Current Market Access Status of AHD Commodities

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Agenda

- Current Status of the AHD Package of Care
- Looking Ahead: Remaining Challenges and Next Steps

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WHO recommended AHD package of interventions

WHO Definition of AHD

- For **adults and adolescents, and children older than five years**, advanced HIV disease is defined **as CD4 cell count <200cells/mm^3 or WHO stage 3 or 4 event**
  - *Includes both ART naïve individuals and those who interrupt treatment and return to care*
- **All children younger than five years old with HIV are considered as having AHD**

Despite increasing access to treatment, the **number of people with AHD at the time of diagnosis remains high** and is not declining very fast, especially among men

The **mortality rate** among people with AHD is **very high even with access to ART**

Key Products

Diagnostics: (POC) CD4, TB LAM, CrAg LFA/SQ

Medicines: L-AmB, 5FC

Status of CD4 testing solutions | point of care testing

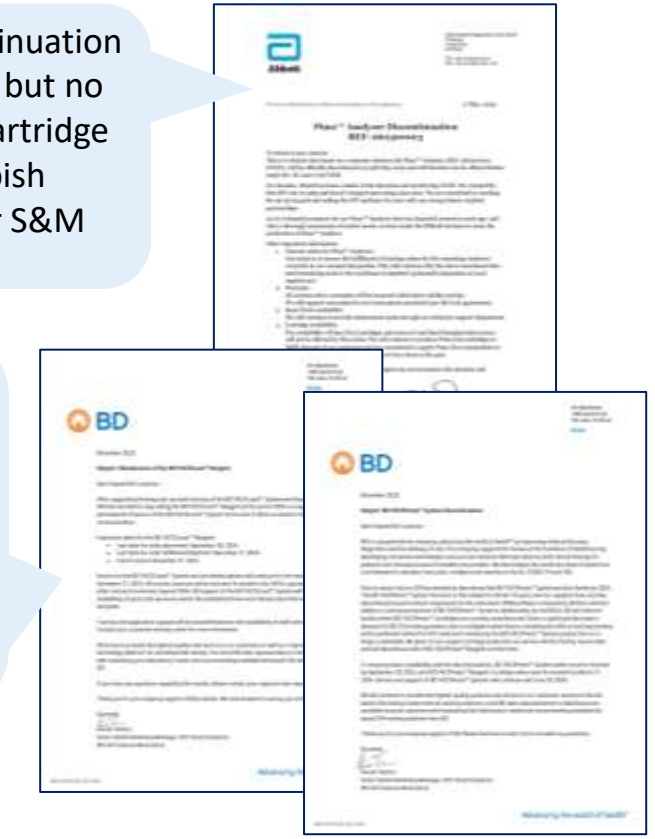
POC CD4 Options at the start of 2022

Product Name	Test Type	Time to Process *Daily Throughput**	Upfront investment	Price per test
Abbott Pima 	• Quantitative • Absolute CD4 count • Finger prick or venous blood	20 min/test *15 - 20 tests/day*	$6,095 + service and maintenance	**$7.60**
BD FACSPresto 	• Quantitative • Absolute CD4 count, CD4 %, Hb • Finger prick or venous blood	22 min/test *60 - 80 tests/day*	$7,910 + service and maintenance	**$8.20**
Accubio VISITECT Advanced Disease *(200 cutoff)* 	• Semi-Quantitative • Absolute CD4 • Finger prick or venous blood	40 min/test *10 - 100 tests/day; >10 possible with batching*	None	**$3.98**

Changes to the market in 2022

Abbott announces discontinuation of the PIMA CD4 analyzer; but no plans to discontinue the cartridge and will continue to refurbish existing devices and honor S&M agreements

BD announces low demand for their CD4 products resulting in a discontinuation of the BS FACSPresto and BD FACSCount cartridges and devices by the end of 2024



Status of CD4 testing solutions | all currently available and known pipeline tests

