

K950148

**IV. 510(k) Summary of Safety and Effectiveness**

**Device Description:** The BioTek Solutions ChemMate™ CD43 is used in combination with the automated TechMate™ staining instrument. The instrumentation and methods employ the capillary action principle, covered by U.S. patent 4,731,335 (and others) and are held by BioTek Solutions, Inc. The instrumentation consists of two parts; the instrument's mechanical arm with its associated work station and the PC-style computer with mouse and color monitor. The mechanical arm picks up and places the slide holder containing test slides on the appropriate "tile" or platform. Solutions and pads are mounted on the tiles in a pattern described by the protocol. The instrument performs the following functions:

- a. Moves the slide holder(s) from one tile position (containing chemistry or pad) to another.
- b. By capillary action adds immunological or chemical reagents in proper sequence as dictated by the protocol instructions.
- c. Employs uniform washing procedures between reagent steps, as per the loaded protocol.
- d. Keeps immunologic reaction conditions uniform by controlling time of incubation and volume of reagent used.
- e. Records real time for incubation steps with the reagent used for the specific step.
- f. Standardizes the immunohistochemistry procedure.

There are two reagent sets in addition to the CD43 (primary antibody) and the Negative Control Reagent. These are the Secondary Detection Kit - Peroxidase/DAB (SDK605) and the Standard Secondary Buffer Kit (SDK601A). All of the ChemMate™ reagents are designed for use with the TechMate™ instrument.

**Note:** The Negative Control Reagent, Secondary Detection Kit - Peroxidase/DAB (SDK605) and the Standard Secondary Buffer Kit (SDK601A) have previously been included in BioTek's 510(k) K936111/A and are awaiting final review and clearance. They are enclosed in this ChemMate™ CD43 510(k) as supportive reference.

**Equivalence:** The ChemMate™ CD43 has undergone testing to demonstrate equivalence to predicate devices. Histopathological studies included a methods comparison study (ChemMate™ CD43 vs. H & E) on tissues suspected to contain T lymphocytes and their derivatives. Additionally, reproducibility staining studies were performed on these same tissues on three separate days. Positive or negative reactivity for the CD43 was assessed for each of the slides stained.

Of the 281 tissues tested, there were 61 lymphomas and normal tissues of lymphoid origin stained with CD43. As expected, all 6 of the normal lymphoid tissues (tonsil and spleen) stained positively for CD43. Of the remaining 55 lymphomas, 47 stained positively with CD43. This ratio, when viewed against the literature summary which revealed an 88 % reactivity (188/224), is consistent with the reported positive immunoreactivity profile represented in the current published findings.

Of the 281 tissues tested, there were 220 neoplastic and normal tissues of non-lymphoid origin expected to be negative for CD43 which did stain negatively. Analysis of staining results yielded a ratio of 117/117 for the normal, non-lymphoid tissues which stained negatively for CD43 and a ratio of 103/103 for the pathological, non-lymphoid tissues which stained negatively for CD43. These ratios are also consistent with reported nonreactive immunoreactivity profiles represented in the current published findings.

Based on the performance comparison detailed in section VI. and its conformance with the immunoreactivity profile established in published studies, as well as the similarity in features of the ChemMate™ CD43 with both the H & E Stain and Becton Dickinson CD43 antibody, substantial equivalence of the ChemMate™ CD43 has been demonstrated. Please see pages 27-31 of Section V. for specific details of the literature summaries referenced above.