

K982166

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COULTER

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

Date: November 4, 1998

Customer Service: (800) 526-7694
Product Information: (800) 526-6932
(800) 327-6531 (305) 327-6531
www.coulter.com

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

Product: CYTO-STAT® triCHROME™ CD45-FITC/CD56-RD1/CD3-PC5 Monoclonal Antibody Reagent with
CYTO-STAT® triCHROME™ CD45-FITC/MsIgG1-RD1/MsIgG1-PC5 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 Reagent with Isotypic Control

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/CD56-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 allows simultaneous identification and enumeration of total CD3+ and CD3-/CD56+ lymphocytes in whole blood by flow cytometry. An isotypic control, CYTO-STAT® triCHROME™ CD45-FITC/MsIgG1-RD1/MsIgG1-PC5, is used to monitor nonspecific staining.

CYTO-STAT® triCHROME™ CD45-FITC/MsIgG1-RD1/MsIgG1-PC5 is a three-color fluorescent reagent comprised of three murine monoclonal antibodies. Each antibody is labeled with a different color fluorochrome. This product is intended for use as a quality control reagent to monitor the levels of nonspecific antibody binding in cell surface staining procedures which use CYTO-STAT® triCHROME™ Monoclonal Antibody Reagents comprised of CD45-FITC and two monoclonal antibodies of the MsIgG1 subclass conjugated to RD1 and PC5.

Substantial Equivalence: 510(k) Premarket Notification: K982172
CYTO-STAT® CD3-FITC/CD56-RD1 Monoclonal Antibody Reagent with CYTO-STAT®/COULTER CLONE® MsIgG1-RD1/MsIgG1-FITC Isotypic Control

Product Comparison:

The CD45/CD56/CD3 and CD3/CD56 systems are essentially identical with respect to features and principles of operation. Each liquid reagent allows simultaneous identification and enumeration of more than one lymphocyte population (CD3+ and CD3-/CD56+) in a single specimen using a single reagent. Each system also requires an isotypic control to monitor nonspecific binding. The difference between the systems is that CD45/CD56/CD3 contains CD45 to identify a lymphocyte gate for making CD3+ and CD3-/CD56+ measurements. CD3/CD56 requires a separate reagent, CYTO-STAT®/COULTER CLONE® Mo2-RD1/KC56 (T-200)-FITC, for this purpose. MAb Conjugation: CD45: FITC (Fluorescein Isothiocyanate). CD56: RD1 (Phycoerythrin). CD3: PC5 (Phycoerythrin-Cy5).

Product Testing: Product testing to assess the performance of CD45/CD56/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/CD56 for comparison purposes. The results of product testing demonstrated that CD45/CD56/CD3 meets all performance specifications and provides mature T (CD3+) and NK (CD3-/CD56+) lymphocyte values comparable to those of CD3/CD56.

1. Accuracy:

Normal and abnormal whole blood specimens were collected from geographically diverse populations of males and females unselected as to race and ranging in age from 19 to 84 years. Specimens were divided, processed as lysed preparations and assayed in parallel with CD45/CD56/CD3 and CD3/CD56. CD3+ and CD3-/CD56+ percentages expressed in terms of the total lymphocyte count and absolute counts (cells/ μ L) were determined with COULTER® EPICS® XL-MCL™ flow cytometers gated on lymphocytes. White blood cell counts and 5-part differentials were obtained for all specimens.

Results analyzed in terms of minimums, maximums, means \pm 1 SD, confidence intervals, regression analyses and analyses of variance demonstrated that CD45/CD56/CD3 and CD3/CD56 identify and enumerate essentially identical numbers of the targeted lymphocytes in whole blood specimens.

2. Linearity:

Three replicate measurements were made on a concentrated COULTER™ CYTO-TROL Cells sample serially diluted to achieve a range of CD3+ and CD3-/CD56+ lymphocyte concentrations. Samples were assayed with CD45/CD56/CD3 and analyzed on a COULTER® EPICS® 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 vs. expected absolute counts demonstrated Linearity of the assay.

3. Precision: Within Run (Intralaboratory):

Ten replicate measurements were made for each of three levels of CD3+ and CD3-/CD56+ lymphocyte concentrations on the same day using a COULTER® EPICS® XL-MCL™ flow cytometer gated on lymphocytes. Levels were obtained by selective screening of normal whole blood specimens and assayed with CD45/CD56/CD3. Values were expressed in terms of percentage of the total lymphocyte count.

