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BLOOD GLUCOSE TEST STRIP MANUFACTURING

A Key to Better Diabetes Care in Low- and Middle-Income Countries?

A GLOBAL AND COUNTRY LEVEL ANALYSIS OF THE GLUCOSE TEST STRIP MANUFACTURING LANDSCAPE, PRICES AND APPROACHES

JUNE 2025

TABLE OF CONTENTS

ACKNOWLEDGEMENTS

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Project management support was provided by Vincent Fiechter (Senior Programme Manager, FIND), Lauréanne Putallaz (Project Manager, FIND), and Priscilla Maxim (Project Manager, FIND).

FIND would like to acknowledge all the various stakeholders who generously contributed their time and insights towards this analysis. These include representatives from industry, Ministries of Health, regulatory authorities, as well as experts in noncommunicable diseases and diagnostics.

The report was designed by Minthical.
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ABBREVIATIONS

AfCFTA	African Continental Free Trade Area
ASEAN	Association of Southeast Asian Nations
BGMS	Blood glucose monitoring systems
CGMs	Continuous glucose monitors
CAPEX	Capital expenditure
CE	Conformité Européene
COGS	Cost of goods sold
DCF	Discounted cash flow
ECOWAS	Economic Community of West African States
FDA	US Food and Drug Administration
GDH	Glucose dehydrogenase
GOx	Glucose oxidase
EIC	Eureka Ideas Consortium
HCPs	Healthcare providers
HIC	High-income country
IRR	Internal rate of return
IVD	In vitro diagnostics
JKN	Jaminan Kesehatan Nasional
LATAM	Latin-America
LMICs	Low- and middle-income countries
MOQ	Minimum order quantity
NCDs	Non-communicable diseases
NGO	Non-government organization
NHIA	National Health Insurance Authority
NPV	Net present value
PET	Polyethylene terephthalate
PLWD	People living with diabetes
PRISMA	Preferred Reporting Items for Systematic reviews and Meta-Analyses
PT CHC	PT Cahaya Hasil Cemerlang
PT SDB	PT Standard Biosensor Healthcare Indonesia
PVC	Polyvinyl chloride
QMS	Quality management system
SKD	Semi-knocked-down
SMBG	Self-monitoring of blood glucose
TKDN	Tingkat Komponen Dalam Negeri
UHC	Universal health coverage
WHO	World Health Organization
WHO PQ	World Health Organization Prequalification
WTP	Willingness-to-pay

INTRODUCTION

Project Background

Diabetes is a growing global epidemic, affecting an estimated 590–830 million people (World Health Organization, 2024; International Diabetes Federation, 2025),[1] most of whom live in low- and middle-income countries (LMICs) where the burden is rising fastest (Zhou, 2024). Regular self-monitoring of blood glucose (SMBG) has been widely recommended as part of routine healthcare in people with diabetes, especially those administering insulin (World Health Organization, 2020; World Health Organization, 2024). Daily glucose monitoring outside of health facilities allows people living with diabetes to adjust their medication dosages to suit their food and activity patterns, helping to avoid potentially life-threatening blood sugar extremes such as hypoglycaemia . Over the longer term, improved glycaemic control reduces the substantial risks associated with diabetes, including cardiovascular disease and debilitating complications such as vision loss, kidney failure, and lower limb amputation.

In 2023, the World Health Organization (WHO) recognized the importance of daily glucose monitoring by adding SMBG systems to the Essential Diagnostics List (World Health Organization, 2023). Despite this, data consistently show that people living with diabetes in LMICs lack access to comprehensive treatment, including SMBG systems (Ogle G D, 2016; Klatman EL M. M., 2019; Ewen M, 2025). A recent multi-country survey found both poor availability and high prices for SMBG devices and test strips in LMICs, with public sector and private pharmacy availability ranging from 0% to 57% and 31% to 100%, respectively. With median strip prices ranging from $0.27 to $0.56, the researchers found that a monthly test strip supply often exceeded insulin costs, putting it out of reach for many individuals and equating to 1 to 12.8 days' wages (Ewen M, 2025).

The Blood Glucose Monitoring System (BGMS) industry has evolved significantly since its inception. SMBG began in the 1970s with the introduction of the first portable glucose meters, which revolutionized diabetes management. Early devices were cumbersome, slow, and required large blood samples, making the process complex and inconvenient. However, technological advancements have led to the development of smaller, faster, and more accurate devices that require no more than a drop of blood (usually 0.3 to 1.0 microlitres).

An important breakthrough occurred in the 1990s with the introduction of electrochemical biosensors in test strips, which enabled more precise readings. This innovation paved the way for continuous glucose monitors (CGMs), which can provide real-time data through wearable sensors, typically in the form of a circular patch affixed to the wearer's arm. CGMs have since become a key part of diabetes care, offering continuous insights into glucose levels and improving patient outcomes.

1. Diabetes estimates vary due to differing methodologies. WHO estimated 828 million people had diabetes in 2022, whereas the International Diabetes Federation estimated 589 million people had diabetes in 2024.

In recent years, innovation in this space has further accelerated, driven by both an increased incidence of diabetes globally and a surge in demand for remote and digital health tools. Additionally, the advent of new therapeutic options for glycaemic control, such as semaglutides and other glucagon-like peptide-1 receptor agonists, has further shaped the self-monitoring industry. However, access to these technologies still remains unequal, particularly in LMICs, where affordability and supply chain constraints have limited widespread use. While CGMs dominate high-income markets, BGMS strips remain the backbone of diabetes monitoring in LMICs due to their lower cost and simple user interface.

Previous research has identified numerous barriers to SMBG along the value chain and care cascade, most notably the prohibitive cost of self-monitoring supplies. High prices result from fragmented buying, inefficient supply chains, and business models based on proprietary device-test systems that prevent brand switching (CHAI, 2021; Klatman EL J. A., 2019). Additionally, the financial burden of testing largely falls on individuals, as there is a lack of public funding for glucose monitoring in LMICs. Lacking the information and expertise to evaluate test performance, individuals often default to trusted brands, rather than considering more affordable BGMS of similar quality (CHAI, 2021). In addition, a low awareness of self-testing guidelines and limited provider counselling may also impede access to SMBG in LMICs.

Several developments present a unique opportunity to address these challenges. First, the growing momentum around non-communicable diseases (NCDs) and universal health coverage (UHC) has increased focus on improving diabetes management in LMICs. The 2021 World Health Assembly resolution on diabetes (World Health Assembly Resolution 74.4, 2021) and the Global Diabetes Compact launch specifically focussed on gaps in essential diabetes care access in low-resource settings, and these were followed by the 2022 global diabetes coverage targets, which included achieving 100% access to BGMS among people with Type 1 diabetes by 2030 (World Health Organization, 2022).

Simultaneously, with the COVID-19 pandemic highlighting the fragility of global supply chains and reinforcing long-standing concerns of over-reliance on distant manufacturing hubs, local manufacturing has risen on the policy agendas of many LMIC governments and global stakeholders (World Health Assembly Resolution 74.6, 2021; Banda G, 2021; Africa CDC, 2025). Local production can reduce reliance on external suppliers, strengthen supply chain resilience, and improve access to essential healthcare products, accelerating UHC and Sustainable Development Goals. Notably, global insulin producers have begun partnering with local companies on the production of insulin in Africa (Lilly, 2022; Novo Nordisk, 2023).

In light of these converging trends - the renewed focus on diabetes care and on local manufacturing – this report examines the feasibility and impact of BGMS manufacturing in LMICs, considering its potential to address access gaps, reduce supply chain dependency, and strengthen diabetes care.

Objectives and Methods

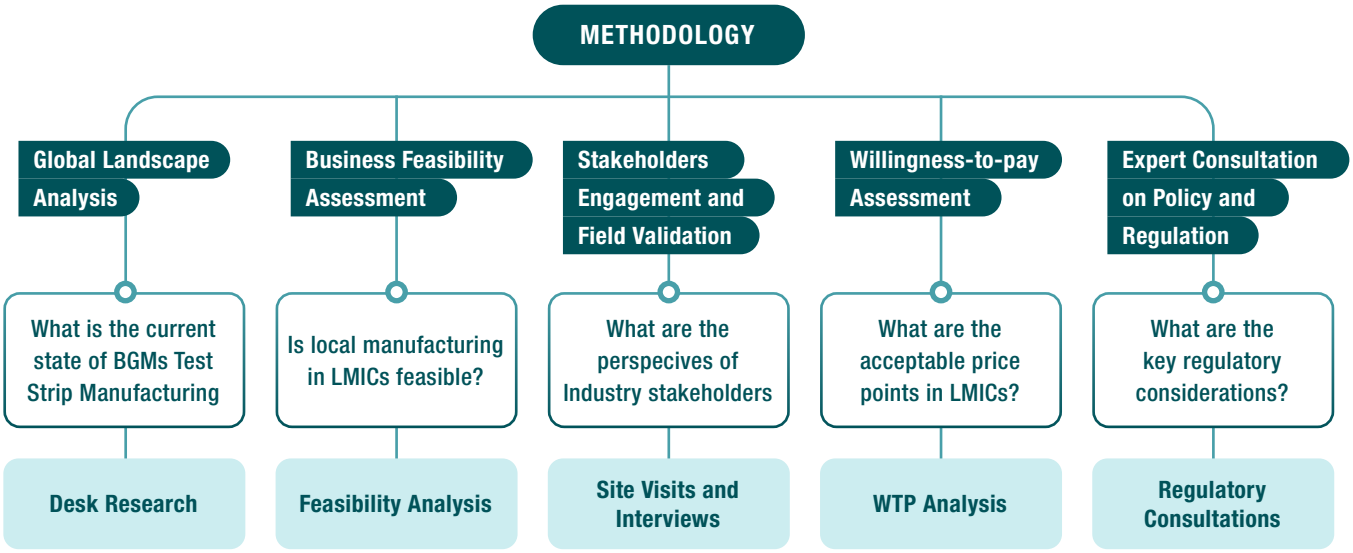
The objective of this project was to evaluate the opportunities for BGMS test strip manufacturing in LMICs). Understanding the cost and access implications of local manufacturing was central to this study - the underlying hypothesis was that producing blood glucose strips locally could bypass key import-related cost drivers, such as international shipping, import tariffs, and multi-layered distributor mark-ups, potentially resulting in more affordable prices for end users. In addition, local manufacturing might enable more responsive and context-specific distribution models, including improved reach to underserved areas. Assessing these dimensions could inform policy and investment strategies in diagnostics manufacturing, particularly in settings where affordability, availability, and continuity of supply remain persistent barriers to access. The main objectives of the study were to assess both the viability and feasibility of local manufacturing operations and the potential benefits for access and availability.

MORE SPECIFICALLY, THE PROJECT AIMED TO:

1. **ASSESS** the global BGMS test strip manufacturing landscape and identify opportunities for local production in LMICs.
2. **EVALUATE** the technical, financial, market, and organizational feasibility of establishing manufacturing capabilities in these settings.
3. **ANALYSE** the potential benefits of local manufacturing on access, affordability, and availability of BGMS test strips.

These objectives lent themselves to a logical progression; for example, findings from research into the global manufacturing landscape informed LMIC site visits for manufacturing feasibility, and countries for market research (Figure 1). Given the project's multifaceted nature, we used a variety of qualitative and quantitative research methods, which are described below. The work was conducted in Q2 2024 through Q2 2025.

FIGURE 1 – Methodology overview for assessing local BGMS manufacturing feasibility in LMICs



1. DESK RESEARCH

The 2021 Market Report (CHAI, 2021) provided an initial knowledge base and supported the contextualization of the evolving market landscape. We conducted desk research to map existing literature and identify existing manufacturers of blood glucose test strips. Following the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) guidelines, we conducted a narrative review between February and May 2025, mapping information from published peer-reviewed articles, reports and grey literature (Page, 2021). This was a scoping narrative review and not a systematic review, however, the steps from the PRISMA checklist ensured that a comprehensive flow of information from both published records and grey literature was mapped appropriately and involved a review of multiple data sources, including:

AVAILABLE INDUSTRY PUBLICATIONS to map out key players in the manufacturing sector.

REGULATORY DATABASES, to confirm compliance status and assess market authorization of manufacturers.

SCIENTIFIC LITERATURE AND TECHNICAL REPORTS to understand innovations, quality standards, and regulatory challenges in the industry.

The search strategy comprised key terms based on key themes, to answer the following research question: What are the key players, production processes, cost structures, and local manufacturing opportunities in the current global landscape of glucose test strip manufacturing? (Table 1)

The following databases were searched: PubMed, Google Scholar, Global Index Medicus, IRIS WHO Digital Publications, industry reports (sourced from manufacturers who were willing to share), regulatory agency reports, academic reports and other FIND partner institutions and civil societies. Potentially eligible records were also identified by searching reference lists of relevant studies that could have been omitted during database searches. Only records that were fully available and published in English from June 2024 to March 2025 were included.

TABLE 1 – Key themes and search terms*

KEY THEME	SEARCH TERMS
Global and regional production ecosystems for glucose test strips	"global production ecosystem glucose test strips", "regional manufacturing diabetes test strips", "supply chain glucose test strip production", "key players in glucose test strip production", "worldwide glucose test strip production"
Cost barriers and affordability issues for glucose test strip-based monitoring devices for diabetes management in LMICs	"cost barriers glucose test strips", "affordability diabetes monitoring LMIC", "economic challenges glucose test strips", "diabetes management cost issues LMIC", "pricing challenges in glucose test strip devices"
Opportunities for local manufacturing and technology transfer	"local manufacturing glucose test strips", "technology transfer diabetes devices, "local production opportunities medical devices", "technology transfer in glucose monitoring"
Market access, policy frameworks, and regulatory	"market access glucose test strips", "policy frameworks diabetes devices", "regulatory landscape glucose test strips", "healthcare policy diabetes monitoring", "regulation of glucose test strip production"

* Search terms used individually and in combination with other terms for in-depth coverage.

2. MAPPING GLOBAL MANUFACTURING

Information used to identify manufacturing sites included desk review and online searches, as well as a targeted expression of interest published on the FIND website and direct outreach (via email) to LMIC-based manufacturers in FIND's database. Consultations with regulatory agencies such as ANVISA (Brazil), SAHPRA (South Africa), and the Ministry of Health (Indonesia) proved especially informative, confirming manufacturing mapping and facilitating industry connections. Additionally, the package inserts from 19 blood glucose strip packages were reviewed for information on technical specifications, product composition, and manufacturing site.

3. TECHNICAL AND ECONOMIC ASPECTS OF GLUCOSE STRIP PRODUCTION

We engaged IQVIA, an external consultancy, to conduct an in-depth review of strip technology, manufacturing processes, and the associated costs of strip manufacturing. IQVIA's methodology included extensive input from an in-house expert with experience in glucose strip manufacturing, complemented by several interviews with manufacturers. Deliverables included technical reports on:

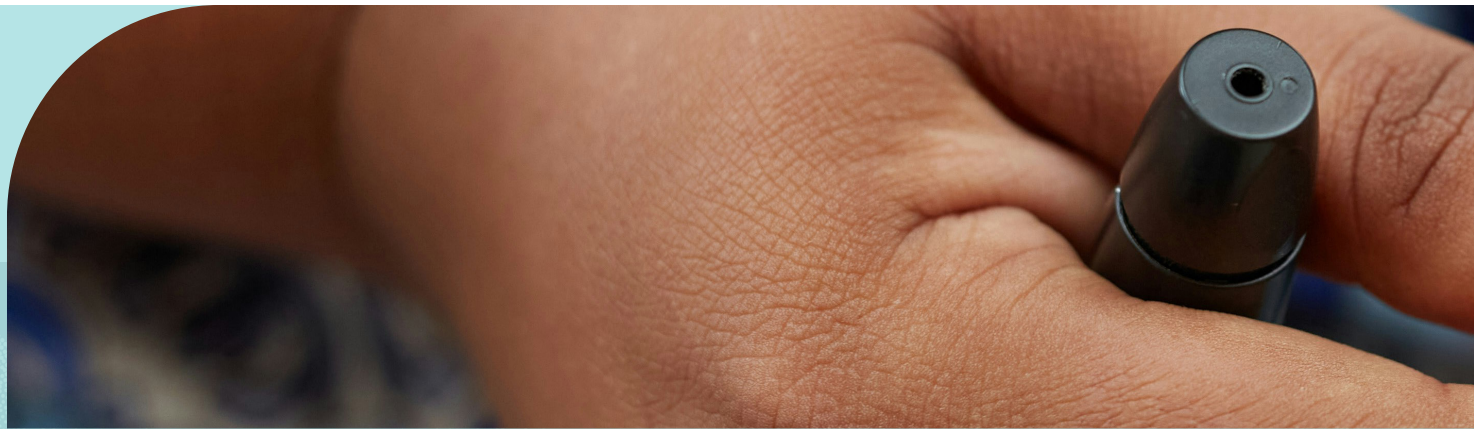
i) Strip components and configurations.

ii) Manufacturing processes, key expertise, infrastructure, equipment, and material requirements.

iii) A costing analysis and model considering varying strip materials and design, process complexity, production volumes, and settings (e.g., LMIC or high-income country [HIC]).

4. DISCOUNTED CASH FLOW (DCF) ANALYSIS

A high-level DCF was developed to support our local manufacturing financial feasibility assessment. The model considered different market conditions, reflecting future cash flows of a hypothetical LMIC-based glucose strip manufacturing project. The assumptions were a critical driver of the analysis, and by incorporating information gathered during our site visits and interviews, we aimed to ground the assumptions in real-world data. The DCF was then used to assess breakeven points, estimate net present value (NPV) and the internal rate of return (IRR).



5. MARKET RESEARCH

We engaged an external consultancy, Eureka Ideas Consortium (EIC), to conduct market studies in three representative countries: Indonesia, Nigeria, and Kenya. EIC's research comprised:

BLOOD GLUCOSE STRIP DEMAND ANALYSIS

Estimations of need and demand were developed using patient care cascade and testing frequency modelling. However, incomplete and limited import and government procurement data limited the formal validation of these estimates.

