BP52: A BIOMARKER OF BENIGN PROSTATE HYPERPLASIA. George L. Wright, Jr., Mary Lou Beckett, Cara Haley, C.-L. Huang, Paul F. Schellhammer, Norfolk, VA, Robert W. Ve tri, Devin P. Patton, David P. Singer, Garry M. Marley and Roberto E. Orozco, Oklahoma City, OK (Presentation b) Dr. Wright)

Benign prostate hyperplasia (BPH) the most common nonmalignant internal organ proliferative abnormality, is a major cause of morbidity in the adult male. Presently there are no reliable diagnostic tests for BPH other than pathological examination of prostate biopsies. The objective of this study was to identify a biomarker with significant specificity to detect the presence, onset, and progression of BPH. This report describes the identification of such a restricted candidate biomarker. Monocional antibodies were generated by established techniques following tolerization of mice with either prostate carcinoma (CaP) or BPH antigens prior to immunization. A hybridoma clone, designated BP52, demonstrating sufficient initial specificity was further evaluated. All tissues (normal prostate obtained at autopsy, BPH and CaP TURP specimens, CaP prostatectomy specimens) were evaluated by immunoperoxidase staining. The BP52 biomarker was detected in 100% (15/15) of the BPH specimens with the number of luminal cells staining ranging from 30-80% for a mean of 68%. Rare staining, i.e. <1-10% (mean 3.3%), was observed in 12/15 (80%) normal prostate specimens, and a mean of 10.3% staining was found in 8/21 (38%) CaP tissues. Most all the staining in the CaP group was observed in the well to moderately differentiated carcinomas. Other than a few scattered positive cells in normal kidney, BP52 reactivity was not found in any of a variety of normal or other malignant tissues. Additionally 94 prostate needle biopsies, stained with BP52, yielded similar results as observed for the TURP and prostatectomy specimens. Scoring in this instance was based on numbers of ducts rather than numbers of cells staining due to technical difficulties in obtaining accurate cell counts in these specimens. The BPH ducts expressing BP52 were clearly delineated from carcinoma in 22/29 (76%) CaP specimens. These results suggest that BP52 may be a useful biomarker of BPH and further studies are warranted to determine its clinical utility. (Supported by NCI grant CA21689 and a grant from CYTODIAGNOSTICS, INC)