

Laboratory-on-a-ship: a microbiology culture media production facility in a sea container for local production in low-resource settings



Low-income and middle-income countries (LMICs), especially those in western sub-Saharan Africa, are hit hardest by antimicrobial resistance¹ and would benefit most from better access to diagnostics.² However, only 1-3% of the diagnostic laboratories in sub-Saharan Africa currently have the capability to perform clinical bacteriology.³ Although used globally, microbiology culture media play a more substantial role in LMICs, which have less access to new-generation diagnostics. The importance of culture media was reinforced by WHO, who in their model list of essential in-vitro diagnostics called for bacterial culture to be included in first-level referral hospitals in LMICs.^{4,5}

Due to the scarcity of local companies and supply chain issues, ready-to-use, quality-assured culture media are either very costly or outright unavailable in LMICs.⁶ This unavailability of culture media highlights the need for local production of high-quality products at affordable prices. However, culture media production is a demanding and complex task. Laboratories in LMICs face additional challenges because of harsh environments (heat, dust, and humidity), faulty infrastructure (poor access to clean water and uninterrupted power supply), and ill-maintained equipment.^{4,7} These laboratories are rarely suited or sufficiently maintained to produce culture media to international quality standards.⁸

The European & Developing Countries Clinical Trials Partnership (EDCTP) 2-funded SIMBLE project aspires to improve access to bloodstream infection diagnostics tailored to low-resource settings. SIMBLE consortium partners from Benin, Belgium, and Spain combined biomedical and technical engineering in a public-private partnership. To strengthen and scale up local production of quality-assured culture media, we developed a dedicated culture media production facility (appendix p 1). The facility was manufactured in Spain and installed in Benin, a west African country with a humid tropical climate and a large seaport.

The preparation and design process took 6 months, with multiple site visits to the Spanish partner to discuss facility design and construction, equipment, and quality

management. We refurbished a sea container into a cleanroom-like facility to physically separate culture media production from existing laboratories, and to ensure a stable environment (temperature, cleanliness, and waste management). The container was equipped with commercially available devices, including a water treatment system, laminar flow, autoclave, media preparator, and automatic plate-filling machine. We also installed custom-made equipment for filling and capping home-made blood culture bottles. Special attention was paid to maintenance and sustainability; for example, by choosing equipment that uses compressed air instead of electricity, which is maintenance-friendly and not dependent on a constant power supply.

In September, 2022, after a 6-month construction phase in Spain and a 3-week overseas journey by cargo ship, the Beninese team coordinated the customs clearance and installation of the container in Cotonou, Benin. Infrastructure, equipment maintenance, and media production training was given with the train-the-trainer model to enable trainees to instruct future maintenance staff and users. The official language of Benin is French, as such user manuals, equipment menus, and operating procedures were written in French. Development of the quality management system is ongoing and a roadmap for future International Organization for Standardization 13485 certification has been prepared.

The current production capacity of the facility is 500 petri dishes and 250 blood culture bottles per batch, with the possibility of producing multiple batches per day. Local production can be done at a lower cost than importing culture media from high-income countries. For example, according to our calculations, a blood culture bottle can be produced at 25% of the price of the commercially available European product. Upscaling production can reduce costs and increase the crucial volume of available clinical bacteriology diagnostics. Due to the shorter time from manufacturing to usage, the user can benefit from a longer shelf life. We are currently piloting production of solid culture media for clinical bacteriology and blood culture bottles for

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see <https://www.itg.be/e/simble>

See Online for appendix

the SIMBLE project. For this project, products will be packaged and transported to the other study sites (Boko, Benin and Ouagadougou, Burkina Faso). In the future, we plan to also supply other Beninese laboratories within a microbiology surveillance network with quality-assured products. To this end, shelf life and transport stability will be validated, and a sustainable long-term business plan will be developed.

To our knowledge, this is the first dedicated microbiology culture media production facility to be installed in an LMIC. The Beninese team has taken over ownership of the laboratory, and implementation and expansion of services to other countries is being explored. Upscaling quality-assured local production in LMICs will increase access to affordable diagnostics and improve the standard of care in these settings.

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