DIAGNOSTIC ACCURACY OF BD FACSPRESTO FOR MEASURING CD4 ON WHOLE BLOOD SAMPLES STORED FOR UP TO 14 DAYS IN BD STABILIZATION TUBES AT ROOM TEMPERATURE IN A RURAL LABORATORY IN ZIMBABWE

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Background:
Among HIV-positive people, CD4 testing is used to assess eligibility for antiretroviral therapy, and to identify late-presenters (CD4 ≤100 cells/µl) who have a high risk of opportunistic infections. In rural settings, access to CD4 testing may be limited. Access can be increased by using point-of-care (POC) tests, and sample collection and storage methods that do not require a cold chain. We did a study at a rural hospital in Zimbabwe, to assess the diagnostic accuracy of BD FACSPresto, a POC CD4 test, and the stability of samples stored in BD CD4 Stabilization Tubes (ST).

Methods:
From February to June 2016, 93 HIV-positive patients provided venous blood, collected in ST. On arrival in the on-site hospital laboratory (Day 0), CD4 was measured using FACSPresto and FACSCount. Samples were stored in ST at room temperature (16oC to 34oC), and retested on Days 3, 5, and 7, using FACSPresto.

Results:
On Day 0, the median CD4 (in cells/µl) was 449 using FACSCount, and 504 using FACSPresto. At a cut-point of 100 cells/µl, the sensitivity of FACSPresto relative to FACSCount was 71.4%, and the specificity was 100%. Of the 52 samples retested at all time points, the median CD4 (in cells/µl) was 533 on Day 0, 457 on Day 3, 463 on Day 5, and 436 on Day 7. At a cut-point of 100 cells/µl, the sensitivity of FACSPresto relative to FACSPresto Day 0, was 100% on Days 3, 5, and 7, and the specificity was 98.6% on Day 3, 97.2% on Day 5, and 98.5% on Day 7.

Conclusion:
In rural resource-limited settings, access to CD4 testing can be increased by POC testing using FACSPresto, and by using ST to transport and store samples, if immediate POC testing is not possible. Among late presenters, this can minimize delays in starting potentially life-saving treatment.