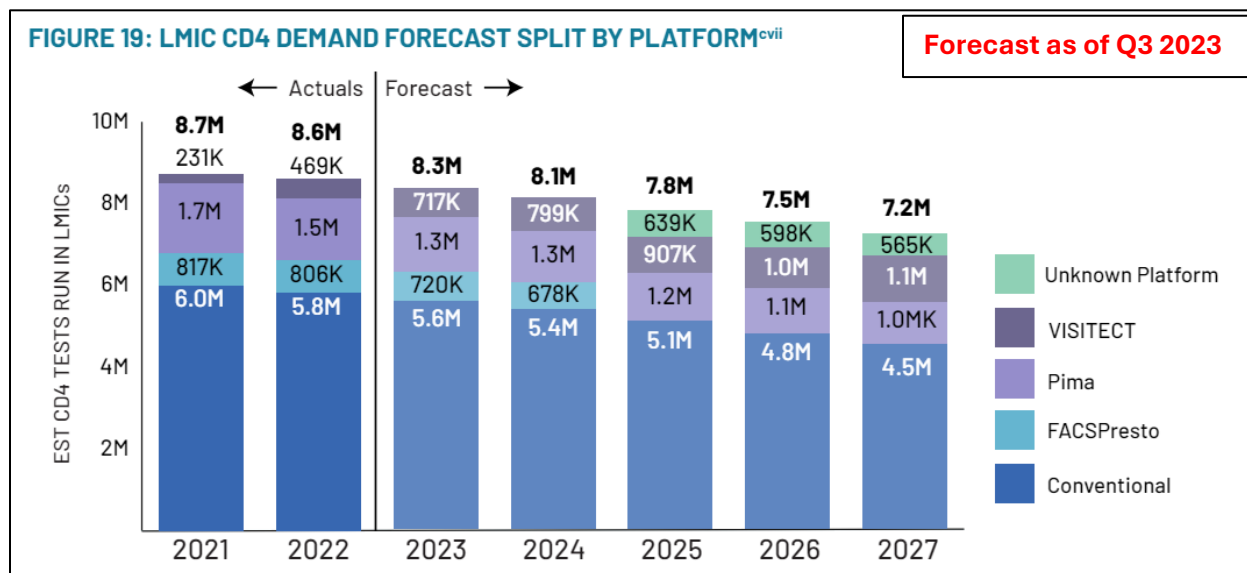


Frequently Asked Questions

What is the forecasted market for CD4?

CHAI’s [Market Memo](#), published in 2023, shares the results of a CD4 forecast on page 22. The forecast was developed based on historical demand, and future facing forecasting may change significantly as the supplier landscape shifts. Note that this forecast does not account for unmet need, which we estimate to be approximately another 3 million tests per year.



What are the CD4 guidelines for people living with HIV?

For all patients entering or re-entering care, the World Health Organization ([WHO](#)) [guidance recommends](#) a CD4 test at treatment baseline for initiating and re-initiating patients, and for patients who are failing treatment.

What is the forecasted market for Histoplasmosis and CrAg screening?

Market forecasts for cryptococcus and histoplasmosis screening are not currently available, both are growing markets as countries continue to scale up their Advanced HIV Disease (AHD) programs and the screening for opportunistic infections within those programs. However, [WHO guidance](#) recommends a CrAg LFA test for all adults and adolescents who are diagnosed with AHD (CD4 <200) before initiating or re-initiating antiretroviral therapy. Published data indicates that between 30-40% of initiating or re-initiating patients who receive a CD4 test have a CD4 count below 200 and are therefore eligible for the AHD OI screening package.^{1,2}

¹ Carmona S, Bor J, Nattey C, Maughan-Brown B, Maskew M, Fox MP et al. Persistent high burden of advanced HIV disease in South Africa: data from a longitudinal nationwide laboratory cohort. 9th IAS Conference on HIV Science, Paris, France, 23–26 July 2017

² Andereg N, Kirk O on behalf of IeDEA-Global Adults and COHERE. Immunodeficiency at the start of combination antiretroviral therapy in low-, middle- and high-income countries. 21st International Workshop on HIV and Hepatitis Observational Databases, Lisbon, Portugal, 30 March–1 April 2017. Abstract 12.

Additionally, researchers from the University of Minnesota, in collaboration with CHAI through the Unitaid-supported Optimal project, developed an [interactive model](#) outlining the burden of cryptococcal meningitis cases by country.

The [WHO/PAHO guidelines for managing Histoplasmosis among People Living with HIV](#) recommend diagnosing disseminated histoplasmosis among people living with HIV by detecting circulating Histoplasma antigens.

What are the product requirements for each test?

The tests should meet or have plans to meet the minimal characteristics as defined in the WHO Target Product Profile (TPP) requirements. Products that meet the optimal characteristics are strongly preferred.

- [Point-of-Care CD4 Test TPP](#)
- [CrAg Rapid Diagnostic Test TPP](#)
- Histoplasmosis tests: No TPP currently exists for Histoplasmosis tests. However, the 2023 edition of the [WHO Essential Diagnostics List](#) recommended an immunoassay test format on urine samples for the detection of Histoplasma capsulatum antigen.

What type of suppliers are eligible?

Suppliers who are seeking regulatory assistance for the registration and/or WHO Prequalification of a new product are invited to apply. Manufacturers based in Africa or with some element of the final distribution already in place or planned for development in Africa are strongly encouraged to apply.

In addition to manufacturers interested in developing a new test, support will also be considered for manufacturers interested in one of the following:

- Support for a technology transfer for regional manufacturing of a new point-of-care (POC) CD4, CrAg or Histoplasmosis test;
- Support with transitioning some manufacturing capacities to Africa;
- Support for WHO expert review panel quality assurance review;
- acquiring a POC CD4, CrAg or Histoplasmosis test from another company and bringing it to market;
- Advance market commitment for partner-funded procurement volumes;
- Support for servicing, and/or redeployment of devices to significantly increase access to POC CD4 testing.

I missed the deadline for submitting the Expression of Interest. Can I still be invited to submit a Request for Proposal?

Unfortunately, only applications received before the closing date of August 2 will be considered. We encourage all interested vendors to complete the EOI form and cover letter ahead of the August 2nd deadline. Only applicants who have completed an EOI in full will be invited to respond to any potential future Request for Proposal (RFP).