Prioritizing Rapid Diagnostics Tests for Local Manufacturing in Ethiopia

Product profile and go-to-market planning

March 2026

Manufacturing Africa

UK International Development
Partnership | Progress | Prosperity

The contents of this document are meant to be informative of a fact base, rather than provide any specific recommendation. They are based on initial research, interviews, and analysis and are subject to change given continued feedback

Executive summary (1/3)

1 Product overview and disease rationale

- Priority RDTs (i.e., HIV, Hepatitis, Syphilis, and Typhoid) **enable rapid diagnosis at the primary-care level**, supporting early treatment initiation, reduced transmission, and improved disease surveillance
- Together, these RDT categories **cover both preventive screening and acute illness detection use cases** across the healthcare system

2 High-level market assessment

- **The total addressable RDT market amounted to 28 Mn units between 2020-23**, split across Malaria (7.7 Mn), HIV (7.3 Mn), Syphilis (2 Mn), Hepatitis (3.8 Mn), Typhoid (1.1 Mn), pregnancy (5.8 Mn) and H. Pylori (1.1 Mn) – due to high demand and lack of local production, HIV, Hepatitis, Syphilis and Typhoid are prioritized for local production
  - **Current priority RDT procurement volumes fall short of Ethiopian MoH target coverage,** closing this gap could unlock **>18 Mn additional tests annually**
  - If coverage targets are progressively achieved, the projected addressable RDT market could reach **~48 Mn tests annually by 2032** (5.5% CAGR 2022-'32)
  - **Hepatitis, Syphilis, and Typhoid** (combined ~17 Mn tests in 2027, 18 Mn in 2032) **have a mixed procurement base** (<50% donor-funded) and therefore present the most immediate ramp-up opportunity supporting viable local production scale (15 Mn p.a.)
  - **HIV RDT demand is 100% donor-funded**, requiring WHO PQ and alignment with centralized tender frameworks
- Existing manufacturers primarily focus on pregnancy kits and malaria RDTs, overlooking prioritized RDTs. As a result, public and private procurement relies on imports, **creating an opportunity for local production to meet the total demand for priority RDTs**
  - **Existing local RDT manufacturers** (e.g., New Millennium, Access Bio) do not manufacture priority RDTs, but focus mostly on Malaria and pregnancy tests where they capture limited market share
  - **Local production portfolio is narrow**, reflecting the regulatory burden and cost of expanding RDT SKUs
- **Successful RDT market entry depends on 3 conditions**
  - **Securing the necessary local and international validations and certifications**, including establishing a GMP-compliant manufacturing, obtain ISO 13485 certification, and achieve WHO PQ to unlock EPSS and donor-funded demand
  - **Capturing majority share (~70-80%) of local Hepatitis, Syphilis, and Typhoid RDT demand** to reach minimum efficient scale (~15 Mn units annually) and compete at international tender pricing
  - **Partnering with an experienced international RDT manufacturer** to access proven technology, regulatory documentation, and validation expertise, accelerating time-to-market and increasing probability of WHO PQ approval

3 Technical and manufacturing overview

- **All 4 priority RDTs use the same core lateral flow manufacturing stages** – reagent preparation, striping, lamination, cutting/assembly, and testing/packaging – enabling multiple SKUs to be produced on a shared production platform
- Biological reagents, performance validation, and WHO PQ requirements drive technical complexity and time-to-market – making **regulatory capability the primary scaling constraint** rather than equipment investment

Executive summary (2/3)

4 Regulatory and IP pathway

- Two regulatory pathways apply to RDT market entry – national product registration with EFDA and WHO Prequalification (PQ) – enabling a phased market entry across private/RDF and donor-funded segments
  - **Non-HIV RDTs (Syphilis, Hepatitis, Typhoid)** can launch after EFDA authorization (~18–24 months from submission), enabling access to private and RDF procurement
  - **HIV RDTs require WHO PQ approval (~6-12 months post-EFDA)** to access donor-funded procurement (e.g., UNICEF), which represents the majority of HIV RDT demand
- **Timely EFDA approval requires parallel preparation of technical dossiers,** clinical performance validation, and manufacturing/QMS readiness (ISO/GMP), as inspection readiness depends on validated processes and documented quality systems
- **Partnering with an experienced RDT manufacturer is critical to accelerate timelines,** providing access to validated product IP, reagents, and clinical data; without a partner, additional R&D and clinical trials would significantly extend time to market

---

5 Supply chain feasibility

- **RDT manufacturing relies on imported medical-grade inputs** (e.g., biological reagents, gold nanoparticles, membranes), as domestic production does not meet required quality standards for critical components
- **No structural supply constraints exist, as all critical inputs are globally available** from multiple suppliers; however, key materials (e.g., reagents and membranes) require stringent qualification and consistent quality control, limiting short-term substitution options

RDTs are foundational to infectious disease detection and public health response in Ethiopia

(x) Strong drivers of product's public health relevance

Public health relevance

Disease burden	A	**Prevalence**	• **HIV:** ~600,000+ people living with HIV in Ethiopia (~0.9% of the adult population); routine screening critical for early diagnosis and treatment initiation • **Hepatitis (B & C):** Estimated intermediate-to-high endemicity; large undiagnosed population (~5% prevalence) • **Syphilis:** Persistent burden in antenatal populations and key risk groups. ~2.5% of the population is infected • **Typhoid:** Endemic febrile illness with 3.5 Mn infections/year; significant diagnostic uncertainty in primary care
	B	**Mortality**	• Untreated HIV, hepatitis, and syphilis contribute to **long-term morbidity and mortality** • Delayed or inaccurate diagnosis of febrile illnesses (e.g., typhoid) increases **complications and inappropriate antibiotic use** • Early detection via RDTs **directly improves survival and treatment outcomes**
Access gap	C	**Stock-outs**	• **Periodic stock-outs** of priority RDTs disrupt screening and case detection
	D	**Supply vulnerability**	• Majority of high-volume RDTs are **imported and donor-procured**
Population reach	E	**Patient volume**	• HIV, hepatitis, syphilis, and febrile illness testing occur at **high volumes across primary healthcare** • HIV and syphilis screening **integrated into antenatal care programs** • Typhoid testing common **in febrile outpatient settings**
	F	**Treatment setting**	• Used in **primary healthcare centers, hospitals, antenatal clinics**, and community outreach programs.
System-level impact	G	**System resilience**	• Local production would **reduce dependency on imported diagnostics** • Improves **continuity of disease surveillance** and outbreak response
	H	**Prevention impact**	• **Enables early case detection** and linkage to care • **Reduces onward transmission** of HIV and syphilis • **Improves antibiotic stewardship** by differentiating bacterial vs non-bacterial illness

Source: Health and health related indicators, 2017 EFY (2024/2025 GC), FDRE Ministry of Health; EPSS annual procurement data for EPSS RDF and EPSS donor for financial year 2020-2023; ECC data for private import market for financial year 2020-2023

Due to high demand and lack of local production, HIV, Hepatitis, Syphilis, and Typhoid RDTs are prioritized for local production

Value and volume figures based on 3-year average, FY2020-FY2023

Shortlisted for local production

	Name of product	Volume, Mn	CAGR FY 2021-23, %	Value, USD Mn	CAGR FY 2021-23, %	Local operational production capacity, Mn
Existing mature RDT market	Malaria	7.7	-21	3.0	-20	4.2
	HIV/AIDS	7.3	23	5.9	7	
Emerging RDT market	Syphilis	2.0	35	0.9	67	
	Hepatitis	3.8	101	2.7	60	
	Cholera	<0.1	NA	<0.1	NA	
	Dengue		NA		NA	
	Typhoid	1.1	4	0.3	NA	
	Rubella		NA		NA	
	Yellow Fever		NA		NA	
	Measles		NA		NA	
High interest from Public Health point of view	Tuberculosis	0.1	0	0.3	2	
	Salmonellosis	<0.1	NA	<0.1	NA	
	Meningitis		NA		NA	
	Chikungunya		NA		NA	
Wider health needs	Pregnancy	5.8	-57	0.4	-42	3.7
	Helicobacter Pylori	1.1	272	0.6	80	0.1
	Anti-Rho	<0	NA	<0.1	NA	

Source:. EPSS, ECC, local manufacturer survey

Key takeaways

There is 100% reliance in import for HIV, Hepatitis, Typhoid and Syphilis RDTs

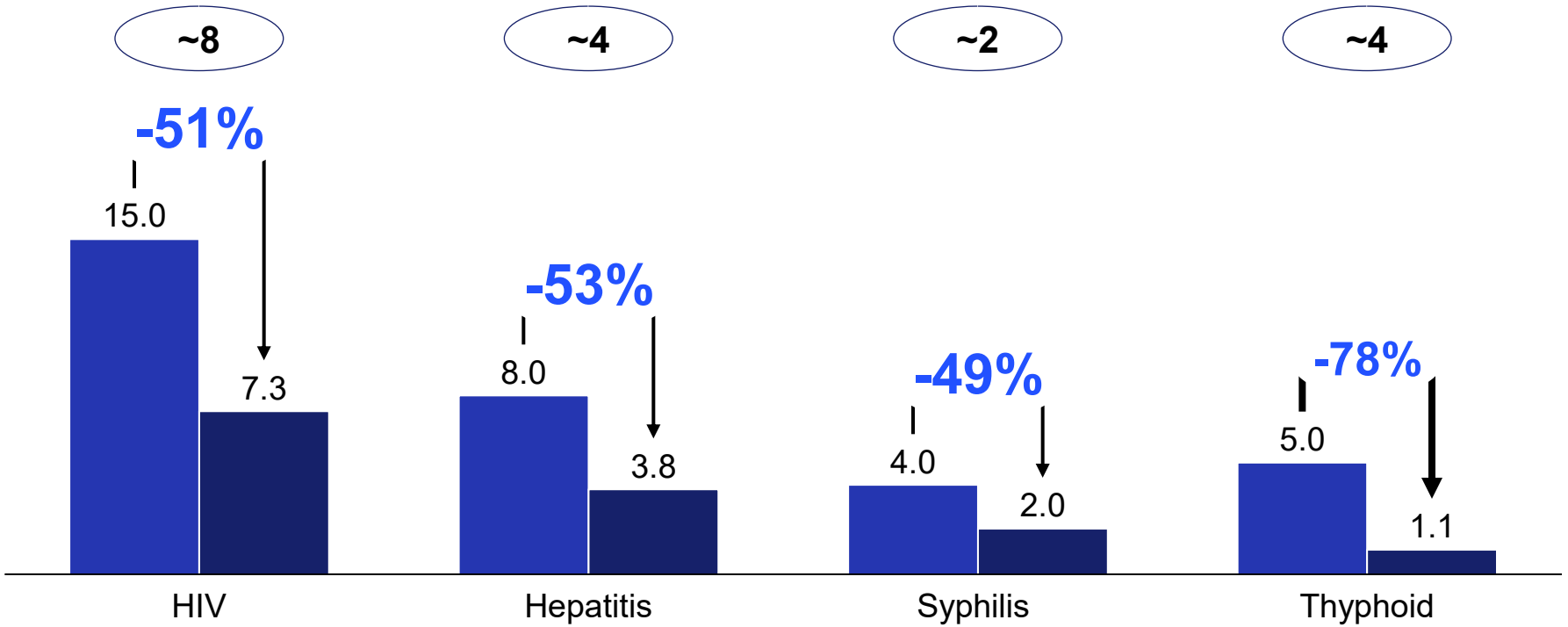
Access Bio majorly produce malaria RDTs in the country with currently 20% production. Acquiring WHO PQ will make the company production sufficient for Ethiopia Malaria demand

Local capacity for pregnancy RDTs already meets >60% of demand in a low-value market

Latent RDT demand accounts for at least ~18 Mn priority RDTs annually, creating scale for local manufacturing

X Latent demand in Mn units | Required tests to reach target coverage | Current test procurement | X % shortfall vs required testing volume

Latent testing kit gap across priority RDTs in Ethiopia, 2022, in Mn units[1]



	HIV	Hepatitis	Syphilis	Thyphoid
	3.8 Mn KPP[2], 4.2 Mn OSPG[2], & 3.8 ANC	4.5 Mn adults plus 3.5 Mn pregnant women per year	0.2 Mn adults plus 3.8 Mn pregnant women per year	~20 Mn febrile patients per year, 25% had typhoid
	1.25 kits/person	1 kit per person	1 kit per person	1 kit/person

1. Other Special population groups which include High risk uniformed men and women (200,000), HIV screened positive blood donors for confirmatory testing need considered 1,539 (three years average performance data), Voluntary Medical Male Circumcision (VMMC)
2. Key and priority population (KPP) which includes Key Populations; Female Sex Workers (FSW) and their clients, Prisoners, People with injecting drug use; Widowed and divorced men and women, long-distance drivers, workers in hot spot areas

Source: EPSS annual procurement data for EPSS RDF and EPSS donor for financial year 2020-2023; ECC data for private import market for financial year 2020-2023;Local manufacturers survey for private local market for financial year 2020- 2023; National Demand Forecasting of HIV Program Pharmaceuticals July 2025–June 2029 (2025), FDRE Ministry of health

Ethiopia faces a **gap between its actual RDT supply and the targets** set by the Ministry of Health (MoH) and WHO