LOCAL MARKET CHARACTERIZATION

Key informant interviews were conducted to identify primary market segments, use cases and relative volume distributions within each country.

RETAIL MARKET SURVEY

A convenience sampling approach was employed to survey retail outlets to assess pricing, product/brand availability, and supply chain markup patterns across different consumer purchasing channels.

POLICY ENVIRONMENT ANALYSIS

Desk research and key informant interviews examined government policies supporting local manufacturing capabilities.

6. STAKEHOLDER ENGAGEMENT AND FIELD VALIDATION

To validate desk-based findings and gain real-world insights, the team conducted:

SITE VISITS WITH FOUR MANUFACTURERS in Indonesia, Nigeria, and Algeria, to observe operations and engage management teams.

WE CONDUCTED 29 STRUCTURED INTERVIEWS WITH STAKEHOLDERS across the value chain. This included a diverse group of stakeholder contributions, including local and prospective manufacturers, industry experts, representatives from regulatory authorities, academic experts and other relevant stakeholders.

Consultations with regulatory agencies such as ANVISA (Brazil), SAHPRA (South Africa), and the Ministry of Health (Indonesia) proved especially informative, providing access to regulatory frameworks and facilitating industry connections.

7. WILLINGNESS-TO-PAY (WTP) ASSESSMENT

To evaluate affordability and pricing dynamics, a WTP analysis was conducted in Brazil and Kenya using the Van Westendorp Price Sensitivity Meter methodology (Kunter, 2016). This assessment was conducted across three BGMS categories:

- Internationally recognized brands.
- White-label brands (typically manufactured in Asia).
- A hypothetical locally-manufactured product.

We used the Premise platform to conduct mobile phone-based surveys in Brazil and Kenya, to:

- Identify acceptable pricing ranges for consumers and providers.
- Determine price thresholds and demand elasticity.
- Highlight affordability barriers that could limit uptake in LMIC settings.

After data cleaning, we analysed 219 responses in Brazil and 186 responses in Kenya, which had 85% and 80–85% confidence ratings, respectively.

8. ASSESSING ACCESS: AFFORDABILITY AND AVAILABILITY ANALYSIS

Using the access framework as presented in USAID's Healthy Markets for Global Health: A Market Shaping Primer (USAID, 2014), we considered the potential impact that local manufacturing might have on access measures, in particular affordability and availability, which prior research by CHAI and FIND had highlighted as critical challenges for people living with diabetes (PLWD) in LMICs.

9. ADVISORY BOARD CONSULTATION

An 8-member advisory board provided an external perspective on the research structure, process, interim findings and working conclusions.

10. LIMITATIONS

As with all studies, there are several important limitations that should be remembered when reviewing the results, including:

INCOMPLETE VISIBILITY OF THE MANUFACTURING LANDSCAPE

Despite efforts to comprehensively map global and LMIC-based BGMS manufacturing, visibility remained limited. Many companies operate through white-label or contract manufacturing arrangements, often without disclosing actual production sites. Confidentiality agreements and the commercial sensitivity of supplier relationships further restricted access to accurate data. In addition, given the rapidly evolving nature of the sector, it is likely that some manufacturers or facilities were unintentionally omitted.

LIMITED AVAILABILITY OF MARKET DATA

Despite the public health relevance of diabetes, there is surprisingly little consolidated or publicly available data on blood glucose test strip markets in LMICs. Information on pricing, sales volumes, procurement levels, and brand market shares is fragmented or missing in most countries. As a result, several of our market size estimates, pricing assessments, and demand forecasts are directional in nature and carry a margin of uncertainty.

CONFIDENTIALITY AND DATA ACCESS CONSTRAINTS

During interviews and site visits, some manufacturers shared sensitive or commercially confidential information, which we have excluded or anonymized in this report. However, data gaps remain, particularly with regard to production costs, volumes, and distribution practices.

SMALL SAMPLE SIZES IN FIELD RESEARCH

While the market research and site visits provided critical country-specific insights, the sample sizes were limited due to time and resource constraints. For example, the number of retail outlets surveyed in each country was modest and therefore may not fully represent rural-urban or public-private differences. Likewise, insights from the four manufacturing site visits may not be generalizable across all LMIC manufacturers.

RELIANCE ON ASSUMPTIONS IN FINANCIAL MODELLING

The DCF analysis provided a high-level view of financial feasibility under different market and volume conditions. While we grounded our assumptions in insights from interviews and site visits, the model should not be considered a substitute for a full business case or country-specific feasibility study, given that small changes in input costs, demand volumes, timelines, or pricing can significantly alter model outcomes.

REGULATORY ENVIRONMENT NOT COMPREHENSIVELY ASSESSED

Although we engaged with regulatory stakeholders and reviewed applicable frameworks, we did not conduct a full regulatory gap analysis in each country visited. While this report notes the impact of regulation and quality standards on local manufacturing, as the challenges are often underestimated, this was not explored in depth. Our experience from other local diagnostics manufacturers shows that meeting regulatory and requalification requirements involves significant costs, technical expertise and long timelines., and that delays in setting up quality systems or navigating unclear pathways can severely affect time-to-market and project viability. Strong regulatory alignment and early planning are thus essential to support sustainable local manufacturing.

LIMITED GENERALIZABILITY OF FINDINGS

As mentioned earlier, insights from country-specific research, such as the site visits in Algeria, Indonesia and Nigeria, and the WTP surveys in Brazil and Kenya, reflect local contexts and may not be broadly applicable to all LMICs. Moreover, WTP findings capture stated preferences, which may not directly translate into actual purchasing behaviour, especially in settings where product access or product information is constrained. While the analysis presented in this report identifies plausible mechanisms and provides supportive case examples, it does not constitute a formal impact evaluation, and evidence of downstream effects on affordability, utilization, or supply continuity remains limited.

GLOBAL BGMS SUPPLY LANDSCAPE

Drawing on the findings from the 2021 landscaping report (CHAI, 2021), we utilized the same three-tier categorization of manufacturers, as this framework remained relevant at the time of the study. The three tiers were defined as follows:

TIER 1

THE BIG 4 – ROCHE, LIFESCAN, ABBOTT, ASCENCIA: these companies dominate the global market with proprietary technology, extensive distribution networks, significant R&D investments and large-scale manufacturing. As per the 2021 market report on Diabetes Self-Monitoring Devices in LMICs, the above-mentioned companies have a combined market share of ~80% of the BGMS strip market (CHAI, 2021). In recent years, however, the strategic focus of these companies has expanded beyond traditional strips to capture market shares in the nascent CGM landscape.

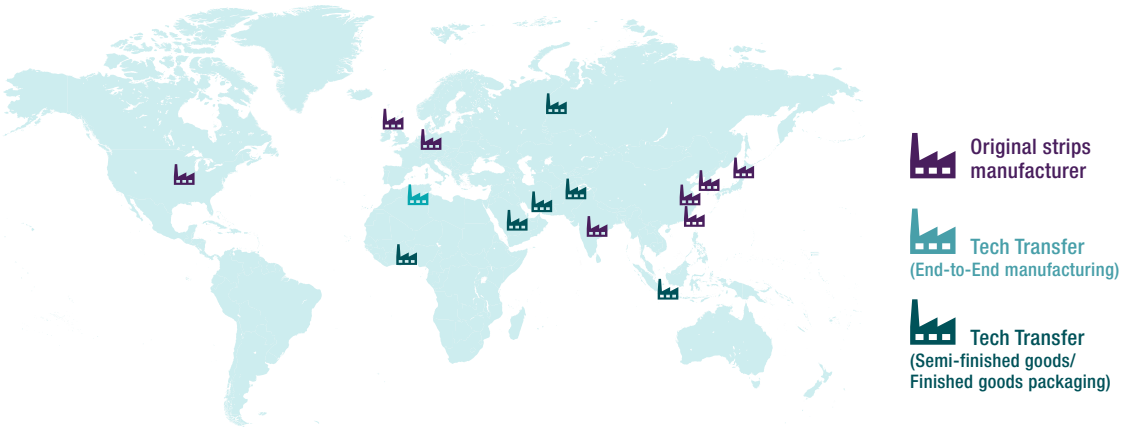
TIER 2

THESE COMPANIES HAVE A STRONG PRESENCE IN SPECIFIC REGIONS – notably Japan, Korea, India and China – and often compete on cost-effectiveness as they have achieved large scale production through high-volume, highly automated processes. These companies frequently collaborate with regional manufacturers, local distributors and governments to access LMIC markets. These partnerships help them navigate regulatory requirements, as well as helping tailor their products to meet local needs (such as language-specific packaging and user instructions), constraints (such as retailing in smaller quantities) and in some cases, secure public sector tenders. In other instances, they also offer private label manufacturing services for local brands, further embedding themselves in regional markets. The companies in this tier include: SD Biosensor (Korea), Arkray (Japan), Acon Labs (USA), Dr. Morepen (India), CareforU (Korea), Shenzhen IMDK (China), Taidoc (Taiwan), Cordx (USA), and VivaCheck (China).

TIER 3

THIS TIER INCLUDES SMALLER, OFTEN NATIONALLY- OR REGIONALLY-FOCUSED COMPANIES WITH LIMITED PRODUCTION CAPACITY. They typically produce low-cost, basic BGMS devices and strips, often through technology transfer agreements or licenses from larger firms. Companies in this categorization include Vital Care (Algeria), Colexa Biosensor (Nigeria) and PT Cahaya Hasil Cemerlang Multi Manufaktur (Indonesia). [these companies are explored further in this report]

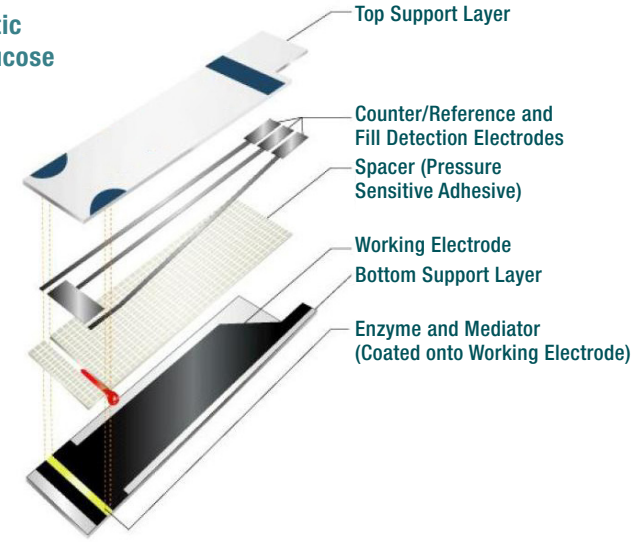
FIGURE 2 – Global presence of BGMS strips manufacturers



BGMS TECHNOLOGY AND MANUFACTURING

The manufacture of BGMS strips is a highly specialized process that requires precision, technological expertise and stringent temperature, humidity and quality controls. The complexity of strip manufacture stems from the intricate construction of the layers and the integration of the biochemical and electrochemical components that ensure the delivery of accurate and precise results.

FIGURE 3 – Exploded schematic of an electrochemical blood glucose test strip (Feldman, 2009)



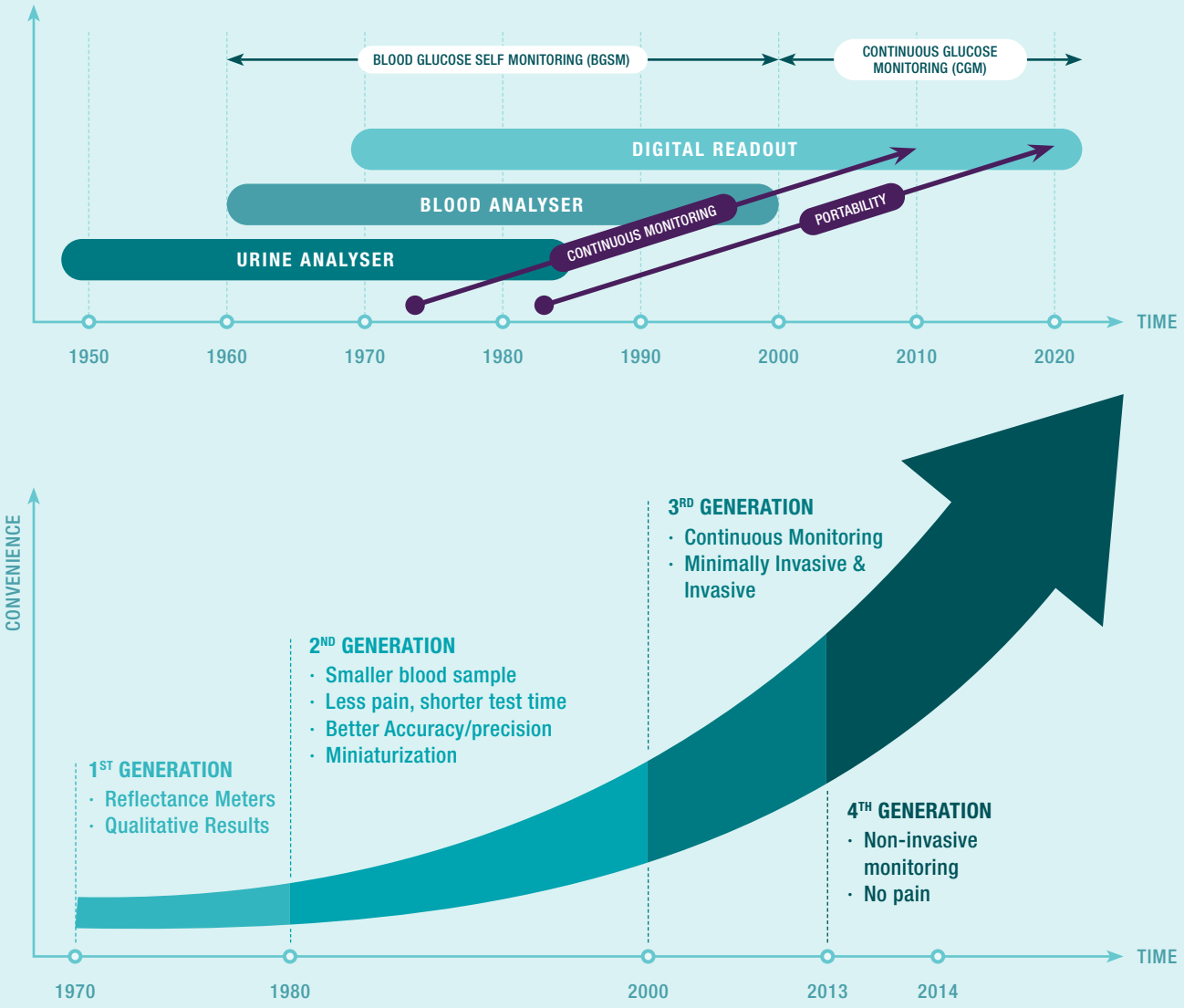
Technology Platform Evolution

BGMS technology has undergone multiple iterations with each successive generation of the technology systematically addressing the limitations of the previous generation. BGMS typically use two assay platforms:

PHOTOMETRIC	ELECTROCHEMICAL

The first generation of strips relied on photometric technology alone. Although this technology represented a significant advancement at the time for at-home diabetes management, the technology also had its limitations. Chief among these was that a variability in ambient oxygen, the presence of interfering substances, and other environmental factors such as temperature, humidity and user technique, could all impact the readings. Nevertheless, they paved the way for the development of user-friendly and accurate BGMS. While photometric methods are still employed in specialized applications, they are no longer the standard for SMBG due to the speed and precision of subsequent electrochemical methods.

FIGURE 4 – The evolution of glucose monitoring



The second generation of BGMS introduced electrochemical technology, reducing the impact of external factors or user interpretation errors. More importantly, electrochemical technology required smaller blood samples and the reaction in the system was quicker, leading to faster results and enhanced user convenience. It also saw the introduction of no-coding technology, which eliminated the need for manual calibration with each new batch of strips. This reduced the risk of incorrect meter coding, a common source of inaccurate readings in earlier systems (Singh, 2023).

Today, the third generation of blood glucose test strips leverages advanced biosensor technology to deliver faster, more accurate, and user-centric results. These strips utilize genetically modified enzyme-based electrochemical reactions combined with advanced mediators to enhance the signal strength and reduce interference from external factors such as temperature, haematocrit levels, and concomitant medications. Many modern strips are compatible with smart meters and mobile applications, enabling real-time data tracking, trend analysis, and seamless integration with digital health platforms.

The next generation of BGMS currently in development will focus on non-invasive methods that should eliminate the need for blood completely.

Material Composition of BGMS

To better understand the cost drivers and technical complexity involved in strip manufacturing and to evaluate the feasibility of local production, it is important to examine the material composition of a BGMS strip. The performance, reliability, and cost of these strips are directly influenced by the materials used in their construction. This also impacts the degree of quality control required, the potential for sourcing inputs locally, and the overall manufacturability in low-resource settings.

Each component of the strip plays a role in ensuring accuracy, user safety, and compatibility with glucose meters. Even minor changes in materials or design can affect how reliably a strip performs under different environmental conditions or user-handling scenarios. These components typically include the following:

ELECTRODES | **ENZYMES** | **MEDIATORS** | **SECONDARY COMPOUNDS**

Layered Structure of BGMS Strips

The basic BGMS strip consists of three insulating layers, generally constructed from polyethylene terephthalate (PET) due to its mechanical stability and uniformity, though polyvinyl chloride (PVC) is occasionally used. The first layer, which serves as the base, is rigid and houses the main electrodes. A second layer acts as a spacer and includes precisely cut holes to define the sample channel without covering the working electrode. A third layer of similar thickness as the second layer is laminated on top, enclosing the capillary tunnel. It features a vent hole at the distal end to allow airflow, ensuring smooth blood flow via capillary action.

All layers are treated to be hydrophilic, which promotes rapid and complete sample transfer and optimizes enzymatic reactions. Adhesives between the layers serve both structural and functional purposes, forming a sealed microfluidic tunnel that guides the blood sample to the active chemistry zone.

