

# Comparison of Advanced HIV Disease identification using CD4 results from a semi-quantitative CD4 point of care test and CD4 flow cytometry in Nigeria

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## Introduction

Advanced HIV Disease (AHD) is associated with an increased risk of morbidity and mortality. For adults and adolescents, and children older than five years, AHD is defined as CD4+ lymphocyte count <200cells/mm<sup>3</sup> or WHO stage 3 or 4 event. Nigeria introduced a package of care for PLHIV with AHD to improve the treatment outcomes for this population. The package of care recommends CD4+ cell count for AHD case identification for all persons enrolling /re-enrolling into HIV care. The VISITECT CD4 Advanced Disease rapid test (VISITECT), a semi-quantitative point of care (PoC) test pre-qualified by WHO, was introduced to address gaps in CD4 coverage including long turnaround time and low testing coverage.

Conducting the VISITECT test requires time-sensitive procedural steps and visual acuity for interpretation, and there has been no experience with its use in Nigeria. To allay concerns of the impact of operational differences on the quality of VISITECT results in the Nigerian context, we compared results from VISITECT to CD4+ flow cytometry (BD FACSPresto and Partec Cyflow), the current gold standard in-country for CD4+ testing.

## Methods

- **Target population:** Newly enrolled PLHIV aged >10 years.
- **Study setting:** 10 ART facilities across Akwa-Ibom (1), Anambra (3), Lagos (6) states in southern and eastern Nigeria implementing the first phase of the AHD package of care.
- **Study enrollment period:** February 2021 to June 2021.
- **Health care worker training:** Health care workers across the selected facilities were trained to conduct the VISITECT tests and passed a competency assessment on the use of VISITECT. Thereafter, VISITECT was integrated into the routine laboratory processes at the facilities.
- **Sample collection:** Venous blood samples were collected from the study participants at enrollment and parallel CD4+ cell count was conducted using VISITECT and the conventional CD4+ flow cytometry platforms.
- **Data collection methods:** VISITECT and the CD4+ flow cytometry test results were documented for each study participant at the facility using the National HIV program laboratory data collection tools.
- **Data analysis:** At the end of 6 months, data on the CD4+ cell count results was abstracted retrospectively. The data was analyzed using STATA version 16. The analysis compared the results from VISITECT and the CD4 flowcytometry test for each study participants to determine how many reported as <200cells/mm<sup>3</sup> (AHD), or ≥200cells/mm<sup>3</sup> by CD4+ cell flow cytometry was correctly identified by VISITECT. The paired tests were tested for agreement using Cohen's Kappa test.

## Results



- A total of 603 patients from the 10 ART facilities received both flow cytometry and VISITECT tests.
- The prevalence of CD4 <200cells/mm<sup>3</sup> was 47.6% (95% CI: 43.6% - 51.6%, 287/603) and 50.9% (95% CI: 46.9% - 54.9%, 307/603) from the flow cytometry and VISITECT platforms, respectively.



- In all, 268 of 307 VISITECT results that were <200cells/mm<sup>3</sup> were identified as correct by the gold standard, giving a positive predictive value of 87.3%.
- 277 of 296 VISITECT results ≥200cells/mm<sup>3</sup> were identified as correct by the gold standard, giving a negative predictive value of 93.6% .

(Kappa = 0.81, Agreement =90.38%, P= <0.001).

### Agreement between Cytometry and VISITECT assay

		Cytometry result		
		<200	≥200	
VISITECT result	<200	268	39	<b>307</b>
	>200	19	277	<b>296</b>
		<b>287</b>	<b>316</b>	

## Conclusion

- This study is the first to review the performance of VISITECT in facility settings in Nigeria.
- The observed positive and negative predictive values are similar to the sensitivity (86.3%) and specificity (92.8%) documented for VISITECT by the manufacturer.
- The observed high agreement between VISITECT and flow cytometry results demonstrates VISITECT can correctly identify patients with AHD and has the potential to improve access to CD4+ cell count and linkage to care when deployed to facilities, particularly for facilities without flow cytometry test platforms.
- The findings show that operational differences have minimal impact on the accuracy of VISITECT results at facilities and Nigeria can deploy the test across the country with minimal concerns provided HCWs are trained appropriately.