

LifeDX

Business Plan

Establishment of a Local Manufacturing
Facility for Rapid Diagnostic Tests
(RDTs) in Tanzania

LifeDX Africa Co. Limited

Address

Warehouse G.05, Plot No. 48A,
Mikocheni Light Industrial Area,
Opp. TRA Administrative College,
Dar es Salaam, Tanzania.

Presented by **Anton Kazmin**

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1. Executive Summary

LifeDX Africa Co. Limited (“LifeDX Africa” or “the Company”) is establishing a local manufacturing facility for rapid diagnostic tests (RDTs) in the United Republic of Tanzania. The project is structured as a strategic foreign direct investment in the healthcare and life sciences sector, aimed at strengthening national health security, reducing dependence on imported diagnostics, transferring advanced manufacturing technologies, and creating an export-oriented industrial platform.

The Company will manufacture essential in-vitro diagnostic (IVD) rapid tests for infectious diseases of high public health relevance, including malaria, HIV, hepatitis B and C, syphilis, and combination tests for antenatal care (ANC) screening. Production will be implemented through a phased localization model, progressing from automated assembly to full-cycle manufacturing within five years.

LifeDX Africa is majority-owned by LifeDX, an international diagnostics group headquartered in Lausanne, Switzerland, and the owner of the core diagnostic technologies used in the project. LifeDX operates large-scale manufacturing and R&D facilities across multiple countries and is the largest producer of rapid diagnostic tests in its home market, with annual production volumes exceeding 100 million tests. This industrial and scientific base underpins the feasibility of full-cycle localization in Tanzania.

The total planned investment exceeds USD 2.0 million. The project will initially create approximately 35–45 direct jobs, expanding to 85–100 skilled positions upon transition to full-cycle manufacturing. From 2029 onward, LifeDX Africa plans to supply selected regional markets in East and Southern Africa, positioning Tanzania as a regional hub for diagnostic manufacturing.





2. Company Overview, Ownership Structure and Technology Base

LifeDX Africa Co. Limited is a company incorporated in Tanzania under the Companies Act and established specifically to develop local manufacturing capacity for advanced medical diagnostics. The Company is structured as a long-term industrial operator with a clear mandate for technology localization, skills transfer, and export-oriented growth.

Ownership Structure

The shareholding structure reflects a combination of international technology ownership and strong local participation:

- LifeDX (Switzerland) – 80%
- Anton Kazmin (Tanzanian citizen) – 20%

This structure ensures direct access to proprietary diagnostic technologies while maintaining deep integration into the Tanzanian regulatory, healthcare, and business environment.

LifeDX Group – Strategic Shareholder and Technology Owner

LifeDX is an international diagnostics group with its headquarters in **Lausanne, Switzerland**, and operational presence in **Russia, Kazakhstan, and Thailand**. LifeDX is the principal technology owner, developer, and strategic investor behind the LifeDX Africa project.

The Group operates as a vertically integrated diagnostics platform. Its **main manufacturing facilities are located in Moscow**, supported by advanced laboratory and R&D infrastructure in:

- Moscow (Russian Federation)
- Saint Petersburg (Russian Federation)
- Lausanne (Switzerland)

Companies within the LifeDX Group represent the **largest developer and manufacturer of rapid diagnostic tests in the Russian Federation**, with **annual production volumes exceeding 100 million rapid tests**.

In addition to rapid diagnostic tests, LifeDX develops and manufactures:

- ELISA kits for laboratory diagnostics
- Diagnostic products based on Next Generation Sequencing (NGS) technologies
- Diagnostic solutions for animal health
- Testing systems for food safety and quality control

The LifeDX Group employs approximately **200 professionals**, more than half of whom are scientists, researchers, engineers, and developers.

As the majority shareholder, LifeDX contributes to LifeDX Africa:

- Ownership of core diagnostic technologies and intellectual property
- Proven industrial-scale manufacturing know-how
- International quality and regulatory expertise
- Structured technology transfer and localization capabilities

This ensures LifeDX Africa is an integral part of a global diagnostics group, not a standalone assembly operation.

Management Team



- **Chief Executive Officer –
Anton Kazmin**

Entrepreneur with more than 15 years of successful business development and project execution in Tanzania.



