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Partnership for Supply Chain Management

The Partnership for Supply Chain Management

Supply chain implications of the latest CD4 market changes

Navigating the changing CD4 landscape to ensure HIV diagnostic service continuity

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Table of Contents

A. Background

Over the last couple of years, the CD4 diagnostic landscape has been changing, and key testing platforms are being discontinued. This supply chain disruption will make it more complicated for countries to secure CD4 stock and may affect health services delivery if stakeholders do not monitor the situation and adapt accordingly.

This is a supply chain scenario for which the Partnership for Supply Chain Management (PFSCM) has been preparing to ensure that we can continue to support our clients with alternative testing products and offer them the best advice for managing risk so that they can continue to serve the millions of people living with HIV and advanced HIV disease (AHD).

In this document, PFSCM explains briefly what CD4 testing is, what production and supply changes are occurring in the market, and what supply chain stakeholders, specifically procurers/buyers, can do to minimize supply disruption and, ultimately, ensure service continuity.

B. Overview of CD4

1. CD4 count measures CD-4 T lymphocytes (T cells) which is an indicator of the immune function in patients.
2. According to the World Health Organization (WHO) guidance[1], CD4 count is the best predictor for HIV disease status and immediate risk of death.
3. A CD4 cell count of <200 cells/mm3 is the defining threshold for diagnosing AHD; in turn, AHD should be managed through a package of care as defined by WHO[2].
4. All patients entering or re-entering care should receive a CD4 test as a treatment baseline and as clinically indicated for patients who are unstable or with AHD.
5. CD4 testing in the fight against HIV can be carried out through Point Of Care (POC), near POC (nPOC), and lab-based CD4 diagnostics.
6. While CD4 count platforms based in central laboratories are widespread in low- and middle-income countries (LMICs), CD4 testing performed near the patient has been especially valuable for people in rural settings who may experience challenges in accessing testing through centralized laboratories[3].
7. Despite conjecture regarding forecasts for CD4 test volumes, one expectation is for the overall demand to remain relatively stable in the near term[4], especially for identifying and monitoring patients with AHD.
8. Through its work as a health products Procurement Services Agent, PFSCM has seen the demand for systems, assays, and RDTs remain relatively stable. Between June 2022 and May 2023, about $6.2 million worth of CD4 commodities were procured by PFSCM clients globally, 95% of which was for assays.

1 WHO. Guidelines for managing advanced HIV disease and rapid initiation of antiretroviral therapy. 1 July 2017.
2 WHO. Providing care to people with advanced HIV disease who are seriously ill, 2023.
3 The Value of Point-of-Care CD4 and Laboratory Viral Load in Tailoring ART Monitoring Strategies to Resource Limitations, R. Walensky, AIDS. 2017 September 24; 31(15): 2135–2145.
4 CHAI. CD4 Demand Forecast, supplemented by data from Avenir and WHO Survey, 2022.