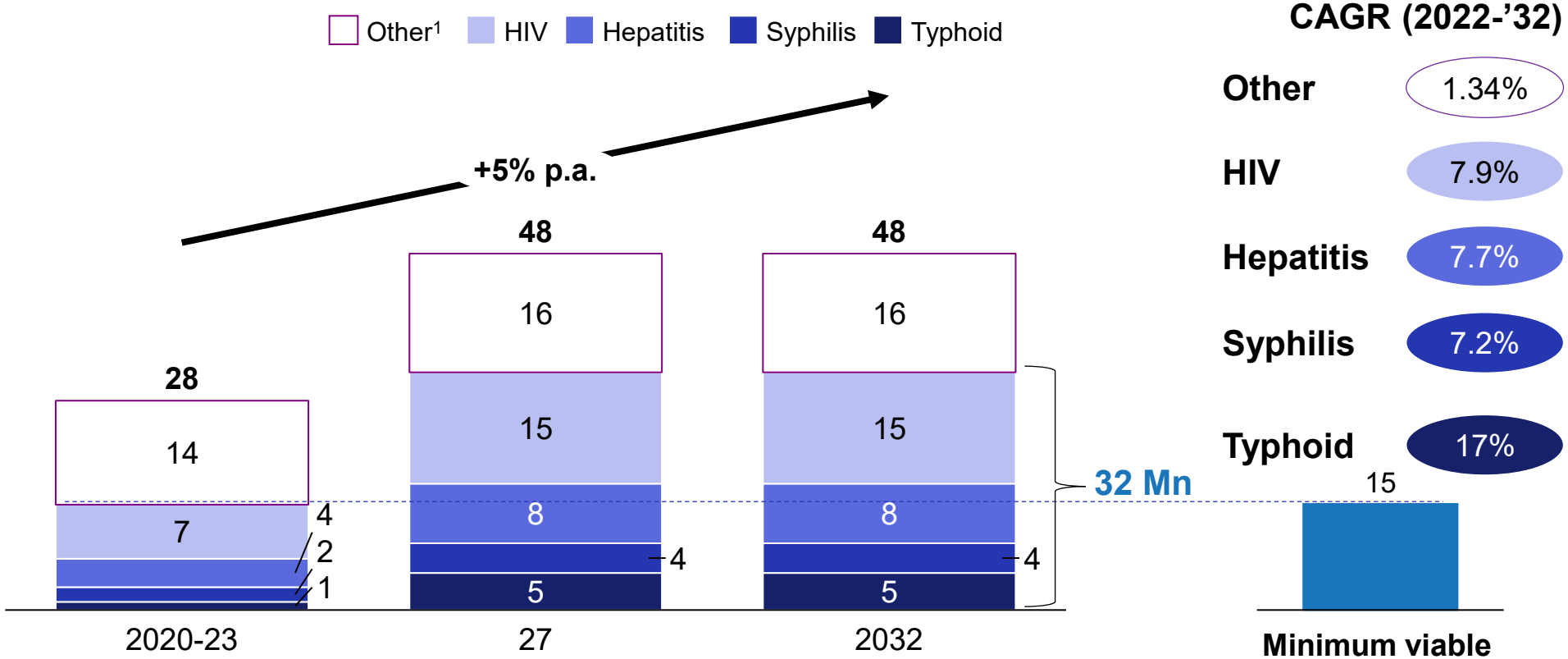
HIV accounts for the largest absolute testing gaps, with **~8 Mn additional tests required** to reach target coverage

Across priority RDTs, procurement covers **only ~65% of estimated required volumes**

Closing the gap would **unlock ~17 Mn additional tests per year**, supporting viable local production scale

The priority RDT market, under MOH targets, could reach 32 Mn units by 2027, 48% market share is needed for viable production capacity

Projected addressable market for RDTs in Ethiopia, Mn units, 2022-2032



CAGR (2022-'32)

Other	1.34%
HIV	7.9%
Hepatitis	7.7%
Syphilis	7.2%
Typhoid	17%

Minimum viable production capacity

Key assumptions

HIV testing aligned to national **95-95-95 targets**, **ANC-based** syphilis screening, **Blood bank screening** for infections, **25% of febrile patients** are Typhoid positive, and **continued Global Fund and donor financing**

Key takeaways

If government targets reached, **HIV RDTs could account for 15 Mn units by 2027** (~31% of market), becoming the top SKU driver

Typhoid, Syphilis and Hepatitis could grow from **7 Mn** to **17 Mn units (35% of market)**

Capturing ~48% of addressable 2027 market (15 Mn units) for the prioritized RDTs would support a sustainable plant

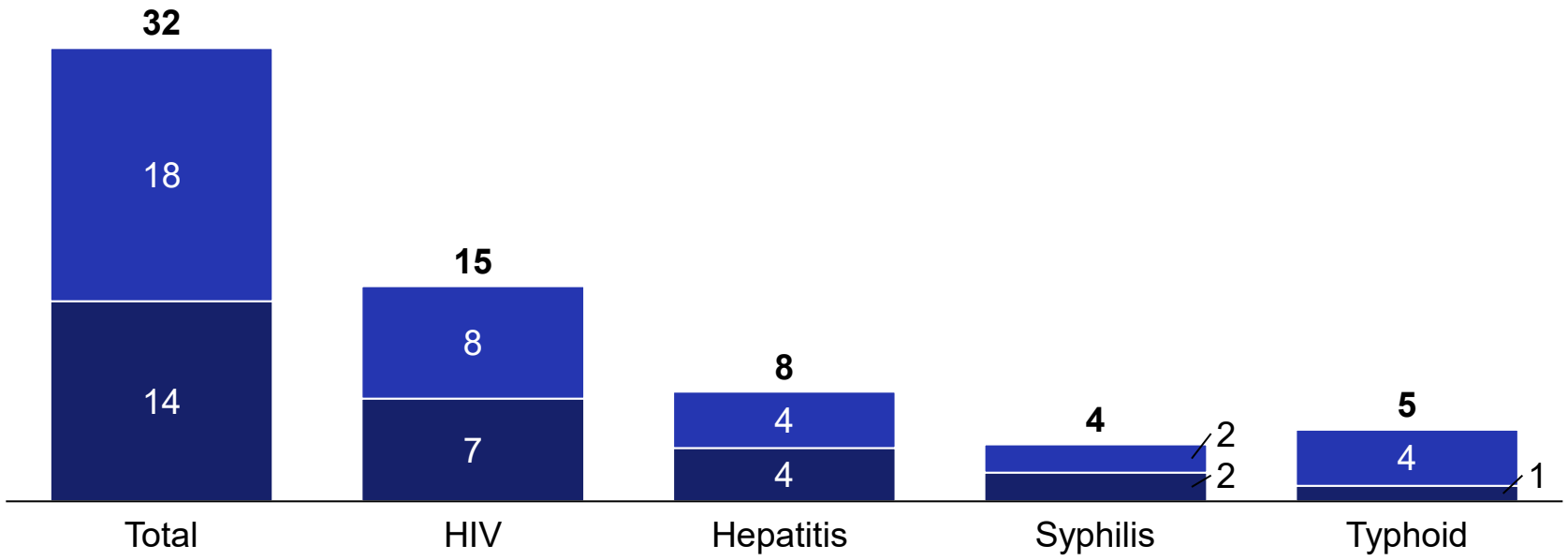
1. Others includes Malaria, Tuberculosis, Helicobacter Pylori, pregnancy, and other multipurpose RDTs

Source: EPSS annual procurement data for EPSS RDF and EPSS donor for financial year 2020-2023; ECC data for private import market for financial year 2020-2023;Local manufacturers survey for private local market for financial year 2020- 2023; National Demand Forecasting of HIV Program Pharmaceuticals July 2025–June 2029 (2025), FDRE Ministry of health

Mixed public and private procurement makes Hepatitis, Syphilis, and Typhoid near-term priorities

Gap vs required testing volume | Current test procurement | X% Customer segment % contribution

Annual average addressable market for RDTs in Ethiopia, Mn units, 2027-2032



Current procurer breakdown[1]

	Total	HIV	Hepatitis	Syphilis	Typhoid
Donor (via EPSS)	100%	49%	8%	0%
RDF (via EPSS)	0%	22%	36%	76%
Private procurement	0%	29%	56%	24%

1. Total market reflects actual EPSS and ECC data (2022), not scaled assumptions

Source: EPSS annual procurement data for EPSS RDF and EPSS donor for financial year 2020-2023; ECC data for private import market for financial year 2020-2023; Local manufacturers survey for private local market for financial year 2020- 2023

Key takeaways

HIV accounts for ~50% of the potential market but is structurally donor-locked, **limiting near-term localization flexibility despite its scale**

Excluding HIV, Ethiopia faces **~10 Mn units of unmet RDT demand annually**, alongside **~7 Mn units currently imported**

Hepatitis, Syphilis, and Typhoid show strong latent demand and minimal donor reliance, **presenting the strongest near-term anchor candidates**

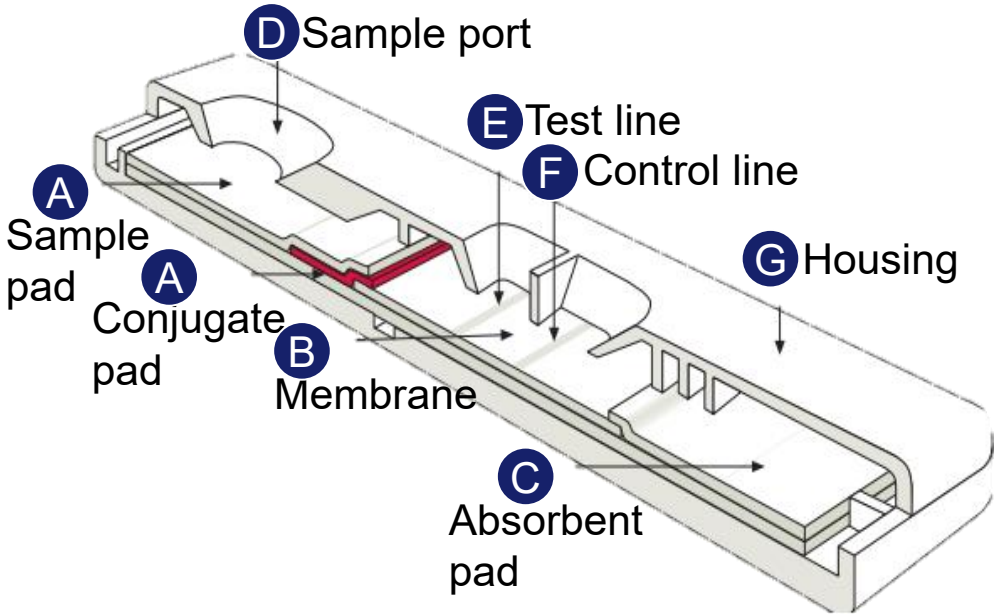
The RDT investment is viable – especially if three key execution conditions are met

Feasibility conditions	Timely acquisition of the required validation and certifications for RDTs	Capture ~75% of local Hepatitis and Syphilis RDT demand	Secure a manufacturing partner for technology and regulatory transfer
What must be true	**Establishes GMP-compliant manufacturing**, obtain ISO 13485 certification, and achieve WHO prequalification in less than 3 years (for HIV and Hepatitis RDTs)	Post GMP-compliance, **capturing majority share in non-HIV RDT segments**, potentially displacing current suppliers (e.g., Roswell and imports)	**Partnering with an experienced international RDT manufacturer** (e.g., via JV, tech transfer, or contract manufacturing) to access proven technology, SOPs and regulatory documentation
Why this matters	• Prior to certification, **only serve the private market** (below minimum efficient scale) • **Access to RDF demand** requires GMP, ISO, WHO PQ • **Certification and validation are time-sensitive**, with limited cost recovery without RDF/donor market access	• **~15 Mn units annual capacity** is required to reach EoS and compete at international tender pricing • Without majority local market capture, **unit economics remain uncompetitive** • Competition from imports and existing local assembler must be addressed on price and quality	**A partnership** • **Accelerates pathway to EPSS eligibility** and donor tenders • **Reduces regulatory failure risk,** trial-and-error development cycles and time-to-market • **Increases probability** of WHO PQ approval

Source: EPSS annual procurement data for EPSS RDF and EPSS donor for financial year 2020-2023; ECC data for private import market for financial year 2020-2023; Local manufacturers survey for private local market for financial year 2020- 2023; Medical Devices: WHO Prequalification of In Vitro Diagnostics Programme – Guidance for Manufacturers (latest update 2022), WHO

RDTs are designed to provide quick and on-the-spot results, typically within minutes, and generally a relatively simple production

Many components of typical RDTs are low-tech: Example of typical components of malaria and HIV RDTs[1]



- **A Sample & conjugate pad:** detector reagent conjugated to colored particles to capture desired analyte and released upon liquid flow
- **B Membrane:** hydrophobic membrane made of nitrocellulose to allow sample flow
- **C Absorbent pad with desiccant:** maintains flow rate of liquid through capillary action
- **D Sample port**: collects blood sample and drops of buffer
- **E Test line**: immobilized biomolecule to capture desired analyte bound to conjugated detector
- **F Control line:** species-specific anti-immunoglobulin against detector reagent
- **G Housing & backing:** inert support for membrane

1. Additional accessories include alochol wipes, lancet, capillary tube, bandages and buffer solution

Source: Expert interviews (former production managers and product managers at major manufacturers); The Global Fund Pooled Procurement Mechanism

RDT manufacturing involves five modular stages, most of which are platform-shared across infectious test SKUs

NOT EXHAUSTIVE

	Prepare and conjugate reagents	Stripe reagents onto nitrocellulose	Prepare pads and laminate materials	Cut strips and assemble cassettes	Testing and package
Description	Antibodies or antigens are **purified and mixed with gold or latex particles** to create the visible detection reagent The conjugated **reagent is stabilized, filtered, and tested** to ensure it binds correctly and produces a clear signal	Capture antibodies or antigens are **dispensed in precise lines onto nitrocellulose membrane sheets** to form the test and control lines Striped **membranes are dried** under a controlled temperature to fix the proteins in place	Sample pads, conjugate pads, nitrocellulose membranes, and absorbent pads are **laminated onto adhesive backing cards** to enable controlled flow The **laminated sheets are pressed and inspected** for alignment and flow	The laminated sheets are **cut into narrow strips** of defined width Each **strip is inserted into a plastic cassette (or prepared as a dipstick)**, labeled, and visually inspected	Finished tests are **validated using positive and negative control samples** to confirm performance Devices are **sealed in foil pouches with desiccant**, boxed, and released after final quality approval
Inputs	Monoclonal capture antibodies Detection antibodies Colloidal gold nanoparticles Conjugation buffers and stabilizers Blocking agents	Nitrocellulose membrane rolls Test line capture antibodies Control line antibodies Striping buffer	Sample pad material Conjugate pad Absorbent pad Adhesive backing cards Blood separation membrane (Hepatitis, HIV -serum-based)	Plastic test cassettes Desiccant sachets Labels and inks Multi-window cassette molds (HIV Ag/Ab combo, Dual-line Typhoid)	Positive control sera (HIV, Hepatitis, Syphilis) Bacterial antigen control (Typhoid) Foil pouches Desiccant
Equipment	Conjugation mixer/reactor Centrifuge or tangential filtration system Protein quantification analyzer Stability chambers	Automated striping machine Precision dispensing head Controlled drying oven Roll-to-roll handler Environmental chamber	Automated laminator Pressure roller system Alignment system	Rotary strip cutter Cassette insertion machine Inkjet coder Vision inspection system	QC test benches Stability chambers Heat-sealing machine Cartoning line

Key observations

Most infectious disease RDTs (HIV, Hepatitis, Syphilis, Typhoid) use **the same five core manufacturing stages**

