Poster # 630

Accuracy of POC CD4 Testing Using Microtube Capillary Sampling in Botswana Households

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ABSTRACT

Background: Point of care (POC) CD4 cell count can reduce the time to eligibility assessment for antiretroviral treatment and improve linkage to care. In a village household setting in Botswana, we evaluated the performance of POC CD4 using EDTA capillary sampling into microtube versus conventional laboratory-based flow cytometry.

Methods: Capillary blood was collected by finger-prick into EDTA microtubes. Venous blood was collected by venipuncture. Both blood collection procedures were performed in households during annual surveys in the village of Mochudi, Botswana. The Alere PIMA® system was used for POC CD4 testing while laboratory testing was performed using BD FacsCalibur. The Bland-Altman method was used to estimate the mean bias and 95% confidence limits of agreement (LOA). Sensitivity and specificity were calculated for a threshold of 500 cells/uL CD4 cell count.

Results: A total of 155 adults were enrolled with CD4 results for both field POC and lab-based testing. The median age was 32 years old and 63% were females. The median CD4 was 827 (IQR 668, 1058) cells/uL. We observed a mean bias between CD4 measurements by POC and FacsCalibur of -14.1 cells/uL [95% CI -39.5 to -11.3], paired t-test p = 0.2740]. Using a threshold of 500 CD4 cells/uL, POC CD4 testing using EDTA capillary sampling into microtube had a sensitivity of 73.3 (95% CI 44.9 – 92.3) cells/uL and specificity of 93.6 (88.1 – 97.0) cells/uL.

Conclusion: The Alere PIMA® POC CD4 testing with EDTA capillary sampling into microtube had one of the lowest non-significant negative mean bias relative to FACScalibur CD4 testing, compared previous findings using finger prick sampling alone. There were few measurements below CD4 threshold of 350 cells/uL and sensitivity was low at threshold of 500 cells/uL, but with good specificity. Coupling HIV testing with POC CD4 in a household setting has potential to close gaps in linkage to HIV care in communities.

METHODS

The Mochudi Study[4] conducted household based testing and counseling in order to estimate HIV-1 incidence and prevalence among 16–64-year-old residents over time. During the household visits, eligible residents were in addition asked to donate a blood sample for a rapid HIV test, POC CD4 and venous blood draw. POC CD4 was tested in the household using capillary blood collected into BD EDTA microtubes (500 microlitres). Flow Cytometry CD4 was tested using BD FACScalibur. The Bland-Altman method was used to estimate the mean bias and 95% confidence limits of agreement (LOA). Sensitivity and specificity were calculated for a threshold of 500 cells/uL CD4 cell count.

RESULTS

Figure 1: Alere PIMA CD4 with **capillary** EDTA Microtube versus BD FACScalibur CD4 (n = 155)

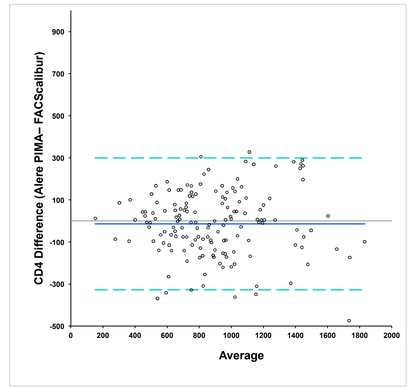
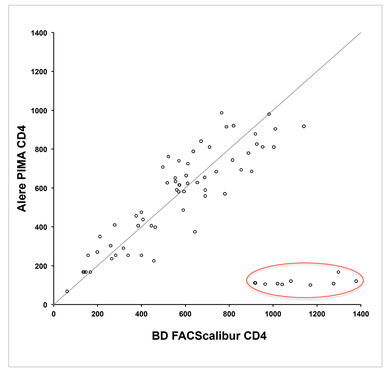


Figure 2: Alere PIMA CD4 with **Finger Prick** Sampling versus BD FACScalibur CD4 (n = 71)



BACKGROUND

- Point of Care CD4 has been shown to accelerate linkage and retention to care and reduce time **TO** enrollment into antiretroviral therapy in many poor resource settings[1]. POC-CD4 at the time of HIV diagnosis has also been shown to be cost-effective and also improves survival compared to laboratory based CD4[2].
- Alere PIMA® CD4 has demonstrated excellent performance compared to laboratory based CD4. However, some multisite studies demonstrated reduced performance when using finger prick sampling as compared to venous blood in field settings[3].
- We evaluated the performance of POC CD4 using EDTA capillary sampling into microtube versus conventional laboratory-based flow cytometry, while coupling with HIV testing in household settings in Mochudi, Botswana.
- We evaluated in a subset a comparison of Finger Prick POC CD4 and Flow cytometry

RESULTS

- The median age was 32 years and 63% were females. The median CD4 was 827 (IQR 668, 1058) cells/uL. We observed a mean bias between CD4 measurements by Alere PIMIA POC and BD FacsCalibur of -14.1 cells/uL [(95% CI -39.5 to -11.3), paired t-test p = 0.2740] (Figure 1).
- Using a threshold of 500 CD4 cells/uL, POC CD4 testing using EDTA capillary sampling into microtube had a sensitivity of 73.3 (95% CI 44.9 – 92.3) cells/uL and specificity of 93.6 (88.1 – 97.0) cells/uL.
- In a subset (n=71), we observed inconsistent performance of Finger Prick sampling versus flow cytometry (Figure 2) with a mean bias of -141 cells/uL (95% CI -228.2 to -53.8).
- The use capillary blood sampling into EDTA microtube shows consistent performance across and is less likely to misclassify especially with higher 500 cells/uL CD4 enrollment threshold.

CONCLUSIONS

The Alere PIMA® POC CD4 testing with EDTA capillary sampling into microtube had one of the lowest non-significant negative mean bias relative to FACScalibur CD4 testing, compared to previous findings using finger prick sampling alone. There were few measurements below CD4 threshold of 350 cells/uL and sensitivity was low at threshold of 500 cells/uL, but with good specificity. Coupling HIV testing with POC CD4 in a household setting has potential to close gaps in linkage to HIV care in communities. Careful considerations including training are essential for improving the filed applications of the Finger prick based POC CD4 testing.

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