1. ELECTRODES

Electrodes are a critical component of BGMS strips that form the interface between the sample and the electrochemical detection system. The electron transfer from the biochemical reaction that results from the introduction of the blood sample is captured by the electrode and translated into an electric signal that the meter can interpret as a readable glucose value.

The basic structure of an electrochemical test sensor consists of three electrodes: the working electrode, responsible for measuring the actual current of the reaction; the reference electrode, maintaining a constant voltage in relation to the working electrode to facilitate the chemical reaction; and the counter electrode, supplying the necessary current to the working electrode.

Most BGMS electrodes are printed onto flexible plastic substrates, most commonly PET, using carbon-based conductive inks. In some cases, especially where stability or signal quality is a concern, manufacturers incorporate metals such as silver/silver chloride or even gold to enhance performance. The electrode printing process can be done by screen or inkjet printing and requires careful quality control and calibration as variabilities in ink formulation, thickness, drying time or reagent deposition can introduce significant errors in the readings.

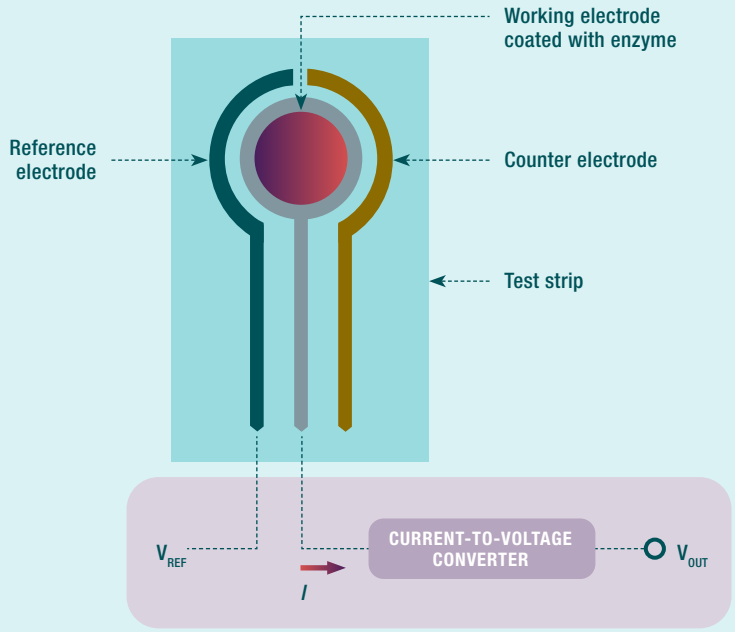


FIGURE 5 – Basic structure of an electrochemical sensor (Hönes, Müller, & Surridge, 2008)

2. ENZYMES

Enzymes are essential to the functioning of BGMS and form the cornerstone of the biochemical reactions required to detect glucose. The two most commonly-used enzymes in BGMS are glucose oxidase (GOx) and glucose dehydrogenase (GDH).

GLUCOSE OXIDASE (GOX)

GOx is extensively used in BGMS due to its high specificity for β-D-glucose, the predominant form of glucose in human blood. When a blood sample is introduced to a GOx-based strip, the enzyme catalyses the oxidation of glucose into gluconolactone, simultaneously producing hydrogen peroxide as a by-product (see below). While gluconolactone is not directly measured, the generated hydrogen peroxide is electrochemically oxidized at the electrode surface. The resulting current is proportional to the glucose concentration, enabling accurate quantification.

GLUCOSE + O_2 → GLUCONOLACTONE + H_2O_2

In modern BGMS, additional compounds are often introduced into the enzyme mix to enhance the test's performance. These typically include mediators, such as ferricyanide or quinone derivatives, which act as electron carriers. Instead of relying solely on the natural reaction that produces hydrogen peroxide, these mediators shuttle electrons directly from the enzyme's active site to the electrode, resulting in a more stable and precise current. This design improves the system's responsiveness and reduces interference from oxygen variability in the sample, which can affect hydrogen peroxide-based detection.

Further, stabilizers such as albumin, trehalose, or polyols, are commonly added to preserve the enzyme's structure and functionality over time, to account for varying storage conditions. These compounds prevent denaturation of GOx and maintain enzyme activity during the shelf-life of the test strips. Detergents and surfactants are also sometimes included to ensure even spreading of the blood sample and enhance reaction efficiency by reducing surface tension.

The end result is an electrochemical reaction at the electrode surface, where the transferred electrons generate an electrical current. This current is directly proportional to the concentration of glucose in the blood sample and is measured by the BGMS to provide an accurate glucose reading.

However, one drawback of GOx in BGMS is the dependency on oxygen as a co-substrate, making its readings sensitive to oxygen concentrations. Specifically, GOx needs oxygen from the blood sample to trigger the chemical reaction that measures glucose. This means the accuracy of GOx test strips can be directly affected by the oxygen concentration in the blood, which can vary between individuals or

under different health conditions. Additionally, ambient oxygen levels can also interfere with the readings. For example, at high altitudes where oxygen levels are lower, or in conditions of poor air circulation, GOx strips may give inaccurate results. Lastly, interference from substances that affect hydrogen peroxide detection could also interfere with the readings in GOx strips, including certain medications or high levels of uric acid in the blood.

From a product stability standpoint, GOx-based strips typically have a shorter usable life once the packaging is opened. While sealed strips often carry a manufacturing shelf life of up to 18 months, exposure to air and humidity after opening can degrade enzyme activity, limiting in-use shelf life to approximately 3 months in many commercial products. Users need to be aware of this limitation to avoid compromised accuracy.

GLUCOSE DEHYDROGENASE (GDH)

By contrast, GDH does not rely on oxygen as a co-substrate, i.e., GDH can function without oxygen being a part of the reaction. Instead, it uses cofactors such as nicotinamide adenine dinucleotide, pyrroloquinoline quinone, or flavin adenine dinucleotide as electron acceptors. After GDH removes electrons from glucose and transfers them to its cofactor, the reduced cofactor can be measured. The system detects this electrical signal, and the strength of that signal correlates with the amount of glucose in the blood sample (see below).

GLUCOSE + ELECTRON ACCEPTOR (COFACTOR) → GLUCONO-δ-LACTONE + REDUCED ELECTRON ACCEPTOR

These cofactors enable GDH to carry out the reaction regardless of oxygen levels in the blood or the environment. This makes GDH-based glucose monitoring strips more reliable in situations where oxygen concentration might fluctuate, such as at high altitudes or in patients with conditions that affect blood oxygenation. GDH-based strips are thus often preferred in clinical settings where consistent and oxygen-independent results are critical. While GDH eliminates oxygen dependency, it is worth noting that it is less specific than GOx in detecting glucose. This means that GDH can sometimes mistake other sugars found in the bloodstream for glucose and include them in the reading.

In summary, while GOx provides high specificity to glucose but is sensitive to oxygen levels, GDH offers oxygen-independent measurements with broader applications in various settings, but it has the potential to cross-react with other sugars. As such, both enzymes have a valuable role in blood glucose monitoring, with the choice depending on the clinical context and user needs.

3. MEDIATORS

Mediators are essential for transferring electrons generated during the enzymatic oxidation of glucose to the surface of electrode in the BGMS. This is crucial in the operation of the BGMS, as the mediators generate an electrochemical signal proportional to the glucose concentration, which is, in turn, measured by the glucometer. In second-generation systems, mediators replaced the oxygen used in first-generation systems, improving the efficiency and reliability of the tests. Mediators also allow for a more efficient transport of electrons to the electrode than oxygen-based systems, leading to improved sensitivity and a faster response time. Examples of commonly-used mediators include ferrocene derivatives, quinones and osmium complexes.

4. SECONDARY COMPOUNDS

Aside from enzymes and mediators, additional secondary compounds are included in the test to support the enzymatic reaction and improve the stability of the reagents. These include:

BUFFERS: Buffers maintain the optimal pH environment for enzyme activity.

STABILIZERS: Stabilizers preserve the activity of the enzymes and mediators over the shelf life of the strips.

WETTING AGENTS: These ensure the blood sample spreads evenly across the reaction surface to enable consistent readings with small sample volumes.

INTERFERENCE SUPPRESSORS: Compounds added to counteract interfering substances in the blood sample that would otherwise affect the reliability of the reading.

BGMS strips are part of an integrated system that includes the glucose meter and ancillary components such as lancets and instructions. Commercial starter kits typically include the meter, lancets, instructions, and a limited number of strips, with consumables (primarily strips and lancets) sold separately thereafter. These systems are generally “closed”, particularly in the way strips interact with meters, meaning that each meter is calibrated to function only with its corresponding brand or model of strip. While this pairing ensures accuracy and consistency, it also limits interchangeability, with strips from earlier models not necessarily compatible with newer generation meters, and third-party strips or strips from different brands or manufacturers not always physically compatible.

Lastly, while strip manufacturing involves biochemical and materials engineering, meter production requires entirely different capabilities, often involving outsourced partners with expertise in electronics and device manufacturing.

In conclusion, the seemingly simple blood glucose test strip is a product of intricate and precise engineering and manufacturing. The precise interplay of enzymes, whether GOx or GDH, alongside carefully selected mediators, forms the core of the glucose detection mechanism. This complex interaction is further refined by the inclusion of secondary compounds like buffers, stabilizers, wetting agents, and interference suppressors, each playing a critical role in ensuring accuracy and reliability. The delicate balance of these components, each with its specific function and potential for interference, underscores the complexity of manufacturing these essential diagnostic tools. The precision required in material selection, enzyme deposition, and quality control shows that producing effective BGMS strips is not merely a matter of assembly, but a sophisticated process requiring deep scientific understanding and rigorous manufacturing standards.

5. MATERIAL FORMULATION AND RAW MATERIALS

The choice and sourcing of raw materials also plays a crucial role in determining the cost and quality of BGMS strips. In particular, the selection of the electrode is a key cost driver in BGMS strip manufacturing. Manufacturers choose between carbon electrodes, which are considered a lower-cost option, and gold electrodes which are a higher-end alternative. On average, gold electrodes are approximately 30% more expensive than carbon electrodes, contributing significantly to the overall cost of production. Despite the cost differential, some of the LMIC-based manufacturers we spoke to reported using gold electrodes. This was influenced by local demand dynamics and supplier marketing, which positions gold-based strips as superior in accuracy, irrespective of the context in which it is used.

Enzyme and mediator selection also impact the cost of goods sold (COGS) for blood glucose strips, but to a lesser extent. The cost difference between GOx and GDH is relatively small, estimated to be around a 4.4% cost increase when switching from Gox to GDH. Similarly, substituting ruthenium with ferricyanide increases the total COGS by 5.2%.

For LMIC-based manufacturers seeking to balance performance characteristics with affordability, costs can be managed by procuring uncut sheets, which are then processed in the manufacturing facility. These sheets can be procured from international suppliers and typically arrive with pre-applied components, particularly in cases involving technology transfer arrangements. However, minimum order quantities (MOQs), which are standard in many supply agreements, pose a significant challenge for small-scale manufacturers. These firms typically purchase inputs from external suppliers at prices that already include the seller's margin, as well as associated freight costs, and, in some countries, import duties. As a result, their per-unit cost is substantially higher than that of larger manufacturers who can produce critical components, such as uncut sheets, in-house and benefit from economies of scale.

Further complicating the cost challenge is the potential situation where MOQs from sheets suppliers might be set at volumes that exceed the near-term production or sales capacity of smaller firms. This mismatch can lead to excess inventory, which is particularly problematic as BGMS strips have a limited shelf life. At the same time, LMIC-based manufacturers may feel pressured to keep retail prices aligned with, or even below, those of dominant international brands, which have greater pricing flexibility due to their scale or ability to hedge against foreign exchange fluctuations. This dynamic further compresses margins and underscores the structural cost disadvantage that smaller firms face when navigating MOQ-driven supply chains.

Additional raw materials include both primary and secondary packaging. Primary packaging typically consists of vials or individual foil-wrapped strips, with desiccants such as silica gel included in the vial caps to protect strip integrity. Secondary packaging, which is used for labelling and transport, is source locally in many cases, which can help reduce overall packaging costs and reliance on imported materials.

Overall, material formulation and raw material sourcing represent key cost levers in BGMS manufacturing. These are shaped not only by technical requirements, but also by the scale of operations, supplier arrangements, and country-specific procurement conditions.

BGMS Manufacturing Process

Manufacturing BGMS involves a range of variables, rather than a single fixed process. While manufacturers aim to achieve consistent quality and performance standards, the choice of raw materials, BGMS strip designs, sourcing strategies and levels of automation can vary widely. These permutations are driven by factors such as cost, production capacity, and regulatory considerations, and can result in diverse manufacturing approaches across the industry. On one end of the spectrum are highly automated roll-to-roll manufacturing systems capable of producing billions of strips per year. On the other end are semi-automated or manual production processes operating at capacities closer to 25 million strips annually on a single shift. This variation underscores the need for contextualized strategies when considering local production feasibility or evaluating global supply resilience.

The general sequence of steps typically followed in strip manufacturing (based on the sheet-to-sheet method) is presented below. This includes technology and equipment variations that are commonly observed across the industry:

1. Electrode printing/engraving (Layer 1 preparation)
2. Dispensing, drying, and lamination
3. Cutting and bottling of strips
4. Secondary packaging of strip bottles

1. ELECTRODE PRINTING/ENGRAVING

The manufacturing process begins with the preparation of the base electrode layer. For BGMS strips using carbon electrodes, a silk-screen printing process is commonly employed. Conductive carbon paste is printed onto sheets of PVC or PET material, which are then dried and sintered in controlled heat tunnel environments. The level of automation used in this step can vary considerably; highly automated production lines use robotic feeding and precision-guided printing, while semi-automated settings may rely on manual sheet handling. Alignment accuracy during the printing process is critical and is generally performed using pre-punched guiding holes in the PVC/PET sheets.

In the case of strips using gold electrodes, the production method differs significantly. Gold is deposited onto substrates using sputtering technology, a specialized and capital-intensive process where a thin layer of gold is sprayed or coated onto a surface using high-energy particles in a vacuum. This is followed by either laser engraving or chemical etching to define the electrode patterns. Given the complexity and cost of sputtering, many manufacturers prefer to source pre-sputtered substrates rather than perform this process in-house.

Regardless of the material used, the electrodes typically undergo surface treatment via either plasma or chemical coating, to enhance enzyme adhesion and ensure consistent sensor performance.

2. DISPENSING, DRYING AND LAMINATION

Following electrode preparation, the next manufacturing stage involves dispensing the biological reagent mix onto the electrodes. This step requires extreme precision, with droplet sizes typically between 0.1 and 1.0 microlitres. Modern dispensing systems must maintain high accuracy in both droplet volume and placement to ensure the reliability and uniformity of the strips. The environment during dispensing is carefully controlled, with humidity maintained at around 60% to prevent premature drying of the reagent.

After dispensing, the sheets pass through drying ovens to stabilize the enzyme layer without compromising its biological activity. Once the drying is complete, the lamination of additional layers, such as protective covers and spacers, is performed to build the final strip structure.
Lamination processes may be manual, semi-automated, or fully automated depending on the production setup. After drying, all subsequent processes are conducted under low-humidity conditions (typically below 20%) to preserve the functional integrity of the dried enzyme mix.

3. CUTTING AND BOTTLING OF BGMS STRIPS

Upon completion of lamination, the sheets are prepared for cutting and bottling. The laminated sheets are first cut into rows and then further divided into individual strips using rotary slitting machines. Precision in this phase is critical to maintain strip uniformity and performance. Following cutting, strips are collected and packaged into primary containers, typically vials containing 25 or 50 strips. Bottling can be done manually in smaller operations, but medium- and high-volume production often employs automated systems. Some manufacturers also integrate a calibration and coding step at this point, where strips are tested and standardized to ensure consistent quality and batch performance.

4. SECONDARY PACKAGING

The final manufacturing stage involves labelling, boxing, and preparing the bottled BGMS strips for shipment. Labelling and packaging can be performed manually, semi-automatically, or through fully automated lines depending on production volumes and investment in automation technology. In fully automated lines, labelling, insert placement, boxing, and lot printing are integrated to achieve high-speed output and minimize manual handling.

Once packaging is complete, the vials are transferred to incubation rooms where they are stored under controlled temperature conditions for a set period of time. This incubation phase allows the enzyme systems within the strips to stabilize and mature, ensuring consistent performance once the products are distributed to the market.