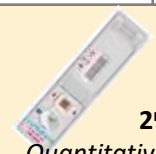
Product	Price/Test	Result	Sample	Turnaround Time	Capacity
 **Beckman Coulter Aquios CL Flow Cytometer**	**$8.00 - $10.00**[2]	Quantitative Absolute CD3, CD4, CD8, CD45 # & % Lymphocyte # & %	Venous WB	20 min/test	>600 tests/day *Assumes 40 samples[1] per batch * 20 mins per batch[1] * batches per hour*
 **Sysmex Partec Cyflow**	**$4.20 - $5.30**[3]	Quantitative Absolute CD4 & CD4%	Venous WB	15 min/test	250 tests/day[4]
 **BD FACSPresto**	**Last orders were accepted through March '24 and support for final orders available through mid '26**				
 **Abbott Pima**	**Production of analysers ceased May '22; mapping and servicing of existing fleet underway; supply of cartridges will continue for foreseeable future**				
 **AccuBio VISITECT® Advanced Disease** *(200 CD4 cutoff)*	**$3.98** Unitaid-CHAI Pricing Agreement[5]	Semi-Quantitative CD4 count above or below 200	Finger prick/ venous blood	40 min/test	12 tests/day *>12 possible with batching*

Pipeline

Epimune Diagnostics
i.Mune CD4
Quantitative *in vitro* PCR test

Glory Bio Technologies Corp
POC CD4 test
Quantitative POC device with cartridges

AccessoBio
VITA POC CD4 test
Quantitative POC device with cartridges



AccuBio
2nd Gen CD4 LFA
Quantitative / semi-quantitative LFA

[1] Beckman Coulter Aquios CL Brochure; [2] Beckman Coulter, April 2024, incl all consumables and controls, excl service costs; [3] Sysmex 2024 (depends on annual volumes); [4] Partec CyFlow Counter brochure. Link; [5] USAID Global Health Supply Chain. Link

Status of TB LAM testing solutions

Pipeline

Product	Test Type	Performance	Time to Process *Daily Throughput*[1]	Regulatory approval	Status	Shelf life at production	Price per test
Abbott Determine TB LAM 	• Qualitative • Urine assay • No infrastructure required	**Sensitivity:** 10.9 – 56.0%[2] **Specificity:** 93.6 – 97.6%[2]	25 min per test[3] *Up to ~48 tests/day*	US FDA CE-IVD	Available (current stockouts since Sept 2023)	18 months *12 months*	$3.70[4]
Abbott HS TB LAM 	• Qualitative • Urine assay • No infrastructure required • Potential for HIV-ve	TBC	TBC	TBC	Pipeline product, clinical trials beginning in 2024, estimated market launch in 2027	TBC	TBC
Fujifilm SILVAMP 	• Qualitative • Urine assay • No infrastructure required	**Sensitivity:** 43.9 – 87.1%[2] **Specificity:** 80.5 – 97.0%[2]	50 - 60 min per test[5] *Up to ~48 tests/day*	*TBD*	Pipeline product, clinical trials beginning in 2024, obtaining WHO recommendation by end of 2025	TBC	$9-10[6]

TB Diagnostics not included here: LAM products expected in 2+ years, GeneXpert, Chest Xray, Miscroscopy, and targeted Next Generation Sequencing

[1] Assumes 8 hour work day and no concurrent testing; [2] Broger T et al (2020) Diagnostic accuracy of 3 urine lipoarabinomannan tuberculosis assays in HIV-negative outpatients. Link; [3] Abbott, Link; [4] USAID e-Catalog, Link. [5] Comella del Barrio (2021) Fujifilm SILVAMP TB-LAM for the Diagnosis of Tuberculosis in Nigerian Adults, Link. [6] Shared at TB Union meeting November 2021. [7] Treatment Action Group Pipeline Report 2023, Link.

Status of CrAg testing solutions

Pipeline

Product	Test Type	Performance	Time to Process *Daily Throughput*[1]	Regulatory approval	Status	Total lead Time	Shelf life at production	Supply security	Price per test
IMMY CrAg LFA 	• Qualitative • Whole blood, serum, plasma, or CSF	**Sensitivity:** 100%[2] **Specificity:** 96.6%[2]	10 min/test *Up to ~48 tests/day*	US FDA CE-IVD	Available	~3 months	18 - 24 months[3] *(12 months)*	High	$2.34 - $3.00 Depending on pack size
Biosynex CryptoPS 	• Semi-Quantitative • Whole blood, serum, plasma, or CSF	**Sensitivity:** 61 - 88%[2,4,5] **Specificity:** 95 - 96.6 %[2,4,5]	10 mins/test *Up to ~48 tests/day*	CE-IVD ERPD Cat. 3	Available	~3 months	TBD	TBD	$2.20[4]
IMMY CrAg SQ 	• Semi-Quantitative • Whole blood, serum, plasma, or CSF	**Sensitivity:** 98%[4] **Specificity:** 98%[4]	10 min/test *Up to ~48 tests/day*	CE	Submitted to FDA in December 2024	TBD	TBD	TBD	$2.34 - $3.50[7]