The main variation across RDT types is in clearance and sanitization, validation requirements, and reagent replacement not in processes or assembly equipment thus requiring no additional major capital investment to produce other RDT types

While manufacturing steps are platform-shared, **WHO PQ, stability testing, and clinical validation** remain barriers to scaling and donor market access

Source: Lateral Flow Immunoassay: Principles and Applications (2016), Koczula & Gallotta, Essays in Biochemistry; WHO Prequalification of In Vitro Diagnostics Programme – Public Report and Manufacturer Guidance (latest update 2022), WHO; Development and Manufacture of Lateral Flow Immunoassay Devices (2014), O'Farrell, in Lateral Flow Immunoassay (Springer Methods in Molecular Biology); Press search

RDT manufacturing relies on imported medical-grade inputs, but global supply availability limits structural supply risk

Process step	Input material	Sourcing strategy	Leading suppliers (top 3 by market size)
Conjugating reagents	**Biological reagents**	**High import dependency across all critical inputs**, as local production capabilities not suitable for medical-grade materials **All imports globally available** from multiple suppliers (no structural supply constraints) **Potential for localizing cassette housing**, by scaling the limited plastic molding and manufacturing in country	abcam, MERCK, Meril Moderately concentrated market dominated by US/EU majors, and emerging Asian suppliers
	Gold nanoparticles		BBI Solutions, CYTODIAGNOSTICS, macro&micro-test Moderately concentrated market dominated by a few experienced producers
Striping reagents	**Nitrocellulose membrane**		MERCK, cobetter, SARTORIUS Moderately fragmented market with cost-competitive production often located in Europe and Asia
Lamination stage	**Sample pad, conjugate pad, and absorbent pad**		danaher, AHLSTROM MUNKSJÖ, mdi Highly competitive landscape with a mix of global filtration specialists and IVD-focused OEMs
	Backing card		danaher, MERCK, NUPORE Moderately fragmented market with few global players leading competitive landscape
Packaging	**Cassette housings and desiccants**		Hysen Biotech, DCN DX, greiner Highly competitive market with numerous global and regional players

Implications

Limited near-term opportunity for local substitution exist, as domestic production does not meet medical-grade requirements for key inputs

But Ethiopia's plastic molding capacity could enable partial localization of cassette housings in the near future

No structural supply constraints, as all critical inputs are globally available from multiple suppliers

However, procurement need to be limited to 1-2 suppliers per input material to enable product equivalence and process validation

Source: Lateral flow assay components market size & growth forecast to 2030, 2025, MarketsandMarkets; Lateral Flow Assay Component Market, 2026, Fact.MR; Asia Pacific Lateral Flow Assay (LFA) Components Market, 2025 , Business Market Insights

Agenda

1. Product overview

2. High-level market assessment
3. Manufacturing process
4. Regulatory and IP pathway
5. Supply chain feasibility
6. Risks and mitigants

RDTs are foundational to infectious disease detection and public health response in Ethiopia

(x) Strong drivers of product's public health relevance

Public health relevance

Disease burden	A	**Prevalence**	• **HIV:** ~600,000+ people living with HIV in Ethiopia (~0.9% of the adult population); routine screening critical for early diagnosis and treatment initiation • **Hepatitis (B & C):** Estimated intermediate-to-high endemicity; large undiagnosed population (~5% prevalence) • **Syphilis:** Persistent burden in antenatal populations and key risk groups. ~2.5% of the population is infected • **Typhoid:** Endemic febrile illness with 3.5 Mn infections/year; significant diagnostic uncertainty in primary care
	B	**Mortality**	• Untreated HIV, hepatitis, and syphilis contribute to **long-term morbidity and mortality** • Delayed or inaccurate diagnosis of febrile illnesses (e.g., typhoid) increases **complications and inappropriate antibiotic use** • Early detection via RDTs **directly improves survival and treatment outcomes**
Access gap	C	**Stock-outs**	• **Periodic stock-outs** of priority RDTs disrupt screening and case detection
	D	**Supply vulnerability**	• Majority of high-volume RDTs are **imported and donor-procured**
Population reach	E	**Patient volume**	• HIV, hepatitis, syphilis, and febrile illness testing occur at **high volumes across primary healthcare** • HIV and syphilis screening **integrated into antenatal care programs** • Typhoid testing common **in febrile outpatient settings**
	F	**Treatment setting**	• Used in **primary healthcare centers, hospitals, antenatal clinics**, and community outreach programs.
System-level impact	G	**System resilience**	• Local production would **reduce dependency on imported diagnostics** • Improves **continuity of disease surveillance** and outbreak response
	H	**Prevention impact**	• **Enables early case detection** and linkage to care • **Reduces onward transmission** of HIV and syphilis • **Improves antibiotic stewardship** by differentiating bacterial vs non-bacterial illness

Source: Health and health related indicators, 2017 EFY (2024/2025 GC), FDRE Ministry of Health; EPSS annual procurement data for EPSS RDF and EPSS donor for financial year 2020-2023; ECC data for private import market for financial year 2020-2023

Priority RDTs are embedded across primary care, ANC, and blood bank settings, serving distinct roles from general screening to illness diagnosis

Dimension	Therapeutic area			Product definition		
Category	Disease	Intended use	User setting	Sensitivity & specificity requirement[1]	Test process	Test types used
HIV RDT	HIV-1 / HIV-2	Screening (asympto-matic)	Primary health center; Blood banks	High sensitivity (99%) & specificity, algorithm-driven	Fingerstick whole blood as a sample, applied to well; Sequential confirmatory testing	• HIV-1/2 antibody rapid test • HIV Ag/Ab combo
Syphilis RDT	Treponema pallidum (Syphilis)			High specificity important	Sometimes need confirmation	• Treponemal antibody rapid test • Non-treponemal • HIV/Syphilis combo
Hepatitis RDT	Hepatitis B ± Hepatitis C (anti-HCV)			High sensitivity critical for blood safety		• HBsAg antigen rapid test • Anti-HCV antibody test
Typhoid RDT	Salmonella Typhi	Disease differentiation (symptomatic)		High specificity important	Single step detection	• IgM antibody • IgM/IgG dual LFA • Antigen-based rapid

1. Sensitivity: The ability of a test to correctly identify people who have the disease; Specificity: The ability of a test to correctly identify people who do not have the disease

Source: Guidelines on Hepatitis B and C Testing (2017), WHO; WHO Consolidated Guidelines on HIV Testing Services" (2019, updated 2023); Rapid diagnostic tests for typhoid and paratyphoid (enteric) fever (2017), Wijedoru L., Mallett S., Parry C.M., Cochrane Database of Systematic Reviews; Sensitivity and specificity of typhoid fever rapid antibody tests for laboratory diagnosis at two sub-Saharan African sites (2011), Keddy K.H. et al., Bulletin of the WHO

Agenda

1. Product overview
2. **High-level market assessment**
3. Manufacturing process
4. Regulatory and IP pathway
5. Supply chain feasibility
6. Risks and mitigants

Due to high demand and lack of local production, HIV, Hepatitis, Syphilis, and Typhoid RDTs are prioritized for local production

Value and volume figures based on 3-year average, FY2020-FY2023

Shortlisted for local production

	Name of product	Volume, Mn	CAGR FY 2021-23, %	Value, USD Mn	CAGR FY 2021-23, %	Local operational production capacity, Mn
Existing mature RDT market	Malaria	7.7	-21	3.0	-20	4.2
	HIV/AIDS	7.3	23	5.9	7	
Emerging RDT market	Syphilis	2.0	35	0.9	67	
	Hepatitis	3.8	101	2.7	60	
	Cholera	<0.1	NA	<0.1	NA	
	Dengue		NA		NA	
	Typhoid	1.1	4	0.3	NA	
	Rubella		NA		NA	
	Yellow Fever		NA		NA	
	Measles		NA		NA	
High interest from Public Health point of view	Tuberculosis	0.1	0	0.3	2	
	Salmonellosis	<0.1	NA	<0.1	NA	
	Meningitis		NA		NA	
	Chikungunya		NA		NA	
Wider health needs	Pregnancy	5.8	-57	0.4	-42	3.7
	Helicobacter Pylori	1.1	272	0.6	80	0.1
	Anti-Rho	<0	NA	<0.1	NA	

Source:. EPSS, ECC, local manufacturer survey

Key takeaways

There is 100% reliance in import for HIV, Hepatitis, Typhoid and Syphilis RDTs

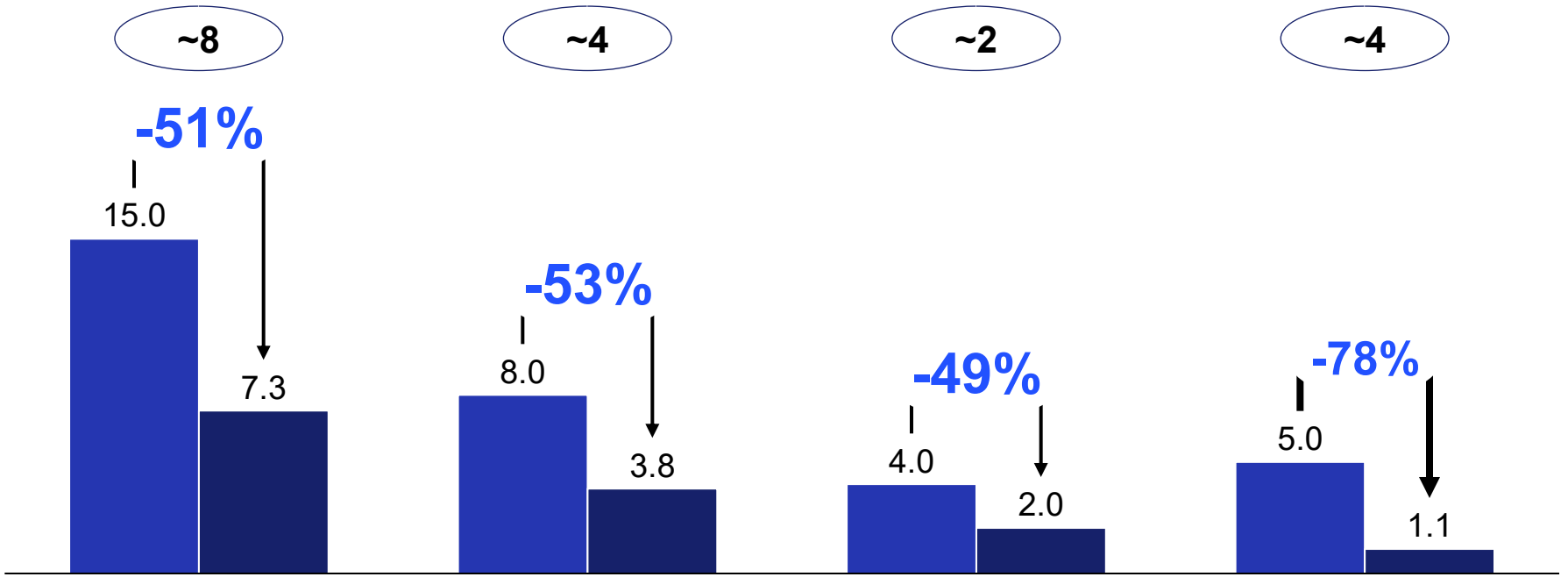
Access Bio majorly produce malaria RDTs in the country with currently 20% production. Acquiring WHO PQ will make the company production sufficient for Ethiopia Malaria demand

Local capacity for pregnancy RDTs already meets >60% of demand in a low-value market

Latent RDT demand accounts for at least ~18 Mn priority RDTs annually, creating scale for local manufacturing

X Latent demand in Mn units | Required tests to reach target coverage | Current test procurement | X % shortfall vs required testing volume

Latent testing kit gap across priority RDTs in Ethiopia, 2022, in Mn units[1]



	HIV	Hepatitis	Syphilis	Thyphoid
	3.8 Mn KPP[2], 4.2 Mn OSPG[2], & 3.8 ANC	4.5 Mn adults plus 3.5 Mn pregnant women per year	0.2 Mn adults plus 3.8 Mn pregnant women per year	~20 Mn febrile patients per year, 25% had typhoid
	1.25 kits/person	1 kit per person	1 kit per person	1 kit/person

1. Other Special population groups which include High risk uniformed men and women (200,000), HIV screened positive blood donors for confirmatory testing need considered 1,539 (three years average performance data), Voluntary Medical Male Circumcision (VMMC)
2. Key and priority population (KPP) which includes Key Populations; Female Sex Workers (FSW) and their clients, Prisoners, People with injecting drug use; Widowed and divorced men and women, long-distance drivers, workers in hot spot areas

Source: EPSS annual procurement data for EPSS RDF and EPSS donor for financial year 2020-2023; ECC data for private import market for financial year 2020-2023;Local manufacturers survey for private local market for financial year 2020- 2023; National Demand Forecasting of HIV Program Pharmaceuticals July 2025–June 2029 (2025), FDRE Ministry of health

Ethiopia faces a **gap between its actual RDT supply and the targets** set by the Ministry of Health (MoH) and WHO

HIV accounts for the largest absolute testing gaps, with **~8 Mn additional tests required** to reach target coverage

Across priority RDTs, procurement covers **only ~65% of estimated required volumes**

