Briefing Note

Navigating Market Changes to Sustain CD4 Access

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Purpose

This document highlights market changes that must be considered for sustaining access to CD4 testing in national HIV programs.

Background

Despite significant scale-up of HIV treatment, AIDS-related mortality remains far too high, with 630,000 deaths from AIDS-related illness in 2022 and AIDS deaths reduction targets being missed.[1] Much of this mortality can be avoided by identifying and appropriately managing people with advanced HIV disease (AHD). CD4 testing is a critical tool to diagnose AHD and connect people living with HIV (PLHIV) to the World Health Organization (WHO) recommended package of care.[2] According to WHO, PLHIV should receive a CD4 test when they:

1. Initiate HIV treatment (at baseline and not as an eligibility criterion for initiation) or re-engaging in care.
2. Are virally unsuppressed and clinically unwell.
3. Stop cotrimoxazole and fluconazole prophylaxis.[3]

As the total investment in CD4 by countries using Global Fund financing has increased from Grant Cycle 6 (GC6) to Grant Cycle 7 (GC7), ongoing discontinuations from two

[1]World AIDS Day 2023: UNAIDS Fact Sheet", UNAIDS, accessed 13 May 2024 https://www.unaids.org/en/resources/fact-sheet
[2] Consolidated guidelines on HIV prevention, testing, treatment, service delivery, and monitoring: recommendations for a public health approach," Guidance, World Health Organization, last updated July 16, 2021 https://www.who.int/publications/i/item/9789240031593
[3] "Consolidated guidelines on HIV prevention, testing, treatment, service delivery, and monitoring: recommendations for a public health approach," Guidance, World Health Organization, last updated July 16, 2021 https://www.who.int/publications/i/item/9789240031593

manufacturers threaten country ability to deliver on ambition and sustain access to CD4 testing. It is therefore important for national HIV programs to understand these market dynamics to inform their CD4 procurement and implementation plans.

Market Update

Key market updates for point-of-care (POC), near-POC, and conventional CD4 suppliers as well as product advantages and limitations are provided below.[4]

1.1 Point-of-Care

Accubio VISITECT CD4 Advanced Disease ('VISITECT') semi-quantitative lateral flow assay (LFA) remains **the only point-of-care (POC) product offering on the market**.

Accubio VISITECT CD4 Advanced Disease	
Advantages	**Limitations**
• Does not require upfront investment related to analyzers. • Most affordable CD4 test currently on the market. • Can be decentralized and used by trained non-lab cadres.	• Provides a semi-quantitative result only, which is not sufficient for certain clinical scenarios. • Has a complex multistep process, limiting ability to carry out other activities concurrently. • Time taken to process one sample may limit feasibility for use in high volume sites.

1.2 Near Point-of-Care

The two near POC manufacturers have ongoing discontinuation plans (see timelines below):

- **Becton Dickinson (BD) FACSPresto** has left the market fully.
- **Abbott PIMA** will no longer sell analyzers but continue to supply reagents.

Abbott PIMA	
Advantages	**Limitations**
• Established footprint. • Underutilized capacity in many settings. • One step process with a 20-minute turnaround. • High performance. • Can be decentralized (on battery use) and used by trained non-lab cadres.	• New analyzer production has stopped. Countries can no longer buy new machines but can still procure cartridges at increased prices. Repair and maintenance of existing machines will continue to be available. • High reported error rates. • Service and maintenance can be expensive.

[4] The advantages and limitations have been adapted from the CHAI CD4 Roundtable Discussion: Summary of Key Takeaways document

Overview: Discontinuation Timelines - BD FACSPresto and Abott PIMA			
Analyzer	**Product Type**	**Scheduled End**	**PO Deadline**
BD FACSPresto	Equipment	Already discontinued	
	Services and spare parts	30 Jun 2026	n/a
	Reagents & cartridges	30 Jun 2024	31 Mar 2024
Abbott PIMA	Equipment	Already discontinued (analyzer is sturdy and expected to run for several years)	
	Services and spare parts	Continuing	
	Reagents & cartridges	Continuing	

1.3 Conventional

Two conventional CD4 platforms will remain on the market: Beckman Coulter's Aquios CL Flow Cytometer and Sysmex Partec Cyflow Counter. The BD FACSCount platform has been discontinued but servicing and spare parts will continue until 31 December 2024.

Conventional CD4 Platforms	
Advantages	**Limitations**
• Highest performance and throughput of available CD4 machines on market.	• Initial up-front investment, unless part of all-inclusive pricing deals. • No suitable for decentralized settings, unless relying on sample transport networks.

1.4 Simplified CD4 Market Overview

Supplier	Product Name	Lowest Level of Deployment	Cost/Test (US$, EXW)[5]	Market Status
Accubio	VISITECT CD4 Advanced Disease	Out of facility (POC)	$3.98	Available on the market
BD	FACSPresto; FACSCount	FACSPresto: Out of facility (near POC) FACSCount: District hospital	N/A	**New devices and cartridges discontinued**. Current testing demand on BD CD4 platforms must move to other devices.
Abbott	PIMA	Out of facility (near POC)	$7.60	No new analyzers are being sold. Cartridges will continue to be sold for the time being.
Sysmex Partec	CyFlow Counter	District hospital	$3.00-5.00	Available on the market
Beckman Coulter	Aquios CL Flow Cytometer	District hospital	$4.00-$6.00	Available on the market

[5] EXW- Ex works

Key Considerations

While countries seek to sustain access to CD4 testing in line with the WHO recommendations, the Global Fund recommends that countries should:

1. Conduct mappings of CD4 testing capacity.
2. Organize dedicated quantification and forecasting exercises to reflect new CD4 networks.
3. Organize decommissioning, removal, and disposal equipment that will become obsolete.
4. Adapt budgets as needed.

In situations where any of these changes affect Global Fund grant budgets, PRs are requested to reach out to their respective Global Fund Country Team.

Resources, such as the Global Advanced HIV Disease Toolkit[6] provide a suite of tools to facilitate and support national CD4 decision-making, trainings, community engagement and programming.

[6]Differentiated Service Delivery (https://www.differentiatedservicedelivery.org/resources/the-global-advanced-hiv-disease-toolkit/)