NATIONAL CANCER INSTITUTE
Technology Transfer Center

Exo-Clean Technology for Purifying Extracellular Vesicle Preparations from Contaminants

Summary

Researchers at the National Cancer Institute (NCI) developed a novel biophysical technique to purify extracellular vesicles (EVs) from contaminants such as proteins and unbound labels. The NCI seeks licensees and/or co-development research collaborations to further advance this technology for EV-based biomarkers and therapeutics to treat a wide range of diseases.

NIH Reference Number

E-227-2017

Product Type

- Research Tools

Keywords

- Extracellular Vesicles, EVs, Exosomes, Microvesicles, Chromatographic, Biomarkers, Affinity, Purification, High-Throughput, Exo-Clean, Resin, Jones

Collaboration Opportunity

This invention is available for licensing and co-development.

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Description of Technology

Extracellular Vesicles (EVs), including exosomes and microvesicles, are nanometer-sized membranous vesicles that can carry different types of cargos, such as proteins, nucleic acids and metabolites. EVs are produced and released by most cell types. They act as biological mediators for intercellular communication via delivery of their cargos. This unique ability spurred translational research interest for targeted delivery of therapeutic molecules to treat a wide range of diseases. EVs also contain interesting information of their specific cellular origin. Thus, EVs can reveal nature, severity, and prognosis of a various pathophysiologic disease states. Such characteristics also make them a reliable and stable source of biomarkers, accessible in several body fluids. However, their small

size makes it difficult to isolate EVs by using standard purification methods commonly used for isolating cells and platelets. Currently available techniques for EV isolation, are non-scalable, labor intensive, time consuming, and ineffective in removing contaminants.

Researchers at the National Cancer Institute (NCI) developed a chromatographic EV purification technology using a custom-made “mixed mode” resin. The resin combines Capto Core-type resin with other affinity-based beads for depletion of unwanted contaminants smaller than 700 MDa – such as proteins, nucleic acids, or other molecules. This Exo-Clean technology is both broadly applicable for biofluid processing and scalable for high-throughput screening (i.e., compatible with robotic 96- or 384- well format). This technology is also suitable for large-scale GMP production of therapeutic exosome and other EV analogue-based therapeutics.

Unique biophysical features of this technology could offer a new avenue for developing EV based clinical biomarkers, and therapeutics. The NCI seeks commercial partners to co-develop and/or license this technology.

Potential Commercial Applications

- Research tool for studying structure and function of EVs
- EV-based clinical biomarkers for detecting various pathological conditions
- Therapeutic exosome and other EV analogue-based therapeutics for targeted drug delivery

Competitive Advantages

- Efficient in removing proteins and various labels from EV preparations
- Scalable for high-throughput screening
- Amenable to a wide range of preparation scales and formats

Inventor(s)

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Development Stage

- Discovery (Lead Identification)

Publications

Welsh JA, et al. A simple, high-throughput method of protein and label removal from extracellular vesicle samples. [33544111]

Patent Status

- **U.S. Provisional:** U.S. Provisional Patent Application Number 62/612,040 , Filed 29 Dec 2017
- **PCT:** PCT Application Number PCT/US2018/067913 , Filed 28 Dec 2018

- **Foreign Filed:** - Patent Application 18847175.9 , Filed 27 Jul 2020
- **U.S. Patent Filed:** U.S. Patent Application Number 16/959,071 , Filed 29 Jun 2020

Therapeutic Area

- Cancer/Neoplasm
- Immune System and Inflammation
- Hormonal Systems, Endocrine, and Metabolic Diseases
- Cardiovascular Systems

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