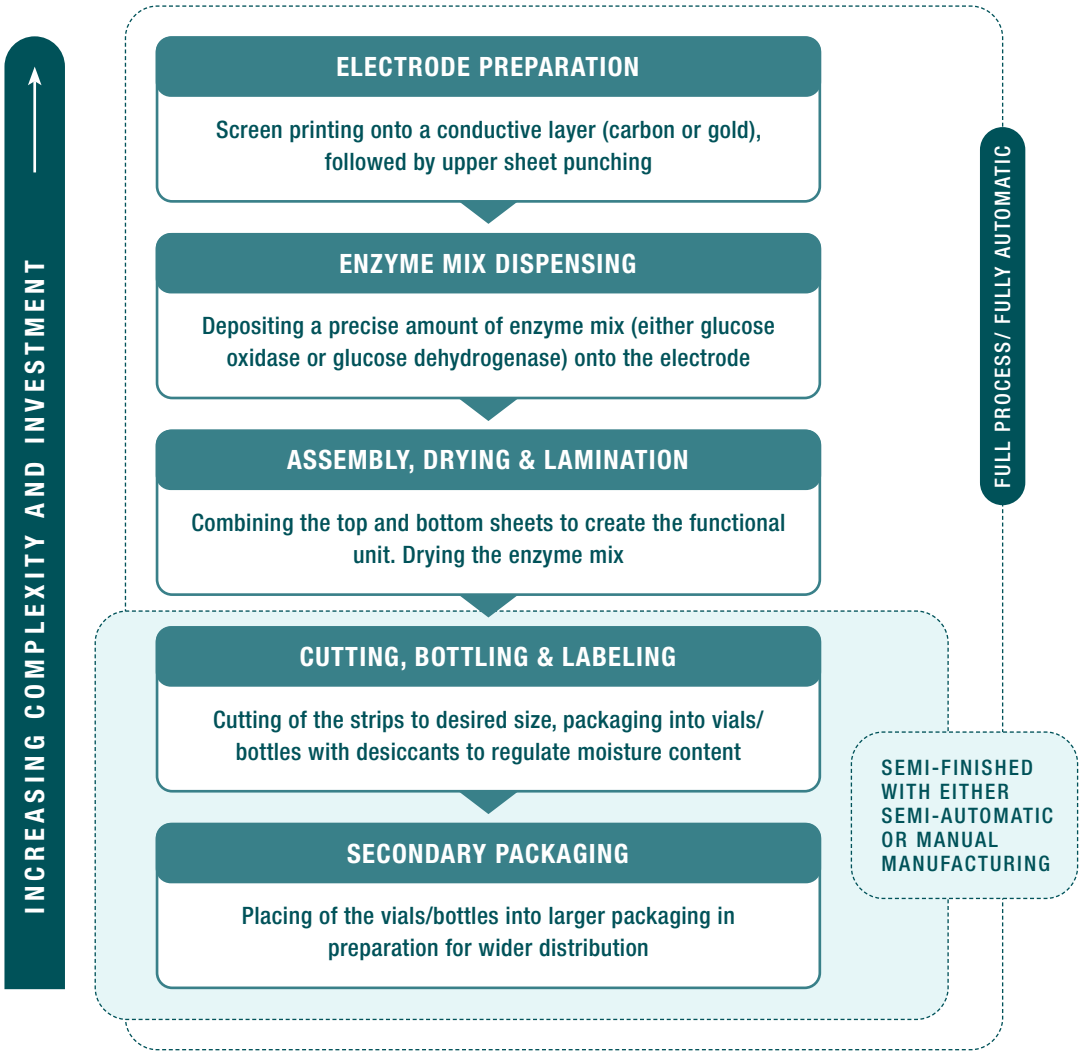
Throughout the BGMS manufacturing process, several risks must be carefully managed. Precision in key steps, particularly dispensing, printing, and lamination, is essential for ensuring strip reliability and minimizing variability across batches. To mitigate these risks, strict quality control measures and robust process validation protocols must be in place. Environmental conditions, especially humidity and temperature, must be tightly regulated throughout production to protect the biological reagents at critical stages. In addition, in-process quality checks, such as visual inspections, electrical testing, and functional strip validation, should be routinely performed to identify defects early and reduce downstream waste. Overall, a well-integrated quality management system is essential to deliver reliable products and ensure compliance with international diagnostic standards.

Factors Affecting the Cost of BGMS Strip Production

Understanding whether it is feasible to produce affordable BGMS test strips in LMICs requires a clear view of the costs involved in setting up local manufacturing. These costs depend largely on the type of production model chosen, whether everything is done in-house, if certain steps are outsourced, or if an external or contract manufacturer is used. Each approach comes with different financial demands and levels of complexity. Key cost areas include the initial investment in equipment and cleanroom facilities, along with ongoing expenses for raw materials, skilled labour, utilities, and quality control. There are also financial risks linked to importing essential components, particularly when these purchases are exposed to foreign exchange rate volatility. By examining these cost factors across different production models, stakeholders can make more informed decisions about the financial viability of local manufacturing and what kind of support or investment might be needed to make it successful.

To inform this analysis, we drew on detailed technical and cost assessments conducted by IQVIA, which were synthesized in a COGS model. This model provided a structured breakdown of the main cost components and manufacturing activities involved in BGMS production, and can serve as a practical tool for policymakers and manufacturers to evaluate the financial landscape of local production, and support strategic decisions around investment, procurement planning, and capacity development.

FIGURE 6 – Infrastructure costs by location and level of automation (Source: IQVIA data/FIND)



1. MANUFACTURING MODELS

Manufacturers adopt different production models based on strategic, operational and financial considerations. In some regions, the availability of technical expertise is another factor that influences these decisions. Some choose to manage the full production cycle in-house, while others outsource specific stages or opt for semi-knocked-down (SKD) manufacturing by importing fully dispensed but uncut sheets. These choices reflect trade-offs between cost, control, and technical capacity, influencing both the investment requirements and the competitive landscape of the local market, as well as shaping infrastructure needs, operational complexity, and the facility's ability to scale.

In an end-to-end manufacturing setup, the facility handles the entire production process on-site. While this requires significant capital expenditure (CAPEX) in facility size, specialized machinery, cleanroom environments, and skilled labour, it also allows for maximum control over quality, supply chain stability, and cost efficiencies, particularly in high-volume production settings.

In contrast, SKD manufacturing involves sourcing partially processed raw materials, with additional manufacturing steps completed on-site. Depending on the stage of completion of the procured materials, such as pre-printed or pre-engraved electrodes, enzyme-coated substrates, or uncut sheets, the facility is responsible for final assembly, cutting, and bottling of the strips. This model strikes a balance between reducing CAPEX and maintaining a degree of in-house production control, making it a viable option for manufacturers seeking to limit upfront investment, or where there are few experienced technical professionals capable of upstream production.

Purchasing uncut sheets is an approach often best suited for LMIC-based manufacturers due to lower capital investment requirements and reduced operational complexity. However, this approach is not without its own set of challenges. While it significantly reduces capital investment and operational complexity, it limits control over upstream processes, leaving manufacturers highly dependent on external suppliers for critical components. High MOQ requirements can also strain operations, especially in price-sensitive or underdeveloped markets. Some manufacturers adopt this model as an entry point and gradually pursue backward integration over time, developing the capability to produce more components in-house as they build technical capacity, secure financing, and gain market experience.

2. DEGREE OF AUTOMATION

The level of automation has a significant impact on cost efficiency, scalability and product quality. Automation choices not only influence per-unit production costs but also influence labour, quality, and capital investment requirements.

Manual production processes rely heavily on skilled technicians operating machinery and trained workers completing assembly steps. While this may offer a low-cost entry point in LMIC settings where wages are lower, manual production is unviable in HICs due to high labour costs. Additionally, manual production severely limits throughput. A typical manual production line may yield only a few million strips per year, whereas a fully automated production facility can produce billions of strips annually, depending on the facility size and line configuration.

Semi-automated facilities offer a practical middle ground, particularly for new market entrants or LMIC-based manufacturers. In these setups, operators work with modular or standalone machines to process uncut sheets. This configuration reduces labour intensity while maintaining flexibility. The costing model developed by IQVIA estimates that semi-automated facilities offer potential cost savings of up to 30% compared with manual production.

A fully automated production line integrates all production steps, requiring minimal labour input, offering the highest consistency in product quality, and ensuring the lowest per-unit cost of strips. However, they also involve significant upfront CAPEX for equipment and facility design, and typically require sophisticated technical expertise to install, maintain/service, and operate.

3. COUNTRY SETTING

The geographic location of a BGMS manufacturing facility significantly influences the cost structure of production, with labour costs presenting one of the more prominent differences between HICs and LMICs.

According to data from the World Bank, average wages in HICs range from 20 to 30 times those in LMICs, depending on the employee's role and the country/region (World Bank Group, 2025). This wage differential makes manual and semi-automated production processes far more viable in LMIC settings. In contrast, HICs typically necessitate a high reliance on fully automated systems to maintain cost-efficiency. This model also depends on high production volumes to justify the high costs of fully automated systems. This reliance on full automation at scale raises important strategic questions about the future of global manufacturing dynamics, particularly as CGMs gain traction and diabetes trends evolve in HICs; a sustained shift away from glucose strip usage in these markets could challenge the volume base that underpins the cost advantage of large-scale producers.

However, while wages, which represent a significant component of COGS, and fixed operating expenses may be lower in LMICs, facilities still require a mix of skilled engineers and technicians to operate and maintain specialized machinery, alongside semi-skilled workers to monitor production lines, manage assembly and packaging, and handle storage logistics. For example, a typical facility might employ 25 staff consisting of the factory manager, 2 to 3 engineers, and the rest as machine operators or monitoring staff and packagers. Many of the respondents we interviewed reported that staffing was a challenge as the local markets in which they operated did not have a lot of workers who were skilled and knowledgeable about BGMS strip production. Unlike more common manufacturing sectors such as fast-moving consumer goods, where skilled workers can often be attracted or poached from competing firms, the niche nature of in vitro diagnostics production and quality management systems means that specialized skilled workers are scarce, making extensive, targeted training and capacity-building essential.

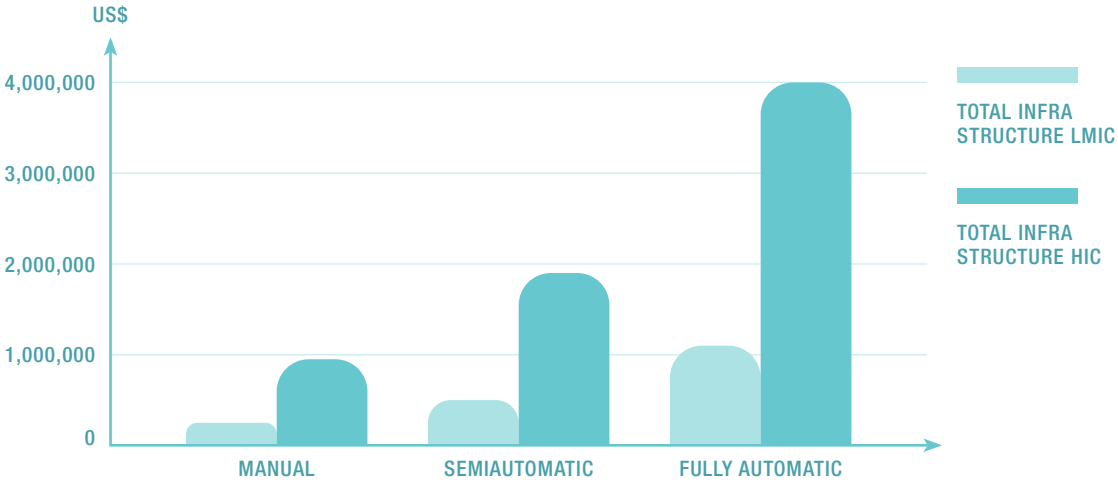
It is worth noting, however, that the big four manufacturers achieved significant economies of scale by combining high-volume, fully automated production lines with outsourcing to specialized contract manufacturers. While many of these contractors are based in lower-wage countries, this was not always the case. We did learn that of one of the big four manufacturers contracted a manufacturer in Japan, demonstrating that automation can make production cost-effective even in higher-wage settings by reducing the amount of labour input required per unit, thereby maintaining competitive pricing irrespective of the location.

Infrastructure costs also differ significantly between country settings. While the cost of specialized manufacturing equipment such as enzyme dispensers, bottling lines, or laminators is relatively consistent globally due to international sourcing, other CAPEX elements could vary widely. HIC facilities typically incur higher costs related to land acquisition, construction, cleanroom setup and utilities, which are all compounded by higher wages for skilled technical personnel.

Country setting (for production) also influences the costs of compliance and meeting regulatory requirements. In general, BGMS are typically classified as Class II in vitro diagnostic (IVD) medical devices and are subject to national regulatory registration in most countries. The process of registration often involves an initial one-time expense, followed by annual maintenance or renewal fees. However, beyond this registration, manufacturers must also comply with broader regulatory requirements that govern IVD manufacturing practices, including the implementation of a quality management system (QMS). This can be a significant barrier for new manufacturers, particularly in LMICs, where access to regulatory expertise and IVD-specific quality assurance professionals may be limited.

Beyond meeting national regulatory approval requirements, many manufacturers pursue internationally recognized certifications to enhance market credibility and build trust with end users, healthcare providers (HCPs), and procurement agencies. Standard facility certifications include ISO 9001 (QMS) and ISO 13485 (QMS specific to medical devices). In addition, ISO 15197 is often sought for BGMS products, as it specifies performance requirements and test procedures for systems used by patients for SMBG. Achieving these certifications not only supports compliance with international procurement standards, but also acts as a strong signal of the manufacturer's commitment to product quality and safety.

FIGURE 7 – Infrastructure costs by location and level of automation (Source: IQVIA data)



For broader market access, manufacturers may pursue:

WHO PREQUALIFICATION (WHO PQ) – In April 2024, WHO expanded its prequalification programme to include IVD devices for diabetes management. The initiative aims to enhance access to quality-assured diagnostics and many LMIC-based manufacturers pursue WHO PQ to facilitate procurement by United Nations agencies and global health programmes. However, at the time of writing this report, there were no known procurement mechanisms for glucose strips that had WHO PQ as a formal requirement.

U.S. FOOD AND DRUG ADMINISTRATION (FDA) APPROVAL – to enter the U.S. market and demonstrate compliance with stringent regulatory standards.

CONFORMITÉ EUROPÉENE (CE) MARKING – to indicate conformity with health, safety, and environmental protection standards for sale within the European Economic Area.

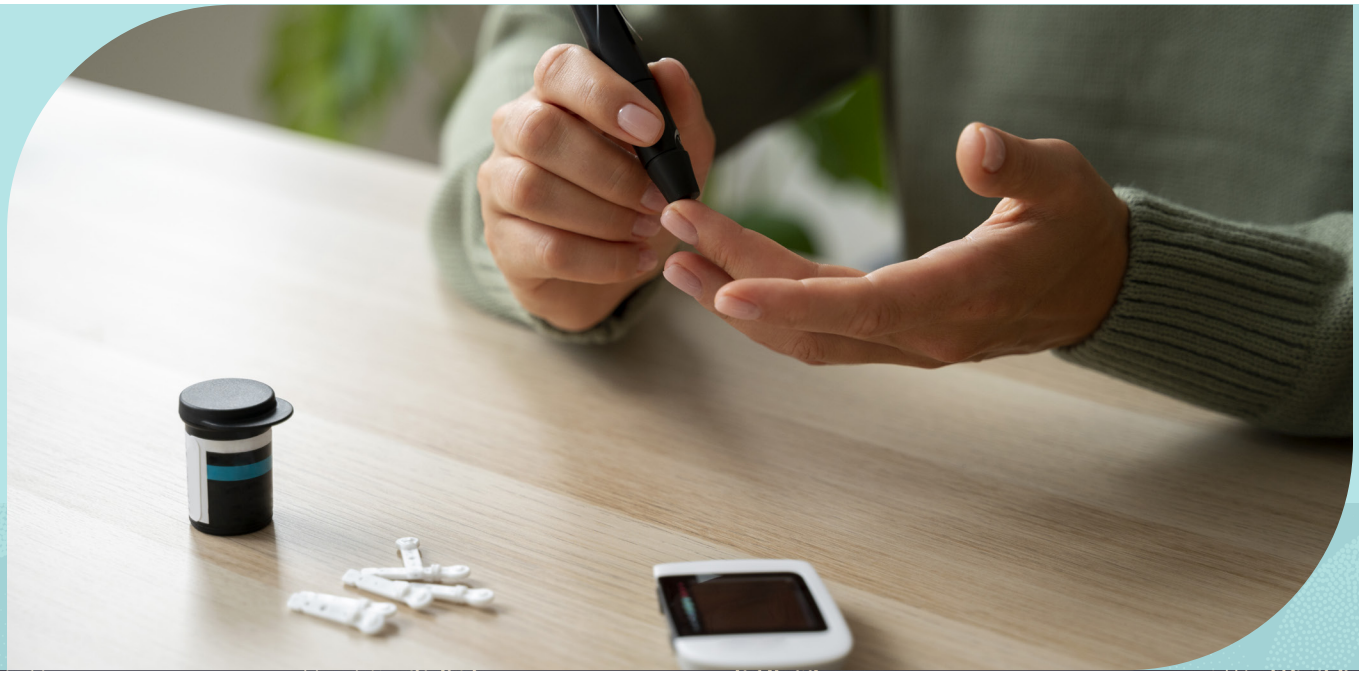


TABLE 2 – Comparative summary of BGMS manufacturing models (Source: FIND/IQVIA)

	END-TO-END MODEL (FULL MANUFACTURING)	SKD / UNCUT SHEET MODEL
CAPITAL INVESTMENT	High – requires large CAPEX for equipment, cleanroom, etc	Moderate – limited to final assembly, packaging and quality control lines
OPERATIONAL COMPLEXITY	High – full upstream and downstream processes handled in-house	Moderate – relies on ability to handle imported pre-treated components
SUPPLY CHAIN CONTROL	Full – allows tighter quality and inventory control	Limited – dependent on external suppliers for core materials
TIME TO MARKET	Longer – requires setup, validation, and regulatory approval	Faster – fewer setup steps
WORKFORCE NEEDS	Requires highly skilled engineers and larger workforce	More semi-skilled operators needed, however, this still requires upskilling engineers
SCALABILITY	Highly scalable immediately with infrastructure in place	Scalable in phases; can evolve to and end-to-end model with investment
COMPLIANCE BURDEN	High – full QMS and national + international standards apply	Lower (if sales are restricted to domestic, LMIC-based markets only)
FREIGHT & LOGISTICS EXPOSURE	Lower – less dependency on import of components	Higher – relies on imports; affected by customs, foreign exchange rates, logistics

While national registration fees are relatively modest, the costs associated with achieving and maintaining international certifications are significantly higher. For many manufacturers, especially in LMICs, these investments represent part of the broader learning curve toward establishing a sustained culture of quality. Aligning with international standards not only demands capital, but also long-term commitments to system strengthening, documentation practices, and technical capacity. Many of the largest LMIC markets, along with regional regulatory authorities, are progressively aligning their registration expectations and requirements with global benchmarks through harmonization efforts. This regulatory ramp-up makes early investment in quality systems a strategic imperative for future competitiveness.

Manufacturers in HICs are typically subject to more stringent regulatory requirements than LMICs, increasing overall compliance expenditures, as LMIC-based manufacturers often align production with local regulatory frameworks. However, those seeking to export products or supply international procurement agencies must invest in upgrading their facilities and processes to meet global standards, thereby incurring additional compliance costs over time.

Lastly, freight and logistics also contribute to the final cost structure. For facilities that depend on imported equipment or raw materials, shipping and custom duties can introduce additional financial and operational burdens. Understanding these regulatory and logistical cost drivers is essential for assessing the full feasibility of local manufacturing, before examining whether sufficient market demand exists to support sustainable operations in LMIC settings.

