Accuracy of CD4 testing and haematology using blood specimens stored in BD Vacutainer® CD4 Stabilization Tubes at room temperature: a study in Buhera District, Zimbabwe

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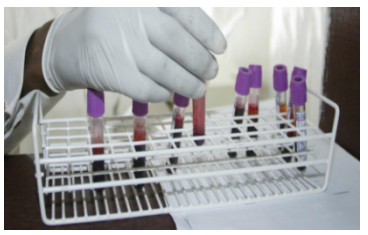
Background

- CD4 testing & haematology of blood specimens collected in standard EDTA Vacutainer® tubes & transported at ambient temperature must be completed within 48 hours, limiting availability of testing in clinics with no on-site testing & limited specimen transportation services.
- Specimens collected in BD Vacutainer® CD4 Stabilization Tubes (STs) are claimed to be stable for up to 7 days when stored at ambient temperature but only one small independent study to support this claim
- Stabilization Tubes cost more than standard EDTA tubes ($70/100 x 4 ml & $40/100 x 2ml vs $11/100)
- We conducted a study in Buhera District, Zimbabwe, to assess the stability of CD4 & haematology results of specimens collected in ST & stored at ambient temperature for varying time periods.



BD FACSCount™ System

Methods

- 50 paired blood samples (1 EDTA tube & 1 ST) collected from patients attending HIV clinics, & transported at ambient temperature. to nearest of 2 district laboratories
- Both samples tested on arrival (Day 0) using a BD FACSCount™ CD4 cytometer and a Sysmex KX-21 haematology analyzer.
- Stabilization tube (ST) samples were stored at room temperature and retested on Days 3, 5 & 7.
- 19 ST samples stored an extra week & tested for CD4 on Day 14.
- Results of tests on ST samples compared to the Day 0 EDTA sample results.
- Wilcoxon signed-rank test was used to establish significance of differences.

Results

- ST samples gave accurate CD4 & haemoglobin results at all time points, including Day 14 CD4 (See Day 7 results in **Figures 1 to 3**) Wilcoxon signed-rank test (p >0.05)
- ST samples also gave comparable results for other haematology parameters at all time points (Results not shown)

Accuracy of CD4 and haemoglobin results on samples stored in Stabilization Tubes for 7 days

Figure 1a: CD4

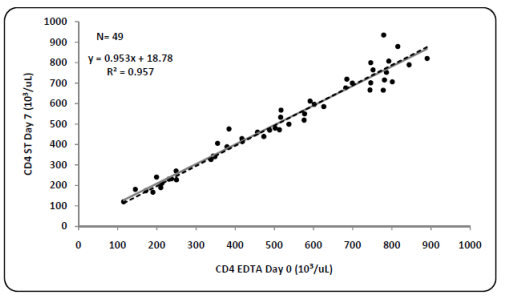


Figure 1b: Haemoglobin

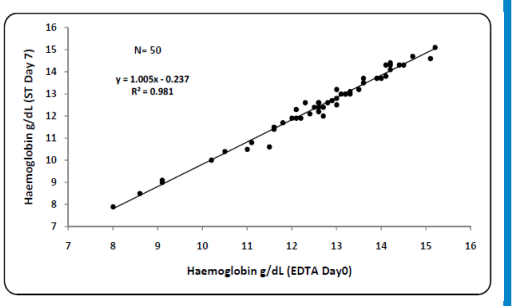


Figure 2a: CD4

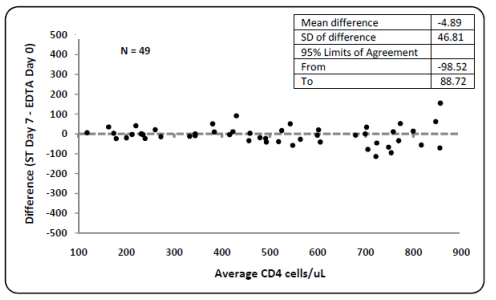


Figure 2b: Haemoglobin

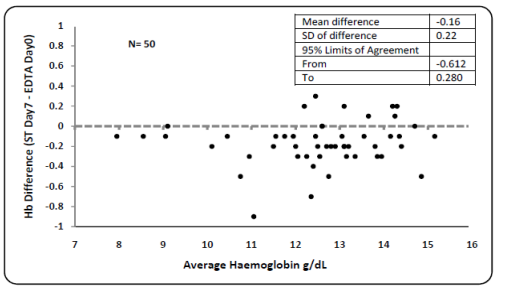


Figure 3a: CD4

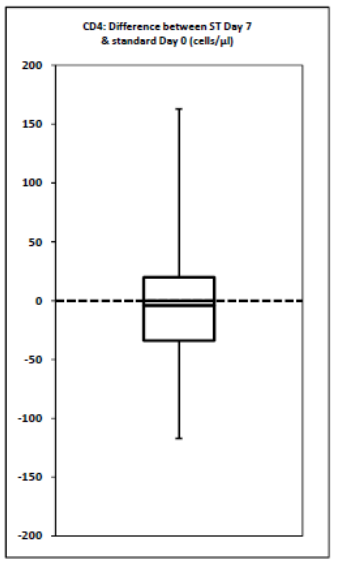


Figure 3b: Haemoglobin

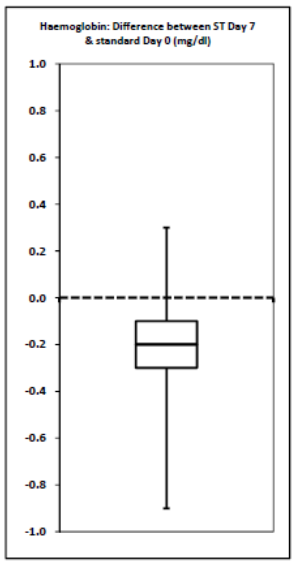


Figure 1: Linear correlation of ST Day 7 vs EDTA Day 0 results

Figure 2: Bland-Altman plots of agreement between ST Day 7 & EDTA Day 0 results

Figure 3: Box-plots showing difference between ST Day 7 & EDTA Day 0 results in quartiles

Conclusions

- CD4 Stabilization Tubes may be used as an alternative to standard EDTA tubes in settings where testing within 48 hours is not feasible
- Higher cost of CD4 Stabilization Tubes may serve as a deterrent to adoption of this technology.

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