

# Exosome Diagnostics

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## Next-generation biomarker discovery and diagnostics

ExosomeDx, together with its parent company Bio-Techne, combines expertise in exosome technologies with experience in the non-invasive liquid biopsy market to create solutions for companion diagnostic development and biopharmaceutical services.

Are you looking to fully characterize diseases and monitor patients, but are frustrated by biomarker limitations and outsourcing to multiple life-science partners? Enter Bio-Techne, a family of companies providing end-to-end custom solutions that no other single business can provide.

Bio-Techne is a world-leading life-sciences supplier, including a comprehensive portfolio of antibodies, proteins and controls, innovative instruments for protein analysis, and original equipment manufacturer reagent manufacturing. Further enhancing its capabilities, the company recently acquired molecular biology experts ExosomeDx and custom diagnostics firm Asuragen.

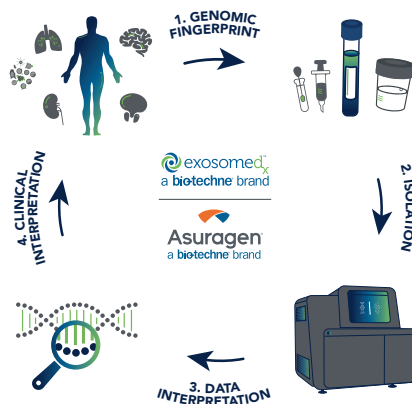
ExosomeDx is a pioneer in exosome technologies and a global leader in the rapidly growing non-invasive liquid biopsy market; the company's ExoDx Prostate test, for example, is the first and only commercially available exosome-based liquid biomarker for prostate cancer risk assessment. Meanwhile, Asuragen, through its AmpliX tests and QuantideX kits, enables fast and reliable testing in complex genetics—including rare neurological diseases—and oncology.

By seamlessly combining a variety of molecular technologies, diagnostic kit manufacturing, comprehensive bioinformatics and regulatory support, Bio-Techne is an ideal partner for biopharmaceutical services and end-to-end companion diagnostic development (Fig. 1).

### Exosome-based molecular diagnostics

Every day, all human cells actively release thousands of exosomes, the communication signals protectively wrapped in a lipid bilayer. These extracellular vesicles contain DNA, RNA, and proteins, providing a snapshot of the physiology within an individual's living cells. "By using our patented technologies to isolate exosomes and analyze their treasure trove of biomarkers, we can establish the cell's origin and whether and how the cell is diseased," explained Johan Skog, Chief Scientific Officer, ExosomeDx. "Therefore, exosomes can be used to accurately characterize and stratify patients, and non-invasively monitor disease progression, personalized therapies, and delivery of therapeutic RNAs and proteins."

This approach is superior to only relying on biomarkers derived from cell-free DNA (cfDNA) and circulating tumor cells (CTCs). Exosomes are considerably more abundant than cfDNA and CTCs and can be found in all biological fluids, making them readily accessible and analyzable through non-invasive liquid biopsies. They are also highly stable, and allow detection of gene rearrangements, splice



**Fig. 1 | Exosome Diagnostic's and Asuragen's technologies and custom diagnostic approach to biomarker discovery and companion diagnostics.**

variants, and RNA editing, which are difficult using cfDNA. Additionally, specific targets from distinct cell/tissue types can be selectively enhanced. For example, selecting for tissue-specific exosomes improves the signal-to-noise ratio, enriching rare or normally undetectable disease signature not accessible using cfDNA or CTCs.

Moreover, ExosomeDx is the only company able to simultaneously isolate and analyze exoRNA and cfDNA, substantially increasing the ability to detect rare mutations. It has also developed a commercially available exosomal long RNA-seq service, enabling the entire transcriptome to be profiled—a powerful way of detecting early disease biomarkers like rare mutations, fusions, and splice variants. "By combining gene expression biomarkers, we can use exosomes to analyze any disease or disorder, not just cancer," explained Skog.

Complementing these capabilities are Asuragen's amplification technologies, which can detect and analyze hard-to-read targets—such as long repetitive sequences, gene conversions, methylation and copy number variation and other complex markers—with unprecedented ease, further enabling applications for rare diseases. The company's AmpliX PCR products for inherited genetic disorders are designed as easy-to-run assays that deliver best-in-class performance. "Addressing challenging targets is our strength," says Bernard Andrus, Chief Operations Officer, Asuragen. "Complex molecular testing is made simple with all-inclusive kits comprising proprietary chemistries, and automated analysis/interpretation software that runs on multiple widely available platforms."

### Neuroscience applications

As exosomes pass through the blood-brain barrier, exosome-based diagnostics are likely to have considerable impact in Alzheimer's and Parkinson's diseases and other neurological conditions with high unmet need. Research into such disorders increasingly requires rapid patient stratification and tailored experimental design—services uniquely suited to the patented technology, experience, and pipelines of Bio-Techne companies. Asuragen, for example, has developed kits for reliably and rapidly detecting and quantifying genetic signatures associated with several neurological diseases, including inherited forms of amyotrophic lateral sclerosis and Huntington's disease. ExosomeDx is establishing a growing body of glioblastoma multiforme research.

### Partnering

The Bio-Techne companies have built product pipelines and services platforms around their unique and complementary capabilities, supporting early discovery, translational and clinical programs, and delivering high-quality solutions to complex clinical questions. Thanks to their combined capabilities—which also include regulatory and reimbursement competence, and centralized laboratory testing for clinical assessment and commercialization—Bio-Techne has the experience and expertise to offer a seamless translational exosome-based biomarker development program.

"Our versatile and synergistic approach makes us ideal partners for biopharmaceutical companies at the cutting edge of academic research, translating basic discoveries to therapeutic leads, or at facilities requiring the highest level of diagnostic testing," said Andrus. "Exosomes are a powerful but emerging tool for biomarker discovery and diagnostics. We are fully leveraging the world-class products and services developed by the broader Bio-Techne family for the benefit of patients suffering from challenging and devastating diseases."

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