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510(k) Summary of Safety and Effectiveness

Ventana Medical Systems, Inc. developed the Ventana CEA Primary Antibody for use on the Ventana ES automated slide staining system. Ventana CEA Primary Antibody (clone TF 3H8-1) is substantially equivalent to a commercially available anti-human cytokeratin (clone CAM 5.2) in that they both stain antigens on cells of epithelial origin.

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 the Ventana CEA Primary Antibody and a commercially available anti-human cytokeratin. 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 on a blinded basis for specific staining intensity and background staining.

Results

Staining with both antibodies occurred in the epithelial cells of normal breast, anexal glandular cells of skin, glandular cells of stomach, prostate and pancreas.

Cytokeratin stained brain, glandular cells of pituitary and tubular cells of kidney. CEA did not stain these tissues. Since the antigens are different, it would not be expected to have 100% concordance. There was however, no inappropriate staining of tissue by either of the antibodies.

When compared with the commercially available anti-human cytokeratin antibody, Ventana CEA Primary Antibody stained the same tissues 78% of the time for epithelial line cancers. Neither Ventana CEA Primary Antibody nor the commercially available cytokeratin antibody stained any of the non-epithelial or non-mesothelial type cancers.

Specificity of both antibodies was shown with appropriate staining of cells of epithelial origin and no staining of cells of endodermal origin. In addition, the specificity seen in this study agrees with the data published by (Verstijnen et al., Anticancer Research 6:97-104, 1986).

The sensitivity of this antibody was shown by consistent staining of 9 of 10 breast and 10 of 10 colon malignancies, and appropriate staining of normal epithelial tissue. As with any immunohistochemical reagent, the sensitivity is dependent on fixation, tissue processing, and slide preparation parameters.

The negative control which was run with each tissue gave negative results with one exception. In this case, the negative control gave the same score as the non-specific

background (1+) which indicates that there was some inteference due to the tissue and not the specific antibody.

Inter-run reproducibility was determined based on samples of the same tissue on 16 different instrument runs with equivalent staining in all 16 slides. Intra-run reproducibility was determined based on 10 samples of the same tissue within one run with equivalent staining in all ten slides.