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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-CD4 (clone SFC112T4D11) for use on the Ventana ES automated immunohistochemistry system. Ventana Anti-CD4 (Clone SFC112T4D11) is substantially equivalent to antibodies detecting cellular elements of lymphocytic origin as reported by Reinherz, et al.¹

Comparative Study

Supporting data for the equivalence statement is shown by the following study. Frozen preparations from normal and pathologic samples were tested using the Ventana Anti-CD4 (Clone SFC112T4D11). Samples were obtained from excess tissues obtained for reasons other than the present study. Pathologic and normal tissues were examined. Slides were processed on the Ventana ES Automated Slide Stainer, prepared for examination, and evaluated by a qualified pathologist for specific staining intensity and background staining.

Results

Staining occurred in the plasma membrane of lymphoid cells from normal tonsil, thymus and blood. Negative control tissue was all negative. There was no inappropriate staining of the tissues in this study.

Sensitivity of the antibody was shown with appropriate staining of cells of lymphoid origin and no staining of cells of non-lymphoid origin. In addition, the Ventana data in this study agrees with the data published by Reinherz *et al.*¹

The reactivity of this antibody was shown by consistent staining of 9 of 9 T cell lymphomas, and appropriate staining of normal lymphoid tissues (4 of 4 peripheral blood lymphocyte cytopins, 4 of 4 thymus tissues and 10 of 10 tonsil tissues). As with any immunohistochemical reagent, the sensitivity is dependent on tissue processing and slide preparation parameters. The negative control which was run with each tissue gave negative results.

Inter-run reproducibility the same positive control (tonsil) was used on each of 10 different instrument runs. All ten slides stained positively for CD4 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 CD4 antigen.

¹Reinherz EL, Kung PC, Goldstein G, Schlossman SF. A separation of functional subsets of human T cells by a monoclonal antibody. *Proc. Natl. Acad. Sci. USA.* 1979; 76:4061.