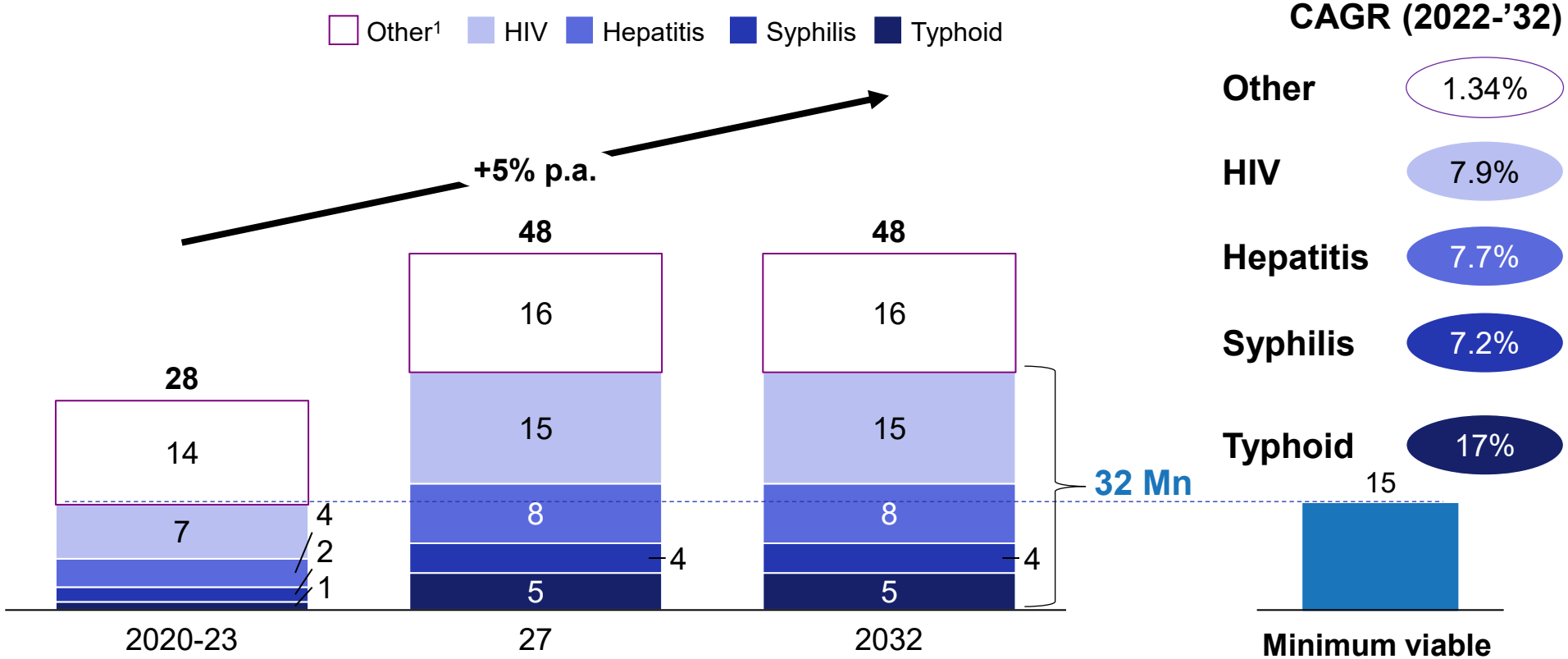
Closing the gap would **unlock ~17 Mn additional tests per year**, supporting viable local production scale

Two demand scenarios could indicate the scale and structure of future RDT market size

Description	I Donor-led procurement guided by MoH targets	II Private market-led procurement
What this would look like	**RDT procurement continues to be led by donors**, e.g., Global Fund **Defined high-risk populations are prioritized** in line with MoH targets and WHO guidelines	A shift from targeted donor-led testing toward **an open market model where RDTs are sold over the counter** (OTC) nationwide, allowing broad public access Testing expected to approach **once-in-a-lifetime global standards**
Key assumptions	• MoH maintains a **risk-based testing** strategy aligned to WHO • Procurement **remains donor and EPSS-controlled**, with limited private market expansion • **No structural shift in testing modality** (LFA remains dominant)	• Policy shift permits **nationwide OTC sale of RDTs,** including pharmacy and retail distribution • Uptake **increases among low-risk and previously untested adults**, driving incremental voluntary demand

Scenario 1: The priority RDT market, under MOH targets, could reach 32 Mn units by 2027, 48% market share is needed for viable production capacity

Projected addressable market for RDTs in Ethiopia, Mn units, 2022-2032



Key assumptions

HIV testing aligned to national **95-95-95 targets**, **ANC-based** syphilis screening, **Blood bank screening** for infections, **25% of febrile patients** are Typhoid positive, and **continued Global Fund and donor financing**

Key takeaways

If government targets reached, **HIV RDTs could account for 15 Mn units by 2027** (~31% of market), becoming the top SKU driver

Typhoid, Syphilis and Hepatitis could grow from **7 Mn** to **17 Mn units (35% of market)**

Capturing ~48% of addressable 2027 market (15 Mn units) for the prioritized RDTs would support a sustainable plant

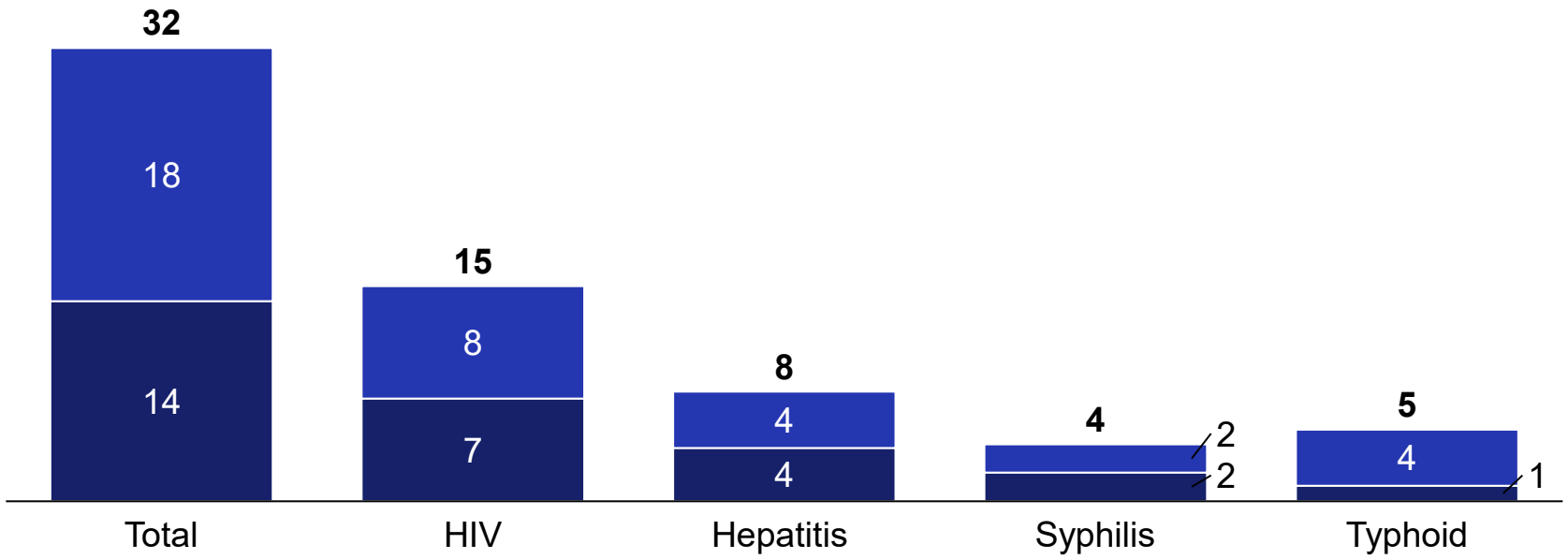
1. Others includes Malaria, Tuberculosis, Helicobacter Pylori, pregnancy, and other multipurpose RDTs

Source: EPSS annual procurement data for EPSS RDF and EPSS donor for financial year 2020-2023; ECC data for private import market for financial year 2020-2023;Local manufacturers survey for private local market for financial year 2020- 2023; National Demand Forecasting of HIV Program Pharmaceuticals July 2025–June 2029 (2025), FDRE Ministry of health

Scenario 1: Mixed public and private procurement makes Hepatitis, Syphilis, and Typhoid near-term priorities

Gap vs required testing volume | Current test procurement | X% Customer segment % contribution

Annual average addressable market for RDTs in Ethiopia, Mn units, 2027-2032



Current procurer breakdown[1]

	Total	HIV	Hepatitis	Syphilis	Typhoid
Donor (via EPSS)	100%	49%	8%	0%
RDF (via EPSS)	0%	22%	36%	76%
Private procurement	0%	29%	56%	24%

1. Total market reflects actual EPSS and ECC data (2022), not scaled assumptions

Source: EPSS annual procurement data for EPSS RDF and EPSS donor for financial year 2020-2023; ECC data for private import market for financial year 2020-2023; Local manufacturers survey for private local market for financial year 2020- 2023

Key takeaways

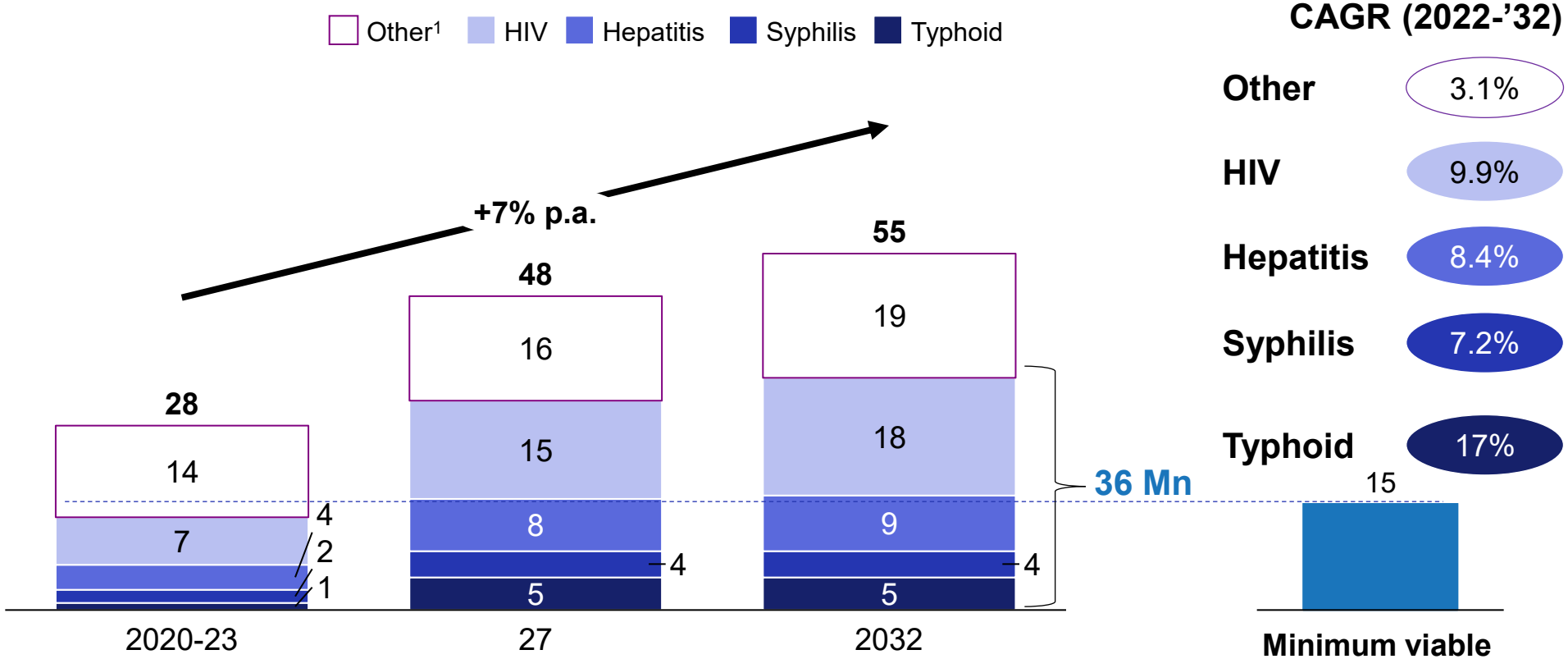
HIV accounts for ~50% of the potential market but is structurally donor-locked, **limiting near-term localization flexibility despite its scale**

Excluding HIV, Ethiopia faces **~10 Mn units of unmet RDT demand annually**, alongside **~7 Mn units currently imported**

Hepatitis, Syphilis, and Typhoid show strong latent demand and minimal donor reliance, **presenting the strongest near-term anchor candidates**

Scenario 2: Under nationwide OTC access[2], priority RDT market could expand to 36 Mn units by 2032

Projected addressable market for RDTs in Ethiopia, Mn units, 2022-2032



CAGR (2022-'32)

Other	3.1%
HIV	9.9%
Hepatitis	8.4%
Syphilis	7.2%
Typhoid	17%

Minimum viable production capacity

Key assumptions

OTC access increases voluntary testing uptake among low-risk and previously untested adults, adding incremental demand equivalent to ~20-25% uplift over MoH-targeted volumes

1. Others includes Malaria, Tuberculosis, Helicobacter Pylori, pregnancy, and other multipurpose RDTs
2. Required tests are estimated based on MoH targets combined with WHO recommendations, which include lifetime HIV testing for adults as a key guideline

Source: EPSS annual procurement data for EPSS RDF and EPSS donor for financial year 2020-2023; ECC data for private import market for financial year 2020-2023;Local manufacturers survey for private local market for financial year 2020- 2023; National Demand Forecasting of HIV Program Pharmaceuticals July 2025–June 2029 (2025), FDRE Ministry of health

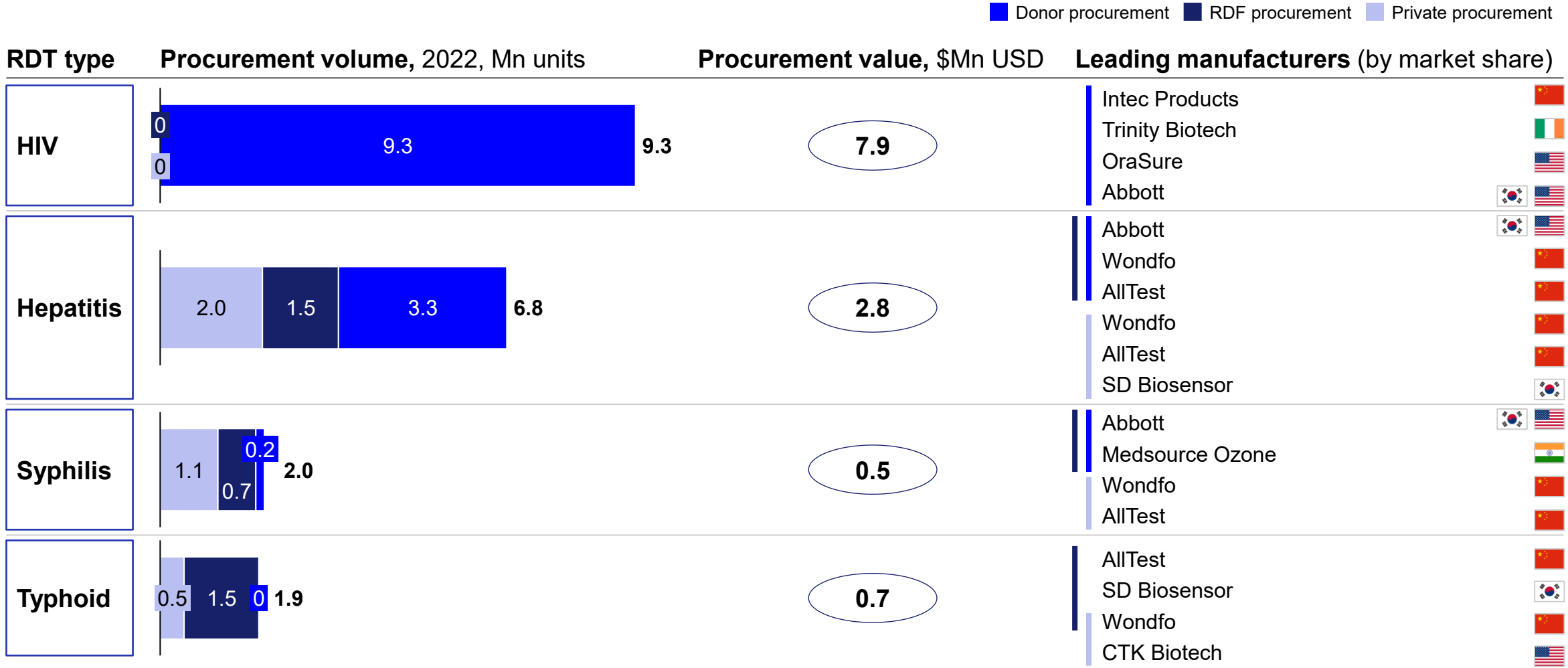
Key takeaways

HIV increases from 15 Mn to ~18 Mn units by 2032, accounting for the **majority of OTC-driven volume expansion**

