

Biomarker Analysis Software for High-Throughput Diagnostic Multiplex Data

Summary

Extracellular vesicles (EVs) are lipid spheres released from cells. EVs contain proteins that can serve as diagnostic biomarkers indicating the cell state at time of release. Improved detection and phenotyping of EVs and their protein cargo could lead to better cancer diagnostic and prognostic tests, as well as improved therapeutic uses. The National Cancer Institute (NCI) seeks research co-development partners and/or licensees for a software package that performs high-throughput multi-dimensional analysis of EV biomarkers.

NIH Reference Number

E-105-2018

Product Type

- Software

Keywords

- Extracellular Vesicles, EV, Lipid Bilayer-Enclosed Particles, Biomarker, High-Throughput, Software, Jones, Berzofsky

Collaboration Opportunity

This invention is available for licensing and co-development.

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Description of Technology

Extracellular vesicles (EVs) are lipid bilayer-enclosed particles that are released from cells. EVs may contain proteins derived from their cells of origin with the potential as diagnostic biomarkers indicating the state of the cells when released. However, due to their small size (50-1000nm), the methods currently used to phenotype EVs have limited sensitivity and scale. A need exists for development of novel technologies improving EV detection and phenotyping.

National Cancer Institute (NCI) scientists have developed a software package to perform high-throughput multi-dimensional analysis of EVs. The software utilizes a multiplex bead-

based approach, coupled with secondary markers, clinical data, and -omics data. This technology provides a mechanism for high-throughput, semi-automated multidimensional data analysis for potential diagnostic and prognostic outcomes. The inventors used the software to identify and visualize a broad range of EV subsets, while also indirectly measuring specific EV populations. Exploratory studies confirmed strong correlations of liquid biopsy EV repertoires with tumor burden and responses to treatment. Furthermore, this software allows a scalable method of using EVs as biomarkers in a highly multiplexed fashion. When coupled with other clinical data, it is a useful means of diagnostic and/or prognostic outcomes.

The NCI seeks research co-development partners and/or licensees for a biomarker analysis software for high-throughput diagnostic multiplex data.

Potential Commercial Applications

- Software package for high-throughput screening of extracellular vesicles as diagnostic and prognostic markers in personalized medicine.
- Can be utilized as software interface for other multiplex assays

Competitive Advantages

- Allows for high-throughput, multiplexed and semi-automated analysis of extracellular vesicles and cargo protein.
- Utilizes secondary markers, clinical data and -omics data to provide diagnostic and/or prognostic determinations.

Inventor(s)

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Development Stage

- Prototype

Publications

Welsh JA et al. MPAPASS software enables stitched multiplex, multidimensional EV repertoire analysis and a standard framework for reporting bead-based assays.

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Patent Status

- **U.S. Provisional:** U.S. Provisional Patent Application Number 62/650,162, Filed 29 Mar 2018
- **PCT:** PCT Application Number US2019/024975, Filed 29 Mar 2019
- **Foreign Filed:** EUROPE - Patent Application 19717657.1, Filed 29 Mar 2019
- **Foreign Filed:** Australia - Patent Application 2019245402, Filed 29 Mar 2019
- **Foreign Filed:** - Patent Application 3095485, Filed 29 Mar 2019
- **U.S. Patent Filed:** U.S. Patent Application Number 17/042,765, Filed 28 Sep 2020

Therapeutic Area

- Cancer/Neoplasm

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