MARKET FOR BGMS TEST STRIPS IN LMICs

To fully assess the viability of local production, it is also necessary to understand demand-side dynamics. The sustainability of domestic manufacturing is contingent on whether sufficient and consistent demand exists to absorb production volumes. It is therefore equally important to examine who is buying the test strips, at what price, and under what conditions. Without a clear picture of market demand size, structure, and constraints, local manufacturing cannot be meaningfully evaluated for commercial or public health viability.

1. IN-COUNTRY DEMAND GENERATION

We found demand generation for BGMS strips to be limited, with national campaigns or programmes for diabetes screening and education being the exception, rather than the norm. For instance, Nigeria's Federal Ministry of Health planned a broad diabetes screening campaign in 2025 aiming to reach over 5 million people. This one-time campaign involved public procurement of test strips and temporarily boosted demand, though it remains uncertain if such efforts will continue in the long term.

In Indonesia, the government and provincial health authorities make recurring purchases for primary care testing, primarily through Jaminan Kesehatan Nasional (JKN), the national health insurance scheme, and in alignment with Tingkat Komponen Dalam Negeri (TKDN), a local content policy that incentivizes the procurement of domestically-produced health products through preferential tendering. However, volumes remain modest, and JKN does not currently cover blood glucose test strips for home use.

Of the countries surveyed, Algeria was the only country where strips were reimbursed. All insulin-dependent PLWDs receive unlimited reimbursement, while people with Type 2 diabetes are reimbursed for up to three vials (150 strips) per quarter. By comparison, Nigeria's National Health Insurance Authority (NHIA) does not cover strips for home use, and private insurers across all three countries typically exclude strips from their benefits packages. As a result, there is little financial incentive through insurance to encourage routine glucose self-monitoring, and out-of-pocket purchasing remains the dominant means of access.

Overall, the lack of insurance reimbursement or large-scale public distribution means most demand must be generated via the private/out-of-pocket segment, often driven by physician recommendations or consumer awareness campaigns by diabetes associations.

Most demand generation efforts are often led by non-government organizations (NGOs), patient groups, or the private sector. Diabetes associations in these countries (for example, local chapters of the International Diabetes Federation) conduct periodic awareness campaigns (e.g., around World Diabetes Day) that encourage testing, but these have limited reach. Some manufacturers and pharmacies run promotions such as free glucometers with the first purchase of strips to entice new users. These tactics can help initial uptake, but sustained growth remains constrained by affordability.

2. REGIONAL EXPORT OPPORTUNITIES

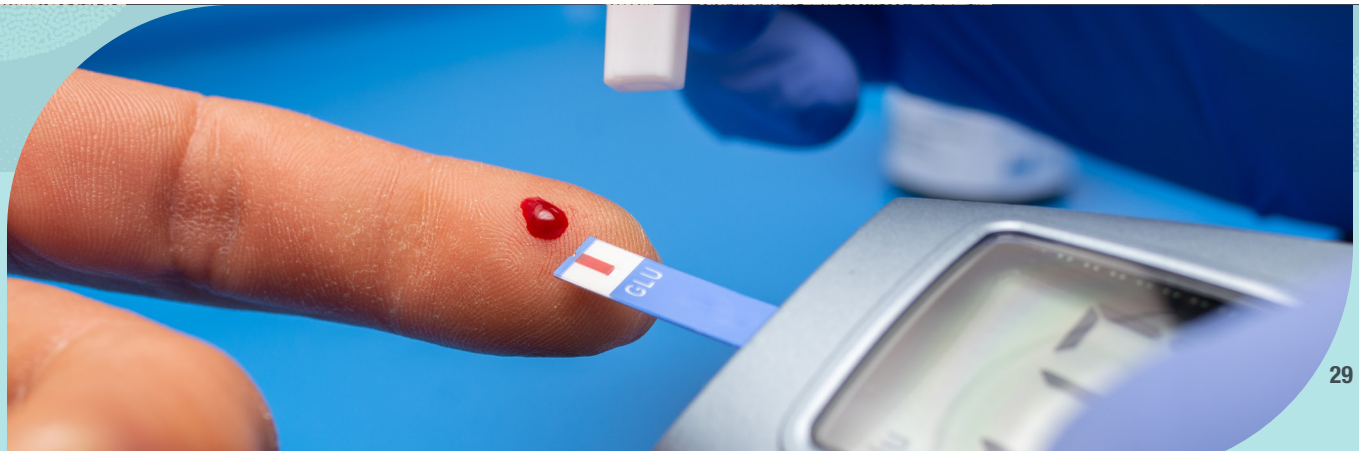
While domestic demand forms the foundation for local BGMS manufacturing viability, the ability to export to nearby countries can significantly strengthen the business, especially in LMICs with modest national market sizes. Many LMICs are part of regional economic communities that offer preferential trade terms, reduced tariffs, and harmonized regulatory frameworks. Leveraging these structures could help local manufacturers reach larger volumes, achieve economies of scale, and balance production risks across multiple markets.

Africa offers several examples. Nigeria and Algeria, for instance, are part of the African Continental Free Trade Area (AfCFTA), which aims to reduce trade barriers and harmonize standards across the continent. Nigeria also belongs to the Economic Community of West African States (ECOWAS), while Algeria is a member of the Arab Maghreb Union. These blocs present a strategic opportunity to export strips to neighbouring countries without facing the full burden of tariffs or duplicative regulatory requirements. For example, under ECOWAS protocols, goods produced within the region may qualify for duty-free trade if they meet rules-of-origin requirements (ETLS, 2021). In Southeast Asia, Indonesia's membership in the Association of Southeast Asian Nations (ASEAN) enables exports to countries like Vietnam, the Philippines, and Thailand, which also face growing burdens of diabetes and limited access to affordable test strips. The ASEAN Trade in Goods Agreement facilitates intra-regional trade with low or zero tariffs, while efforts are ongoing to harmonize health product regulations under the ASEAN Medical Device Directive.

In practice, however, implementation of such protocols remains uneven, and some non-tariff barriers persist, including inconsistent registration and regulatory procedures, customs delays, and quality assurance requirements that vary across borders.

Expanding export potential also depends on regulatory alignment and quality assurance. Many regional blocs are pursuing harmonization of IVD regulations, but in most LMIC regions country-by-country approval is still required. For local manufacturers to export at scale, they would likely need to pursue FDA approval, CE-marking or WHO PQ. These represent significant time and capital investments with no guarantees of resulting demand as BGMS strips are a tough and competitive market in the international landscape.

While regional export across economic communities such as ECOWAS, AfCFTA, and ASEAN presents a potential opportunity to expand market reach and unlock new sources of demand, practical barriers still remain. In reality, many countries within these blocs exhibit the same degree of fragmented procurement, regulatory variability, and limited public financing that manufacturers face in their domestic markets. Without harmonized registration pathways or pooled procurement mechanisms in place, entering these markets often requires navigating complex and duplicative processes. As such, while the regional trade frameworks offer long-term potential, they are not yet a viable strategy for near-term demand consolidation or scale-up for local BGMS manufacturers.



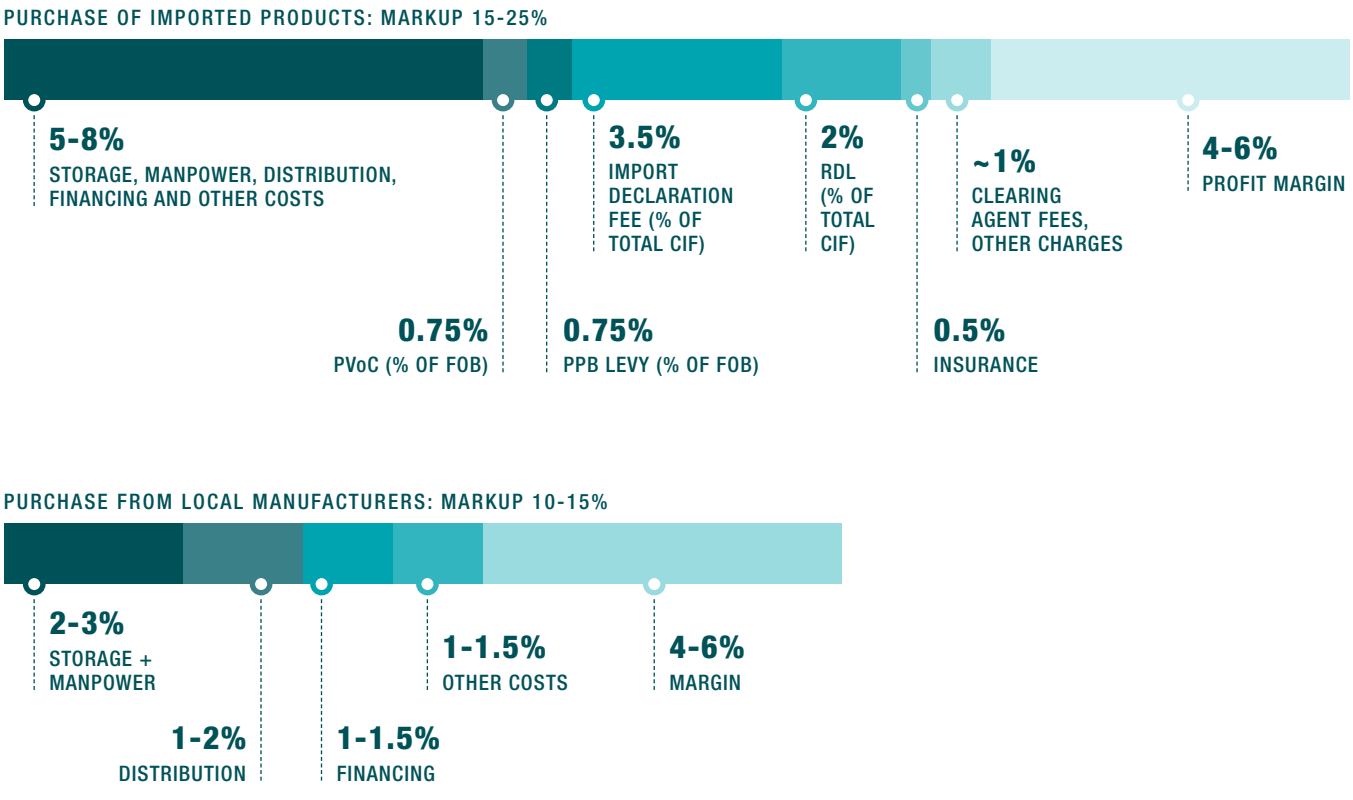
3. PRICING AND AFFORDABILITY OF BGMS

Affordability remains one of the most significant barriers to widespread and consistent use of BGMS strips in LMICs. Across countries surveyed during this study, BGMS strips were found to be relatively expensive when compared with average daily wages and household purchasing power.

Retail prices for test strips ranged from US$0.17 to US$0.76 per strip, with premium international brands such as Accu-Chek and FreeStyle consistently occupying the upper end of the range. For people living on just a few dollars per day, even spending US$0.30 per strip makes regular glucose monitoring financially unsustainable.

In the absence of price regulation or reimbursement schemes, fragmented and informal distribution systems contribute to wide pricing disparities both across and within countries. While global producers benefit from economies of scale, as BGMS strips are a high-volume, low-margin product manufactured in highly automated, efficient facilities, these cost advantages are often not reflected in final retail prices in LMICs. EIC surveys in Indonesia, for example, documented that test strips sold in some private pharmacies cost up to eight times more than those on online platforms. These discrepancies were largely attributed to multi-layered mark-ups across the value chain (i.e, importer, distributor, wholesaler, and retailer) each adding margins of 20–50% or more. Notably, pharmacies often apply mark-ups of 30–50% over the wholesale cost, incentivizing them to push higher-priced products where profit margins are more attractive. It is also possible that local pricing reflects a deliberate market positioning strategy. However, without visibility into the true nature of margin breakdowns across the supply chain, or the pricing approaches of international brands, it is difficult to draw definitive conclusions.

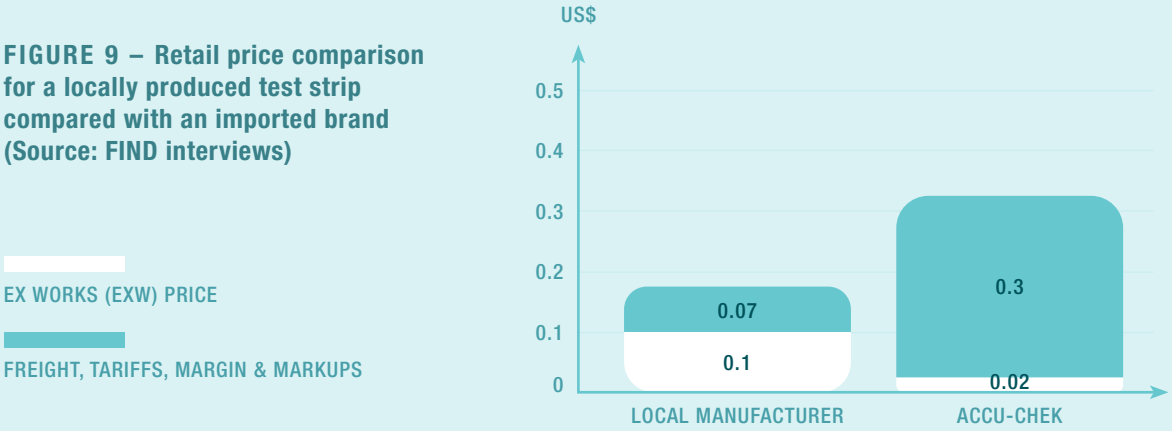
FIGURE 8 – Indicative cost breakdown of BGMS strips (Source: EIC, MOH 2021. Pricing of health products & technologies (HPT), (MOH Kenya, 2021), Kenya Pharmaceutical Industry Diagnostic Report 2020 (IFC World Bank Group, 2020)



These pricing dynamics are further confirmed by data from Health Action International (HAI) and the ACCISS Initiative (HAI; ACCISS, 2024), which conducted multi-country analyses on the affordability of essential diagnostic commodities. In Uganda, mark-ups along the private-sector supply chain exceeded 100%, primarily driven by distributor and pharmacy margins. In Peru, although the cost at import was lower, the retail price remained elevated due to similar value chain mark-ups. Even in China, where public procurement policies have helped reduce public-sector prices, the private retail market remained fragmented, with pricing varying substantially across provinces and pharmacy types.

A critical finding from the various sources of evidence across multiple settings is that lower manufacturer selling prices do not automatically translate into lower consumer prices. Instead, cost savings are often absorbed by intermediaries rather than being passed on to end users. Moreover, the lack of data on price tracking due to the prevalence of cash-based, informal sales makes it difficult to monitor or address pricing inconsistencies. In many markets, strips are sold in small quantities or single vials, which further complicates analysis of bulk pricing strategies and procurement efficiencies.

FIGURE 9 – Retail price comparison for a locally produced test strip compared with an imported brand (Source: FIND interviews)



4. BUYER PROFILES AND SUPPLY CHAIN STRUCTURE

Across most of the LMICs included in this analysis, the buyer landscape is dominated by private retail channels, with individual consumers paying out-of-pocket for the majority of purchases. The supply chain itself is multi-layered and fragmented, often involving several intermediaries before reaching the end user. Products are typically brought into the country by commercial importers, who sell to regional wholesalers or large pharmacy chains. These actors then supply smaller pharmacies, clinics, and other informal channels, particularly in rural and peri-urban areas. As a result, product availability and brand offerings can vary widely even within the same geographic region, depending on the distributor networks in place. This decentralization makes it difficult to ensure consistent pricing or product access and complicates efforts to monitor the flow of goods or plan for scale-up.

Shelf life is another key consideration in strip manufacturing and distribution. Strips contain biological reagents that degrade over time or under suboptimal storage conditions, affecting performance. Proper packaging, desiccant use, and clear expiration labelling are essential for ensuring strips remain effective until their stated end date. Shelf life also plays a strategic role in production planning, as manufacturers must align production volumes with demand forecasts to avoid waste from expired inventory, especially in markets with uncertain or fluctuating procurement cycles.

HCPs also play a significant role in influencing purchasing behaviour. Doctors, nurses, and pharmacists frequently advise patients on which glucose monitor to buy, which, in turn determines their choice of test strips. However, most purchases remain individual and uncoordinated, meaning there is little assurance that patients will continue to purchase the same brand of strips over time. This presents a specific challenge for local manufacturers, who must market their products to one clinic or pharmacy at a time unless they succeed in securing a major institutional buyer.

While EIC's survey data show that some high-traffic urban pharmacies can sell between 500 and 1,000 strips daily, and major distributors may move between 75,000 and 350,000 strips per month, test strips still represent a relatively small share of total pharmaceutical sales; typically between 5 and 24% of a pharmacy's revenue. Given this, retailers may have limited incentive to prioritize stocking or promoting strips.

In summary, the current buyer and distribution landscape is heavily reliant on fragmented, private-sector channels and out-of-pocket expenditure, with few incentives for coordination or scale-up. For local manufacturers, this environment poses real challenges to achieving market traction and building sustainable demand without significant public-sector engagement or policy support.