Hepatitis (~9 Mn), Syphilis (~4 Mn), and Typhoid (~5 Mn) **together represent ~36 Mn units**

Capturing ~50% of addressable 2032 market (15 Mn units) for the prioritized RDTs would support a sustainable plant

Donor, RDF and private procurement currently flows primarily through global RDT manufacturers



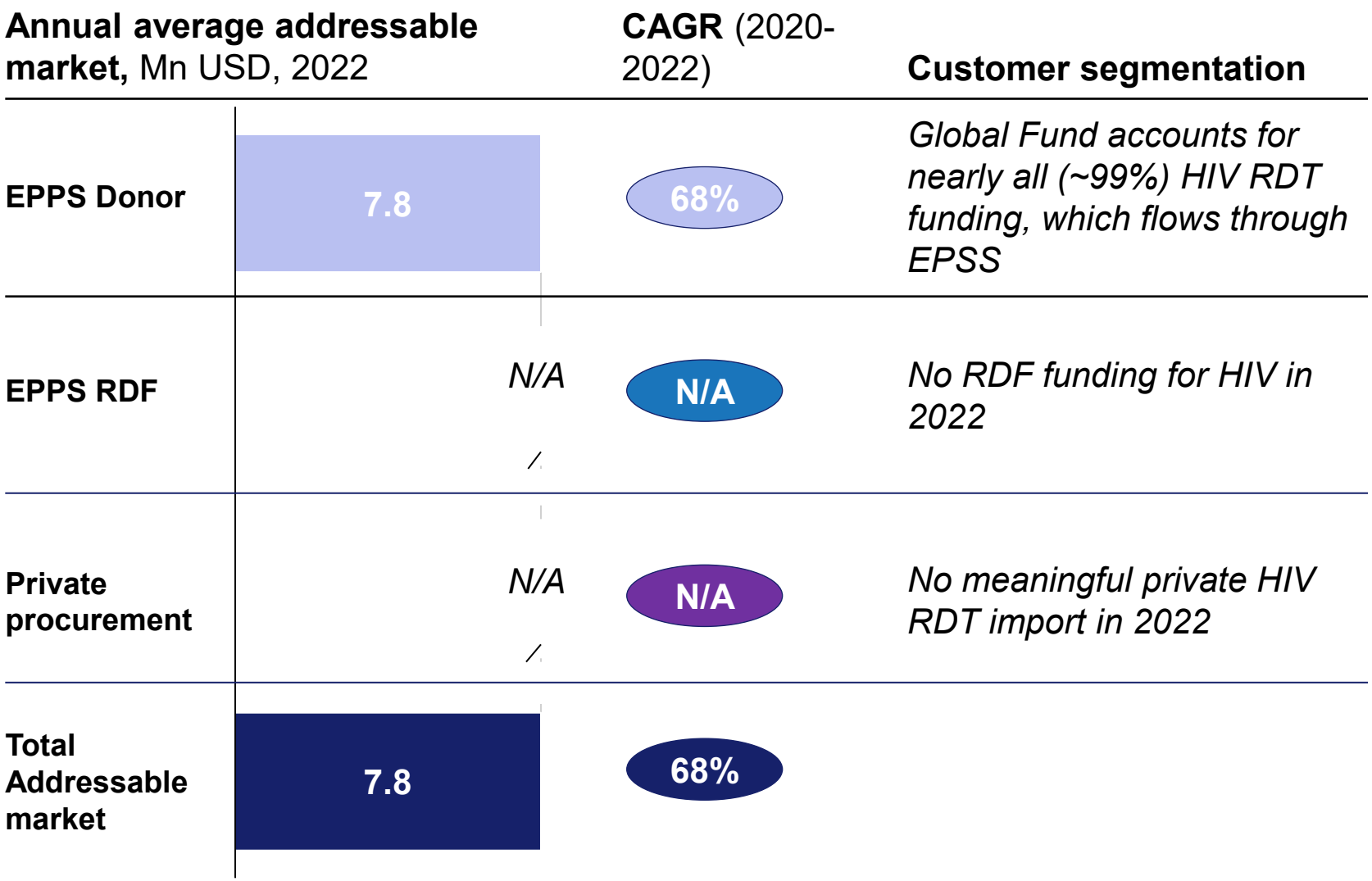
Key observations

- Leading suppliers across all customer segments are **international manufacturers** (Abbott, Intec, Wondfo, AllTest, etc.)
- **Local Ethiopian manufacturers do not currently capture significant share** in any of the customer segments

1. Total market reflects actual EPSS and ECC data (2022), not scaled assumptions

Source: EPSS annual procurement data for EPSS RDF and EPSS donor for financial year 2020-2023; ECC data for private import market for financial year 2020-2023;Local manufacturers survey for private local market for financial year 2020- 2023

The total addressable market for HIV is ~7.5 Mn USD, primarily driven by donor support



Source:. EPSS, ECC, local manufacturer survey

Key takeaways

HIV RDTs represent the largest RDT segment in Ethiopia (~$8M implied 2022 market)

The volume is driven by donor-funded public procurement with demand being structurally programmatic and tied to national HIV testing strategies

HIV RDT landscape is dominated by antibody LFAs, with limited use of antigen-based combos and differentiated detection formats

XX% Share in procurement Dominant global configuration

	Options				Production flexibility
Test types	**Antibody-based** ~98%[1] Detect host anti-HIV-1/2 antibodies in blood/oral fluid			**Antigen & antibody** ~2% Detect p24 antigen and anti-HIV-1/2 antibodies	✓ No major retooling required – formats run on the same LFA platform with reagent and striping adjustments only
Detection	**HIV-1/2 Ab (IgM/IgG)** Detects established infection	**HIV-1 Ab only** Detects established infection	**HIV-1 vs HIV-2 on Ab** Distinguishes HIV-1 vs HIV-2	**HIV Ag/Ab combo (p24 and Ab)** Detects p24 antigen (for early infection) and antibodies (for established infection)	✓ No new assembly change - Ag/Ab formats just need additional striping precision and chemistry optimization
Common brands	**Determine™ HIV-1/2** (Abbott, USA)	**INSTI® HIV-1/2** (bioLytical, Canada)	**Geenius™ HIV 1/2 Supplement al (**Bio-Rad,USA)	**Determine™ HIV-1/2 Ag/Ab Combo** (Abbott, USA)	

Key observations

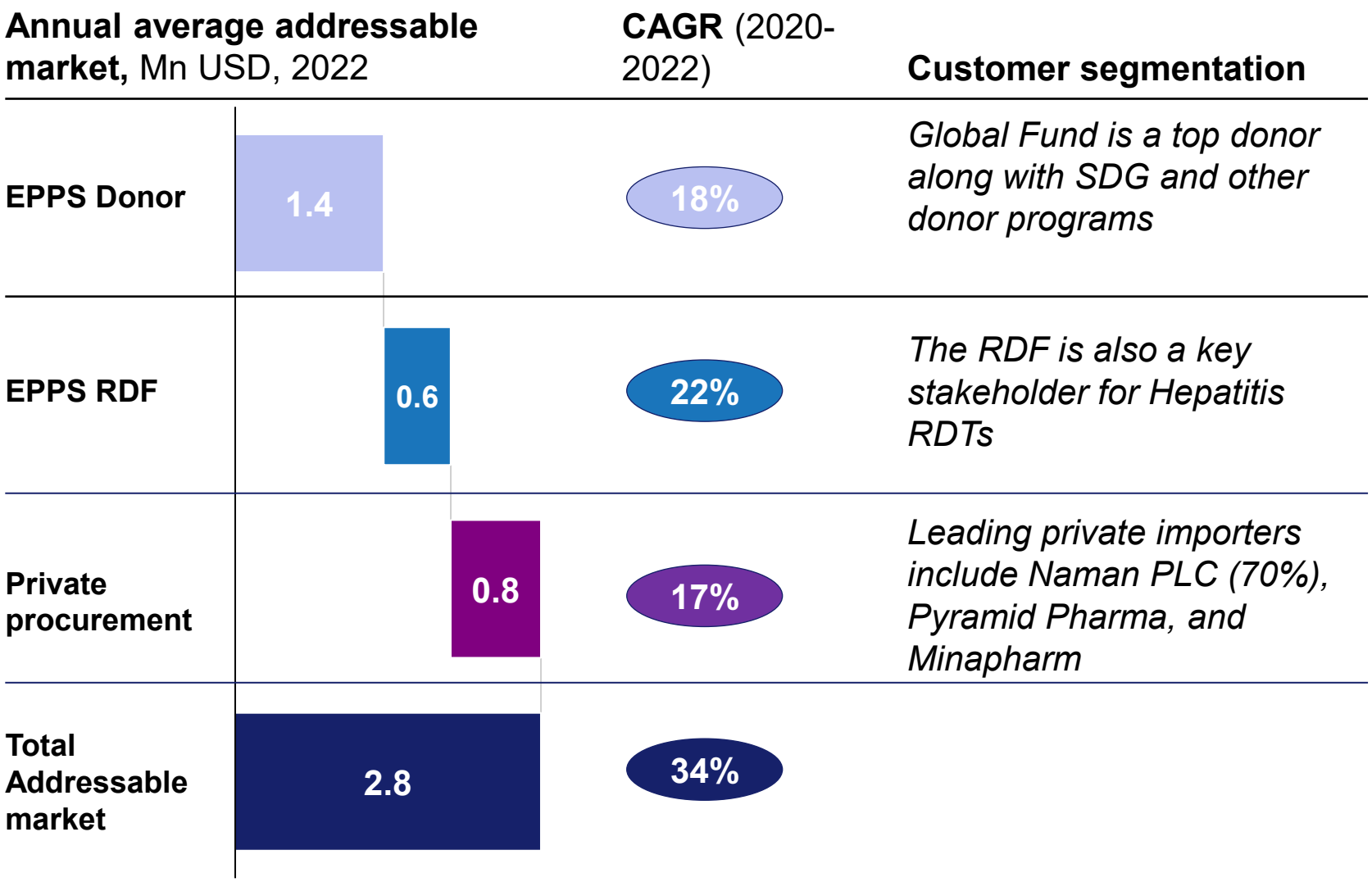
Antibody-based RDTs (~98%) dominate the market, detecting host anti-HIV-1/2 antibodies and primarily identifying established infections

Most RDTs rely on similar lateral flow technology, with variation driven more by detection targets than by platform differences

1. HIV rapid testing is largely Ab-based and tied to a national 3-test algorithm, Ag/Ab combo rapid tests are less consistently used in routine algorithms

Source: WHO Consolidated Guidelines on HIV Testing Services (2019; updated 2023), WHO; WHO Consolidated Guidelines on HIV Testing Services (2019; updated 2023), World Health Organization (WHO)

The total addressable market for Hepatitis is ~3 Mn USD, with donors as strongest localization anchor



Source:. EPSS, ECC, local manufacturer survey

Key takeaways

Hepatitis is the most balanced RDT category (~$3M total in 2022), with meaningful donor, RDF, and private participation

Demand is anchored in blood safety and hospital screening, **making it the strongest near-term localization candidate**

Hepatitis (HBV) RDTs are predominantly antigen-based, with both antigen and antibody tests manufacturable on the same LFA lines

XX% Share in procurement Dominant global configuration

	Options				Production flexibility
Test types	**Antibody-based** ~30% Detect host antibodies to HBV markers (primarily anti-HBs / anti-HBc)			**Antigen based** ~70% Detect HBV antigens (primarily HBsAg) in blood/serum/plasma	✓ Antibody and HBsAg antigen formats run on the same LFA platform; with minor reagent stability control changes
Detection	**Anti-HBs Ab** Detects immunity marker	**Anti-HBc Ab** Detects past/current exposure	**HBV combo Ab panels** Identifies exposure	***HBsAg antigen*** Detects surface antigen and an active HBV infection	✓ Multi-marker antibody panels add striping complexity but remain compatible with the same LFA line
Common brands	**Surface Antibody HBsAb** (Fortress Diagnostics, UK)	**Anti-Hbc One Step** (Fortress Diagnostics, UK)	**Advanced Quality,** (InTec, China)	**InTec HBsAg Rapid** (InTec, China) **SD BIOLINE HBsAg** (SD Biosensor, South Korea)	

