priority health areas, including the global supply and challenges, regional burden, and projected health benefits.

- **Market sustainability**: consider existing and forecasted market/demand against these priorities, competitive landscape, and level of interest from key buyers such as MOH and global procurement agencies.

- **ROI**: high-level projections would ideally show revenue streams that directly tie back to these regional priorities and help determine strength and risks of an investment opportunity.
Notes on country priority health areas

Surveying PATH country program representatives from DRC, Tanzania, Uganda, Zambia, and Senegal, we were able to collect feedback on priority health areas and reactions.

- **DRC**: Advanced HIV disease and opportunistic infections are strong focuses, as well as diarrheal diseases, self tests for COVID, flu, pneumonia, respiratory infections, eradication of yellow fever, polio, Ebola, cholera, measles, typhoid, and more.

- **Tanzania**: Neonatal disorders, lower respiratory infections, HIV/AIDS, TB, ischemic heart disease, malaria, diarrheal diseases, cirrhosis and other chronic liver diseases, as well as NCDs are high-priority areas; changing demographics and epidemiological transitions in the country impact health area prioritization as well.

- **Uganda**: In addition to common priority areas such as AHD and OI, triple elimination (HIV/syphilis/hepatitis B), malaria, diarrheal diseases, zoonotic diseases, and One Health are very important to health focus in Uganda.

- **Zambia**: Malaria, respiratory infections, AMR, TB, diarrheal diseases, and anemia are health area priorities in Zambia.

- **Senegal**: Point-of-care diagnostics for diabetes, high blood pressure, and NCDs such as heart disease, as well as laboratory diagnostics for VHF are important health areas to address; pregnant women, children under 5 years old, and elders should be prioritized for lab-based diagnostics.
Details on priority health areas
Chronic condition affecting blood sugar regulation.

• **Importance of diagnosis:**
  - Diagnosis allows for proper management, treatment, and prevention of complications.

• **Relevant diagnostic tools:**
  - Blood tests (e.g., fasting glucose, HbA1c), oral glucose tolerance test, random blood glucose test, continuous glucose monitoring.

16 manufacturers headquartered in Africa

<table>
<thead>
<tr>
<th>Global leaders</th>
<th>Country</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abbott</td>
<td>USA</td>
</tr>
<tr>
<td>Roche</td>
<td>Switzerland</td>
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<tr>
<td>Siemens</td>
<td>Germany</td>
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24M affected across Africa in 2019

1.43% burden of disease across Africa

<table>
<thead>
<tr>
<th>Greatest burden of disease</th>
<th>Country</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mauritius</td>
<td>14.3%</td>
</tr>
<tr>
<td></td>
<td>Tunisia</td>
<td>4.4%</td>
</tr>
<tr>
<td></td>
<td>Gabon</td>
<td>3.6%</td>
</tr>
</tbody>
</table>
**CVD**

Broad term encompassing heart and blood vessel disorders

- **Importance of diagnosis:**
  - Early diagnosis helps prevent complications, guides treatment, and promotes heart health awareness.

- **Relevant diagnostic tools:**
  - Electrocardiogram (ECG), echocardiogram, stress tests, lipid profile.

8 manufacturers headquartered in Africa

### Global leaders

<table>
<thead>
<tr>
<th>Global leaders</th>
<th>Country</th>
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</thead>
<tbody>
<tr>
<td>Philips</td>
<td>Netherlands</td>
</tr>
<tr>
<td>GE Healthcare (USA)</td>
<td>USA</td>
</tr>
<tr>
<td>Siemens Healthineers</td>
<td>Germany</td>
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</tbody>
</table>

Bacterial infectious disease primarily affecting the lungs, though can occur elsewhere. Highly contagious and has various manifestations.

- **Importance of diagnosis:**
  - Early diagnosis enables prompt treatment, reduces transmission, and prevents severe complications.

- **Relevant diagnostic tools:**
  - Tuberculin skin test, interferon-gamma release assay (IGRA), chest X-ray, sputum tests.

