

Immune-related Gene Signature to Influence Treatment Decisions and Predict Immunotherapy Outcomes in Cancer



Use of an immune-related gene signature (GES) potentially allows physicians to influence treatment decisions, and monitor the effectiveness of immunotherapy against solid tumors. The GES is comprised of 12 chemokines that predicts whether or not immune cells are organized as unique, tumor-localized ectopic lymph nodes within the tumor micro-environment. To date, This gene signature has been tested in colorectal cancer and melanoma.

COMMERCIAL OPPORTUNITY

- High expression of the 12-chemokine GES significantly correlates with increased survival in metastatic melanoma ($p=0.008$) and primary colorectal cancer patients ($p=0.004$).
- Predictive biomarkers of response to immunotherapy could stratify the patient population and better tailor therapy, potentially prolonging patient lives and saving money.
- Nearly 68% of melanoma patients treated with the immunotherapy drug Ipilimumab do not respond to therapy (*Hodi et al. 2010. NEJM*), supporting the need for an immunotherapy predictor.
- The immunotherapy market is growing with the approval/investigation of the use of Provenge, Stimuvax, ICT-107, IPILIMUMAB, and other immune-based agents, which this technology could be paired with to potentially predict response.

TECHNOLOGY

A majority of patients treated with immune-based therapies do not achieve a response or show clinical benefit, so the ability to select patients for immunotherapy interventions based on an immune-related GES is highly valuable. This technology is a GES comprised of 12 distinct chemokine genes biologically related to inflammation and the immune cell infiltration within solid tumors. RNA is isolated from tumor biopsies and then measured using a qPCR or microarray-based platform to determine the relative expression of the immune genes (i.e.: CCL2, CCL21, etc.). The higher the expression of the immune-related GES in the tumor environment indicates immune cell infiltration organized within the tumor as unique ectopic lymph nodes, better patient prognosis and survival, and a potential for response to immunotherapy. This technology may also be used to identify tumors for *ex vivo* growth of potent, autologous tumor infiltrating lymphocytes for subsequent adoptive transfer into patients. To date, this immune gene signature has been interrogated retrospectively on >300 colorectal carcinoma and >100 melanoma samples from the Moffitt Cancer Center biorepository. Immunohistochemical staining in a representative group of samples confirmed the presence or absence of tumor-localized, ectopic lymph nodes correlating with the 12-chemokine gene signature interrogation.

PUBLICATION/PATENT

- International PCT application - PCT/US2011/022845
- Related publications: Coppola et al. 2011. *Unique ectopic lymph-node like structures present in human primary colorectal carcinoma are identified by immune gene array profiling.* Am. J. Pathol. 179(1): 37-45.

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LICENSING OPPORTUNITY

