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COULTER

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COULTER CORPORATION
P.O. Box 169015
Miami, Florida 33116-9015 USA

(305) 380-3800
(800) 327-6531

Product Information: (800) 526-6932

Date: June 14, 1996

Title: Summary of Safety and Effectiveness Information For 510(k) Premarket Notification

Product: CYTO-STAT® triCHROME™ CD45-FITC/CD4-RD1/CD3-PC5 Monoclonal Antibody Reagent With Isotypic Control

Company: Coulter Corporation
11800 SW 147 Avenue
Miami, FL 33196-2500

Contact: Dr. Marion S. Gaide (M/C: 31-B06)
Senior Regulatory Affairs Specialist
Corporate Regulatory Affairs

Telephone: 305-380-2594

Common or Usual or Classification Name: Lymphocyte Immunophenotyping Monoclonal Antibody Reagents

Product Classification: Product Code: GKZ; C.F.R. Section: 864.5220; Classification Panel: Hematology and Pathology Devices; Device Class: II

Intended Use: CYTO-STAT® triCHROME™ CD45-FITC/CD4-RD1/CD3-PC5 is a three-color fluorescent reagent comprised of three murine monoclonal antibodies. Each antibody is labeled with a different color fluorochrome. The reagent identifies a lymphocyte gate based on CD45 staining (vs. side scatter) and allows simultaneous identification and enumeration of total CD3+, total CD4+ and dual-stained CD3+/CD4+ lymphocytes in whole blood by flow cytometry. An isotypic control, CYTO-STAT® triCHROME™ CD45-FITC/MsIgG1-RD1/MsIgG1-PC5, is used to monitor non-specific binding.

Substantial Equivalence: 510(k) Premarket Notification: K922745
CYTO-STAT®/COULTER CLONE® CD3(IgG1)-FITC/T4-RD1
Monoclonal Antibody Reagent

Product Differences: CD45/CD4/CD3 and CD3/T4 are essentially identical with respect to features and principles of operation. Each liquid reagent allows simultaneous identification and enumeration of more than one T lymphocyte population (CD3+; CD4+; CD3+/CD4+) in a single specimen using a single reagent. Each reagent also requires a separate isotypic control to monitor non-specific binding.

The one difference between the reagents is that CD45/CD4/CD3 contains CD45 to identify a lymphocyte gate for making CD3, CD4 and CD3+/CD4+ measurements. In contrast, CD3/T4 requires a separate reagent, CYTO-STAT®/COULTER CLONE® Mo2-RD1/KC56 (T-200)-FITC, for this purpose.

Mab Conjugation: CD45: FITC (Fluorescein Isothiocyanate). CD4: RD1 (Phycoerythrin). CD3: PC5 (Phycoerythrin-Cy5).

Product Testing: Product testing to assess the performance of CD45/CD4/CD3 is described below. Studies were designed in line with instructions for use in the Product Package Insert and performance specifications. Specimens were assayed with CD3/T4 for comparison purposes. The results of product testing demonstrated that CD45/CD4/CD3 met all performance specifications and provided mature T (CD3+) and inducer T (CD4+; CD3+/CD4+) lymphocyte values comparable to those of CD3/T4.

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/CD4/CD3 and CD3/T4. CD3+, CD4+ and CD3+/CD4+ 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/CD4/CD3 and CD3/T4 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 CD3+ and CD4+ (CD3+/CD4+) lymphocyte concentrations. Samples were assayed with CD45/CD4/CD3 and analyzed on a COULTER EPICS XL/XL-MCL flow cytometer gated on lymphocytes. Values were expressed in terms of absolute counts (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 CD4+ (CD3+/CD4+) 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/CD4/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.

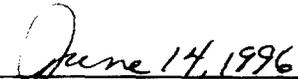
4. Precision (Interlaboratory):

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/CD4/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.



Marion S. Gaide, Ph.D.
Senior Regulatory Affairs Specialist
Corporate Regulatory Affairs
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Date