ExosomeDx
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a bio-techne® brand

Exosomes—the next frontier in biomarker discovery and diagnostics

ExosomeDx harnesses biological information from exosomes for biomarker discovery and diagnostic development. The company's pipeline of products includes the ExoDx Prostate test, the first exosome-based liquid biopsy on the market, and various discovery platforms to help solve biopharma's biomarker-related needs.

Exosome Diagnostics, founded in 2008, is a global leader in the rapidly growing non-invasive liquid biopsy market. The company has built a product pipeline and service platforms around its unique capability of using exosomes—a universal type of extracellular microvesicle containing biomolecules representative of a cell's composition—to identify biomarkers for the diagnosis, treatment and monitoring of disease.

In 2016, ExosomeDx launched the ExoDx Prostate test, the world's first exosome-based liquid biopsy diagnostic. ExoDx Prostate is a simple, non-invasive urine test that helps assess the risk of developing prostate cancer. Backed by more than 250 issued and filed patents, ExosomeDx has a pipeline of other diagnostic solutions in development for conditions such as bladder cancer and kidney rejection.

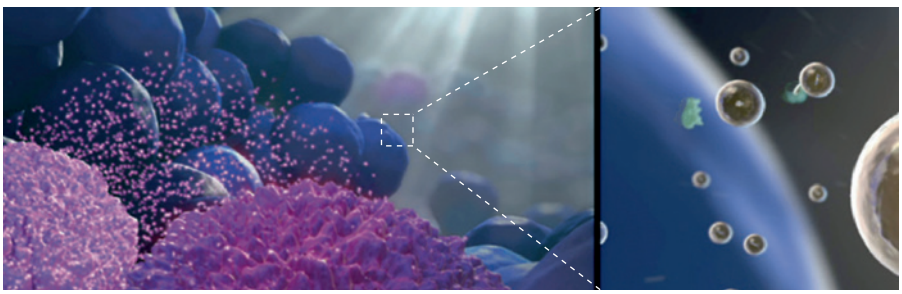
In addition to its diagnostics program, the company offers a suite of custom services for biopharma partners, including biomarker discovery, patient stratification tools and therapy decision trees, to serve their clinical trial and companion diagnostic needs. The company offers services using RNA, cell-free DNA and proteins with its proprietary technology to explore and identify biomarkers. ExosomeDx is the first and only company that can simultaneously isolate and analyze exosomal RNA and cell-free DNA (cfDNA) in a single step to achieve highest sensitivity for detecting rare mutations.

ExosomeDx joined forces with Bio-Techne Corporation in 2018 to augment its CLIA and ISO-certified molecular biology and diagnostic capabilities with Bio-Techne's small-molecule, protein and antibody manufacturing, assay development and instrument design and manufacturing capabilities.

"ExosomeDx is a partner of choice for companies looking to develop liquid biopsy-based tests to help accelerate therapeutics through clinical trials with the end goal of FDA approval for the therapies and associated companion diagnostics," said Mario Morken, director of business development at ExosomeDx. "Exosomes are a treasure trove of biological information, and we have developed the most advanced methods to harness this information for diagnostic, therapeutic and monitoring applications."

Exosomes—a window into the cell

As part of their normal physiology, all cells in the human body release thousands of extracellular vesicles of an average size of about 100 nm in diameter known as exosomes. Exosomes contain many cell constituents, including RNA, DNA, metabolites, lipids and proteins that provide a snapshot of a cell's physiology. A primary role of exosomes is intercellular and interorgan communication within the body, in both health and disease. Exosomes have been associated with disease development in cancer, neurodegeneration and inflammatory disorders.



ExosomeDx harnesses biological information from exosomes for biomarker discovery and diagnostic development. ExosomeDx has built a product pipeline and service platforms around its unique capability of using exosomes. Source: U.S. National Library of Medicine.

In 2008, ExosomeDx cofounder and CSO Johan Skog was one of the first scientists to describe the central biological role played by exosomes in the body, and to recognize their therapeutic and diagnostic potential[1]. Crucially, exosomes provide a protective environment for the various analytes contained in them that shield them from degradation. Exosomes have been reported in all biological fluids, including blood, plasma, serum, urine, cerebrospinal fluid and saliva, making the highly informative cargo of exosomes readily accessible via liquid biopsies.

Exosomes—powerful early disease sentinels

Biomarker signals in exosomes provide a snapshot of a living cell and as such are fundamentally different from biomarkers derived from cfDNA and circulating tumor cells (CTCs). CTCs are living cells shed from a tumor and are typically associated with later disease stages, while cfDNA, including circulating tumor DNA, originates in dying cells, which are representative of even more advanced stages of disease. In contrast, exosome generation is an active metabolic process that provides biomarkers from growing cells typically associated with health or very early stages of disease.

Most clinically actionable RNA biomarkers are messenger RNAs (mRNAs) and long non-coding RNAs (lncRNAs). ExosomeDx has developed a highly reproducible long RNA-Seq assay capable of profiling more than 10,000 mRNAs and thousands of lncRNAs in exosomes, a tremendous expansion over existing methods.

ExosomeDx also has developed technology to co-isolate RNA and DNA. Since mutant DNA is often transcribed into RNA, and mutated copies in early stages of disease are typically rare, combined detection of both RNA and DNA substantially increases the ability to detect very low abundance mutations.

Partnering on exosomes

ExosomeDx partners with biopharma to develop custom molecular solutions for their liquid biopsy needs, including clinical research services and companion diagnostics. ExosomeDx deploys its unique expertise to jointly solve a partner's challenges and focuses on exosome-based RNA, protein and cfDNA analysis from any biofluid and from volumes as small as 0.5 ml.

ExosomeDX supports early discovery, translational and clinical programs. Typically, the company engages at the pre-clinical or phase 1 stage of drug development, but it can also engage at a later point if, for example, an existing biomarker approach requires optimization.

1. Skog, J., Würdinger, T., van Rijn, S. et al. Glioblastoma microvesicles transport RNA and proteins that promote tumour growth and provide diagnostic biomarkers. *Nat. Cell Biol.* **10**, 1470–1476 (2008).

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