Objective: Human kallikrein 11 (hK11) is a secreted serine protease, highly expressed in hormonally regulated tissues, including the prostate and the ovary. Our preliminary studies indicate that hK11 may represent a diagnostic and prognostic biomarker for ovarian cancer. The aim of the present study was to examine the prognostic value of hK11 expression in ovarian tumors.

Methods: Using our established immunofluorometric assay, hK11 levels were quantified (ng per mg of total protein) in 134 ovarian tumor extracts and correlated with various clinicopathological variables and outcome [progression-free survival (PFS), overall survival (OS)], over a median follow-up period of 42 months.

Results: hK11 concentration in ovarian tumor cytosols ranged from 0 to 155 ng/mg of total protein, with a median of 1.45 ng/mg. An optimal cutoff value of 6.3 ng/mg was selected to categorize tumors as hK11-positive or negative. hK11-positive tumors were most often of early stage (Stage I/II) and grade (G1/G2) (P < 0.05). Univariate analysis revealed that patients with hK11-positive tumors had a significantly longer PFS (HR of 0.39, P = 0.005) and OS (HR of 0.44, P = 0.033). Cox multivariate analysis indicated that hK11 was an independent prognostic indicator of PFS (HR of 0.47, P = 0.042). Kaplan-Meier survival curves further confirmed that women with hK11-positive tumors have longer PFS.
and OS (P = 0.003 and P = 0.028, respectively). Also, a weak positive correlation was found between the expression levels of tissue hK11 and tissue CA125 (rs = 0.508; P < 0.001). CONCLUSIONS: These results further validate our initial findings that hK11 is an independent marker of favorable prognosis in ovarian cancer patients.