C. Problem statement

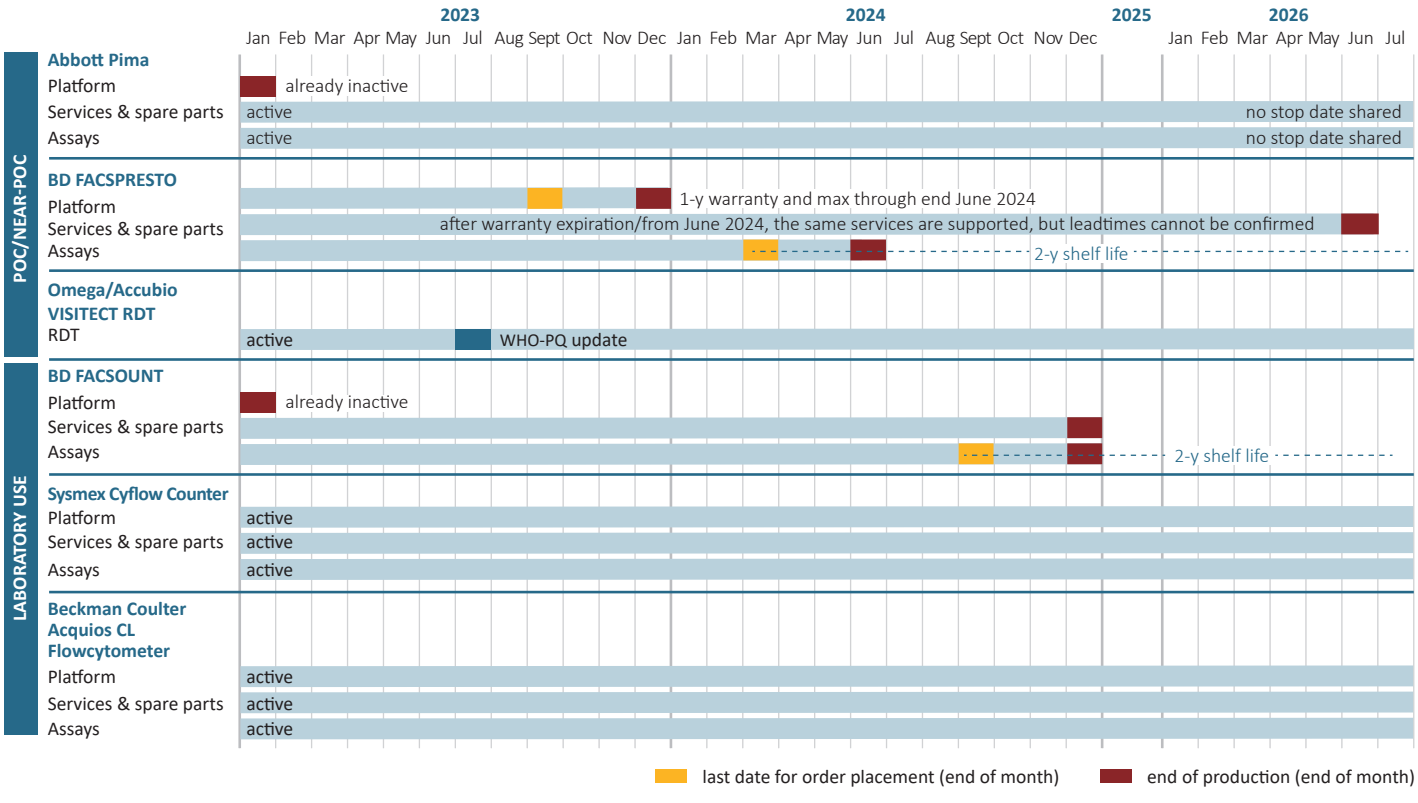
While the demand for CD4 testing in LMICs is projected to stay relatively stable, the supply, on the other hand, is constrained. This is in part due to the limited number of WHO Prequalified (PQed) CD4 diagnostics and systems, and the lack of additional products in the WHO qualification pipeline.

The supply constraints may be further exacerbated by the discontinuation of three platforms: the Abbott PIMA, BD FACSPresto, and BD FACSCount systems. In 2022, based on commercial considerations, the discontinuations of the Abbott PIMA and of the BD FACSPresto were announced while they are the only WHO-PQed systems for use at the nPOC and POC levels. In addition, BD had already announced the discontinuation of the FACSCount system, which is one of the few WHO PQed systems for use in centralized laboratories.

The landscape of the WHO PQed CD4 platforms and assays is evolving as follows:

Use	Brand	Product type	CD4 type	Availability Status
Point-of-care (POC)	Omega/Accubio Visitect	Rapid Diagnostics Test (RDT)	Semi-quantitative (above/below the 200 cells/mm3 threshold)	• Remains active
	Abbott PIMA	Platform and assays	Quantitative	• Platform discontinued since May 2022. • Assays continued until further notice.
Near Point-of-care (nPOC)	BD FACSPresto	Platform and assays	Quantitative	• Platform to be discontinued in December 2023. • Assays to be discontinued in June 2024.
Lab-based	BD FACSCount	Platform and assays	Quantitative	• Platform discontinued since December 2022 • Assays to be discontinued in June 2024.
	Sysmex Cyflow Counter	Platform and assays	Quantitative	• Remains active
	Beckman Coulter Aquios CL Flowcytometer	Platform and assays	Quantitative	• Remains active

Specifically, the detailed timelines are as follows:



D. Managing risk associated with the evolving CD4 supply landscape

Procurers need to manage the following risks and disruptions in the supply market to ensure a continuous supply of CD4 services:

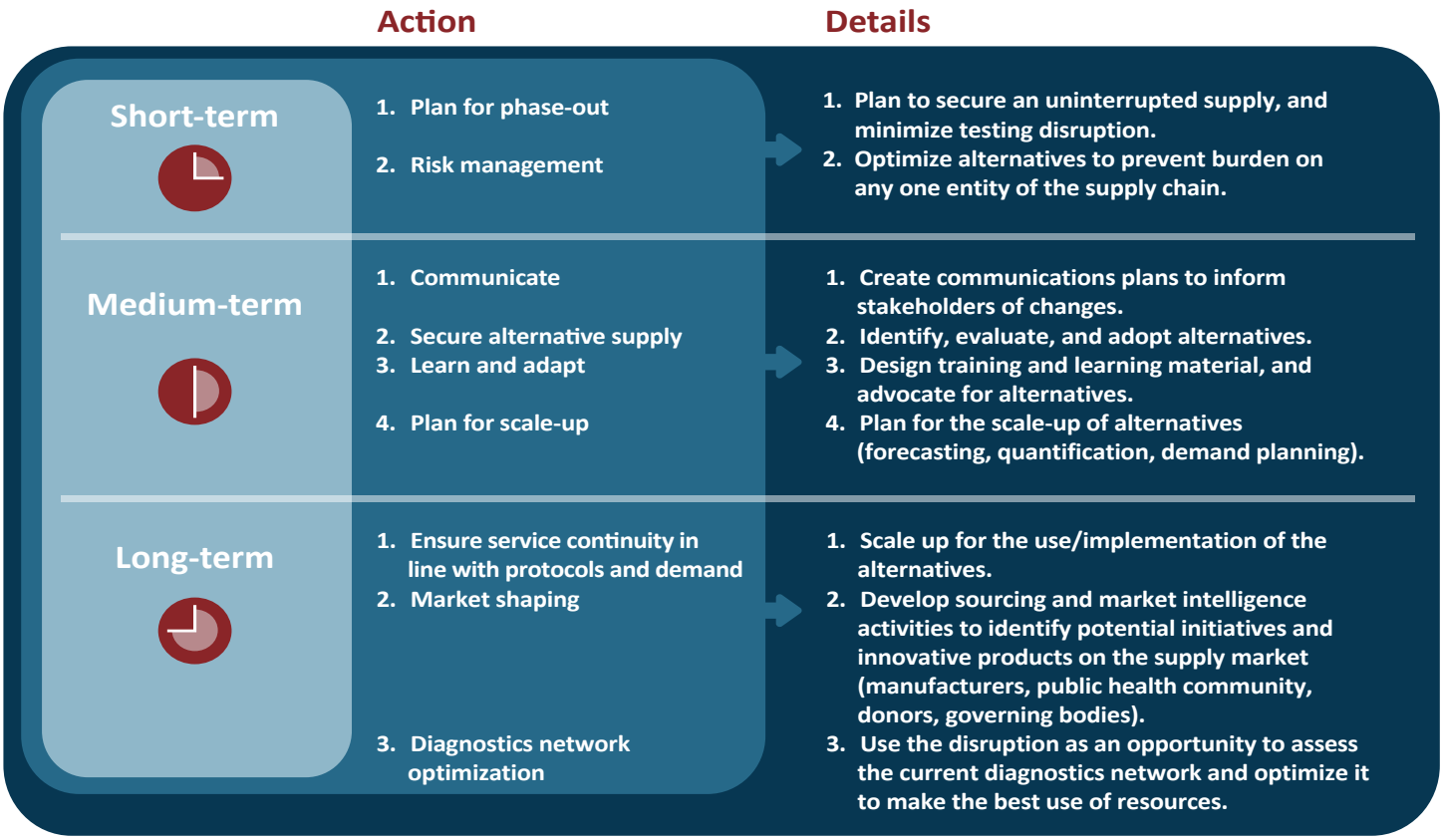
1. A limited time to plan and organize the procurement of assays to continue using the installed base of the platforms.
2. The discontinuation of the nPOC-POC segment and the reduction of the central laboratories segment in the near future.

In such a disrupted supply context, procurers may face longer lead times, limited supply, commodity shortages, and an overall lack of visibility or reliable information regarding supply.

In turn, these can translate into potential interruption of commodity security and interruption of services, meaning, in this case, the inability to diagnose AHD and efficiently monitor adequate treatment.

D.1 Best practices for managing a supply chain disruption

In order to best limit the associated risks on the supply chain, procurers would typically adapt and carry out activities linked to the following best practices:



D.2 Proposed recommendations to maximize the service delivery of the installed base and to reduce the supply risks

Depending on the installed base, the direct supply chain implications and suggested next steps for countries are slightly different:

D.2.1 COUNTRIES WITH AN INSTALLED BASE OF ABBOTT PIMA PLATFORMS

Platforms will continue to be serviced by Abbott throughout their warranty period, and **assays** will remain available, but Abbott will ultimately stop the production of assays when demand decreases significantly.

Consequently, countries can continue conducting CD4 testing with their Abbott PIMA as long as their platforms can function and as long as Abbott maintains the manufacturing of assays.

Next steps

These countries should mitigate the risk of Abbott stopping the production of the assays by:

- **Reviewing their forecasts.**
- **Closely managing their stock levels.**
- **Potentially increase the fre-quency of their usual quantifications.**

D.2.2 COUNTRIES WITH AN INSTALLED BASE OF BD FACSPresto AND BD FACSCount PLATFORMS

Platforms will continue to be serviced by BD throughout their warranty period and no later than the end of June 2026; afterward, the same services will be supported, but lead times and spare parts/replacement platforms cannot be committed to.

