

#244 The KLK10 Gene (also known as the Normal Epithelial Cell-Specific 1 Gene; Nes1): A New Serum Biomarker for Ovarian Cancer. Liu-Ying Luo, Peter Bunting, and Eleftherios Diamandis. *Mount Sinai Hospital, Toronto, ON, Canada, University of Toronto, Toronto, ON, Canada, and University of Toronto, Dept. of Lab Medicine and Pathobiology, Toronto, Canada.*

The KLK10 gene encodes for a secreted serine protease, hK10. Although KLK10 was shown by functional analysis to be a putative tumor suppressor, levels of the protein in tissues or biological fluids have not as yet been measured. In order to examine the possible diagnostic value of hK10 protein analysis in biological fluids, we have undertaken an effort to first develop a highly sensitive immunoassay for hK10 protein. This immunoassay (detection limit of 0.05 $\mu\text{g/L}$) is suitable for measuring hK10 protein in serum. We have then undertaken a study to measure hK10 protein in a total of 374 serum samples from patients with ovarian cancer (N = 80) or normal volunteers (N = 82), patients with breast cancer (N = 22), medullary thyroid carcinoma (N = 27), testicular cancer (N = 51), gastrointestinal cancer (N = 48), prostate cancer (N = 41) and lung cancer (N = 23). We found that hK10 concentration was elevated ($> 1.5 \mu\text{g/L}$) in 56% of ovarian cancer patients, in 15% of patients with gastrointestinal cancer, in 13% of patients with lung cancer and in none of the other patients with cancer or normal controls. Serial serum hK10 analysis in patients with ovarian cancer (post-surgery) indicated that hK10 concentration changed with disease progression and regression, in parallel to CA125 analysis. These data strongly suggest that hK10 may represent a new ovarian cancer biomarker which may have utility for disease diagnosis and monitoring.