Key observations

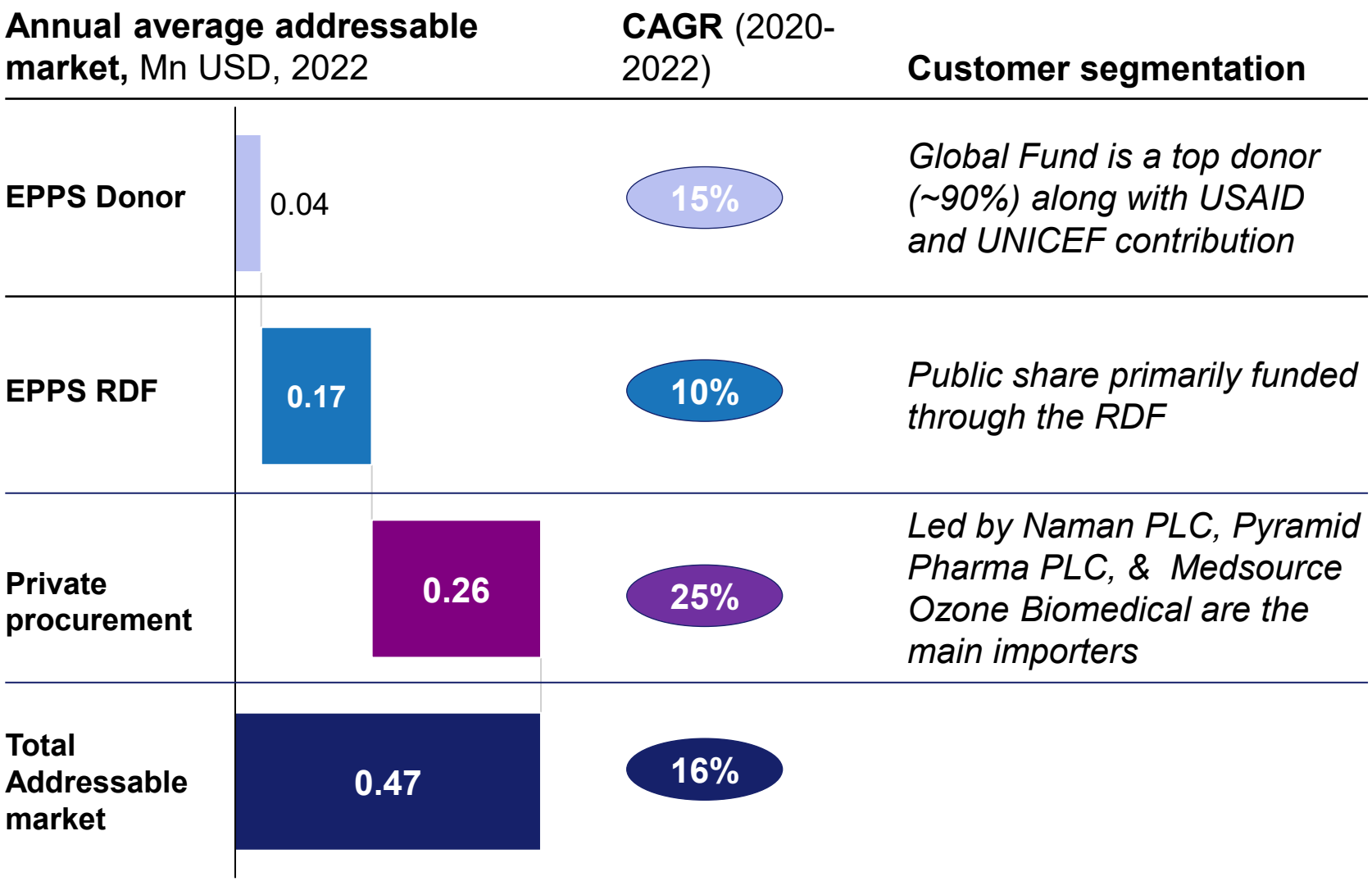
Antigen-based RDTs (~70%, HBsAg) dominate, detecting active HBV infection and representing the primary use case

Antibody-based tests (~30%) serve complementary roles, **identifying immunity or past exposure** (anti-HBs, anti-HBc)

The market is fragmented with multiple manufacturers, with **no single dominant player across formats**

Source: Guidelines on Hepatitis B and C Testing (2017), World Health Organization;

The total addressable market for Syphilis is ~0.5 Mn USD, primarily driven by private procurement



Source:. EPSS, ECC, local manufacturer survey

Key takeaways

Syphilis is a smaller market (~$0.5M in 2022) but private-heavy and linked to ANC/STI screening mandates

While not scale-driving alone, **it strengthens portfolio economics when bundled with other tests**

Emerging **HIV/Syphilis combo RDTs could displace standalone syphilis tests**, potentially reshaping the SKU prioritization strategy

Screening mandates offer **demand stability despite small market size**

Syphilis RDTs are overwhelmingly antibody-based, with limited antigen formats and straightforward production on standard LFA lines

XX% Share in procurement Dominant global configuration

	Options				Production flexibility
Test types	**Antibody-based** >99% Detect host antibodies to Treponema pallidum (treponemal) or reagin (non-treponemal proxy)			**Antigen-based** <1% Direct antigen detection exists in principle but is not common in routine RDT procurement	✓ Antigen-based formats are rare and would require additional assay development but no new assembly line
Detection	**Treponemal Ab (TP)** Current or past infection	**Non-treponemal Ab** Detect active infection	**Dual TP and RPR rapid** Differentiates likely active vs past	**T. pallidum antigen** Detects active infection	✓ Dual-line versions require additional signal balancing but not new equipment
Common brands	**SD BIOLINE Syphilis 3.0** (SD Biosensor, S.Korea)	**RPR Card test** (Biorex Diagnostics, United Kingdom)	**DPP Syphilis Screen** (Chembio, USA)	**EZER™ Syphilis Rapid Test** (Genesis Biotech, India) **Bioline™ HIV/Syphilis Duo** (SD Biosensor, South Korea)	

Key observations

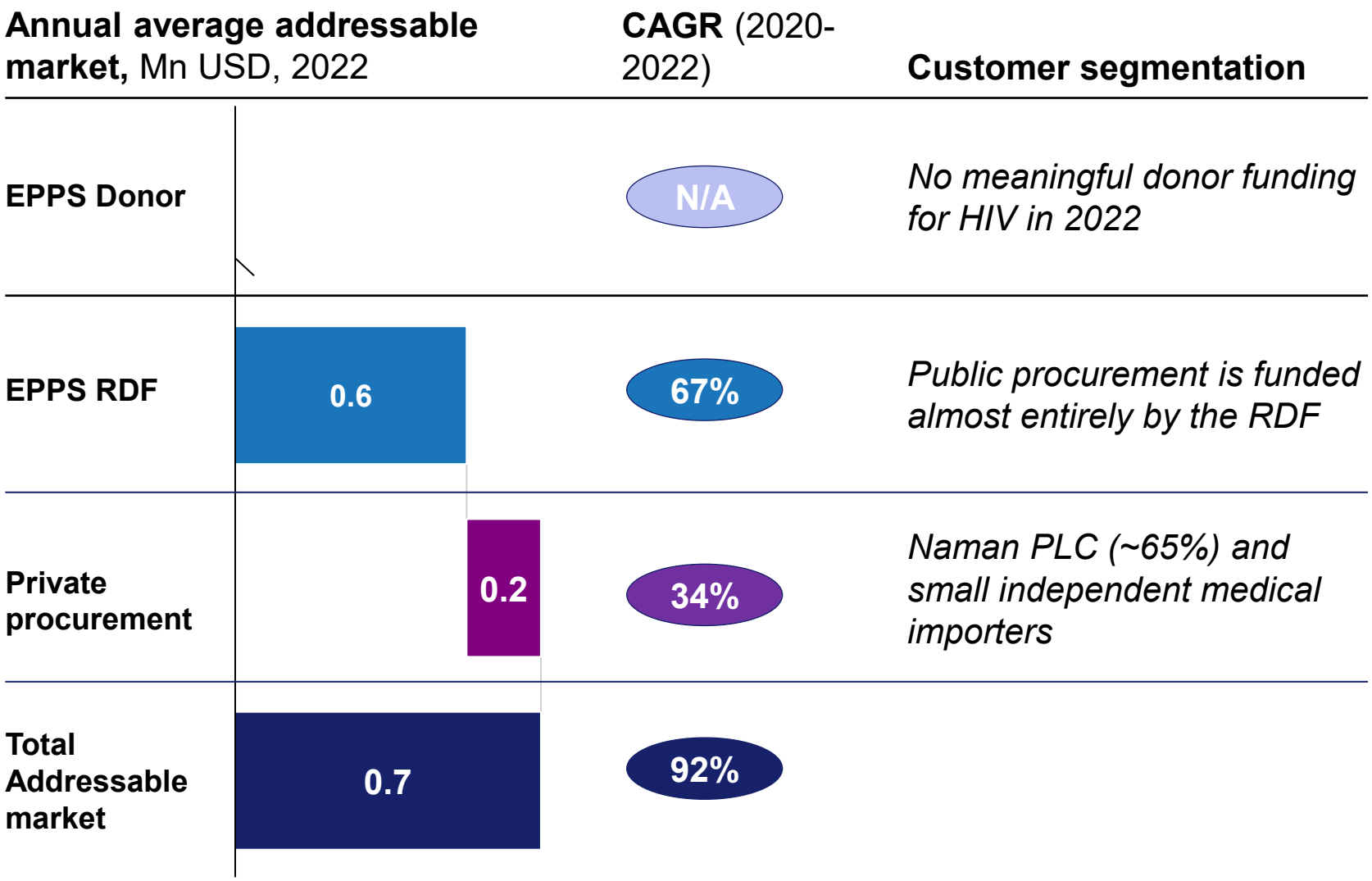
All formats **are compatible with standard LFA production lines**, with minimal changes to core assembly processes

Antigen-based formats are rare (<1%), requiring additional assay development but not fundamentally different manufacturing

Combination "screen and confirm" formats exist but face lower penetration due to higher cost and more complex QC

Source: WHO Guidelines for the Treatment of Treponema pallidum (Syphilis) (2016), World Health Organization

The total addressable market for Typhoid is ~0.7 Mn USD, primarily driven by the RDF



Source:. EPSS, ECC, local manufacturer survey

Key takeaways

Typhoid represents a modest segment (~$0.7M in 2022), **driven by RDF procurement and episodic demand**

Growth is program-dependent, and **scale would require deliberate public health prioritization**

Typhoid RDT demand may fluctuate depending on availability of alternative febrile illness diagnostics or changes in clinical treatment guidelines

Typhoid RDTs are predominantly antibody-based LFAs, with limited antigen formats and a fragmented supplier landscape

XX% Share in procurement

Dominant global configuration

	Options				Production flexibility
Test types	**Antibody-based** >99% Detect IgM/IgG antibodies against S. Typhi antigens in patient blood/serum			**Antigen-based** <1% Detect S. Typhi antigens (e.g., LPS or other surface markers)	✓ Antigen-based formats require additional assay development and validation but still use the same platform
Detection	**IgM** Suggests recent/acute infection	**IgG** Indicates past and recent exposure	**IgM & IgG** Dual-line: acute vs past differentiation	***S. Typhi* antigen** Direct bacterial antigen detection	✓ Dual-line formats demand tighter signal balancing and stability control, but remain compatible with the LFA line
Common brands	**TUBEX TF** (IDL Biotech, Sweden)	**OnSite Typhoid IgG** (CTK Biotech, USA)	**SD BIOLINE Typhoid IgG/IgM** (SD Biosensor, South Korea)	**OnSite Typhoid Ag Rapid** (CTK Biotech, USA) **Standard Q Typhoid Ag** (SD Biosensor, South Korea)	

Key observations

All formats are **compatible with standard LFA manufacturing lines**, with moderate complexity in antibody-based designs

Antibody-based RDTs (>99%) dominate, detecting IgM/IgG responses to S. Typhi antigens

Source: Rapid diagnostic tests for typhoid and paratyphoid (enteric) fever (2017), Lalith Wijedoru, Sue Mallett, and Christopher M Parry

Local RDT production exists in Ethiopia, but lacks certifications required to access RDF or donor-funded procurement

Procured by EPSS

Local manufacturer	Annual production capacity, Mn units	List of products		Value chain depth
The New Millenium		• HCG pregnancy • Urine dipstick[1] • H.Pylori Antigen	• H.Pylori Antibody • Malaria PF/PV	End-to-end production – *but no record of GMP certification or ISO accreditation*
Access Bio		• COVID-19 RDT (CareStart)	• Malaria RDT	End-to-end production – *but no valid WHO PQ certification (expired in 2021)*
Synergy Pharma	-	• HCG pregnancy • HCV	• H.Pylori	Import and distribution
Rosewell Remedies	-	• Malaria • Chikungunya • Dengue • Syphiilis	• HIV • Typhoid • Troponin I • Pregnancy	Import and branding

Key observations

Several players operate as **assemblers, packagers, or importers**, rather than fully integrated manufacturers

Existing end-to-end producers (New Millennium, Access Bio) focus on a **limited portfolio of RDTs and primarily serve the private market**, as they lack GMP certification and/or WHO PQ required for RDF or donor-funded procurement

Obtaining WHO PQ and ISO 13485 involves **high upfront investment, extensive validation studies, and time-intensive regulatory processes**

1. Contribute 50% of total local production

Source: Local manufacturers survey for private local market for financial year 2021- 2023; Press search

The RDT investment is viable – especially if three key execution conditions are met

Feasibility conditions	Timely acquisition of the required validation and certifications for RDTs	Capture ~75% of local Hepatitis and Syphilis RDT demand	Secure a manufacturing partner for technology and regulatory transfer
What must be true	**Established GMP-compliant manufacturing**, obtain ISO 13485 certification, and achieve WHO prequalification in less than 3 years (for HIV and Hepatitis RDTs)	Post GMP-compliance, c**apture majority share in non-HIV RDT segments**, potentially displacing current suppliers (e.g., Roswell and imports)	**Partnership with an experienced international RDT manufacturer** (e.g., via JV, tech transfer, or contract manufacturing) to access proven technology, SOPs and regulatory documentation
Why this matters	• Prior to certification, **only serve the private market** (below minimum efficient scale) • **Access to RDF demand** requires GMP, ISO, WHO PQ • **Certification and validation are time-sensitive**, with limited cost recovery without RDF/donor market access	• **~15 Mn units annual capacity** is required to reach EoS and compete at international tender pricing • Without majority local market capture, **unit economics remain uncompetitive** • Competition from imports and existing local assembler must be addressed on price and quality	**A partnership** • **Accelerates pathway to EPSS eligibility** and donor tenders • **Reduces regulatory failure risk,** trial-and-error development cycles and time-to-market • **Increases probability** of WHO PQ approval