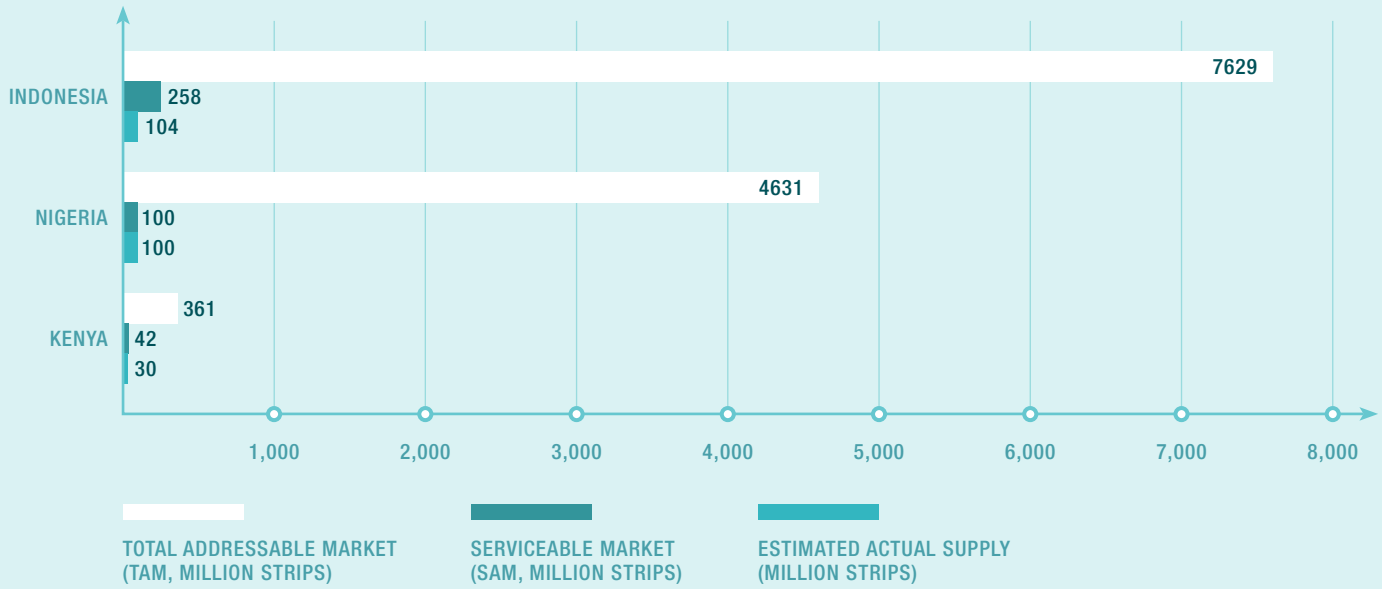
5. MARKET SIZING ACROSS LMICs

The market size for glucose test strips in LMICs remains substantially underdeveloped relative to the epidemiological need. According to modelling done by EIC's market assessment, the serviceable annual market, representing the estimated volume of strips currently in demanded via health systems, is approximately 260 million strips/year in Indonesia, 100 million/year in Nigeria, and 55 million/year in Kenya. In contrast, the total addressable market, which reflects the volume required if all diagnosed PLWD tested at recommended intervals, is estimated at over 3.3 billion strips/year for Indonesia, 1.5 billion/year for Nigeria, and nearly 400 million/year for Kenya. These estimates suggest that current usage in these countries accounts for only 2–10% of the potential need.

This testing gap has important implications. It signals a missed opportunity for achieving optimal diabetes control and points to the potential for future growth if access and affordability barriers are overcome. Most PLWD are currently unable to test as frequently as recommended due to high out-of-pocket costs, weak integration with public health systems, and limited availability of strips in some settings.

Apart from Algeria, where imports of BGMS have been banned in favour of local production, most LMICs remain heavily reliant on imports to meet local demand. In Indonesia, EIC data indicates that approximately 85% of strips are imported (by volume), while in Nigeria, nearly all strips on the market are imported aside from small volumes produced by a single local manufacturer. These estimates vary depending on the analysis methodology and assumptions used, but there is general agreement across sources that the markets are far from saturated. As diagnosis rates improve, testing recommendations are more widely adopted, and test strips become more affordable, demand for LMICs is likely to expand considerably.

FIGURE 10 – BGMS market potential versus actual supply (Source: EIC)



6. CONSUMER TRUST/BRAND PREFERENCE

Consumer trust and brand preference is a critical element when evaluating the demand landscape for BGMS strips. Historically, patients and HCPs in LMIC markets gravitate towards well-known international brands for glucose meters and strips, largely because of their perceived reputation for accuracy and reliability. Even when cheaper alternatives of similar quality exist, many consumers still prefer a trusted brand, which poses a significant challenge for lesser-known brands.

For example, survey data collected from Kenya via Premise (Table 3) indicate a trade-off between trust, affordability and availability. Respondents perceived local brands to be affordable and available, but significantly less trustworthy than imported options.

TABLE 3 – Perceptions of BGMS strips in Kenya (2024 Survey Data)

	DOMESTIC (AFRICAN)	WHITE LABEL	INTERNATIONAL
TRUSTWORTHY	85%	90%	97%
AFFORDABLE	91%	67%	54%
AVAILABLE	75%	53%	53%

TABLE 4 – Perceptions of BGMS strips in Brazil (2024 Survey Data)

	DOMESTIC (LATAM)	WHITE LABEL	INTERNATIONAL
TRUSTWORTHY	91%	68%	89%
AFFORDABLE	93%	69%	72%
AVAILABLE	74%	58%	74%

However, survey data collected from Brazil (Table 4) painted a different picture, indicating a more balanced perception of trustworthiness and availability between domestic (Latin-America [LATAM]-manufactured) and international brands, despite the absence of local BGMS strip manufacturing in either market.

This divergence suggests that trust in domestic or regional brands is not solely dependent on local production, but is shaped by the broader maturity of regional manufacturing ecosystems and the historical presence of recognizable regional brands in the market. In Brazil, proximity to established LATAM manufacturers may have contributed to higher consumer confidence, whereas in Kenya, the domestic label may be associated with newer or less-established products.

These findings underscore that affordability and availability alone are insufficient to drive consumer uptake of locally positioned BGMS strips. Building and sustaining trust, through validated quality standards, partnerships with national diabetes associations, endorsements from HCPs, and clear branding strategies, is critical. For example, in Algeria, consumer hesitation toward newly-localized products was only overcome through sustained efforts to demonstrate quality equivalence with imported brands.

In summary, achieving high consumer acceptance for locally manufactured BGMS strips will require more than just cost advantages. A coordinated approach combining quality assurance, regulatory recognition, trusted endorsements, and investment in brand credibility will be essential if local manufacturers wish to compete with established international brands and drive long-term uptake.

7. IMPORT DEPENDENCIES IN LOCAL MANUFACTURING

Local manufacturing is heavily dependent on imported inputs. These inputs, which are priced in US dollars, introduce a susceptibility to foreign exchange risk as well as evolving tariff and import duty policies. For example, the Nigerian Naira has depreciated by approximately 345% against the US dollar over the past 5 years (Trading Economics, 2025). As much as this level of depreciation, which substantially increases the cost of importing fully finished strips, should present a clear advantage for local manufacturing, this is not immediately the case. While local manufacturers may avoid some of these fully imported costs, their COGS still remain vulnerable due to continued reliance on imported materials.

Despite this, cost mitigation is still possible. Manufacturers that source packaging materials or distribution services locally can reduce exposure to global supply chain shocks and control downstream costs. These efficiencies are not sufficient to erase the structural disadvantage at scale, but they can help improve price stability. Additionally, working with domestic logistics providers may help to control distribution expenses and improve affordability for end users.

A National Success Story in Local Diagnostics Manufacturing

Algeria offers a compelling example of how coordinated policy action and aligned private sector response can accelerate domestic production of diagnostics. By the late 2010s, diabetes had become a major public health concern, with over 13 million vials of glucose test strips consumed annually, mostly imported, and dominated by a handful of multinational brands.

Algeria already had foundational elements in place that laid the groundwork for the establishment of a local manufacturing ecosystem: blood glucose test strips were reimbursed by social security, which created strong baseline demand. However, this reimbursement was entirely unrestricted, leading to unchecked consumption and a bloated import-dependent market. The result was a rapidly escalating financial burden on the state which was effectively covering the costs of imported strips at a large scale without pricing controls or volume caps. In addition, existing laws such as the 49/51 rule required foreign companies to partner with local entities as a prerequisite for market access and localization, further supporting domestic industrial growth.

In 2016, Algeria's Ministry of Health gave a 2-year notice of its intention to suspend import licenses for finished products by 2018, signaling a strategic pivot toward local manufacturing. At the time there were no domestic manufacturers of blood glucose strips, and the 2-year localization window was given to allow international companies to set up domestic production, enabling a smooth transition by the time restrictions were enforced. This was accompanied by fiscal incentives and foreign ownership limits to encourage partnerships.

Algeria also amended its procurement and reimbursement systems to correct a bloated market and create stable demand. The national social security fund introduced restrictions on the reimbursement policy for test strip use. Insulin-dependent PLWD had unlimited reimbursement preserving high-demand segments, while reimbursement for people with type 2 diabetes was capped at three vials per quarter. While the Ministry of Health's decisions raised concerns about potential shortages, the government clearly signaled its intention to prioritize companies capable of manufacturing domestically. These efforts, combining trade restrictions, investment incentives, ownership caps, and health system reforms, transformed Algeria from a country dependent on strip imports to one with several domestic manufacturers by 2019. This case illustrates how coordinated policy across industrial and health sectors can reshape local manufacturing landscapes and secure sustainable access to essential health products.

One company, Vital Care SPA, emerged as a leading player. Founded in 2016 in response to the government's directive, it launched its BGMS through technology transfer agreements and gradually scaled up from partial to full-process manufacturing. Within three years of the 2018 import suspension, Vital Care's market share grew from 13% to over 51%, making it Algeria's largest supplier of test strips.

Vital Care invested not only in production capacity, but also in quality systems and knowledge transfer. It obtained ISO certifications, initiated clinical studies, built training programmes in partnership with regulators and academia, and advocated for scaling the quality standards of domestically-produced products. Today, it produces more than 7 million vials annually and covers a large portion of Algeria's BGMS strips needs.

The Algeria–Vital Care experience illustrates how policy clarity, stable demand, and industrial capability can converge to shift diagnostic supply from import dependence to local resilience.

Charting a Path Forward: Unlocking Opportunities in Indonesia's Evolving Diagnostic Landscape

Indonesia's journey toward localizing BGMS is shaped by a complex mix of policy, market dynamics, and industrial capacity. The government's long-standing TKDN policy, which requires a minimum percentage of domestic content in products purchased by the public sector, was a key driver behind the development of local manufacturing. Additionally, the high burden of diabetes and its link to costly complications helped elevate the importance of BGMS in national health agendas, including its inclusion in public screening programmes such as PROLANIS (Program Pengelolaan Penyakit Kronis).

Several domestic manufacturers have since emerged, including PT Cahaya Hasil Cemerlang (PT CHC) and PT Standard Biosensor Healthcare Indonesia (PT SDB), both of which reflect differing strategies and challenges. PT CHC operates a fill-and-finish model using imported uncut strips and aims to gradually integrate upstream processes through technology transfer agreements. PT SDB, by contrast, leverages international expertise and local production capacity to serve the public sector through Indonesia's e-catalogue procurement system. Both companies benefit from TKDN-based incentives that prioritize local producers in public tenders, but still face intense pricing pressure from global brands and low-cost imports from India and China.

Despite Indonesia's regulatory push and clear public sector demand, the path to sustainable scale remains difficult. Companies must navigate decentralized procurement cycles, cost constraints, and consumer bias toward international brands. While public procurement provides guaranteed volumes, it also limits growth potential due to infrequent tendering and capped pricing. In addition, quality expectations, regulatory hurdles, and the challenges of expanding into the private market make it difficult for firms to recover high upfront capital investments. Domestic firms also struggle with input supply chain limitations, labour costs (especially in Jakarta), and underutilization of production lines during off-cycle periods. As a result, manufacturers have to consider expanding into the production of other higher-margin diagnostics, as well as export markets, to ensure their survival in a highly competitive space.

Nevertheless, the case of Indonesia demonstrates that public health policy and industrial policy can work hand-in-hand to nurture a domestic manufacturing sector. Continued investment in technical capacity, regulatory alignment, and market development, especially through regional procurement, export readiness, and improved demand forecasting, will be critical in realizing the full potential of BGMS localization.

Navigating Adversity to Champion Self-Reliance; Colexa Biosensor's Journey as a Pioneer in Sub-Saharan Africa

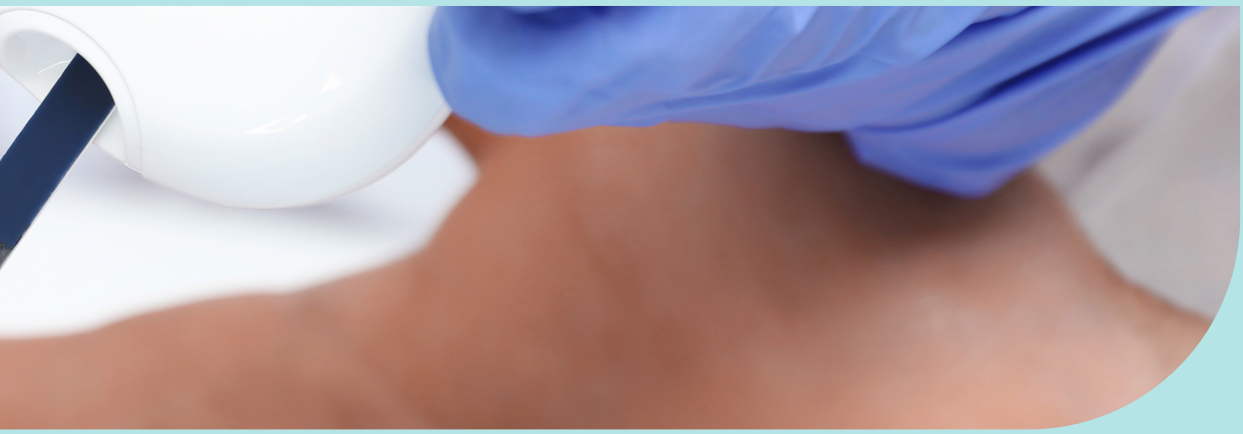
Colexa Biosensor – a subsidiary of Codix Pharma – is the first and only manufacturer of BGMS strips in Sub-Saharan Africa. Founded in 2023, the company emerged from the founder's deep conviction that Nigeria and the broader region needed to move away from dependency on imported diagnostics. Leveraging experience as a distributor of BGMS strips, Colexa established local production capacity.

Despite achieving the necessary international certifications and navigating the knowledge and skill gap to effectively run manufacturing operations in Nigeria, Colexa has faced structural challenges. Chronic power outages have necessitated heavy investments in independent power production systems, including diesel generators and solar-inverter systems to maintain the environmental conditions necessary for BGMS strip manufacture. The economies of local production are further constrained by long lead times for the delivery of critical raw materials, rigid shelf-life timelines, and the disconnect between dollar-denominated input costs and naira-based revenues; challenges familiar to other manufacturers operating in Nigeria.

In a market dominated by Accu-Chek and saturated with low-cost imports from China and India, Colexa is also trying to translate production capacity into financially sustainable volumes. The company in their sales strategy focuses on direct-to-patient channels, aiming to build a user base that will generate recurring demand.

Colexa also has its sights set on the lofty export market. The company has had to navigate the complex registration requirements for market access into each country, with the help of the West African Health Organization and National Agency for Food and Drug Administration and Control. To further strengthen its regulatory credibility, Colexa is exploring pursuing CE-marking. They are also exploring other channels to maximize access to strips and utilization of their manufacturing capacity.

Despite the challenges faced, the business case for Colexa remains strong. With an estimated 10.2 million PLWD (60% of whom are still unaware of their status), recent initiatives by the Nigerian Federal Government to raise awareness of diabetes should position Colexa to become the model for self-reliant, resilient manufacturing within the region.



EVALUATING THE FINANCIAL VIABILITY AND SUSTAINABILITY OF LOCAL PRODUCTION

Previously, we explored the feasibility of local BGMS strip manufacturing and how it could reduce unit costs by avoiding import-related expenses such as international shipping, duties, and mark-ups along the value chain. However, lower production costs alone do not ensure long-term commercial viability.

This section evaluates whether local manufacturing models can achieve sustainable operations under realistic market conditions. A key consideration is whether manufacturers can produce BGMS strips at a cost low enough to compete with imported alternatives, while still covering fixed and variable costs, servicing capital investments, and maintaining operations over time. Through financial modelling and context-based assumptions, the analysis examines whether domestic production provides lower retail prices and greater price stability, particularly when foreign exchange volatility and global supply disruptions are considered. We also investigate whether manufacturers are likely to reach the scale needed to reduce unit costs through economies of scale, and what role demand aggregation or policy support may play in making operations sustainable.

The findings presented here aim to offer a practical perspective on the commercial feasibility of local manufacturing in LMICs, drawing from real-world inputs and projected scenarios.

1. FINANCIAL VIABILITY AND THE SUSTAINABILITY OF LOCAL PRODUCTION

While local manufacturing can reduce the retail price of BGMS strips by avoiding import-related costs, the COGS (and in some cases, ex-works prices) offered by large-scale global producers and other mid-tier companies often remain significantly lower.

However, evidence suggests that local manufacturing models can yield competitive end-user prices, particularly when supported by policy. In Algeria, for example, targeted import substitution policies led to the suspension of import licenses for BGMS strips. This incentivized domestic production, allowing local manufacturers to enter the market and scale operations. As a result, retail prices fell by 33%for end users. A Korean supplier similarly reported that by providing uncut sheets to a regional partner (in an unspecified country) who managed final production and distribution within the country, the local seller was able to offer BGMS strips at a lower price than would have been possible through direct importation.

Nevertheless, having a lower market price alone does not determine the viability of local production. In LMICs where the market for BGMS strips is dominated by out-of-pocket spending and little public funding, the volume of demand is often too low to justify or sustain a manufacturing operation over time.

