

**Establishing Reference Intervals for CD4⁺ and CD8⁺ T
Lymphocyte Subsets in HIV Negative Adults in Nairobi, Kenya
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ABSTRACT

The Human Immunodeficiency Virus infections have grown to pandemic proportions with morbidity of more than 65 million people and mortality of over 25 million people. The health of infected individuals deteriorates rapidly to the AIDS stage and consequent fast death when not treated. The advent of anti retroviral treatment has brought hope for living longer lives for those who are infected and living with the virus. In Kenya, the decision on when to start therapy is largely based on the baseline CD4⁺ and CD8⁺ T-cell count whose reference intervals are of a Caucasian population. Information on CD4⁺ and CD8⁺ T-cell count reference values for the Kenyan population is seldom available.

A cross-sectional study was carried out to establish reference intervals for CD4⁺ and CD8⁺ T-cell subsets for select reference blood donors as a local guideline to reference intervals. The study assumed there was no significant difference between the Kenyan population living in Nairobi and Western countries Caucasian CD4⁺ and CD8⁺ T-cell counts. These reference intervals could be used to influence change in policy on when and how to treat people infected with HIV among Nairobi residents. This can possibly be replicated to the whole country after further studies for different regions in order to have a nationwide reference interval guideline.

A total of 424 reference blood donors were recruited as study subjects after passing a donor recruiting interview. After preliminary testing 17 (4.5%) blood donor samples were excluded due to positive serological tests and a further 7(1.7%) were eliminated due to extreme values. Thus a total of 400 (215 (54%) males, 185 (46%) females) were considered. The CD4⁺ and CD8⁺ T-cell count values obtained from the study

were subjected to statistical treatment and reference intervals were determined using the mean \pm 2SD based on a normal distribution. Reference intervals obtained included CD4⁺:CD8⁺ 1.8 (0.7-4), CD4⁺ % 40 (27 – 53), CD4⁺ absolute count 790 (392 – 1,405) cells/ μ L, and CD8⁺ absolute count 500 (202 – 1,131) cells/ μ L. The CD8⁺ % data did not attain a Gaussian distribution and the reference interval was determined as the median and the 2.5th and 97.5th interval at 95% CI i.e. 26% (15 – 50). Overall, Females had a higher mean ratio, CD4⁺ % and absolute count than males and was statistically significant (P<0.0001) whereas males had a higher CD8⁺ % than females that was statistically significant (P<0.001). In both sexes, the CD4⁺ absolute mean counts were always higher than the CD8⁺ absolute mean counts irrespective of age. There was no significant difference between the age groups for all the T-cell subsets. Reference mean CD4⁺ values obtained in this study were much lower than those of Burkina Faso but compared well with intervals from Tanzania and current BD multiSET values from a Caucasian population used in the FACsCalibur machine in Kenya. The reference intervals obtained in this study though different, they are relatively comparable to the USA based reference intervals and can be used to compliment these values. Country wide reference intervals would add value to decision making about HIV/AIDS therapy especially where differences in geographical conditions exist.