### 16 manufacturers headquartered in Africa

<table>
<thead>
<tr>
<th>Global leaders</th>
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<tbody>
<tr>
<td>Cepheid</td>
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<tr>
<td>Becton Dickinson</td>
<td>USA</td>
</tr>
<tr>
<td>bioMérieux</td>
<td>France</td>
</tr>
<tr>
<td>Thermo Fisher Scientific</td>
<td>USA</td>
</tr>
</tbody>
</table>

### Public health overview

- **35% diagnostic gap**
- **5% treatment gap**
- **10.6M affected across Africa in 2021**
- **3.10% burden of disease across Africa**

<table>
<thead>
<tr>
<th>Country</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zimbabwe</td>
<td>6.4%</td>
</tr>
<tr>
<td>Mozambique</td>
<td>5.3%</td>
</tr>
<tr>
<td>Kenya</td>
<td>4.0%</td>
</tr>
</tbody>
</table>

HIV
Viral infection that attacks the immune system.

- **Importance of diagnosis:**
  - Early diagnosis allows for timely antiretroviral therapy, improves outcomes, and prevents HIV transmission.

- **Relevant diagnostic tools:**
  - HIV antibody/antigen tests, viral load tests, CD4 count test.

26 manufacturers headquartered in Africa

<table>
<thead>
<tr>
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<tr>
<td>Abbott</td>
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<tr>
<td>Siemens</td>
<td>Germany</td>
</tr>
<tr>
<td>Thermo Fisher Scientific</td>
<td>USA</td>
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<tr>
<td>Danaher</td>
<td>USA</td>
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</table>

Global leaders

Manufacturing overview

Public health overview

<table>
<thead>
<tr>
<th>Country</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eswatini</td>
<td>30.18%</td>
</tr>
<tr>
<td>South Africa</td>
<td>29.71%</td>
</tr>
<tr>
<td>Eq. Guinea</td>
<td>26.77%</td>
</tr>
</tbody>
</table>

20.6M affected across Africa in 2021
7.19% burden of disease across Africa

Over 30 different bacteria, viruses, and parasites are known to be transmitted through sexual contact; some can be transmitted from mother to child during pregnancy, childbirth, or breastfeeding (e.g., gonorrhea, syphilis, chlamydia).

- **Importance of diagnosis:**
  - Initiation of treatment, partner testing, reducing further spread; in pregnant women, prevention of mother-to-child transmission.

- **Relevant diagnostic tools:**
  - Molecular tests (NAATs), enzyme immunoassays, and rapid diagnostic tests using blood and urine sample, with many offering some combination on multiplex platforms.

### 6 manufacturers headquartered in Africa

<table>
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<tr>
<td>Roche</td>
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<tr>
<td>Siemens</td>
<td>Germany</td>
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<tr>
<td>DiaSorin S.p.A</td>
<td>Italy</td>
</tr>
<tr>
<td>Hologic, Inc.</td>
<td>USA</td>
</tr>
<tr>
<td>bioMérieux</td>
<td>France</td>
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</tbody>
</table>

*Excluding HIV*

Inflammation of the liver caused by viral infections of varying types, most commonly types B, C

**Importance of diagnosis:**
- Diagnosis helps guide treatment, prevent liver damage, and prevent transmission to others.

**Relevant diagnostic tools:**
- Blood tests (e.g., hepatitis B surface antigen, hepatitis C antibody), liver function tests, viral load tests.

17 manufacturers headquartered in Africa

<table>
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</tr>
<tr>
<td>Siemens</td>
<td>Germany</td>
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</tbody>
</table>

60M affected across Africa in 2019

0.15% burden of disease across Africa

<table>
<thead>
<tr>
<th>Country</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kenya</td>
<td>0.33%</td>
</tr>
<tr>
<td>Egypt</td>
<td>0.20%</td>
</tr>
<tr>
<td>Ethiopia</td>
<td>0.19%</td>
</tr>
</tbody>
</table>

Malaria

Mosquito-borne infectious disease caused by parasites which can be serious and sometimes fatal. The severity of malaria varies on species of *Plasmodium*.