This presents a critical paradox: although local production can yield more affordable pricing at the point of sale, manufacturers may still struggle to achieve the volume of sales necessary to break even or reach sustainable scale. To penetrate the market and compete with

TABLE 5 – Comparative Assumptions for DCF Modelling: Commercial vs Public Procurement Scenarios

FEATURE	SCENARIO A: COMMERCIAL MODEL	SCENARIO B: PUBLIC PROCUREMENT MODEL
MARKET POSITION	New entrant competing with multinationals in a private market	New entrant anchored by coordinated government policies for procurement
PRODUCTION SETUP	Semi-automated line using uncut enzyme-coated sheets	Same technical configuration as Scenario A
MARKET SPLIT	100% Private Market	70% Government procurement 30% Private Market
INTEGRATION WITH HEALTH SYSTEM	No alignment with public health channels	High; public sector programmes drive uptake and distribution
REVENUE STRATEGY	Aggressive sales growth strategy with higher sales and marketing costs (as a percentage of revenue). No government support	Government-anchored, more predictable volume uptake through procurement commitments and reimbursement mechanisms
VOLUME DRIVERS	Brand marketing, HCP influence, and out-of-pocket affordability	Procurement contracts and integration into health programmes
COST FACTORS INCLUDED	Labour, utilities, import duties, packaging, distribution	Labour, utilities, import duties, packaging, distribution
PRODUCT TYPE	Standard GOx strips compatible with common meters	Standard GOx strips compatible with common meters

established brands, manufacturers must keep prices low, but given the limited size of most LMIC markets, these low prices rarely generate sufficient volume or high-enough margins to reach financial sustainability. Our conversations with manufacturers in Nigeria and Indonesia highlighted this challenge, and even with Vital Care's success in Algeria, the company noted that early market traction was difficult even with local production advantages and that a decisive shift only occurred after import restrictions and public reimbursement created consistent, high-volume demand. Without the presence of large institutional buyers, pooled procurement mechanisms, government support and subsidies, or the combination of all of the above, a local manufacturer would have to balance material resource planning with scattered, unpredictable private sales.

To further examine this challenge and validate the conclusion that scale and thus financial sustainability is dependent on demand consolidation, we developed a DCF model simulating two scenarios for a hypothetical local manufacturer operating in a "median-profile" LMIC context. Median-profile in this context meant a representative country that reflected average characteristics in terms of population size and diabetes burden, which we also validated against our observations in the countries we studied.

In Scenario A, the model simulates a conservative growth pathway, where sales volumes start small and only gradually increase. In the first 2 years, no significant revenue is generated. Even in years 3 and 4, volumes remain low compared with typically requirements for sustained industrial operations. By year 5 the revenue generated is still insufficient to cover both fixed and variable costs, let alone recoup the initial investment.

Several issues therefore emerge for the manufacturer in this scenario. First, the inability to grow revenue to cover fixed costs places a heavy financial burden on early-stage operations. Second, the costs of inputs, sales and marketing expenses, meter subsidies, and working

capital requirements also weigh down the cash flow of the company.

The model projects an NPV of US$2.66million over 5 years, with no break-even point. The internal rate of return is not calculable because the project does not generate any net positive cash flow that outweighs the upfront investments. NPV refers to the sum of all expected future cash flows (both income and expenditure), adjusted to reflect their value in present day terms. A negative NPV indicates that the business is expected to incur more costs than it generates over time, while cumulative NPV represents the total net loss or gain over the modelling period, taking into account the time value of money. This essentially means that the operation continues to burn cash through the entire 5-year period. In practical terms, this scenario demonstrates that with low sales volume assumptions, high fixed costs and no external support, local strip manufacturing is not financially viable.

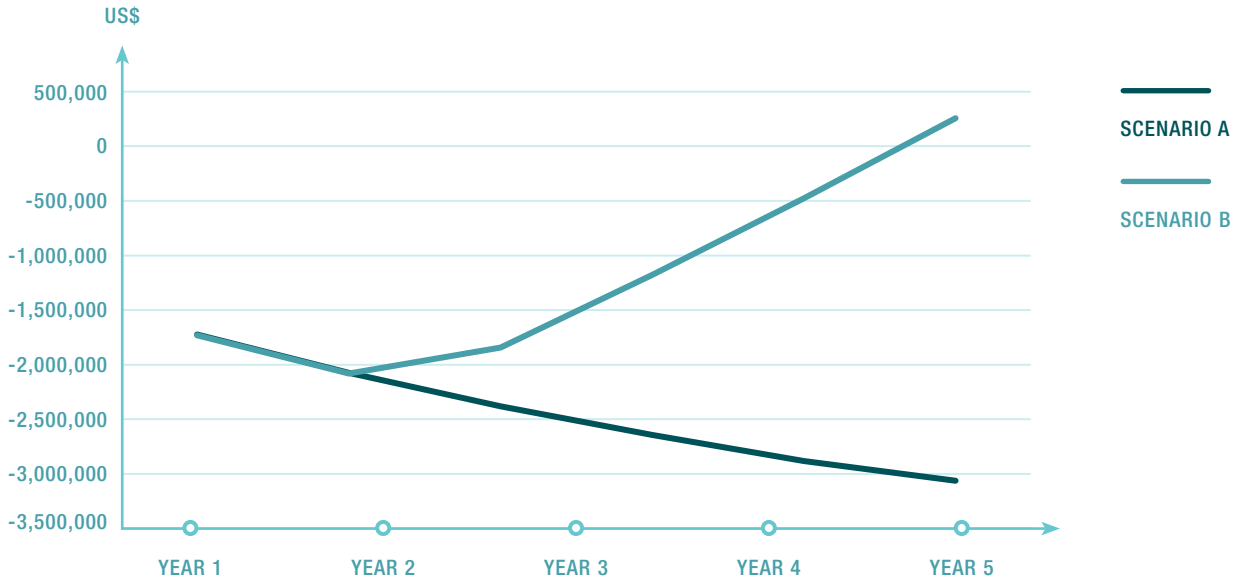
Scenario B reflects a more optimistic but still grounded pathway. The growth trajectory modelled here is more in line with what would be expected if the manufacturer had secured long-term procurement contracts or had strong national demand driven by public health programmes or subsidies.

In this scenario, although fixed costs remain the same, the per-unit cost efficiency improves dramatically due to economies of scale. Variable costs rise, as expected, with increased production, but revenues grow even faster. The model also assumes that sales and marketing expenses, along with working capital needs, increase in proportion to revenue at 10%each. Even with these growing expenses, the operation begins to generate positive free cash flow starting in year 2, with strong gains in years 4 and 5.

The key result is a modest, but positive, NPV and IRR value with the operation breaking even by year 5. This shows that under the right conditions, such as stable high-volume demand and access to financing, local manufacturing can be financially sustainable. Importantly, this scenario does not require large price increases; more important is the ability to produce volumes that market demand can absorb.

In summary, financial modelling shows that consistently low unit costs are only feasible at scale and often depend on some form of public-sector involvement, because relying solely on private demand is unlikely to bring prices down or fully cover production costs.

FIGURE 11 – Projected Cumulative NPV Under Commercial vs Public Procurement Scenarios



	NPV	IRR
SCENARIO A	~US$-2.66m	Incalculable
SCENARIO B	~US$220k	18.68%

2. MODEL LIMITATIONS AND REAL-WORLD CONSIDERATIONS

As with all analyses, it is important to consider the limitations of the modelling approach and how model assumptions differ from real-world manufacturer behaviours:

PRODUCT MIX

The model treats BGMS strips as a stand-alone product line from a hypothetical pure-play BGMS manufacturer. In reality, large manufacturers often have a broader product mix that can cross-subsidize or complement the costs, as well as the sales, of strips. For example, the companies that we visited had diverse diagnostics portfolios which allowed them to spread the costs of production across product lines, as well as balancing out operational profitability with higher-margin or faster-volume products.

BGMS strips are also sold in a variety of packaging that allows the manufacturer to charge higher costs on a per strip basis, for instance, costs will differ if strips are sold in packs of 25 or individually in their own foil packs.

IN-COUNTRY MARKET DYNAMICS

The model assumed a certain efficiency from the deployment of capital expenditure, to the start of production, through to sales. Actual manufacturing facility preparations and operations typically face a learning curve, with manufacturers facing initial low yields and inefficiencies leading to higher levels of material wastage. Staffing productivity is often lower or mismatched until experience is gained as the new entrant company learns how to penetrate an established market. Additionally, the regulatory agencies we spoke to mentioned that many companies would benefit from technical assistance and guidance with product registrations, as it was often observed that companies had to make multiple dossier submissions before the company had all the appropriate and correctly filled documentation. It is also well-known that LMIC markets have an affinity for foreign-made products. Having to navigate the learning process, in addition to aggressive sales and marketing strategies to encourage brand switching in a market where there is a domestic preference for foreign brands, would raise the true COGS above the modelled US$0.10 in the early phase. Also, the company would have to bear the costs of meter seeding as part of the costs of effective customer acquisition.

ASSESSING ACCESS OUTCOMES OF LOCAL MANUFACTURING TO END USERS OF BGMS STRIPS

Improving access to BGMS strips requires more than localizing production. This section considers whether local manufacturing can be meaningfully enhanced by examining five critical dimensions, adapted from USAID's Healthy Markets for Global Health: A Market Shaping Primer. These dimensions, often referred to as the "5A's of Market Characteristics" are:

Affordability	Availability	Assured quality	Appropriate design	Awareness

By triangulating the financial modelling results, field findings, and access pillar analyses, the report provides a directional assessment of the potential for local manufacturing to influence the cost and availability of BGMS strips in LMICs.

1. AVAILABILITY (SUPPLY RELIABILITY AND LAST-MILE REACH)

Local manufacturing can support more stable and responsive supplies by shortening production and delivery timelines. In Algeria, for example, stakeholders reported a noticeable reduction in public pharmacy stockouts after local strip production began, due to quicker replenishment times compared with the long lead times of imported strips. Similarly, in Indonesia, one manufacturer reported the ability to fulfil emergency hospital orders within days, demonstrating improved responsiveness and continuity of supply.

However, last-mile reach remains a persistent challenge. International brands typically concentrate their distribution in urban areas with higher purchasing power. Local manufacturers may be better positioned to understand and navigate underserved areas, yet without public support, reaching rural or remote populations remains commercially unviable. In Nigeria, local distributors cited poor rural coverage from global brands, yet also acknowledged the costliness of expanding distribution networks without subsidies or guaranteed public procurement. In short, while local production may improve national availability, last-mile delivery often requires public-private partnerships or health system alignment.

2. AFFORDABILITY (END-USER PRICE)

Affordability remains a major barrier to access, even for locally manufactured BGMS strips. In the absence of subsidies or pricing regulations, test strips made locally and sold through private channels may still remain out of reach for people with low-incomes. For example, a vial of 50 locally made strips priced at US$0.17 per strip will still cost around US$8.50, an unaffordable expense for many PLWDs in LMICs, particularly when combined with the cost of other medications and supplies.

Our analysis showed that while local production can reduce some upstream costs such as import duties and freight costs, final retail prices depend heavily on downstream mark-ups and distribution models. Without targeted demand-side measures such as insurance coverage, government-supported programmes, or bulk procurement subsidies, affordability for the end user is unlikely to improve significantly through local manufacturing alone.

3. APPROPRIATE DESIGN (PRODUCT SUITABILITY AND INTEGRATION INTO HEALTH SYSTEMS)

Locally manufactured BGMS strips must not only meet the relevant quality standards, but also be integrated into national health systems to be truly accessible. Countries that include test strips in their essential diagnostics lists or procurement plans are more likely to ensure consistent supply and equitable access. In Algeria, locally made strips were included in the public supply chain and reimbursed by the national health insurance system for patients with insulin-dependent diabetes. This institutional integration directly contributed to their availability in public pharmacies and their broader usage.

By contrast, in countries like Nigeria, the NHIA does not cover SMBG test strips, limiting their use to those who can pay out-of-pocket. Locally produced products can only be transformative if supported by policy measures that integrate them into essential services and financing mechanisms.

4. ACCEPTABILITY (TRUST AND USE)

Consumer trust in locally produced BGMS strips varies across markets. In general, users tend to favour internationally recognized brands due to the perception of a difference in quality, accuracy, and reliability. Interviews conducted by EIC in Indonesia and Nigeria revealed scepticism about the accuracy of lesser-known or generic brands, even when priced lower, with pharmacists and HCPs often echoing these concerns and preferring to stock familiar brands.

That said, acceptability can be improved over time through quality assurance, regulatory endorsements, and targeted provider engagement. Building professional and public trust in locally produced BGMS strips will require investment in quality control, strong branding, and alignment with clinical protocols.

5. AWARENESS (DEMAND GENERATION AND HEALTH-SEEKING BEHAVIOUR)

The potential for local manufacturing to improve access to BGMS strips is also limited by low awareness of diabetes management tools and inconsistent testing behaviour. Many PLWDs are either undiagnosed or unaware of the need for regular glucose monitoring. Even when strips are available, usage remains low without concurrent investment in health education, patient support, and provider training.

Demand generation activities such as Nigeria's 2025 national screening campaign can boost short-term uptake, but sustainable increases in strip usage depend on embedding self-monitoring guidance into care protocols and making strips routinely available at affordable prices. Local manufacturers can play a role by collaborating with health systems, NGOs, or pharmacy networks to promote awareness and educate users, but this typically falls outside their commercial scope.

Local manufacturing alone is not a silver bullet for BGMS strip access unless accompanied by broader measures in the health system. Specifically, local production was expected to improve certain access dimensions but would not automatically translate into affordability or widespread use unless strips are included in public programmes or made affordable to end users (e.g., via subsidies or insurance reimbursement schemes).

CHALLENGES TO SUSTAINABLE LOCAL MANUFACTURING

During the course of our study, we identified nine key barriers to sustainable local manufacturing of BGMS strips that we grouped into three distinct categories:

1. POLICY AND REGULATORY CHALLENGES

- **Fragmented and complex regulatory requirements:** Lack of harmonization, duplicative approval pathways, weak understanding of regulatory pathways
- **Weak enabling environment and incentives:** Limited tax breaks, absence of local preference schemes
- **Weak regulation enforcement and presence of unregulated products:** making it difficult for quality-assured products to compete on price, especially those moving through formal procurement channels

2. OPERATIONS AND SUPPLY CHAIN CHALLENGES

- **Raw material availability and resource planning:** Reliance on imported inputs with unpredictable lead times and price volatility from FX exposure; restrictive product shelf lives further complicate production planning
- **Access to financing:** Limited funding for capital expenditures, working capital, R&D.
- **Technical expertise and high-quality manufacturing capability:** Gaps in quality systems, automation, and specialized skills

3. MARKET AND DEMAND SIDE CHALLENGES

- **Insufficient and fragmented consumer demand:** Low testing volumes, Big 4 dominance & absence of pooled procurement result in a small-scale, unpredictable markets
- **Low integration into national health programs:** Strips not routinely reimbursed or included in countries diagnostics schemes
- **Increased testing does not always lead to predictable demand:** Without volume guarantees or long-term procurement commitments, higher test uptake will not necessarily create demand stability

FIGURE 12 – Barriers to scaling local BGMS manufacturing

Policy and Regulatory Challenges

In many LMICs, the regulatory landscape for medical diagnostics remains fragmented, with overlapping, duplicative processes and limited regional harmonization. Market entry often requires multiple product registrations and approvals across different regulatory bodies, with limited guidance and inconsistent timelines. These complexities increase transaction costs for manufacturers and disproportionately impact small- and medium-sized local enterprises with limited regulatory capacity.

Furthermore, mechanisms to incentivize local manufacturing remain underutilized. While some countries have adopted policies aimed at promoting domestic manufacturing, such as tax exemptions or preferential procurement schemes, these measures were not observed to in many LMICs.

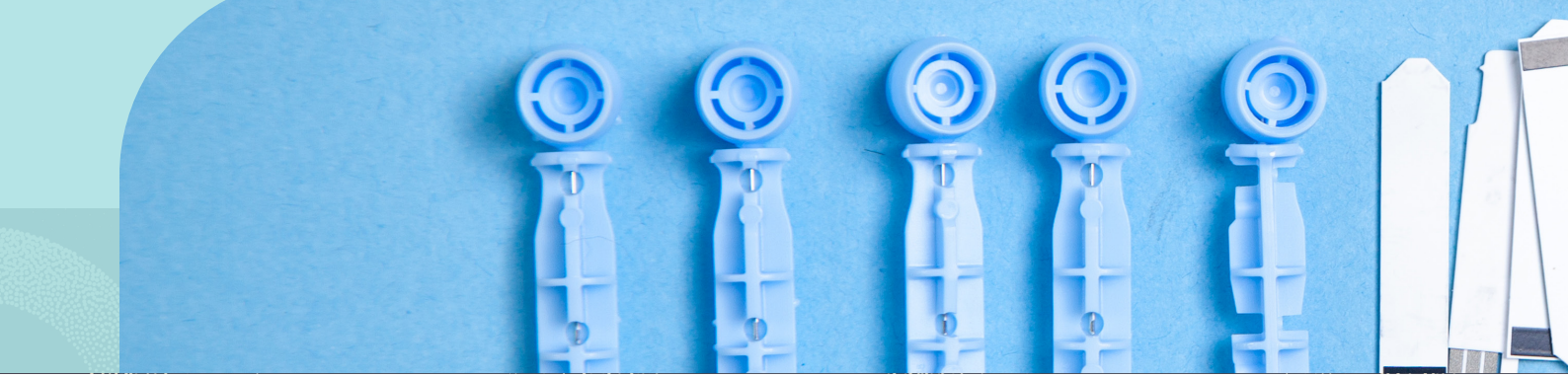
Quality assurance and post-market surveillance systems also remain underdeveloped in several LMICs. The weak enforcement of existing regulatory requirements allows the continued entry and circulation of low-cost, substandard, and sometimes unregulated BGMS strips. These products, often imported through informal channels, are able to underprice quality-assured locally manufactured alternatives, thereby distorting the competitive landscape.

Overall, these factors undermine the business case for compliant local BGMS strip manufacturing. Producers investing in Good Manufacturing Practices and regulatory compliance are not adequately protected or rewarded in the market. Without coherent policies that link regulatory oversight, quality assurance, and procurement to support local industry, structural barriers to sustainable local production will persist, limiting progress toward improved access to safe and affordable diagnostics.

