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510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Ventana Medical Systems, Inc. developed the **Ventana Anti-CD5 (clone L17F12/Leu-1)** for use on the Ventana ES automated immunohistochemistry system. Ventana's Anti-CD5 (clone L17F12/Leu-1) is substantially equivalent to antibodies detecting cellular elements of lymphocytic origin as reported by E. G. Engleman *et. al.*¹ and J. K. C. Chan *et. al.*²

Comparative Study

Supporting data for the equivalence statement is shown by the following study. Frozen tissue preparations from normal and pathologic samples as well as cytopins and blood smears from normal subjects were tested using the Ventana Anti-CD5 (clone L17F12/Leu-1). Samples were obtained from excess tissues and specimens obtained for reasons other than the present study. Pathologic tissues examined were lymphoma specimens. Normal specimens examined were tonsil, thymus, cytopins and blood smears. Slides were processed on the Ventana ES Automated Slide Stainer, prepared for examination and evaluated by a qualified independent pathologist for specific staining intensity and background staining. These results were compared to literature reports.

Results

L17F12/Leu-1 detects an antigen present on 95-100% of human peripheral T lymphocytes, the majority of thymocytes and acute lymphocytic leukemia T cells¹ and less than 5% of peripheral blood B lymphocytes, 54-87% of T cell lymphomas, most all B cell chronic lymphocytic leukemia and centrocytic (mantle cell) lymphomas^{2,3}.

In Ventana's testing, the antibody showed appropriate staining of normal cells of lymphoid origin from normal tonsil, thymus and blood. For example, in tonsil a majority of lymphocytes in the interfollicular areas (T cell predominant) stain positive. Scattered cells in the mantle zone (B cell predominant), germinal centers (dendritic rich), subepithelial and perivascular regions also stain positively. Staining of cells of non-lymphoid origin was not undertaken nor reported. There was no inappropriate staining of the specimens in this study. In addition, this study agrees with the data published by Engleman, *et.al.*¹ and Chan, *et.al.*²

The reactivity of this antibody was shown by consistent staining of lymphoid cells in 8 of 9 T cell lymphomas, 0 of 11 B cell lymphomas and 0 of 11 Hodgkins lymphomas. As with any immunohistochemical reagent, the sensitivity is dependent on tissue processing and slide preparation parameters. The negative control antibody which was run with each tissue produced negative results.

Inter-run reproducibility was determined based on samples of the same frozen tonsil tissue on ten different instrument runs using Ventana DAB Detection Kit. All ten slides stained positively for CD5 antigen.

Intra-run reproducibility was determined based on ten samples of the same frozen tonsil tissue within one run. All ten slides stained positively for CD5 antigen.

¹Engleman EG, Warnke R, Fox RI, Dille J, Benike CJ and Levy R: Studies of a human T lymphocyte antigen recognized by a monoclonal antibody. Proc Natl Acad Sci, USA 1981, 78:1791-1795.

²Chan JKC, Ng CS and Hui PK: A simple guide to the terminology and application of leucocyte monoclonal antibodies. Histopathology 1988, 12:461-480.

³Zukerberg LR, Medeiros LJJ, Ferry JA, Harris NL. Diffuse low-grade B cell lymphomas. Four clinically distinct subtypes defined by a combination of morphologic and immunophenotypic features. Am J Clin Path 1993; 100:373-385.