- **Importance of diagnosis:**
  - Accurate diagnosis allows for timely treatment, reduces severe complications, and prevents deaths.

- **Relevant diagnostic tools:**
  - Blood smear microscopy, rapid diagnostic tests (RDTs) especially *Plasmodium*-specific.

21 manufacturers headquartered in Africa

<table>
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<th>Global leaders</th>
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<tbody>
<tr>
<td>Roche</td>
<td>Switzerland</td>
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<tr>
<td>Abbott</td>
<td>USA</td>
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<tr>
<td>Access Bio</td>
<td>USA</td>
</tr>
<tr>
<td>Premier Medical Corporation</td>
<td>India</td>
</tr>
<tr>
<td>Siemens</td>
<td>Germany</td>
</tr>
<tr>
<td>bioMérieux</td>
<td>France</td>
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</table>

247M affected across Africa in 2019

7.54% burden of disease across Africa

<table>
<thead>
<tr>
<th>Country</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ghana</td>
<td>11.7%</td>
</tr>
<tr>
<td>Nigeria</td>
<td>11.2%</td>
</tr>
<tr>
<td>Eq. Guinea</td>
<td>11.1%</td>
</tr>
</tbody>
</table>

Focuses on the health of pregnant women and newborns, encompassing various conditions and complications (e.g., hemorrhage, high blood pressure, obstructed labor).

- **Importance of diagnosis:**
  - Diagnosis helps ensure appropriate care during pregnancy, childbirth, and newborn care, reducing maternal and neonatal mortality and morbidity rates.

- **Relevant diagnostic tools:**
  - Prenatal care assessments, ultrasound, blood tests (e.g., hemoglobin), clinical examination.

3 manufacturers headquartered in Africa

<table>
<thead>
<tr>
<th>Global leaders</th>
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<tbody>
<tr>
<td>GE Healthcare</td>
<td>USA</td>
</tr>
<tr>
<td>Philips</td>
<td>Netherlands</td>
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<tr>
<td>Siemens</td>
<td>Germany</td>
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</table>

Infections affecting the respiratory system; may occur in the upper or lower respiratory tract and may be viral or bacterial (e.g., common cold, COVID-19, pharyngitis, pneumonia, tonsillitis, and influenza).

**RTIs**

- **Importance of diagnosis:**
  - Appropriate treatment selection, prevention of further transmission.

- **Relevant diagnostic tools:**
  - Chest X-ray, lung CT scan, nasal/throat swab + rapid or molecular test, Gram staining, microscopy, bacterial culture.

**20 manufacturers for COVID-19,**

**1 for other RTIs headquartered in Africa**

### Global leaders | Country
--- | ---
Cepheid | USA
Abbott | USA
Medtronic | Ireland
COSMED | Italy
GE | USA
Philips | Netherlands
Roche | Switzerland

Asthma is the most common chronic disease in African children, with an increasing prevalence in both urban and rural settings.

**300M** affected across Africa in 2019

**400K** deaths in children under 5 across SSA and Asia in 2018

**11.8%** burden of disease across Africa

### Greatest prevalence by country

<table>
<thead>
<tr>
<th>Country</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Congo</td>
<td>38.1%</td>
</tr>
<tr>
<td>Gabon</td>
<td>35.2%</td>
</tr>
<tr>
<td>Lesotho</td>
<td>35.2%</td>
</tr>
</tbody>
</table>

*Excluding TB*

A group of epidemic-prone diseases that are caused by several distinct families of viruses causing severe multi-system syndrome transmitted initially through infected rodents (e.g., Marburg virus, Ebola).

• **Importance of diagnosis:**
  • Early diagnosis allows for prompt isolation, treatment, and containment of outbreaks.

• **Relevant diagnostic tools:**
  • Reverse transcription-polymerase chain reaction (RT-PCR), antibody tests, ELISA.

