A Triple Staining Assay to Diagnose Prostate Cancer

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Technology description

This invention describes a highly sensitive tissue-based assay that can be used for the diagnosis, molecular characterization and risk stratification of prostate cancer. It relies on a specific triple immunostaining method by combining ERG, TFF3 and HMWCK as in situ diagnostic biomarkers. Prostate cancer can usually be diagnosed based on morphology alone from viewing the standard hematoxylin and eosin stained tissue that indicates the architectural and cellular features of the tumor. However, there is an unavoidable variability in diagnosis among pathologists when challenged with small atypical foci on prostate needle biopsies. Consequently, it becomes increasingly important to have tissue biomarkers that can supplement the conventional standard method. ERG over-expression is observed in approximately 50% of prostate cancer whereas trefoil factor 3 (TFF3) has been proposed as a promising candidate gene to identify ERG-negative prostate cancer. Additionally, high-molecular weight cytokeratin (HMWCK) expression in basal cells further helps to distinguish benign glands from cancerous glands in challenging cases.
The inventors have evaluated the performance of the triple immunostain of ERG, TFF3 and HMWCK in 96 tumors and 52 benign cases. The sensitivity and the specificity of the combined ERG and TFF3 expression in detecting prostate cancer is 76% and 96%, respectively. After optimization of this triple staining assay on tissue microarrays, the inventors further validated this method in 76 prostate biopsies.

Application area

This method represents a comprehensive diagnostic test for prostate cancer. The feasibility of this triple immunostain as a supplemental diagnostic tool for prostate needle biopsies has been demonstrated and could potentially be applied in clinical practice for prostate cancer diagnosis.

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