- **Chief Operating Officer –
Jaykumar V. Kamli, M.Sc.**

Operations executive with experience in regulated manufacturing environments, quality systems, and industrial scale-up.



- **Chief Financial Officer –
Sergey Krylov (LifeDX Group)**

Strategic finance leader with expertise in financial planning, investment modelling, and cost optimization, supporting sustainable growth in regulated and technology-driven environments.

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3. Burden of Infectious Diseases and Strategic Importance of Rapid Diagnostics in Tanzania

3.1. Burden of Infectious Diseases on the Healthcare System

Infectious diseases continue to impose a substantial and persistent burden on Tanzania's healthcare system and socio-economic development. Malaria, HIV/AIDS, viral hepatitis, and syphilis remain among the leading causes of morbidity and healthcare utilization.

Malaria accounts for a large share of outpatient visits and hospital admissions, particularly among children under five and pregnant women, generating both direct healthcare costs and indirect economic losses.

HIV/AIDS requires continuous nationwide screening, including routine testing within antenatal care (ANC) programs to prevent mother-to-child transmission.

Viral hepatitis (Hepatitis B and C) and syphilis represent a growing and often under-diagnosed burden, contributing to chronic disease progression and adverse pregnancy outcomes.

Together, these diseases create **structural, recurring demand for diagnostic testing**.

3.2. Rapid Diagnostic Tests as the Gold Standard

Rapid diagnostic tests (RDTs) are widely recognized as the **gold standard** for frontline screening and diagnosis of infectious diseases due to:

- Point-of-care usability without laboratory infrastructure
- Rapid turnaround time enabling immediate clinical decisions
- Cost-effectiveness for high-volume public health programs
- Suitability for decentralized and rural healthcare settings
- Alignment with national disease control strategies

For malaria, HIV, syphilis, and hepatitis, RDTs are the primary diagnostic modality.

3.3. Size and Structure of the Tanzanian Rapid Diagnostics Market

Due to its population size and epidemiological profile, Tanzania represents one of the largest rapid diagnostics markets in East Africa.

Estimated annual national need includes:

- **Malaria rapid diagnostic tests:** approximately **30 million tests**, driven by routine outpatient diagnosis, community-based testing, and malaria control programs.
- **HIV rapid diagnostic tests:** approximately **15 million tests**, including general population screening, targeted testing programs, and antenatal care (ANC) screening.
- **Syphilis and hepatitis rapid diagnostic tests:** several million tests per year, with increasing demand driven by expanded screening policies and integration into maternal and adult health services.

At present, nearly **100% of this demand is met through imported diagnostic products**, supplied by multinational manufacturers and financed through a combination of government procurement and international donor funding.

3.4. Structural Risks of Import and Donor Dependency

The current market structure creates systemic vulnerabilities, including exposure to global supply chain disruptions, dependence on external donor funding, limited domestic value creation, and reduced strategic autonomy during public health emergencies.

3.5. Strategic Rationale for Local Manufacturing

Local manufacturing of rapid diagnostic tests strengthens national health security, reduces dependency on imports and donor financing, enables faster response to outbreaks, and builds sustainable industrial and scientific capacity.

4. Project Location and Current Status

The manufacturing facility is located at **Plot No. 48A, Mikocheni Light Industrial Area, Dar es Salaam**, covering approximately 1,200 m² under a five-year lease with extension option. Utilities include a 200 kW grid connection, backup generator, and municipal water supply. Refurbishment is ongoing.

5. Products and Technology Platform

The product portfolio includes:

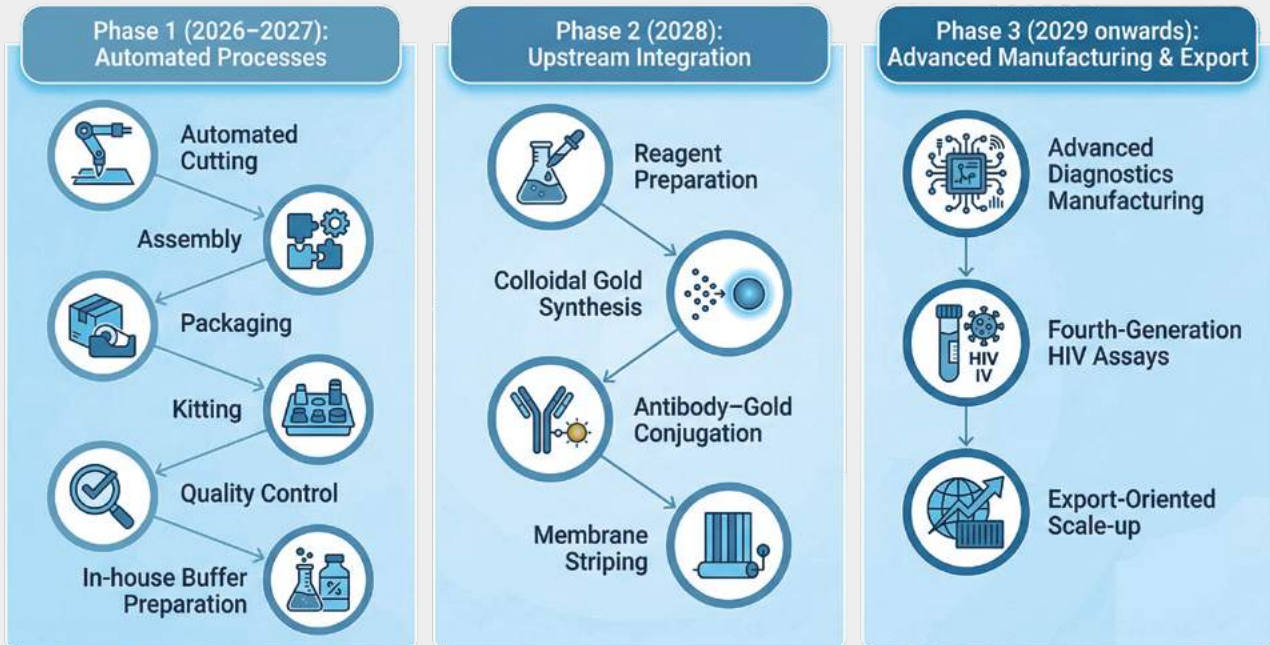
- Malaria P.f./PAN
- HIV antibody (HIV Ab)
- Hepatitis B
- Hepatitis C
- Syphilis
- HIV/Syphilis combination tests (ANC)
- HIV Ab/Ag rapid diagnostic tests (4th generation)

All products are intended for professional use in public healthcare facilities, donor-funded programs, and regulated private healthcare settings.



6. Manufacturing and Localization Roadmap

The project follows a phased localization strategy.



While key biological raw materials and antibodies will continue to be sourced from established international suppliers to ensure quality and regulatory compliance, **LifeDX Africa commits to sourcing packaging materials, cartons, labels, and instructions for use (IFU) from local Tanzanian printing and packaging suppliers**, thereby supporting indirect employment and local supply chain development.

Full-cycle localization is planned within five years.

7. Regulatory and Quality Framework

LifeDX Africa is engaged with the Tanzania Medicines and Medical Devices Authority (TMDA), having submitted premises layouts and approval requests.

Key milestones include:

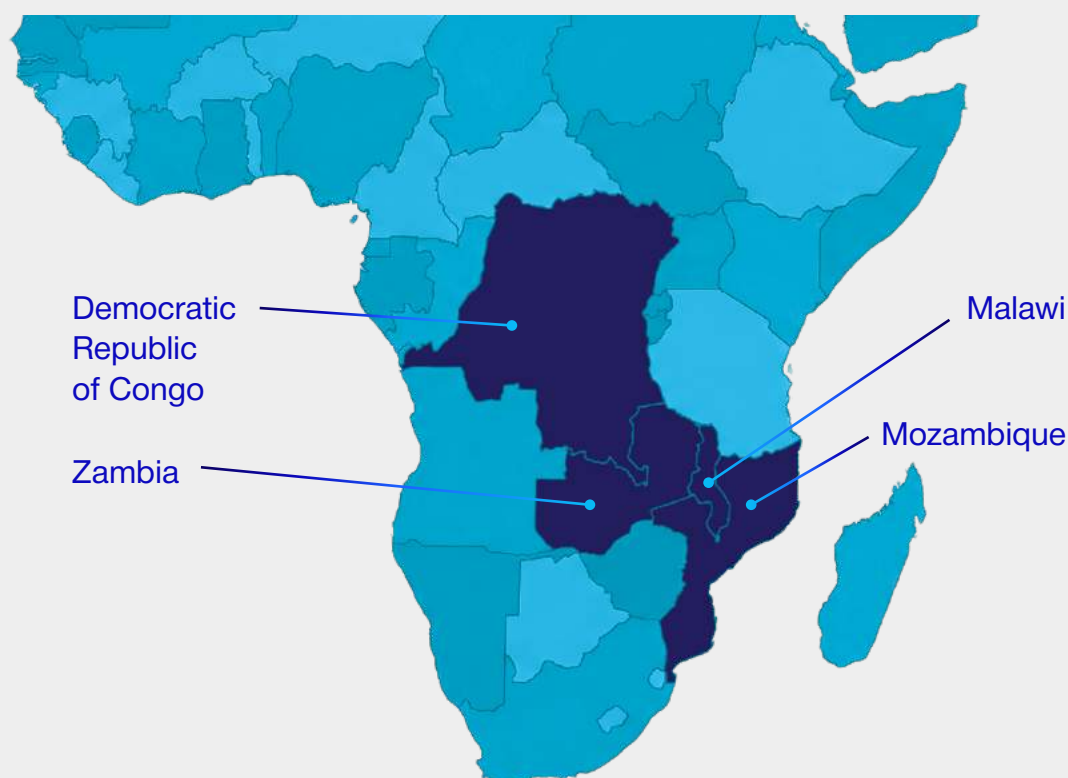
- Product registration with TMDA: October 2026
- WHO Expert Review Panel for Diagnostics (ERPD): 2027
- **Initiation of WHO Prequalification (PQ): 2027; expected completion 2029–2030. This accelerated timeline is supported by the existing technical dossiers, validation data, and Quality Management System (QMS) protocols of the parent company, LifeDX, which will be adapted and transferred to the Tanzanian facility.**

Operations will be conducted under an ISO 13485–aligned Quality Management System.

8. Market, Sales, and Export Strategy

Primary sales will be through direct supply to the Medical Stores Department (MSD), supported by secondary distribution to private hospitals and laboratories.

From 2029 onward, LifeDX Africa plans structured exports to:



9. Competitive Landscape and Positioning

The Tanzanian diagnostics market is dominated by imported products from multinational manufacturers such as Abbott (Bioline) and Meril Diagnostics. A limited local assembly presence exists through KAS, associated with Artemis Life Sciences (Dubai).

LifeDX Africa is positioned as a **qualitatively new generation diagnostics manufacturing platform**, differentiated by technology ownership, automation, academic integration with MUHAS, and a clear roadmap toward full-cycle manufacturing and exports.

10. Employment, Skills Transfer, and ESG Impact

Employment creation:



Expatriate staff will be limited to 1–2 at the initial stage and 3–5 at full-cycle manufacturing. Priority is given to Tanzanian nationals, with strong emphasis on employment of women in production and quality control roles.

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11. Academic Partnership and Innovation (MUHAS)

Collaboration with MUHAS will focus on workforce training, applied R&D, and development of new diagnostic products, including tuberculosis tests and HIV drug-resistance NGS panels.

12. Summary Financial Model (Adjusted Growth Case)

Year	Tests (M)	Avg Price	Revenue (USD M)	EBITDA (USD M)	Margin
2027	1.6	0.70	1.1	0.1	~10%
2028	5.5	0.76	4.2	0.7	~17%
2029	8.7	0.75	6.5	1.3	~20%
2030	12.0	0.74	8.9	1.9	~21%
2031	15.0	0.73	11.0	2.3	~21%
2032	18.5	0.72	13.3	2.9	~22%
2033	22.0	0.70	15.4	3.4	~22%
2034	22.0	0.70	15.4	3.5	~23%

Total planned CAPEX exceeds USD 2.0 million. A portion of operating profits will be reinvested into capacity expansion, R&D, and educational initiatives.

13. Strategic Importance and Investment Request

LifeDX Africa aligns with Tanzania's priorities in health security, import substitution, industrialization, skills development, and export diversification. The Company seeks recognition as a strategic investor and eligibility for applicable investment incentives under Tanzanian law.

14. Conclusion

LifeDX Africa represents a long-term, high-impact investment combining global technology ownership with local manufacturing and capacity building, strengthening Tanzania's healthcare resilience and positioning the country as a regional diagnostics manufacturing hub.

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