**6 manufacturers headquartered in Africa**

<table>
<thead>
<tr>
<th>Global leaders</th>
<th>Country</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cepheid</td>
<td>USA</td>
</tr>
<tr>
<td>ZEBOV</td>
<td>USA</td>
</tr>
<tr>
<td>Fast Track Diagnostics</td>
<td>Luxembourg</td>
</tr>
</tbody>
</table>

**Most common types of viral hemorrhagic fevers afflicting SSA:** Marburg and Ebola hemorrhagic fevers, Crimean Congo hemorrhagic fever, Rift Valley fever, Lassa fever, yellow fever, and the newly emergent arenavirus

34K cases of Ebola across 34 outbreaks in SSA

14K deaths from Ebola across 34 outbreaks in SSA

28-75% case fatality rate across WHO and CDC reported cases in African countries prior to 2020

<table>
<thead>
<tr>
<th>Number of viral hemorrhagic fever types across African countries</th>
<th>Number of countries</th>
<th>Number of viral hemorrhagic fever types</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>10</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>8</td>
<td>2</td>
</tr>
<tr>
<td>4</td>
<td>1</td>
<td>4</td>
</tr>
</tbody>
</table>

Infections leading to frequent loose, watery stools; mostly result from contaminated food and drinking water (e.g., rotavirus, E. coli, cryptosporidium, Shigella).

**Importance of diagnosis:**
- Diagnosis guides appropriate treatment, prevents dehydration, and helps identify outbreaks and potential interventions. Antibiotics often not appropriate for diarrheal disease, with exception of Shigella.

**Relevant diagnostic tools:**
- Stool culture, polymerase chain reaction (PCR), fecal rapid test kits and immunoassays; environmental surveillance tools/water testing kits.

### Global leaders

<table>
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<tr>
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<tbody>
<tr>
<td>bioMérieux</td>
<td>France</td>
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<tr>
<td>Qiagen</td>
<td>Germany</td>
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<tr>
<td>Abbott</td>
<td>USA</td>
</tr>
<tr>
<td>Becton Dickinson</td>
<td>USA</td>
</tr>
<tr>
<td>Bio-Rad Laboratories</td>
<td>USA</td>
</tr>
</tbody>
</table>

Diarrheal diseases are the leading global cause of child mortality and morbidity.

Unsafe water sources and wasting among children under 5 are main contributors to years living with disability and lives lost.

350K+ deaths in children under 5 in SSA in 2019

1.01% burden of disease across Africa

### Greatest burden of disease

<table>
<thead>
<tr>
<th>Country</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uganda</td>
<td>3.2%</td>
</tr>
<tr>
<td>Equatorial Guinea</td>
<td>2.7%</td>
</tr>
<tr>
<td>Liberia</td>
<td>2.4%</td>
</tr>
</tbody>
</table>

Emergence of microorganisms resistant to antibiotics and other antimicrobial drugs.

**Importance of diagnosis:**
- Diagnosis helps identify resistant strains, guides appropriate treatment, and supports antimicrobial stewardship efforts.

**Relevant diagnostic tools:**
- Culture and sensitivity testing, molecular diagnostics.

2 manufacturers headquartered in Africa

<table>
<thead>
<tr>
<th>Global leaders</th>
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</tr>
</thead>
<tbody>
<tr>
<td>bioMérieux</td>
<td>France</td>
</tr>
<tr>
<td>Roche</td>
<td>Switzerland</td>
</tr>
<tr>
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</table>

Prevalence varies across different antimicrobial-resistant pathogens

SSA experienced the greatest mortality rates from AMR in 2019

6 leading pathogens for death associated with AMR in SSA: Streptococcus pneumoniae, Klebsiella pneumoniae, Escherichia coli, Staphylococcus aureus, Pseudomonas aureus, and Acinetobacter baumannii

5M deaths associated with AMR-related causes in SSA

1.3M deaths directly linked to bacterial AMR in SSA