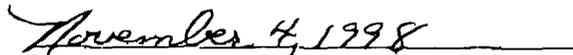
Results analyzed in terms of mean \pm 1 SD and CV demonstrated Within Day (Intralaboratory) Precision of the assay.

4. Precision (Interlaboratory):

Ten replicate measurements on were made on the same day using different laboratories and COULTER® EPICS® XL-MCL™ flow cytometers. All measurements were made on a single normal whole blood specimen divided and assayed with CD45/CD56/CD3. Values were expressed in terms of percentage of the total lymphocyte count.

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


Marion S. Gaido, Ph.D.
Senior Regulatory Affairs Specialist
Corporate Regulatory Affairs


Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Marion S. Gaide, Ph.D.
Senior Regulatory Affairs Specialist
Coulter Corporation
P.O. Box 169015
Miami, Florida 33116-9015

NOV 5 1998

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Re: K982166/S1
Trade Name: CYTO-STAT® trichROME™ CD45-FITC/CD56-RD1/CD3-PC5
Monoclonal Antibody Reagent with CYTO-STAT® trichROME™
CD45-FITC/MsIgG1-RD1/MsIgG1-PC5 Isotypic Control
Regulatory Class: II
Product Code: GKZ
Dated: September 29, 1998
Received: October 1, 1998

Dear Dr. Gaide:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

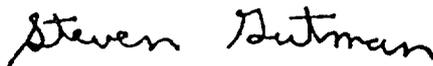
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): Not Yet Assigned

Device Name: CYTO-STAT® triCHROME™ CD45-FITC/CD56-RD1/CD3-PC5 Monoclonal Antibody Reagent
with
CYTO-STAT® triCHROME™ CD45-FITC/MsIgG1-RD1/MsIgG1-PC5 Isotypic Control

Indications For Use:

CYTO-STAT® triCHROME™ CD45-FITC/CD56-RD1/CD3-PC5 Monoclonal Antibody Reagent is a three-color fluorescent reagent comprised of three murine monoclonal antibodies. Each antibody is labeled with a different color fluorochrome. The reagent allows simultaneous identification and enumeration of total CD3+ and CD3-/CD56+ lymphocytes in whole blood by flow cytometry. An isotypic control, CYTO-STAT® triCHROME™ CD45-FITC/MsIgG1-RD1/MsIgG1-PC5, is used to monitor nonspecific staining.

CYTO-STAT® triCHROME™ CD45-FITC/MsIgG1-RD1/MsIgG1-PC5 Isotypic Control is a three-color fluorescent reagent comprised of three murine monoclonal antibodies. Each antibody is labeled with a different color fluorochrome. This product is intended for use as a quality control reagent to monitor the levels of nonspecific antibody binding in cell surface staining procedures which use CYTO-STAT® triCHROME™ Monoclonal Antibody Reagents comprised of CD45-FITC and two MsIgG1 subclass monoclonal antibodies conjugated to RD1 and PC5.

CD3+ lymphocyte percentages and absolute counts may be used as aids to evaluate immune competency underlying known or unknown disease states and to monitor lymphocyte levels following organ transplantation.

To illustrate, identification of abnormal levels of CD3+ lymphocytes may aid in the diagnosis and/or prognosis of unidentified disease conditions in patients with low white blood cell counts. Measurement of CD3+ lymphocytes, in conjunction with CD4+ (inducer) and CD8+ (suppressor/cytotoxic) T lymphocytes and corresponding T4/T8 ratios, may aid in the diagnosis and/or prognosis of immunodeficiency disease such as infection with human immunodeficiency virus (HIV), the etiologic agent of acquired immunodeficiency syndrome (AIDS). Altered percentages of CD3+ lymphocytes recorded following organ (for example, kidney, heart, liver, lung) transplantation suggests T lymphocyte quantitation may be useful as an aid in monitoring these cellular populations.

NK (Natural Killer) lymphocyte populations have been functionally defined as a lymphocyte population capable of mediating non-MHC restricted cytotoxicity against targets such as certain tumor and virus-infected cells.

As part of a Three Color Lymphocyte Immunophenotyping Panel which includes the B lymphocyte reagent, CYTO-STAT® triCHROME™ CD45-FITC/CD19-RD1/CD3-PC5, CYTO-STAT® triCHROME™ CD45-FITC/CD56-RD1/CD3-PC5 provides the ability to comprehensively identify and enumerate an individual's major lymphocyte subsets: T, B and NK. The reagent also functions as a quality control check for a specimen in terms of total lymphocyte percentage and CD3+ lymphocyte measurements across the panel.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

Over-The-Counter Use

(Division Sign-Off)
Division of Clinical Laboratory Devices