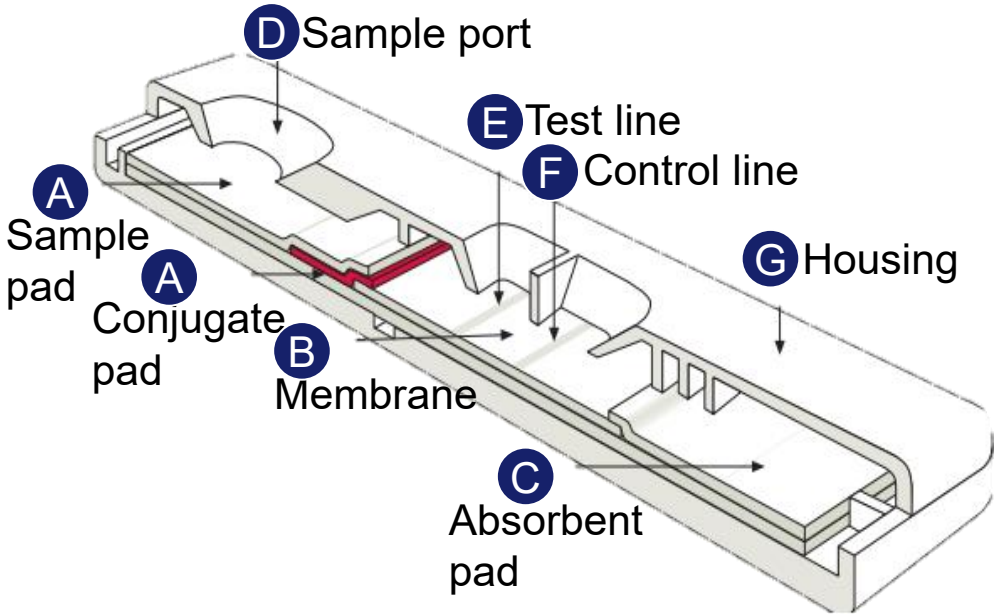
Source: EPSS annual procurement data for EPSS RDF and EPSS donor for financial year 2020-2023; ECC data for private import market for financial year 2020-2023; Local manufacturers survey for private local market for financial year 2020- 2023; Medical Devices: WHO Prequalification of In Vitro Diagnostics Programme – Guidance for Manufacturers (latest update 2022), WHO

Agenda

1. Product overview
2. High-level market assessment
3. **Manufacturing process**
4. Regulatory and IP pathway
5. Supply chain feasibility
6. Risks and mitigants

RDTs are designed to provide quick and on-the-spot results, typically within minutes, and generally a relatively simple production

Many components of typical RDTs are low-tech: Example of typical components of malaria and HIV RDTs[1]



- **A Sample & conjugate pad:** detector reagent conjugated to colored particles to capture desired analyte and released upon liquid flow
- **B Membrane:** hydrophobic membrane made of nitrocellulose to allow sample flow
- **C Absorbent pad with desiccant:** maintains flow rate of liquid through capillary action
- **D Sample port**: collects blood sample and drops of buffer
- **E Test line**: immobilized biomolecule to capture desired analyte bound to conjugated detector
- **F Control line:** species-specific anti-immunoglobulin against detector reagent
- **G Housing & backing:** inert support for membrane

1. Additional accessories include alochol wipes, lancet, capillary tube, bandages and buffer solution

Source: Expert interviews (former production managers and product managers at major manufacturers); The Global Fund Pooled Procurement Mechanism

RDT manufacturing involves five modular stages, most of which are platform-shared across infectious test SKUs

NOT EXHAUSTIVE

	Prepare and conjugate reagents	Stripe reagents onto nitrocellulose	Prepare pads and laminate materials	Cut strips and assemble cassettes	Testing and package
Description	Antibodies or antigens are **purified and mixed with gold or latex particles** to create the visible detection reagent The conjugated **reagent is stabilized, filtered, and tested** to ensure it binds correctly and produces a clear signal	Capture antibodies or antigens are **dispensed in precise lines onto nitrocellulose membrane sheets** to form the test and control lines Striped **membranes are dried** under a controlled temperature to fix the proteins in place	Sample pads, conjugate pads, nitrocellulose membranes, and absorbent pads are **laminated onto adhesive backing cards** to enable controlled flow The **laminated sheets are pressed and inspected** for alignment and flow	The laminated sheets are **cut into narrow strips** of defined width Each **strip is inserted into a plastic cassette (or prepared as a dipstick)**, labeled, and visually inspected	Finished tests are **validated using positive and negative control samples** to confirm performance Devices are **sealed in foil pouches with desiccant**, boxed, and released after final quality approval
Inputs	Monoclonal capture antibodies Detection antibodies Colloidal gold nanoparticles Conjugation buffers and stabilizers Blocking agents	Nitrocellulose membrane rolls Test line capture antibodies Control line antibodies Striping buffer	Sample pad material Conjugate pad Absorbent pad Adhesive backing cards Blood separation membrane (Hepatitis, HIV -serum-based)	Plastic test cassettes Desiccant sachets Labels and inks Multi-window cassette molds (HIV Ag/Ab combo, Dual-line Typhoid)	Positive control sera (HIV, Hepatitis, Syphilis) Bacterial antigen controls (Typhoid) Foil pouches Desiccant
Equipment	Conjugation mixer/reactor Centrifuge or tangential filtration system Protein quantification analyzer Stability chambers	Automated striping machine Precision dispensing head Controlled drying oven Roll-to-roll handler Environmental chamber	Automated laminator Pressure roller system Alignment system	Rotary strip cutter Cassette insertion machine Inkjet coder Vision inspection system	QC test benches Stability chambers Heat-sealing machine Cartoning line

Key observations

Most infectious disease RDTs (HIV, Hepatitis, Syphilis, Typhoid) use **the same five core manufacturing stages**

The main variation across RDT types is in clearance and sanitization, validation requirements, and reagent replacement not in processes or assembly equipment thus requiring no additional major capital investment to produce other RDT types

While manufacturing steps are platform-shared, **WHO PQ, stability testing, and clinical validation** remain barriers to scaling and donor market access

Source: Lateral Flow Immunoassay: Principles and Applications (2016), Koczula & Gallotta, Essays in Biochemistry; WHO Prequalification of In Vitro Diagnostics Programme – Public Report and Manufacturer Guidance (latest update 2022), WHO; Development and Manufacture of Lateral Flow Immunoassay Devices (2014), O'Farrell, in Lateral Flow Immunoassay (Springer Methods in Molecular Biology); Press search

Key infrastructure components for successful positioning of an RDT manufacturing facility

1 Controlled environment

- **Temperature-Controlled Storage:** A significant portion of RDT raw materials, including biological materials (antibodies, antigens, enzymes) and chemical reagents, require strict temperature-controlled storage.
  - Refrigerators: Typically maintained between 2-8°C.
  - Freezers: Temperatures may reach -20°C, -70°C, or lower.
- **Cleanroom Environment for Nitrocellulose**: Preparations Class 7 or 8 cleanroom is required to prevent contamination during membrane preparation.
- **Controlled Environment for Dispensing:** Automated dispensing systems (air jet dispensers, micro-plotters) require a stable temperature and humidity-controlled environment to ensure consistent reagent application.
- **Refrigerated and frozen storage** to maintain the stability of antigens, particles, and conjugates after creation.

2 Advanced quality control system

- **Quality Control Laboratory for Incoming Materials (IQC):** Visual inspection and dimensional checks using tools like calipers and micrometers. There is a potential need for advanced equipment like spectrophotometers for material analysis.
- **Conjugation Quality Control:**
  - **Electron Microscopes**: For detailed inspection of conjugated particles.
  - **PH meters and Conductivity Meters:** For buffer preparation and quality control.
- **Quality Control in Dispensing:** Automated vision systems with high-resolution cameras for inspecting dispensing accuracy (continuity, width, placement).
- **Bonding & Alignment Tests:** Including peel testers and visual inspection stations to verify integrity and alignment of laminated strips**.**

3 High precision machines

- **Accuracy and consistency:** Accuracy and consistency are crucial in RDT production. This involves precise dispensing of reagents (e.g., conjugated antigens) onto nitrocellulose membranes in very narrowly defined lines using high-precision equipment like air jet dispensers or micro-plotters. Additionally, precise lamination and cutting processes are essential to ensure uniform test strips, with accurate alignment of components such as the conjugate pad, sample pad, and absorbent pad. These processes require specialized machinery to maintain uniformity and prevent defects that could affect test performance
- **High regulatory standards requirements:** Regulatory agencies require that RDTs provide consistent results each time they are used. Precision in manufacturing ensures that the test's accuracy does not vary from batch to batch, which is a key requirement for regulatory approval. If a test produces different results on different runs or in different environments, it would fail to meet regulatory standards for reliability and safety.

Source: Press search, manufacturer interviews

Ethiopia possesses several strengths that can be leveraged to position it as an RDT manufacturing hub

Competitive advantage	Description
Extra capacity and ready to be used infrastructure	• Kilinto park is Africa's first **dedicated industrial park to pharmaceutical and medical device manufacturing** and is state-of-the-art, covering 270 hectares of land and being **equipped with all necessary infrastructure** including wastewater treatment plants • Local manufacturers are **operating at only <25%** while the cost of leasing land remains low, at approximately $10 per square meter for a 40-year term
Guaranteed price preference vs importers	• Ethiopia has pharmaceutical public procurement incentive that provides **25% price preference for local producers and a prepayment of 30% of the tender value** to local manufacturers that are awarded the supply contract by EPSS
Fiscal incentives	• Ethiopia offers incentives for FDI in the pharmaceutical and medical diagnostics sectors. Presence **of income tax exemptions to local pharmaceutical players** operating in industrial parks depending on the segment of the value chain, location of the park and export performance
Guaranteed government market	• EPSS has identified **a list of products that will be prioritized for local procurement**, provided they meet the required standards, qualifications, and demand. The goal of this initiative is to achieve local self-sufficiency and reduce reliance on imports.

Source: Press search, local manufacturer interviews

The advantage lies in state mandates and ecosystem strengths, with success dependent on offtake, and strategic SKU sequencing

Competitive advantage	Description
Ecosystem tailwinds	**Location in Kilinto** (pharma-focused industrial zone) improves feasibility: shared utilities, wastewater treatment, and a cluster effect that lowers execution risk versus dispersed sites, while **demand for RDTs is increasing in Ethiopia**
Pathway to demand aggregation	State-owned platform**s are uniquely positioned to align with public procurement architecture** (EPSS/RDF and national programs) and negotiate long-term offtake, often the main differentiator in successful localization plays
State mandate and funding	Set up organization as a public enterprise to **drive import substitution at scale** (and coordinate across biologics/health manufacturing), giving it stronger “right to win” than a greenfield private entrant
Improving regulatory credibility	**Ethiopia’s regulator (EFDA) achieving WHO Maturity Level 3** is a material unlock for quality oversight and future international credibility, critical for export pathways and donor confidence

Source: Ethiopia Achieves WHO Maturity Level 3 for Medicines Regulation (2025), World Health Organization (WHO); The Council of Ministers Endorses Regulations to Enhance Local Vaccine Manufacturing Capacity (2023), National Veterinary Institute (NVI); Kilinto Industrial Pharmaceutical Park Profile (2022), Ethiopian Investment Commission (EIC); Local Pharmaceutical Production in Africa: Business Plan (2012; updated references 2020), WHO & African Union Commission

Key drivers of success

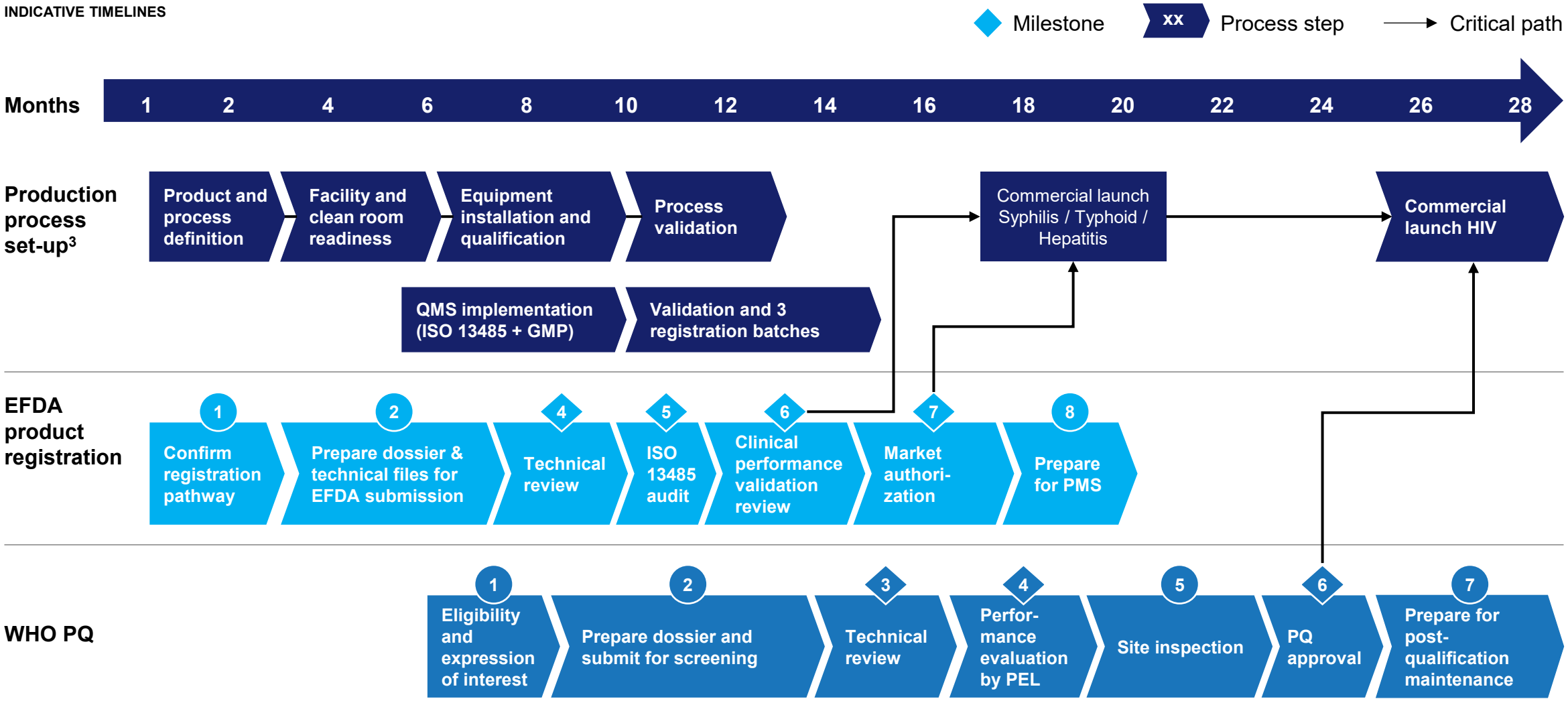
- **Technology transfer partnerships:** that include know-how (not just equipment). The winning model is partner-led capability building: process recipes, QC methods, validation packages, training, and ongoing tech support
- **Win by sequencing:** start with simpler, high-volume, domestically defensible SKUs then expand into more regulated/donor-tied products only after quality maturity and track record
- **Bankable offtake:** lock multi-year procurement commitments where feasible; pair with a clear cost-down roadmap (yield, scrap, automation, local sourcing) to avoid becoming a high-cost protected producer
- **Talent engine:** Strong attraction and retention plan for QA/QC, regulatory, and engineering talent are crucial