[1] Assumes 8 hour work day and no concurrent testing | [2] Temfack et. al. , 2018, link. NB: The CryptoPS LFA had 78% sensitivity in serum, 92% in plasma, and 100% in CSF. For cross-study comparison we report the sensitivity based on serum.
[3] US FDA approval; in 2021 an increase in temperature stability range (20-25 C to 2-30 C) saw some batches released with a reduced shelf life of ~13 months; this has been revised up to 18-24 months | [4] Skipper et. al., 2020, link
[5] Tenforde et. al., 2020, link | [6] USD equivalent of €2.00- 2.50/test at a rate of 1 EUR = 1.16 USD as of 1 Nov 2020
[7] Pre-market entry discussions with supplier indicate suggest price may be ~$1 higher than the LFA; Unitaid is targeting price parity

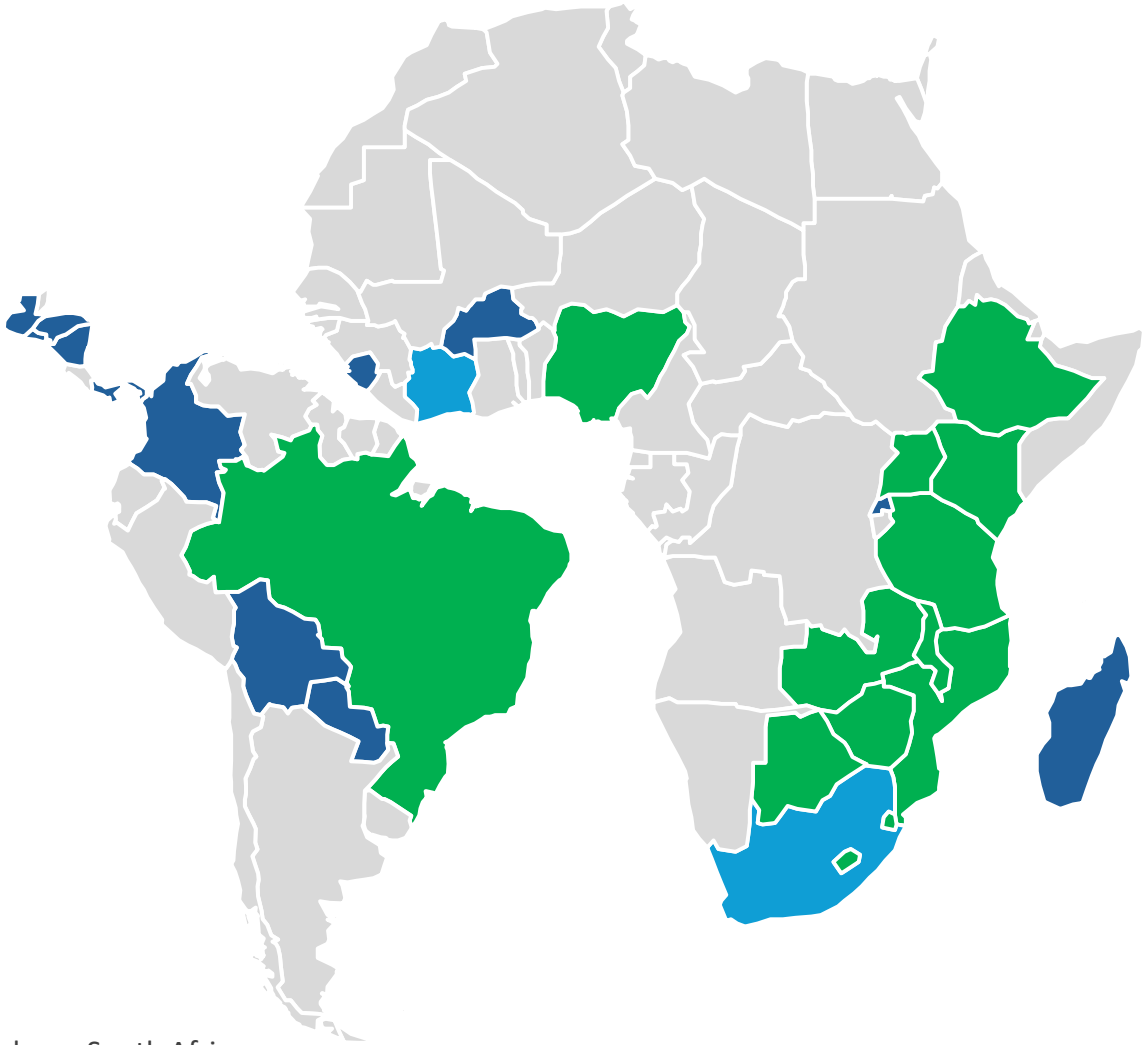
Status of L-AmB and 5FC

L-AmB

- 30 LMICs procuring as of December 2023
- Gilead increased the access price from US $16.25 (EXW) per vial to US $23.00 (EXW) per vial in 2023

5FC

- 21 LMICs procuring as of December 2023
- The market remains stable with two generic suppliers, Strides and Viatris



L-AmB Orders Placed
Not pictured: Armenia, Mexico

5FC Orders Placed
Not pictured: Haiti, India

L-AmB and 5FC Orders Placed
Not pictured: Georgia, Nepal, Sao Tome & Principe, Trinidad and Tobago,

Source: ARV Procurement Working Group, November 2024

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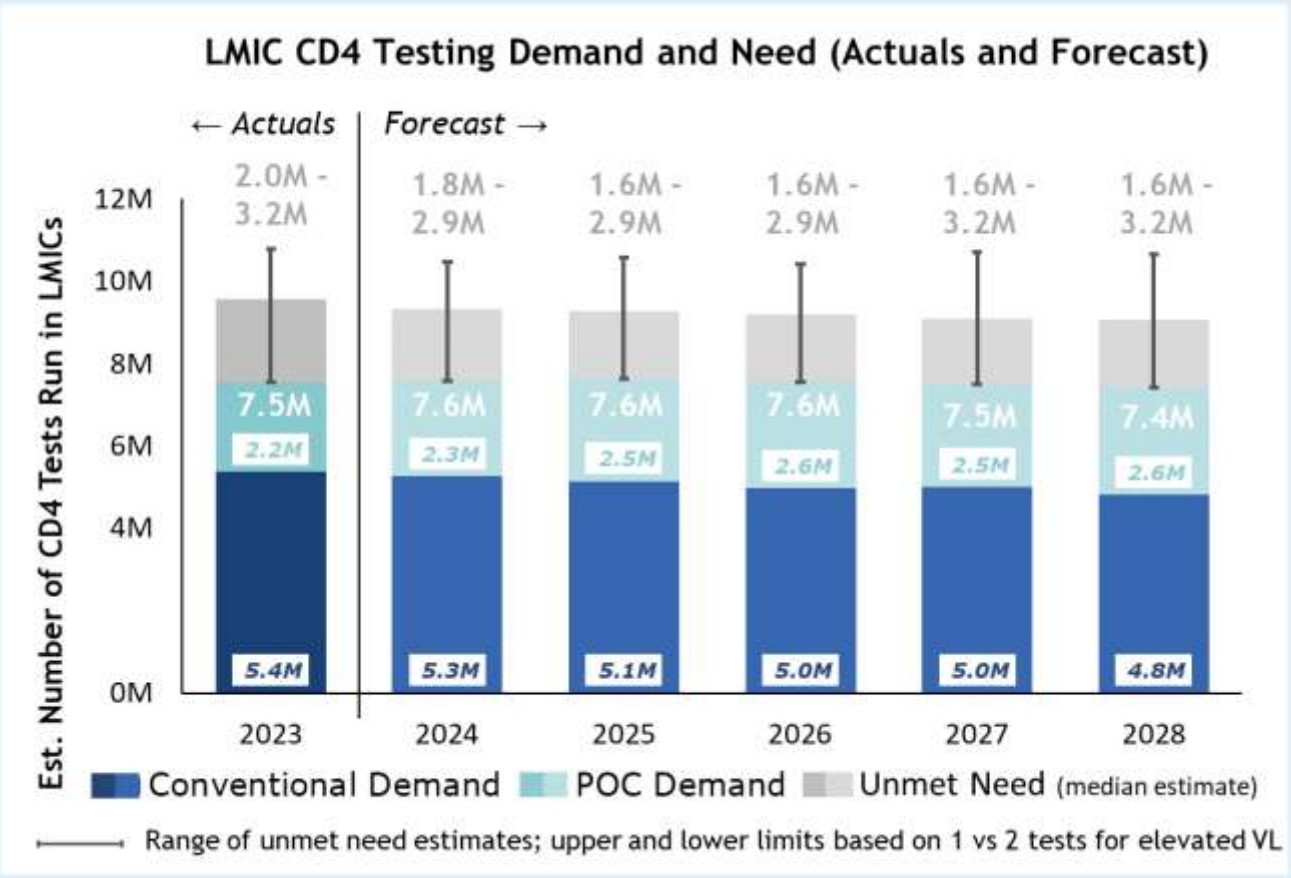
Global CD4 Forecast



