

Diagnostic for the Classification of Carcinomas of Unknown Primary Site (CUP)



Hybrid model integrating immunohistochemistry (IHC) and expression profiling for the classification of carcinomas of unknown primary site (CUP). Identification of the site of origin for CUP remains a challenge for modern pathology, and correct diagnosis is critical to determining the most efficacious treatment for the patient.

COMMERCIAL OPPORTUNITY

- CUP is estimated to be 3-5% of all metastatic cancers, with the American Cancer Society estimating in 2010 that there were 30,680 new cases of CUP and 44,030 deaths resulting from CUP.
- The resulting products would be targeted to Pathology laboratories. This is an attractive market as evidenced by the number of companies that are marketing or developing diagnostics to determine the site of origin of CUP. These companies include Agendia, Pathwork Diagnostics, bioTheranostics, Rosetta Genomics, and Veridex.
- There is also an ongoing effort to transition this technology to a platform that does not require RNA extraction.

TECHNOLOGY

Standard pathological approaches combine morphology and IHC studies to first subclassify cytokeratin-positive carcinomas into adenocarcinoma, squamous cell carcinoma, neuroendocrine carcinoma, and urothelial carcinoma. Subsequently, organ-specific IHC-markers, if available, are used to assign the tumor's primary site of origin. Previous gene expression classifiers have shown promise in tumor classification but cannot readily be integrated into standard practice because they ignore the algorithmic hierarchy used by pathologists. This approach however follows the standard work flow used in the every day practice pathology, and can be directly compared with or integrated with the results of IHC staining. In this method, a tumor is initially assigned to one of the carcinoma subclasses by the top tier gene expression classifier. Then second tier gene expression classifiers are used to assign the site of origin, resulting in both carcinoma subtype and primary site classification. The signature was developed from a retrospective set of 561 samples.

PUBLICATION/PATENT

- PCT application filed March 21, 2011 for Drs. Centeno, Bloom, and Yeatman.
- Published in the Journal of Molecular Diagnostics 2010 Jul;12(4):476-86 by Centeno et al.

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LICENSING OPPORTUNITY

