

K961435

JUN 14 1996

510(k) Summary

Submitter: DAKO Corporation
6392 Via Real
Carpinteria, CA 93013
(805)566-6655

Contact: Gretchen M. Murray, Ph.D., Regulatory Affairs Asst. Manager

Date Summary Prepared: December 27, 1995

Device Name: Mouse Anti-Human T-cell, CD2/FITC, MT910 +
Mouse Anti-Human B-cell, CD19/RPE, HD37

Device Classification: Class II according to 21 CFR 864.5220, on the basis that monoclonal antibodies are accessories for automated differential cell counters.

Panel: This device classification is under the Hematology and Pathology devices panel, Division of Clinical Laboratory Devices.

Product Code: GKZ

Predicate Device(s): DAKO Monoclonal Mouse Anti-Human T-cell, CD2/FITC, MT910 (DAKO Code Number F0767, FDA K945692) and
DAKO Monoclonal Mouse Anti-Human B-cell, CD19/RPE, Clone HD37 (DAKO Code Number R0808, FDA K943284)

Device Description: Purified mouse anti-human CD2, Clone MT910, conjugated with fluorescein isothiocyanate, isomer 1 (FITC) + purified mouse anti-human CD19, Clone HD37, conjugated with R-phycoerythrin, present in 0.05M Tris-HCl buffer, pH 7.2, 15 mM NaN₃, 0.1M NaCl, stabilized with 1% carrier protein.

Subpopulations of lymphocytes may be stained with fluorochrome-conjugated antibody and evaluated in peripheral blood specimens when contaminating red blood cells (RBC's) are lysed prior to flow cytometric analysis. A subpopulation of WBC's are selected for assessment based upon cell morphology.

Intended Use: For *In Vitro* Diagnostic Use

Mouse Anti-Human T-cell, CD2/FITC, MT910 + Mouse Anti-Human B-cell, CD19/RPE, HD37 (DAKO Anti-CD2/FITC and Anti-CD19/RPE) has been developed for use in flow cytometry for the analysis of CD2⁺ T-cells and CD19⁺ B-cells. This reagent allows simultaneous detection and quantification of T- and B-cells in normal and pathological conditions such as immunodeficiency disorders. It is one component of the suggested monoclonal antibody (MAb) combinations for routine immunophenotyping of lymphocytes in peripheral blood using flow cytometry.

Comparison of Technological Characteristics

Performance characteristics have been established by clinical evaluation of compared to the individual single reagent predicate devices that quantitatively measure CD2⁺ T-cells and CD19⁺ B-cells that have been previously cleared by FDA (DAKO CD2/FITC, Code No. F0767 and DAKO CD19/RPE, Code No. R0808). When flow cytometric tests of peripheral blood samples obtained from apparently healthy adults were completed, correlation of Anti-CD2, MT910 with

DAKO Anti-CD2/FITC and Anti-CD19/RPE approached a direct 1 : 1 comparison for measurement of CD2+ cells. Correlation of Anti-CD19, HD37 with DAKO Anti-CD2/FITC and Anti-CD19/RPE approached a direct 1 : 1 comparison for measurement of CD19+ cells. Data for the measurement of CD2+ T-cells by DAKO Anti-CD2/FITC and Anti-CD19/RPE reagent compared to DAKO CD2/FITC gave a correlation greater than 0.99 using the whole blood method for flow cytometry on peripheral blood samples from normal and ill patients. Data for the measurement of CD19+ T-cells by DAKO Anti-CD2/FITC and Anti-CD19/RPE reagent compared to DAKO CD19/RPE gave a correlation greater than 0.99 using the whole blood method for flow cytometry on peripheral blood samples from normal and ill patients.

The CD2 antibody clone, MT910, was clustered at the Second Leukocyte Typing Workshop, Boston, 1984. The CD19 antibody clone, HD37, was clustered at the Second Leukocyte Typing Workshop, Boston, 1984.

Linearity testing of DAKO CD2/FITC using JM cells gave the following linear equation:

$$y = -0.02 + 0.997x; r = 0.9965$$

Linearity testing of DAKO CD19/RPE using Raji cells gave the following linear equation:

$$y = -0.49 + 0.99x; r = 0.999$$

In addition, reproducibility of DAKO reagents using replicates (from peripheral blood) run on two different flow cytometers was measured at three concentrations of each antigen. Cross-reactivity of Anti-CD2/FITC, plus Anti-CD19/RPE with peripheral blood cells (red blood cells, monocytes, granulocytes, lymphocytes, and platelets) was measured.

Conclusions:

Results of the above testing as well as the information provided by the Second Leukocyte Typing Workshop indicate that the DAKO Anti-CD2/FITC plus Anti-CD19/RPE reagent performs as well as DAKO CD2/FITC in the detection and enumeration of CD2+ lymphocytes while the DAKO Anti-CD2/FITC plus Anti-CD19/RPE reagent performs as well as DAKO CD19/RPE in the detection and enumeration of CD19+ lymphocytes using flow cytometry. Safety of the DAKO Anti-CD2/FITC plus Anti-CD19/RPE reagent and its individual predicate devices is high as all reagents are used for in vitro testing.