

# The Manufacturing to Accelerate Diagnostic Excellence in Africa project



Africa bears the greatest burden of many deadly diseases, accounting for [95% of malaria deaths](#) worldwide. Despite this, the continent remains heavily reliant on imported critical health products, including diagnostic technologies. This dependency leaves African health systems vulnerable to global supply chain shocks, as starkly revealed during the COVID-19 pandemic, and results in diagnostics being designed and developed far from end users—the health care providers and patients who rely on them.

The global in vitro diagnostics market is dominated by manufacturers in China, Europe, and the United States, with only a handful of African companies meeting international regulatory and manufacturing standards. This imbalance limits access to timely and affordable diagnostics and stifles local innovation and resilience.

Several underlying challenges drive Africa's limited production and heavy reliance on imported diagnostics. [A 2022 report by PATH and Accenture](#) highlighted nine key barriers: limited investment, insufficient workforce, deterring regulations, inefficient purchasing and procurement, operational inefficiencies, limited infrastructure and technology, high costs, low trust, and limited government support and policy development.

## The rise of regional manufacturing in Africa

Africa's push for health sovereignty began with the Pharmaceutical Manufacturing Plan for Africa, which laid the groundwork for strengthening regional production. Building on this, regional and continental initiatives now aim to expand manufacturing of diagnostics, vaccines, and therapeutics.

Key efforts include the Africa Collaborative Initiative to Advance Diagnostics and the Platform for Harmonised African Health Manufacturing, coordinated by Africa Centres for Disease Control and Prevention and partners, which support local companies through technology transfer, workforce development, and market access. Regulatory harmonization is also advancing through African Union Development Agency-New Partnership for Africa's Development's African Medicines Regulatory Harmonization initiative and the establishment of the African Medicines Agency by the Africa Union, which are critical steps to streamline

approvals and enable cross-border access to African-made products.

Global partners like the World Health Organization are supporting procurement and regulatory acceleration. While most diagnostics are still imported, these efforts mark significant progress. Sustained investment and coordination are essential to build strong markets for African-made health products and are key to better health, economic resilience, and self-reliance.



PATH/Georgina Goodwin

## The Manufacturing to Accelerate Diagnostic Excellence (MADE) in Africa project

With support and funding from Unitaid, PATH is leading MADE, which forms part of Unitaid's Regional Manufacturing for Equitable Access portfolio. The project aims to fulfill the goals of existing efforts to strengthen Africa's diagnostic supply landscape by supporting the development and scaling availability of regionally manufactured affordable, high-quality diagnostics in alignment with existing regional and continental efforts. By developing regional capacity, the MADE consortium aims to reduce import dependency, improve health outcomes, and build a more self-reliant and responsive health care ecosystem across the continent.

MADE will work at national, regional, and global levels and partner with African institutions to address these inequities by strengthening the manufacturers and ecosystem required to support sustainable production of

quality-assured diagnostics in Africa to meet the region's needs for endemic diseases and enhance preparedness for outbreaks and pandemics.

## Project snapshot

From 2025 through 2029, the MADE will work across three major outputs:

1

**Manufacturer level:** Provide funding and technical support to Africa-based manufacturers to produce quality-assured, affordable diagnostics, while building their capacity to respond to future health emergencies and improve climate-smart practices.

2

**Ecosystem level:** Enhance research and development (R&D) capabilities in Africa's diagnostics industry by tackling policy, regulatory, and quality barriers that limit sustainable manufacturing and market access.

3

**Demand generation:** Collaborate with country health decision-makers responsible for health product procurement to design market-shaping interventions that boost product uptake, and work with communities to advocate for a reliable supply of regionally made diagnostics.

By achieving these core objectives, MADE will catalyze increased regional manufacturing of quality-assured diagnostics, tailored to local needs through sustainable R&D. This will include technology transfer and climate-smart innovation; stimulation of demand and procurement of regionally produced products; and streamlining of regulatory processes through harmonized continental frameworks. These efforts will accelerate the introduction and adoption of diagnostic tools in low- and middle-income countries, establish sustainable and equitable systems for long-term access, and strengthen inclusive, demand-driven partnerships that foster innovation and respond to Africa's public health priorities.

During the first six months of the project, MADE will focus on identifying companies and diagnostic products to support laying the foundation for strengthening regional manufacturing. As part of this phase, the MADE consortium will also be conducting a landscape analysis of molecular diagnostic manufacturing in Africa. This will help identify the most promising opportunities for regional production, especially for diagnostics that would be prioritized during a pandemic; it may also inform future expansion of the MADE portfolio.

By project close, regionally manufactured, MADE-supported diagnostics produced by a portfolio of sustainable companies will be in African supply chains and reaching patients. In addition, a diagnostics lab-to-market ecosystem will have been strengthened, ultimately enabling the continent to respond to surges in diagnostics demand during pandemics.

## Implementation through partnership

PATH will partner with five Africa-based organizations across the project's three outputs:

The **African Society for Laboratory Medicine** and PATH will focus on the diagnostics ecosystem and sustainability and promoting diagnostics manufacturing in Africa. The **Solina Centre for International Development and Research** will lead demand generation and collaborate on market-shaping activities. The **University of Cape Town** will develop training programs on R&D for commercialization and quality management for companies and students. **WACI Health** will work with local community stakeholders to conduct advocacy workshops and lead campaigns that engage civil society organizations. **Open Capital** will assess commercial viability and create investment cases for manufacturers.

For additional information regarding our work, please contact [made@path.org](mailto:made@path.org).

### About PATH

PATH is a global nonprofit dedicated to achieving health equity. With more than 40 years of experience forging multisector partnerships, and with expertise in science, economics, technology, advocacy, and dozens of other specialties, PATH develops and scales up innovative solutions to the world's most pressing health challenges. Learn more at [www.path.org](http://www.path.org).

### About Unitaid

We save lives by making new health products available and affordable for people in low- and middle-income countries. We work with partners to identify innovative treatments, tests and tools, help tackle the market barriers that are holding them back, and get them to the people who need them most – fast. Since we were created in 2006, we have unlocked access to more than 100 groundbreaking health products to help address the world's biggest health challenges, including HIV, TB, and malaria; women's and children's health; and pandemic prevention, preparedness and response. Every year, more than 300 million people benefit from the products we've helped roll out. Learn more at [www.unitaid.org](http://www.unitaid.org). Learn more about Unitaid's investments in regional manufacturing: <https://unitaid.org/regional-manufacturing/>

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