Operation and Supply Chain Challenges

Local manufacturers of BGMS strips face a complex array of operational and supply chain constraints that significantly undermine their cost-efficiency, production capacity, and overall sustainability. One of the most persistent challenges is the high dependency on imported raw materials. Essential materials such as enzyme-coated sheets, conductive substrates, adhesives, electronic components, and specialized packaging are rarely available locally and must be sourced from international suppliers. This dependence exposes manufacturers to volatile foreign exchange markets, long procurement lead times, and rigid MOQs that are often misaligned with current production volumes and domestic market demand. For example, we found emerging manufacturers that said they were required to purchase enzyme-coated strip sheets in bulk quantities far exceeding their production needs or what their market could absorb. This resulted in excess inventory, elevated storage costs, and an inability to scale production responsively to real-time demand, further compounding working capital pressures.

Access to affordable financing remains a significant barrier to the growth and modernization of local manufacturing. Capital investments required for automation, cleanroom infrastructure, and robust quality control systems are substantial and often beyond the reach of most small-scale manufacturers without external support. While a few entrepreneurs have successfully mobilized private financing, such cases were the exception rather than the norm. In some LMICs such as Nigeria, prevailing commercial interest rates have recently approached 40% per year. These high rates, combined with restrictive loan terms, make borrowing prohibitively expensive and significantly limits the ability of manufacturers to scale operations or invest in R&D.



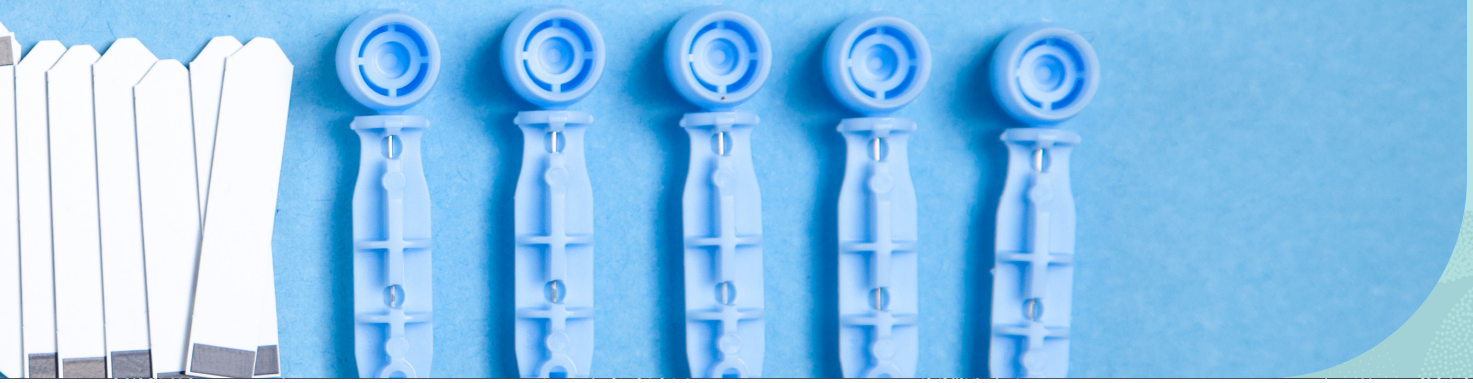
Compounding these issues is a shortage of specialized technical expertise. Most new entrants into BGMS strip manufacturing have limited prior experience with strip production and must build core competencies. While technical transfer partnerships often include the provision for a trainer, there is still considerable ramp-up time to be considered, and in the event of personnel mobility companies find it hard to adequately staff their manufacturing operations. Additionally, local logistics capacity is not always sufficient. For example, in Indonesia, several manufacturers reported difficulties in identifying logistics partners capable of handling temperature- and humidity-sensitive materials. Inadequate storage and transport conditions led to product spoilage in some cases, with batches of strips rendered unusable and ultimately discarded. These challenges underscore the importance of investing not just in local production, but also in quality-assured supply chain infrastructure.

Market and Demand-side Challenges

A critical constraint facing local manufacturers is the absence of stable and sufficient demand for BGMS strips. In many LMICs, demand remains fragmented and testing volumes are low relative to the number of PLWDs. Domestic manufacturers must also contend with markets dominated by established multinational companies, which benefit from strong brand recognition, extensive distribution networks, and long-standing relationships with HCPs. These competitive advantages make it challenging for local producers to secure market share or build trust among clinicians and consumers.

Most LMICs also lack mechanisms to aggregate demand, such as pooled procurement, framework contracts, or long-term volume guarantees. In the absence of such mechanisms, local manufacturers face significant unpredictability in demand, making it difficult to plan production, invest in scaling operations, or achieve the cost efficiencies needed to remain commercially viable. In Indonesia, for example, local manufacturers said they relied heavily on intermittent public tenders, and that during off-cycle periods production lines were often idle due to limited private sector demand, which meant that manufacturers had to consider producing other diagnostics with more stable demand or with higher margins. In Nigeria, the situation was more acute, with limited public sector purchasing of BGMS strips and no integration into routine public health supply chains. The absence of coordinated demand and sustained government procurement created a challenging environment for local production to gain traction.

Even in cases where national diabetes awareness or screening programmes exist, the lack of linkage between diagnostic policy and product access means that increases in testing demand do not necessarily benefit local suppliers. Imported BGMS strips continue to dominate the market due to preferential pricing, established logistics channels, or clinician familiarity. It becomes clear that no single intervention will unlock sustainable local manufacturing. Each challenge needs to be addressed collaboratively across policy, operational and market domains. As one working conclusion from our analysis states: “There is no silver bullet: addressing isolated challenges won’t unlock sustainable manufacturing. Progress requires coordinated action across multiple fronts.”



In conclusion, these illustrative examples from the site visits underscore these challenges. With the exception of the facility in Algeria, the other facilities we visited used varying degrees of semi-automated production from uncut sheets. Their inability to scale and achieve cost optimization meant they have not yet scaled up, and MOQ requirements force them to produce volumes far above domestic sales, leading to unsold inventory and high per-strip costs. In Indonesia, two newer manufacturers could theoretically produce millions of vials per year, but output is currently tied to infrequent government procurement cycles, leaving their capacity sitting idle much of the year. Also, the manufacturers reported that the government-imposed tender prices barely cover costs. By contrast, Algeria's leading local producer has achieved profitability and even moved toward end-to-end production. However, while strong government support enabled this success, challenges still remain for domestic manufacturers of strips in Algeria. For example, certain specialized raw materials must still be imported as there is not enough demand domestically to facilitate local supply. It was also reported that intellectual property protections are weak, allowing copycat products with little to no repercussions.

1. OPPORTUNITIES FOR LOCAL MANUFACTURING OF BGMS STRIPS IN LMICs

Historically, the focus of local manufacturing efforts in LMICs has largely been on combating infectious diseases. However, there is a growing recognition that chronic conditions such as diabetes also need to be addressed. For example, a recent partnership has been established to initiate human insulin production in South Africa, aiming to supply approximately 4.1 million PLWDs across the African continent by 2026 (Novo Nordisk, 2023). This shift underscores the opportunity for local BGMS manufacturing to complement efforts in supporting PLWDs, as well as strengthening health system resilience in LMICs.

Local BGMS strip manufacturing could offer many significant benefits:

FOR END USERS – Sustainable local production can enhance accessibility and affordability of BGMS devices, addressing the high costs and limited availability that often hinder effective diabetes management in LMICs.

FOR COMPANIES – The successful implementation of local manufacturing offers companies new revenue growth opportunities and for companies based outside of the LMICs, an opportunity to partner with local companies and tap into new markets.

FOR GOVERNMENTS AND MINISTRIES OF HEALTH – Governments stand to gain from enhanced healthcare resilience, reduced dependency on imports, and local industrial growth. From an economic development perspective, benefits include the development of the workforce, economic empowerment and the creation of regional supply chains that meet the broader LMIC public health agenda and sustainable development goals.

CONCLUSION

Despite the high need for diabetes testing in LMICs, local manufacturing of BGMS strips remains extremely limited. Our research found that local manufacturing is technically feasible, but the investment is sizable and risky. Our analysis highlighted that sizeable, early-year volumes are essential for a positive financial return. As such, a major challenge for local manufacturers is securing reliable, sizeable orders from the start of operations. Many LMIC markets are too modest in size to deliver the necessary scale. Moreover, because demand stems primarily from out-of-pocket consumer spending, it is greatly limited by people's ability to pay. BGMS strip buying is also fragmented, with individuals at times influenced by HCPs who essentially select the particular product bought by the patient. Information asymmetries and brand allegiance also prevent consumers from selecting cost-effective products, leading to overreliance on imported brands.

While it is early days for many local BGMS strip manufacturing efforts, we saw success in Algeria, a country with a high burden of diabetes that has ensured strong test strip demand through insurance coverage. Additionally, the government implemented a ban on imported products, ensuring demand for local producers.

1. IMPACT OF LOCAL MANUFACTURING ON AFFORDABILITY AND ACCESS

Affordability and availability challenges have long limited BGMS strip access in LMICs, and our analysis suggests that local production alone is not likely to move the needle significantly on affordability or availability.

Regarding affordability, local production COGS are higher than global supplier COGS who deal in very-high product volumes. Nevertheless, the savings from lower LMIC labour costs would offset some of the efficiencies that the high-volume manufacturers enjoy. Additionally, elimination of international finished goods freight costs and importation costs could offset the higher ex-works price of locally produced products. Anecdotal evidence indicates that locally made products can also remain within the current end-user price ranges.

For example, local production can directly improve supply security, reducing the market's exposure to supply chain and currency shocks. However, local manufacturing alone is unlikely to increase retail or facility availability without focused attention to local distribution, which is arguably a higher priority for local versus international suppliers.

2. NEXT STEPS

Our research indicates that progress in SMBG requires government-coordinated action across multiple fronts, primarily focused on increasing demand. If local manufacturing is pursued, demand generation should be supplemented by interventions that both accelerate the entry of quality assured local products and drive demand towards them.

We recommend several near term activities to increase demand for BGMS:

- **Increased screening for diabetes and strengthening linkages in the care cascade.**
- **Support for-self testing in guidelines and essential diagnostic lists, with insurance reimbursement.**
- **Health workforce capacity strengthening, by improving the care provision through guideline dissemination and training.**
- **End-user awareness campaigns to ensure patient knowledge and adherence to recommendations.**
- **Resource mobilization for diabetes care, including both in-facility and self-monitoring of glucose.**

For successful local manufacturing, assessing the market size, growth potential, and government support, as well as the competitive landscape and the customer acquisition costs, are critical. Assuming these are favourable, policy makers and stakeholders should consider other interventions to steer demand towards quality-assured local products, for example:

- **Pooling or coordinating public sector and institutional demand; designing multi-year tenders that favour local production.**
- **Supporting independent clinical studies to demonstrate safety, efficacy and quality of local products. Dissemination of results, especially to policy makers, providers and pharmacists, and professional associations.**
- **Fast-track regulatory pathways for local production.**
- **Inclusion of local manufactured tests in formularies and procurement lists.**

While local manufacturing offers many benefits, careful evaluation of financial viability and market considerations is essential before implementation. Key factor for success includes the market size and the supplier's ability to capture substantial market share in the early years. After reviewing test manufacturing from many angles in several LMICs, most lack the conditions necessary to support viable manufacturing. As a result, in most LMICs, focused efforts to increase demand should precede or accompany investments in local BGMS strip manufacturing.

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APPENDIX

DCF Calculations and Assumptions

SCENARIO A

Year	Price per Vial (USD)	Sales Volume (Vials)	Revenue (USD)	CapEx (USD)	Fixed Costs (USD)	Variable Costs (USD)	Sales & Marketing (USD)	Working Capital Change (USD)	Meter Cost (USD)	Free Cash Flow (USD)	Discounted Cash Flow	Cumulative NPV
0	5	-	-	-1,730,000	-	-	-	-	-	-1,730,000	-1,730,000	-1,730,000
1	5	-	-	-	-400,000	-	-	-	-	-400,000	-347,826	-2,077,826
2	5	3,311	16,555	-	-400,000	-9,933	-2,483	-4,138	-1,324	-401,324	-303,458	-2,381,285
3	5	6,622	33,111	-	-400,000	-19,866	-4,966	-4,138	-2,648	-398,510	-262,026	-2,643,311
4	5	66,222	331,112	-	-400,000	-198,667	-49,666	-74,500	-26,488	-418,211	-239,113	-2,882,425
5	5	99,333	496,668	-	-400,000	-298,000	-74,500	-41,389	-39,733	-356,955	-177,469	-3,059,895
									NPV	-$2,660,778		
									IRR	-		
									Breakeven	No		

SCENARIO B (10% WC, 10% S&M Assumption)

Year	Price per Vial (USD)	Sales Volume (Vials)	Revenue (USD)	CapEx (USD)	Fixed Costs (USD)	Variable Costs (USD)	Sales & Marketing (USD)	Working Capital Change (USD)	Meter Cost (USD)	Free Cash Flow (USD)	Discounted Cash Flow	Cumulative NPV
0	5	-	-	-1,730,000	-	-	-	-	-	-1,730,000	-1,730,000	-1,730,000
1	5	-	-	-	-400,000	-	-	-	-	-400,000	-347,826	-2,077,826
2	5	1,186,675	5,933,378	-	-400,000	-3,560,026	-593,337	-593,337	-474,670	312,005	235,920	-1,841,905
3	5	1,364,677	6,823,385	-	-400,000	-4,094,031	-682,338	-89,000	-545,870	1,012,144	665,501	-1,176,404
4	5	1,569,164	7,845,822	-	-400,000	-4,707,493	-784,582	-102,243	-627,665	1,223,837	699,732	-476,671
5	5	1,804,667	9,023,337	-	-400,000	-5,414,002	-902,333	-117,751	-721,867	1,467,382	729,548	252,877
									NPV	$219,893		
									IRR	18.68%		
									Breakeven	year 5		

1. COUNTRY ASSUMPTIONS

Population	50 million
Adult population (20 - 70)	55%
Diabetes prevalence	14.5% of Adults
Diagnosed Cases	~2 million

T1DM (5%)	99,688
T2DM (95%)	1,894,063
T2DM on insulin	568,219 (30% of T2DM)
T2DM not on insulin	1,325,844 (70% of T2DM)

2. WORKING MARKET SIZE ASSUMPTIONS

SCENARIO A – Working market size assumption

	STRIPS	
T1DM needs	109,157,813	3 strips/day
T2DM on insulin needs	311,099,766	1.5 strips/day
T2DM not on insulin needs	241,966,484	0.5 strips/day
Total Diagnosed Cases Demand	662,224,063	13,244,481
Affordability factor (1 in 2 cannot afford OOP payment)	**331,112,031**	

SCENARIO B – Working market size assumption

Total Diagnosed Cases Demand	662,224,062	
Goverment Market (70%)	463,556,843	
Healthcare access filter (85%)	394,023,317	
Reimbursement cap (T2DM not on insulin)	118,331,554	
Private Market (30%)	198,667,218	
Affordability factor	99,333,609	
	611,688,481	

3. REGULATORY PATHWAY ASSUMPTIONS

Regulatory Pathway Assumptions	Country waives or fast-tracks product registrations that have already been approved by a more stringent regulatory authority
WACC	15%
CAGR	15%

4. VOLUME GROWTH SCENARIOS

	SCENARIO A	SCENARIO B
Market Position	Newly established company competing in a mature private market against established multinationals (The Big 4 and other low-priced mid tier brands)	Newly established company alight with national/ local government policy to build self-reliant manufacturing
Market Access Model	Pure private market play. Pharmacies, Retail Distributors, Diagnostic Chains, eCommerce and other online retailers	Government does not restrict importation, but prioritizes domestically produced strips for procurement and distribution in-country. MoH, public health systems, national procurement agencies, etc.
Government Support	None. The company is not beneffiting from any volume guarantees or procurement guarantees	Access to volume guarantees, offtake agreements
Market Split	**100% Private**	**70% Government - 30% Private**
Revenue Ramp Up	Aggressive sales growth strategies	
Sales & Marketing	15% of revenue	10% of revenue
Working Capital	25% of the incremental revenue	10% of incremental revenue
Tax Assumptions	0%	0%
Risk Profile	High	Lower, demand is anchored in government commitment, predictable payment cycles.

Assumed Market Share (As a % of Estimated Market Size)		**% AGE OF Government Market Share**	**% AGE OF Private Market Share**
Year 1	0%	0%	0%
Year 2	0.05%	13%	2%
Year 3	0.1%	14.95%	2.30%
Year 4	1%	17.19%	2.65%
Year 5	1.5%	19.77%	3%

5. CAPITAL INVESTMENT ASSUMPTIONS

CapEx	1,530,000
Tech Transfer Costs (US$)	200,000
Timeframe (years)	5
CapEx+TT Cost+Delivery and Installation	1,730,000

6. FACILITY, SALES AND REVENUE ASSUMPTIONS

Facility Assumptions

Formulation	Variations in enzyme (GOx vs. GDH), electrode (gold vs. carbon), or mediator are assumed to have negligible impact on financial modeling for simplification
Degree of Automation	Semi-automatic
Facility Capacity	3.6m vials/year
Upstream RM production	None, uncut sheets are imported with pre-dispensed enzymes
Packaging	50 strips per vial
Fixed Costs (US$)	400,000
Salaries (30 - 50 core staff covering core admin and production activities)	250,000
Utilities & maintenance	30,000
Insurance & Licenses	10,000
Regulatory and Compliance (Renewal, audit, recertiification, documentation including ISO and national regulatory authority fees)	30,000
Facility lease costs	50,000
Misc and Contingency	30,000
Variable Costs (US$/vial)	3
Uncut sheet with predispensed enzyme mix/vial of 50	1.4
Labour	0.3
Consumables	0.2
QC/wastage allowance	0.3
Packaging	0.4
Internal logistics & handling	0.4
WORKING CAPITAL	
Scenario A	25% of incremental revenue
Scenario B	10% of incremental revenue
SALES AND MARKETING COSTS	
Scenario A	15% of revenue
Scenario B	5% of revenue

Sales & Revenue Assumptions

Sales Volume Assumption	100% of annual production is sold
Retail price/strip (US$)	0.1
Retail price/vial (US$)	5
WACC	15%
Glucose meters price (US$)	Glucose meters are provided free of charge in both scenarios to encourage brand switching and are not considered in the model
Glucose meters cost (US$)	4
Glucose meter seeding	1 meter to 10 vials

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