

K960531

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510(k) Summary

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Device Name: Mouse Anti-Human T-cell, CD3/FITC, UCHT1 +
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): Becton Dickinson Simultest CD3/CD19

Device Description: Purified mouse anti-human CD3, Clone UCHT1, 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, CD3/FITC, UCHT1 + Mouse Anti-Human B-cell, CD19/RPE, HD37 (DAKO Anti-CD3/FITC and Anti-CD19/RPE) has been developed for use in flow cytometry for the analysis of T-cells and B-cells. This reagent allows simultaneous detection and quantification of total T-cells and B-cells in peripheral blood of 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 CD3⁺ T-cells and CD19⁺ B-cells that have been previously cleared by FDA (Becton Dickinson's Simultest CD3/CD19). When flow cytometric tests of peripheral blood samples obtained from apparently healthy adults were completed, correlation of Simultest CD3/CD19 with DAKO Anti-CD3/FITC and Anti-CD19/RPE approached a direct 1 : 1 comparison for measurement of CD3+ cells. Correlation of Simultest CD3/CD19 with DAKO Anti-CD3/FITC and Anti-CD19/RPE approached a direct 1 : 1 comparison for measurement of CD19+

cells. Data for the measurement of CD3+ T-cells by DAKO Anti-CD3/FITC and Anti-CD19/RPE reagent compared to Simultest CD3/CD19 on peripheral blood samples obtained from apparently healthy adults as well as ill patients gave a correlation greater than 0.98 using the whole blood method for flow cytometry. Data for the measurement of CD19+ T-cells by DAKO Anti-CD3/FITC and Anti-CD19/RPE reagent compared to Simultest CD3/CD19 gave a correlation greater than 0.99 using the whole blood method for flow cytometry.

The CD3 antibody clone, UCHT1, was clustered at the First Leukocyte Typing Workshop, Paris, France, 1982. The CD19 antibody clone, HD37, was clustered at the Second Leukocyte Typing Workshop, Boston, 1984.

Linearity testing of DAKO CD3/FITC using JM cells gave the following linear equation:

$$y = 0.02 + 0.98x; r = 0.999$$

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-CD3/FITC and 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 First and Second Leukocyte Typing Workshops indicate that the DAKO Anti-CD3/FITC and Anti-CD19/RPE reagent performs as well as Simultest CD3/CD19 in the detection and enumeration of CD3⁺ lymphocytes and the DAKO Anti-CD3/FITC and Anti-CD19/RPE reagent performs as well as Simultest CD3/CD19 in the detection and enumeration of CD19⁺ lymphocytes using flow cytometry. Safety of the DAKO Anti-CD3/FITC plus Anti-CD19/RPE reagent and its predicate device is high as are all reagents used for in vitro testing.