Agenda

1. Product overview
2. High-level market assessment
3. Manufacturing process
4. **Regulatory and IP pathway**
5. Supply chain feasibility
6. Risks and mitigants

Syphilis, Typhoid, and Hepatitis RDT launch can occur in ~18-24 months subject to EFDA authorization; HIV launch requires subsequent WHO PQ

INDICATIVE TIMELINES



1. Post-market surveillance
2. Outlining process steps relevant for national registration and WHO PQ approval – full production ramp-up roadmap outlined in last chapter
3. Incase of greenfield development, clinical trials are required which will come before technical reviews

Source: Guideline for Registration Requirements of In Vitro Diagnostic Medical Devices, 2020, Ethiopian Food and Drugs Authority; Regulatory Process of In Vitro Diagnostic Medical devices in Ethiopia, 2021, Arazy Group Consultants Inc; Overview of the WHO prequalification of in vitro diagnostics assessment, 2017, WHO; In Vitro Diagnostics Important Update - Changes to WHOs Prequalification of IVD Assessment Procedure (from 2026), 2026, WHO

Timely EFDA approval requires parallel dossier preparation and inspection-ready manufacturing

◆ Technical review, GMP inspection, market authorization

	1 Confirm registration pathway (1-2 months)	2 Prepare dossier & technical files for EDFA submission (3-5 months)	6 Prepare for post-market surveillance (1-2 months)
Critical actions to take	• Confirm device classification (typically Class C/D for RDTs; HIV is Class D) • Confirm applicable standards (ISO 13485, ISO 14971, ISO 23640, ISO 18113) • Confirm local validation requirements (mandatory for HIV RDTs) and GMP inspection requirements • Conduct optional pre-submission meeting with EFDA • Align on labeling language requirements (English plus local)	• Compile full IVD technical dossier (IMDRF format) • Finalize device description & intended use • Complete risk management file (ISO 14971) • Document manufacturing process flow Include sterilization validation plan/results (Include Analytical performance and clinical validation data from a partner) • Compile QMS evidence (ISO 13485 certification or readiness) • Prepare labeling & IFU[2] per EFDA format	• Establish complaint handling system • Establish vigilance/adverse event reporting • Define recall procedures • Train staff on reporting timelines • Establish post-market data review system
Final documents required	• Device classification justification memo • Applicable standards list • Regulatory strategy memo • Proof of legal manufacturer registration	• Administrative dossier (application form, fees, legal docs) • Technical file[1] • Labeling and IFU • Batch manufacturing record samples	• PMS plan • Vigilance SOP • Complaint handling SOP • Incident reporting template • Record-keeping procedure

Independent development of an RDT line would require **building R&D capabilities** and **conducting clinical trials** as part of the regulatory process to achieve **certification**.

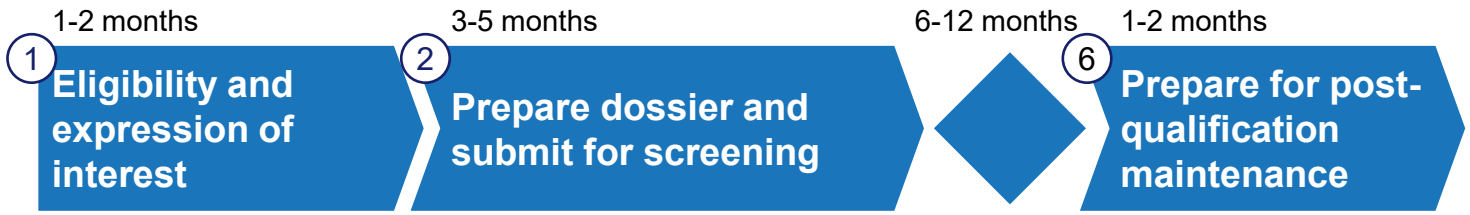
Key observations

- **EFDA readiness is driven by manufacturing maturity,** incl., validated sterilization, documented QMS implementation and inspection readiness
- **Technical file submission must run in parallel with facility set-up** to meet launch timelines
- **GMP inspection is the primary regulatory gate** before market authorization
- **Early alignment with EFDA** (e.g., a pre-submission engagement) reduces timeline and inspection risk

1. Should include device description, design specifications, risk management reports, manufacturing process description, performance testing results, QMS documentation summary, Device classification justification (Class C/D), Applicable standards list, Regulatory strategy memo, Legal manufacturer registration | 2. Instruction for use

Source: Guideline for Registration Requirements of In Vitro Diagnostic Medical Devices, 2020, Ethiopian Food and Drugs Authority; Regulatory Process of In Vitro Diagnostic Medical devices in Ethiopia, 2021

WHO PQ approval for RDTs is gated by validated product performance, GMP manufacturing readiness, and site inspection



Critical actions to take	• Align on applicable international standards	• Compile full technical file per WHO device PQ guidance • Demonstrate QMS implementation (ISO 13485) • Align labeling and IFU to WHO format • Ensure EFDA status documentation is included	**Technical review, site inspection, PQ approval**	• Maintain vigilance reporting • Notify WHO of significant changes • Undergo periodic re-inspection
Final documents required	• Expression of Interest (EOI) submission • Legal manufacturer status documentation • Preliminary product information	• WHO PQ technical dossier • Sterilization validation report • Risk management report • QMS documentation summary • EFDA regulatory status evidence		• PQ maintenance plan • Change control records • Annual performance reports • Annual performance reports

Key observations

- **WHO PQ timelines are primarily driven by technical review** and **site inspection scheduling,** both largely outside direct control by external parties
- WHO PQ should be initiated during facility build-out but will typically conclude **3–6 months after EFDA authorization**, supporting a phased launch strategy
- **Dossier preparation, clinical validation, and facility build could run in parallel** to avoid major delays

Source: Overview of the WHO prequalification of in vitro diagnostics assessment, 2017, WHO; In Vitro Diagnostics Important Update - Changes to WHOs Prequalification of IVD Assessment Procedure (from 2026), 2026, WHO

Agenda

1. Product overview
2. High-level market assessment
3. Manufacturing process
4. Regulatory and IP pathway
5. **Supply chain feasibility**
6. Risks and mitigants

RDT manufacturing relies on imported medical-grade inputs, but global supply availability limits structural supply risk

Process step	Input material	Sourcing strategy	Leading suppliers (top 3 by market size)
Conjugating reagents	**Biological reagents**	**High import dependency across all critical inputs**, as local production capabilities not suitable for medical-grade materials **All imports globally available** from multiple suppliers (no structural supply constraints) **Potential for localizing cassette housing**, by scaling the limited plastic molding and manufacturing in country	abcam, MERCK, Meril Moderately concentrated market dominated by US/EU majors, and emerging Asian suppliers
	Gold nanoparticles		BBI Solutions, CYTODIAGNOSTICS, macro&micro-test Moderately concentrated market dominated by a few experienced producers
Striping reagents	**Nitrocellulose membrane**		MERCK, cobetter, SARTORIUS Moderately fragmented market with cost-competitive production often located in Europe and Asia
Lamination stage	**Sample pad, conjugate pad, and absorbent pad**		danaher, AHLSTROM MUNKSJÖ, mdi Highly competitive landscape with a mix of global filtration specialists and IVD-focused OEMs
	Backing card		danaher, MERCK, NUPORE Moderately fragmented market with few global players leading competitive landscape
Packaging	**Cassette housings and desiccants**		Hysen Biotech, DCN DX, greiner Highly competitive market with numerous global and regional players

Implications

Limited near-term opportunity for local substitution exist, as domestic production does not meet medical-grade requirements for key inputs

But Ethiopia's plastic molding capacity could enable partial localization of cassette housings in the near future

No structural supply constraints, as all critical inputs are globally available from multiple suppliers

However, it will likely need to limit procurement to 1–2 suppliers per input material to enable product equivalence and process validation.

Source: Lateral flow assay components market size & growth forecast to 2030, 2025, MarketsandMarkets; Lateral Flow Assay Component Market, 2026, Fact.MR; Asia Pacific Lateral Flow Assay (LFA) Components Market, 2025 , Business Market Insights

Agenda

1. Product overview
2. High-level market assessment
3. Manufacturing process
4. Regulatory and IP pathway
5. Supply chain feasibility
6. **Risks and mitigants**

RDT manufacturing is viable but subject to key market, execution, and cost risks, which require active mitigation (1/3)

✓ Risks that would be mitigated through partnership build

Dimensions		Key risks	Mitigation levers
Market access and demand		**High dependence on donor-funded demand** (e.g., Global Fund), creating exposure to funding cycles and procurement decisions	**Engage early with Global Fud, RDF, and key donors** to secure demand visibility and align on requirements
	✓	**Failure to secure tender access or preferred supplier status** (e.g., due to delayed WHO PQ), limiting access to the largest demand pools	**Achieve WHO PQ and prequalification early** to unlock access to donor-funded tenders
	✓	**Price pressure from international suppliers** (primarily Asia), with risk of undercutting local production economics	**Build and continuously track cost competitiveness** vs. Asian suppliers to ensure pricing viability in tenders
		Limited near-term access to donor-funded HIV market, with WHO PQ timeline stretching to 2-3 years	Prioritize non-HIV RDTs, especially syphilis, for near-term revenue (Month 18-26) and use revenue to fund WHO PQ process, also exploring long term regional export potential
Manufacturing and operations		**Underutilization of capacity**, with economics highly sensitive to achieving scale (>14-15 Mn units)	**Phase production ramp-up and secure anchor volumes upfront** to ensure early utilization
	✓	**Delays in ramp-up or yield stabilization**, delaying revenue generation and impacting IRR	**Leverage experienced operators and technical partners** to accelerate ramp-up and stabilize yields
	✓	**Workforce capability gaps impacting quality and operational efficiency**, particularly during early scale-up	**Invest early in workforce training, SOPs, and quality systems** to ensure consistent performance at scale

Strategic partnerships (particularly for conjugate formula, technology transfer, and manufacturing capabilities) **can significantly de-risk execution** across multiple dimensions.

RDT manufacturing is viable but subject to key market, execution, and cost risks, which require active mitigation (2/3)

✓ Risks that would be mitigated through partnership build

Dimensions		Key risks	Mitigation levers
Supply chain and foreign exchange		**Reliance on imported inputs (e.g., regents and strips)**, exposing operations to external supply dependencies	**Negotiate supplier agreements** with price and volume stability; qualify 2 suppliers per input (1 Western, 1 Asian)
		Exposure to FX volatility and logistics disruptions, impacting input costs and continuity of supply	**Maintain buffer inventory for critical components;** secure DBE[1] priority FX allocation for pharmaceutical manufacturing
	✓	**Potential quality variability from suppliers**, affecting product quality and regulatory compliance	**Implement supplier qualification and dual sourcing strategies** to ensure consistent quality and reliability
Regulatory and compliance		**Delays in EFDA approval or WHO PQ**, delaying access to donor-funded markets and pushing out revenue ramp-up	**Initiate WHO PQ preparation during facility build-out** to enable parallel regulatory and manufacturing readiness
	✓	**Misalignment between facility readiness and regulatory timelines**, resulting in idle capacity or costly rework	**Align regulatory roadmap with production ramp-up milestones** to avoid delays and idle capacity
	✓	**Failure to meet donor and international quality standards**, limiting eligibility for key tenders and reducing competitiveness	**Implement GMP-compliant QMS early** and leverage external regulatory expertise to ensure compliance with donor standards
Financial attractiveness		**IRR highly sensitive to utilization and pricing**, with downside risk if scale (>14M units) is not achieved	**Secure minimum viable volumes** (~14M units) early to ensure utilization
		Margin erosion from input cost inflation or tender price pressure, particularly in a highly competitive global market	**Maintain strict cost discipline** and continuously benchmark against international competitors
		Delayed accounts receivable from EPSS, constraining working capital	Account for working capital buffer in initial investment and **expand into the donor and private procurement** market to the extent possible

Strategic partnerships (particularly for conjugate formula, technology transfer, and manufacturing capabilities) **can significantly de-risk execution** across multiple dimensions.

1. The Development bank of Ethiopia

RDT manufacturing is viable but subject to key market, execution, and cost risks, which require active mitigation (3/3)

✓ Risks that would be mitigated through partnership build

Dimensions		Key risks	Mitigation levers
Partner model		**Selection of suboptimal partner model** leading to slower capability build or limited control over key decisions	**Evaluate partner models upfront** based on trade-offs between speed, control, and long-term capability ownership
		Dependence on partners for critical capabilities (technology, WHO PQ, commercialization), creating execution risk and potential misalignment on incentives	**Negotiate clear and beneficial partnership terms** (e.g., scope of technology transfer, access to PQ dossiers, comercial rights) to ensure alignment & reduce dependency risks
		Insufficient knowledge transfer limiting long-term capability ownership and scalability	**Ensure structured knowledge transfer and capability build provisions are embedded** in partnership agreements
Route-to-market and execution		**Misalignment between production ramp-up and tender timelines**, leading to missed procurement cycles and delayed revenue realization	**Align product roadmap with procurement cycles and tender timelines** to ensure timely market entry
	✓	**Suboptimal product sequencing** (e.g., delayed HIV RDT launch) limiting access to donor-funded demand	**Sequence product launches** (e.g., Hepatitis and Syphilis RDTs first, Typhoid second, and HIV last) to enable early revenue while building capabilities
	✓	**Weak coordination across engineering, regulatory, and commercial functions**, delaying execution and increasing complexity	**Establish a central program management office (PMO)** to drive coordinated, cross-functional execution

Strategic partnerships (particularly for conjugate formula, technology transfer, and manufacturing capabilities) **can significantly de-risk execution** across multiple dimensions.

The contents of this document are meant to be informative of a fact base, rather than provide any specific recommendation. They are based on initial research, interviews, and analysis and are subject to change given continued feedback

UKaid
from the British people