

# Gene Signature to Distinguish Lung Squamous Cell Carcinoma from Metastatic Head & Neck Squamous Cell Carcinoma



*Our technology is a 22-gene signature that can distinguish between primary lung squamous cell carcinoma and head & neck squamous cell carcinoma (HNSCC) that has metastasized to the lung. Determining whether a solitary lung nodule is lung cancer or metastasized head & neck cancer is particularly hard in a patient with HNSCC or a history of HNSCC. However, it is important because the treatments are different. Based on gene expression from a tumor biopsy, this technology could help physicians identify the appropriate treatment for patients.*

## COMMERCIAL OPPORTUNITY

- An estimated 61,760 head and neck cancer cases were diagnosed in 2016. More than 90% of head and neck cancers are HNSCC, and 5-15% of HNSCC patients will develop lung metastasis.
- There is no standard existing to distinguish the two types of cancer. The distinction is currently based on histological appearance or by the presence of other premalignant changes; however, given their morphologic similarities, lung metastases and primary lung SCCs cannot be distinguished in most cases.
- It is important to differentiate the two conditions because the prognosis and treatment of a lung cancer versus metastatic head & neck cancer are different. The surgical approach for a primary LSCC is a lobectomy whereas pulmonary metastasectomy is used for metastases. Adjuvant chemotherapy is also available for patients with LSCC. With expression data from a limited number of genes, our signature shows the highest accuracy for identifying LSCC (100%) and the highest accuracy seen (91.7%) for identifying HNSCC compared with several previous studies including a 10-gene signature and whole-genome based clustering.
- Our 22-gene signature can be measured by multiplex PCR using tumor biopsy samples, allowing easy integration into the current procedure for screening and early detection of second lung cancers for HNC survivors. If the test were priced at \$3,000, then an estimated market size would be  $61,760 \times 0.9 \times 0.15 \times \$4,000 = \$25M$ .

## TECHNOLOGY

A total of 268 lung SCC samples and 38 head & neck SCC samples from the Moffitt Cancer Center Total Cancer Care (TCC) database were used as the training dataset. The gene expression data are on HuRSTA chips, each with 60607 probe sets for 25587 genes. The top 22 most differentially expressed genes were selected for PCA. PC1 of the 22 genes was used as the signature which was first self-validated on the training dataset with 33 of 38 correctly identified as “head-and-neck” primary (sensitivity = 86.8%) and 254 out of 268 correctly identified as “lung” primary (specificity = 94.8%). The signature was further validated on external datasets publicly available at the GEO and TCGA databases, with 130 SCC lung cancer samples from GSE4573, 134 SCC lung cancer samples from TCGA and 96 SCC head-and-neck cancer samples from GSE31056, total of 666 samples. The signature correctly identified all of the 130 samples of GSE4573 as “lung” (specificity = 100%), all 134 samples of TCGA data as “lung” (specificity = 100%), and 88 out of the 96 SCC head-and-neck samples as “head-and-neck” (sensitivity = 91.7%).

## PUBLICATION/PATENT

- US provisional patent application filed on 2/23/2017 for Drs. Magliocco, Altiock, Khalil and Xiong.

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### LICENSING OPPORTUNITY



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