Evaluation of Pima CD4 Point-of-Care Device in Western Kenya for Potential use in Field Settings

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Abstract (updated)

BACKGROUND: The increased need for follow-up has been cited as a barrier to effective antiretroviral treatment programs. The use of CD4 count as a key screening parameter has been established as a consistent marker in the progression and management of HIV infection. The Pima CD4 point-of-care (POC) device has been developed to allow for rapid testing in resource limited settings (RLS). Limited data exist on the performance of the Pima CD4 POC in RLS settings.

METHODS: In Phase I of this study, the Pima CD4 POCT was evaluated against the FACSCalibur as a gold standard. The study was conducted in the KEMRI/CDC HIV Research and Public Health Collaboration Reference Laboratory (KEMRI/CDC RLC) in Kisumu, Kenya and among the KEMRI/CDC day-to-day clients in the HIV care and treatment program.

RESULTS: No significant difference was found between the Pima CD4 and FACSCalibur CD4 counts, with a mean bias of 16 cells/mm³. The sensitivity and specificity of the Pima CD4 POC testing was 99% and 97%, respectively. The test performance was assessed against the conventional laboratory-based FACSCalibur platform, with high concordance for CD4 count with FACSCalibur in RLS settings.

CONCLUSION: The Pima CD4 POC testing is a rapid test with high sensitivity and specificity for CD4 count assessment, which can be utilized in resource limited settings.

Summary and Conclusion

The Pima CD4 POC accurately identifies the majority of patients requiring ART, demonstrated by the high sensitivity and specificity in RLS settings. The test performance was comparable with the FACSCalibur CD4 testing, indicating its feasibility for use in resource-limited settings. Further studies are needed to evaluate its long-term performance and impact on patient care in these settings.

Keywords: Point-of-care, CD4, Resource Limited Settings, HIV, Antiretroviral Treatment

Aims and Objectives

The objective of this study is to evaluate the performance of the Pima CD4 POC device in RLS settings.

Study Design

- Cross-sectional study of adults with a positive HIV viral load and CD4 count within the past six months.

Inclusion Criteria

- HIV-infected adults aged 18 years or older.

Exclusion Criteria

- Pregnant women.

Laboratory Procedures

- CD4 Count: The FACSCalibur CD4 testing was performed by KEMRI/CDC RLC staff using the FACSCalibur instrument.
- Pima CD4 POC: The Pima CD4 POC (including the reagents and software) was used for testing by trained staff.

Statistical analysis

- Correlation analysis and linear regression were used to assess overall performance of PIMA.
- Specificity and Sensitivity were used for classification analysis.

Results

- Correlation and misclassification analysis of PIMA on Venous Blood vs CD4 category>n=407
- Correlation and Misclassification Analysis of PIMA on Capillary Blood n=147

Table 1: Correlation and Misclassification Analysis of PIMA on Venous Blood by CD4 category (n=407)

<table>
<thead>
<tr>
<th>CD4 Category</th>
<th>Venous Blood PIMA</th>
<th>Venous Blood FACSCalibur</th>
<th>Venous Blood FACSCalibur PIMA</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;200 cells/mm³</td>
<td>78.9% (223/282)</td>
<td>78.6% (223/282)</td>
<td>78.6% (223/282)</td>
</tr>
<tr>
<td>200-349 cells/mm³</td>
<td>70.9% (135/190)</td>
<td>70.9% (135/190)</td>
<td>70.9% (135/190)</td>
</tr>
<tr>
<td>≥350 cells/mm³</td>
<td>70.9% (135/190)</td>
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</tbody>
</table>

Table 2: Correlation and Misclassification Analysis of PIMA on Capillary Blood (n=147)

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<tr>
<th>CD4 Category</th>
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Summary of Findings

- The Pima CD4 POC testing is a rapid test with high sensitivity and specificity for CD4 count assessment, which can be utilized in resource limited settings.

Acknowledgments

- Study participants
- Study staff
- KEMRI/CDC HIVR Branch
- CDC, CDC Atlanta

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References

- CDC. Laboratory validation of POC CD4 testing: we assessed the new PIMA CD4 POC correctly identifies majority of patients requiring ART, and demonstrated by the high sensitivity and specificity in RLS settings.
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- Division of HIV/AIDS Prevention

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