

MAR 22 1990

K935161

510(k) Summary of Safety and Effectiveness

Ventana Medical Systems, Inc. developed the Ventana Keratin Primary Antibody for use on the Ventana 320 automated immunohistochemistry system. Ventana Keratin Primary Antibody (clone 5D3) is substantially equivalent to a commercially available anti-human cytokeratin (clone CAM 5.2).

Comparative Study

Supporting data for the equivalence statement is shown by the following study. Paraffin embedded preparations from normal and pathologic samples were tested using Ventana Keratin Primary Antibody and a commercially available anti-human cytokeratin. Samples were obtained from excess tissues obtained for reasons other than the present study. Pathologic tissues evaluated for staining included colon carcinomas, breast carcinomas, prostatic carcinomas, adenocarcinoma, squamous cell carcinomas and nonepithelial cancers. Normal tissues examined were breast, ureter, thyroid, skin, small intestine, stomach, liver, adrenal, muscle, prostate, tonsil, pituitary, thymus, esophagus, ovary, testes, pancreas, cardiac muscle, spinal cord, spleen, adenoid, kidney, connective tissue and salivary gland. Slides were processed on the Ventana 320 Automated Slide Stainer and prepared for examination, then evaluated on a blind basis for specific staining intensity and background staining.

Results

When compared with a commercially available anti-human cytokeratin antibody, Ventana Keratin Primary Antibody stained the same tissues 91% of the time in epithelial line cancers. Neither Ventana Keratin Primary Antibody nor the commercially available antibody stained any of the nonepithelial type cancers. The staining patterns of the normal tissues were considered to be appropriate.

Staining intensity was scored on a scale of 0 - 4+. Non parametric analysis of the staining intensity results (Wilcoxon matched pairs) shows no difference in the performance of the two antibodies tested, even at the .01 level of significance.

Specificity of both antibodies was proven with appropriate staining of cells of epithelial origin and no staining of cells of mesodermal or endodermal origin. Sensitivity of keratin antibodies, based on comparison of 37 epithelial line cancers, showed that Ventana Keratin Primary Antibody stained 30 of 37 and the commercially available anti-human cytokeratin antibody stained 31 of 37.

Inter-run reproducibility, based on samples of the same tissue on 16 different instrument runs, and intra-run reproducibility, based on 10 samples of the same tissue within one run, were identical for both antibodies. The mean staining intensity and standard deviation of each antibody was 2.5 ± 0.00 .