For **assays**, the following deadline will apply:

- FACSPresto: **Assays** can no longer be ordered after the end of March 2024 and will no longer be produced after the end of June 2024.
- FACSCount: **Assays** can no longer be ordered after the end of September 2024 and will no longer be produced after the end of December 2024.

Consequently, countries can continue conducting CD4 testing with their BD FACSPresto and FACSCount platforms as long as they function and the countries have assays, but in any case, not beyond the end of June 2026 (FACSPresto)/ end of December 2026 (FACSCount) when the last-produced assays will expire at the end of their two-year shelf life.

Next steps

These countries should consider actions to secure and actually maximize CD4 testing through the end of June 2026 (FACSPresto)/end of December 2026 (FACSCount) by:

- **Updating their consumption forecast of assays thru the end of June 2026 (FACSPresto)/end of December 2026 (FACSCount).**
- **Subsequently updating their procurement forecasts thru the end of June 2024 (FACSPresto)/end of December 2024 (FACSCount).**
- **Checking and adequately adapting their budget needs, and securing funding.**

D.2.3 COUNTRIES WITH AN INSTALLED BASE OF SYSMEX CYFLOW COUNTER AND BECKMAN COULTER AQUIOS CL FLOWCYTOMETER PLATFORMS

These two WHO-PQed CD4 platforms for use in central laboratories remain available.

Next steps

These countries should consider actions to secure the supply of assays and/or platforms to mitigate the risk of supply tension in case of switching demand, such as:

- **Updating their consumption and procurement forecast of assays.**
- **Updating their potential plan of platform expansion.**
- **Checking and adequately adapting their budget needs and securing funding.**

D.2.4 ALL COUNTRIES

There are no direct alternatives to the nPOC/POC Abbott PIMA and BD FACSPresto since there are no products in the late stage of development in the pipeline of WHO PQ.

Introducing or scaling up the VISITECT CD4 Advanced Disease RDT for use at the POC level

This CD4 rapid diagnostic test (RDT) is a semi-quantitative test that has a threshold sensitivity of 200 cells/mm3 which is the defining threshold for diagnosing AHD. This test was approved by WHO PQ in 2020 under the Omega brand, and again in July 2023 under the AccuBio brand. Further, a survey conducted by Médecins Sans Frontières (MSF) showed the utility of this RDT in 75% of the clinical cases[5].

In addition, Uganda, through the Clinton Health Access Initiative's Early Market Access Vehicle, reported that early adoption for use at lower-level healthcare facilities within a hub and spoke specimen referral and testing network showed a high acceptability of this RDT and a high degree of confidence in the results for clinical decision-making when health care workers are adequately trained.

However, countries should be mindful that the use of this RDT is somewhat more demanding than other non-CD4 RDTs, as it requires several steps and takes about 40 minutes to obtain a result.

Finally, this RDT has a 12-month total shelf life, and the remaining shelf life at the time of release from production and before shipment is actually further reduced to nine to ten months because of the Quality Control (QC) release protocol of this product.

Integrating this new WHO-PQed CD4 landscape when designing their CD4 testing network, and specifically note the following:

- The discontinuation of the already-installed PIMA and BD FACSPresto ultimately means a declining capacity of quantitative CD4 testing at the nPOC and POC levels.
- Testing at the nPOC and POC levels with the Visitect RDT would only provide semi-quantitative CD4 testing and the diagnosis of AHD patients, and would require a strong initial training plan.
- Meanwhile, quantitative CD4 testing would become mainly centralized, with the Sysmex CyFlow Counter and the Beckman Coulter Aquios CL Flow Cytometer. The need for potential sample transport network optimization and data connectivity would subsequently need to be assessed.
- Countries should closely follow potential new WHO guidance regarding the use of CD4 testing to potentially rapidly adapt and adjust their CD4 testing networks and the associated supply chain needs, and they should monitor the supply market of CD4 testing to potentially rapidly leverage the availability of new products and innovations.

5 Make It Count: Access to Point-of-Care CD4 Testing Under Threat, MSF Technical Brief, May 2023.

E. PSA perspective on supply chain risk management

PFSCM is already engaged and committed to activities across the whole supply chain of CD4 products and services. PFSCM can provide our clients with support and advice on all non-clinical CD4 matters, including forecasting, demand and supply planning, laboratory network optimization, technical assistance, supplier management, risk management, and more.

Clients of the Pooled Procurement Mechanism can contact their PFSCM Client Services representative to learn more about how the changes in the supply of CD4 products may affect supply chains and service delivery. Alternatively, write to pfscm@pfscm.org, and one of our supply chain professionals will contact you.

F. Additional reading

- Open Letters: Civil society calls on Abbott and BD to ensure access to HIV CD4 tests
- Impact of Treatment Guideline Changes on Global Health Supply Chains

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