

Product Testing: Product testing to assess the performance of CD45/CD8/CD3 is described below. Studies were designed in line with instructions for use provided in the Product Package Insert and performance specifications. Specimens were assayed with CD3/T8 for comparison purposes. The results of product testing demonstrated that CD45/CD8/CD3 met all performance specifications and provided mature T (CD3+) and suppressor/cytotoxic T (CD8+; CD3+/CD8+) lymphocyte values comparable to those of CD3/T8.

1. Accuracy:

Normal and abnormal (e.g., Human Immunodeficiency Virus, organ transplant, autoimmune disease, low white blood cell count) whole blood specimens were collected from geographically diverse populations of males and females unselected as to race and ranging in age from 18 to 85 years. Specimens were divided, processed as lysed preparations and assayed in parallel with CD45/CD8/CD3 and CD3/T8. CD3+, CD8+ and CD3+/CD8+ percentages expressed in terms of the total lymphocyte count and absolute counts (cells/ μ L) were determined with COULTER® EPICS® XL/XL-MCL flow cytometers gated on lymphocytes. White blood cell counts and 3-part differentials were obtained for all specimens.

Results analyzed in terms of minimums, maximums, means \pm 1 SD, regression and correlation analyses, and analyses of variance demonstrated that CD45/CD8/CD3 and CD3/T8 identify and enumerate essentially identical numbers of the targeted lymphocytes in whole blood specimens.

2. Linearity:

Three replicate measurements were made on a concentrated normal whole blood specimen serially diluted to achieve a range of ten CD3+ and CD8+ (CD3+/CD8+) lymphocyte concentrations. Samples were assayed with CD45/CD8/CD3 and analyzed on a COULTER EPICS XL/XL-MCL flow cytometer gated on lymphocytes. Values were expressed in terms of absolute count (cells/ μ L).

Results analyzed in terms of regression and correlation analyses for recovered versus expected absolute counts demonstrated linearity of the assay.

3. Precision (Within Day/Intralaboratory):

Ten replicate measurements were made for each of three levels of CD3+ and CD8+ (CD3+/CD8+) lymphocyte concentrations on the same day using a COULTER EPICS XL/XL-MCL flow cytometer gated on lymphocytes. Levels were obtained by selective depletions of a normal whole blood specimen and assayed with CD45/CD8/CD3. Values were expressed in terms of % of the total lymphocyte count.

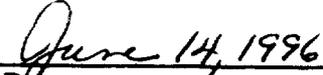
Results analyzed in terms of mean \pm 1 SD and CV demonstrated within day/intralaboratory precision of the assay.

4. Precision (Interlaboratory):

Ten replicate measurements on were made on the same day using different laboratories and COULTER EPICS XL/XL-MCL flow cytometers. All measurements were made on a single normal whole blood specimen divided and assayed with CD45/CD8/CD3. Values were expressed in terms of % of the total lymphocyte count.

Results analyzed in terms of mean \pm 1 SD and CV demonstrated interlaboratory precision of the assay.


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