CD4 Still Counts

The Partnership for Supply Chain Management

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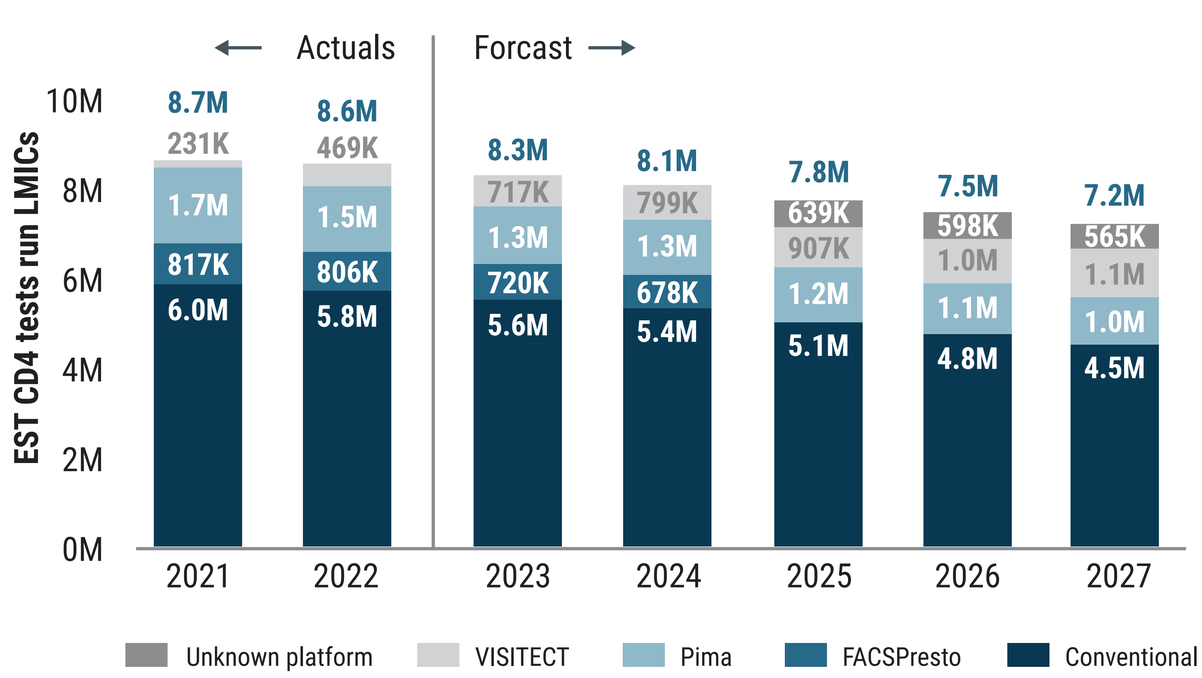
PFSCM

CD4 count is a key diagnostics tool

- CD4 cells are a type of white blood cell and serve an essential role in the immune system. HIV attacks and kills CD4 cells thereby weakening the immune system.
- The proportion of CD4 cells in the blood (vs. other white blood cells) is an indication of the strength of the immune system.
- CD4 count was the first laboratory test used for HIV patient care and it has been essential to tracking the clinical risk of opportunistic disease and death in people living with HIV.[1]
- CD4 count is used to diagnose severe HIV disease (CD4 < 200 cells / µL= severe HIV disease).
- CD4 count is needed to identify individuals who should receive the advanced HIV disease package of care recommended by the World Health Organization (WHO).[2]
- According to the recent WHO guidance, people living with HIV admitted to hospital or presented to care because of serious illness should have their CD4 cell count measured.[3]
- In rural settings, annual point-of-care (POC) CD4 compared to clinical monitoring improves life expectancy by 2.8 years, reduces time on failed antiretroviral therapy by 0.6 years, and yields an cost-effectiveness ratio of $480/YLS.[4]

LMIC CD4 testing via the VISITECT RDT is forecast to increase[5]



Changing near POC CD4 market

1. **The CD4 diagnostics 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 diagnostic commodities and may affect health services delivery if stakeholders do not monitor the situation and adapt.**
2. **There are no POC CD4 pipeline platforms in late stage of development which could fill the gap in market in the near term.**
3. **Programs may wish to consider the implications of the market changes and if the VISITECT CD4 Advanced Disease Rapid Diagnostic Test (RDT) provides value.**

Scan the QR code to learn what supply chain stakeholders, specifically procurers/buyers, can do to minimize supply disruption and, ultimately, ensure service continuity.

Market status of WHO prequalified (PQ) CD4 tests

	Diagnostic	Market status
POC lateral flow test	Accubio VISITECT	Available without changes
Near Point-of-Care (nPOC) platforms	Abbott PIMA	Platform discontinued 6/22 Assays available until further notice
	BD FACSPresto	Platform to be discontinued 12/23 Assays available until 7/24
Laboratory-based platforms	BD FACSCount	Platform discontinued 12/22 Assays available until 6/24
	Sysmex CyFlow Counter	Available without changes
	Beckman Coulter AQUIOS CL	Available without changes

Opportunities & challenges of POC CD4 RDT

- The VISITECT rapid test is a manually operated semi-quantitative assay for the estimation of CD4 protein on the surface of CD4 T cells in human whole blood (capillary or EDTA venous) to indicate whether the level is above or below 200 cells/µL within pre-diagnosed HIV patients.
- VISITECT is an aid in the management of patients with advanced HIV disease (patients with CD4 count below 200 cells/µL). This visually read test is designed to be used at the point-of-care and therefore has utility in decentralized diagnostic settings.[6]
- PEPFAR supports adoption of the VISITECT rapid test.[7]
- Although this test requires more hands-on time and has longer time to result than nPOC platforms (Pima, Presto), the RDT enables community approach and mitigates loss to follow up for test and treat on the same day.[9,10]

Clinical performance[8]

	Venous whole blood	Capillary whole blood
Sensitivity for detection of specimens with <200 CD4+ T cells/µL % (N=100)	96.0% (95% CI: 90.1-98.9)	95.0% (95% CI: 88.7-98.4)
Specificity (> 200 CD4+ T-cells/µL) (N= 200)	96.0% (95% CI: 92.3-98.3)	97.0% (95% CI: 93.6-98.9)

VISITECT feasibility test

In 2021, Uganda Ministry of Health performed a feasibility field test of VISITECT in 11 health care facilities.[11,12]

Healthcare workers highlighted the long turnaround time (45 minutes) as a challenge, however reported that access to such a test would facilitate quick clinical action with limited technical expertise in lower-level facilities without direct access to platform-based CD4+ testing.

Considerations

VISITECT currently has a 12-month shelf life (and only ~10 months remaining shelf life at time of release for shipment).

There are **no other WHO PQed POC CD4 products in the market**. This can result in **over-reliance on one supplier**.

QA panel for **VISITECT is needed for training** and **routine testing performance assessments**.

References

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