Sources: CHAI and Avenir 2024 CD4 Demand Forecast; EGPAF CD4 Coverage Data

Key Callouts

- Demand volumes based on Avenir/CHAI data from 45 countries representing 89% of adults living with HIV in LMICs
- Challenges accessing supplier sales data to validate baseline reports from countries
- South Africa makes up ~1/3 of conventional testing, but even excluding RSA there are considerable conventional testing volumes

Unmet Testing Need

Significant unmet testing need represents opportunity for expansion of CD4 market

Methodology:

- Need is based on 1.1 CD4 tests at initiation (accounting for wastage/retesting) and 1-2 tests for those with an elevated VL result
- National guidelines and implementation may differ from these assumptions
- Need estimates do not include CD4 testing used for treatment monitoring

Remaining challenges and next steps

Addressing national stockouts

- **Improve quantification, forecasting, and consumption models**
- **Optimize commodity inventory management**

Enhancing healthcare worker capacity

- **Conduct “trainings of trainers” to improve HCW confidence around using products across the package of care**
- **Develop targeted DSD models for the adult AHD screening package**

Continuing market-shaping activities

- **Develop a regional manufacturing plan for WHO-prequalified azithromycin and fluconazole to empower more Africa-based suppliers to enter the market**
- **Coordinate engagements to develop a CD4 market entry strategy, ensuring regulatory and quality assurance for market introduction**

icap Global Health

THE CQUIN NETWORK

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Thank You!

Status of histoplasmosis testing solutions

Product Name	Test Type	Time to Process *Daily Throughput*[1]	Regulatory approval	Sensitivity	Specificity	Price per test
IMMY Histoplasma Galactomannan HGM201 EIA 	• Urine	135 min/test *3 tests/day*	US FDA CE-IVD	82.76-91.3%[2]	90.9-98.92%[2]	**$515/kit (96 tests)**
Optimum Imagining Diagnostics LFA 	• Urine, serum	15 min/test *40 tests/day*	CE-IVD	96-100%[3]	89-98.3%[3]	**TBC**
MiraVista EIA	• Quantitative • Urine, Bronchoalveolar fluid, serum, plasma, CSF	180 min/test *2 tests/day*	US FDA CE-IVD	91.8-100%[4]	98-99%[4]	**TBC**
MiraVista LFA 	• Urine	40 min/test *12 tests/day;*	CE-IVD	89-96%[5]	82-94%[5]	**$15**
Pipeline **IMMY Histo GM LFA**	• Urine	60 min/test *8 tests/day*	FDA submission expected July 2025	TBC	TBC	**<$5** ***anticipated***

[1]Assumes 8-hour work day and no batch testing [2]IMMY, Link; Martinez-Gamboa, 2021, Link; [3]Ocansey, 2022, Link; OIDx site, Link; [4]Hage et Al, 2011, Link; Connolly et. Al, 2007, Link; Gutierrez et. Al, 2008, Link; [5]Caceres et. Al, 2019, Link; Lopez et. Al., 2018 Link