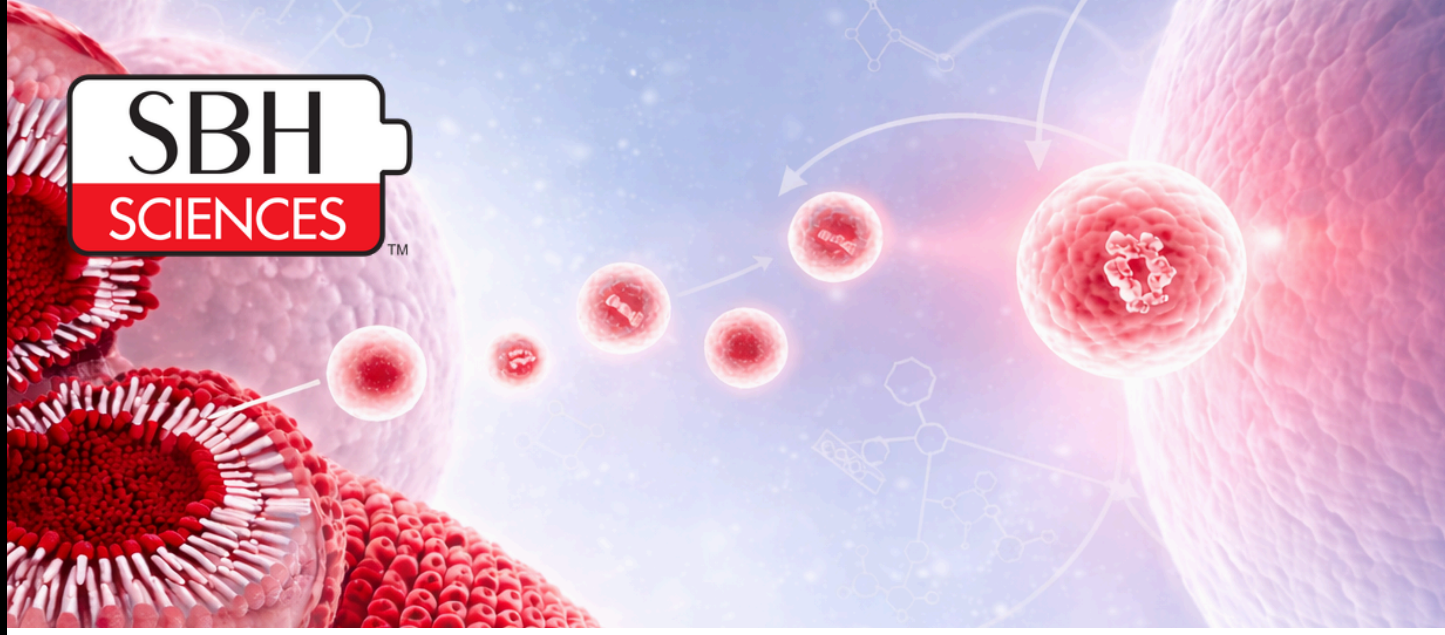
white paper



Exosomes: The Missing Piece in Precision Biomarker Discovery

OVERVIEW

Exosomes are tiny messengers released by every cell, carrying proteins and RNA that reveal the health and state of their cell of origin. Found in blood, urine, and other biofluids, they enable minimally invasive "liquid biopsies" and offer tissue-specific insights that make them ideal for discovering next-generation biomarkers. Their protective membranes preserve delicate molecular cargo, unlocking powerful opportunities for patient stratification, therapeutic monitoring, and precision medicine. While challenges like standardization, scalability, and regulatory validation remain, SBH Sciences' exosome research platform helps overcome these barriers. Partnering with a CRO like SBH accelerates biomarker discovery, translating cutting-edge science into actionable clinical insights faster.

IN THIS RESOURCE

- **Why exosomes are so valuable for biomarker discovery**
- **How exosomes are isolated and analyzed**
- **What exosomal cargo can reveal about diseases**
- **How CROs support exosome and biomarker programs**

SBH Sciences is a preclinical contract research organization who has provided expertise in drug discovery and development for 28 years and has partnered with over 350 biotech companies worldwide.

EXOSOMES EXPLAINED

Exosomes are a type of extracellular vesicle (30–150 nm) released by all cells that can be detected in fluids like plasma, cerebrospinal fluid, urine, breast milk, semen, blood, amniotic fluid,and saliva [1–4]. They form as intraluminal vesicles within multivesicular bodies, which fuse with the plasma membrane to release exosomes [2,5]. Exosomes carry a conserved set of proteins involved in vesicle formation and trafficking (TSG101, Alix, HSC70, HSP90β) and are enriched in tetraspanins (CD9, CD63, CD81), alongside lipids and nucleic acids such as mRNA and miRNA [2,6–8]. Their molecular cargo reflects the physiological and pathological state of the parent cell.

Functionally, exosomes mediate intercellular communication, influencing immune modulation, tissue repair, and neuronal processes, but can also propagate disease by transferring pathogenic proteins [3,9–11]. In cancer, tumor-derived exosomes carry oncogenic proteins and EGFR variants that promote tumor growth, angiogenesis, and metastasis [12–14]. Their stability in biofluids and encapsulation of disease-relevant molecules makes exosomes powerful candidates for minimally invasive “liquid biopsy” biomarker discovery, patient stratification, and therapeutic monitoring [3,15,16].

WHY EXOSOMES MAKE GOOD BIOMARKERS

Exosomes are highly promising biomarkers because they combine stability with biological specificity. Their protective lipid membrane preserves proteins and nucleic acids, while their molecular cargo reflects the originating cell type, allowing tissue- and cell-specific insights. These features make exosomes particularly useful for minimally invasive liquid biopsies across diseases such as cancer, cardiovascular conditions, and immune disorders.

Enhanced Stability: The exosome’s lipid bilayer protects proteins and nucleic acids from degradation.

Cell- and Tissue-Specific: Exosome cargo reflects the molecular state of the parent cell

Reliable Liquid Biopsy: Accessible in biofluids for minimally invasive sampling.

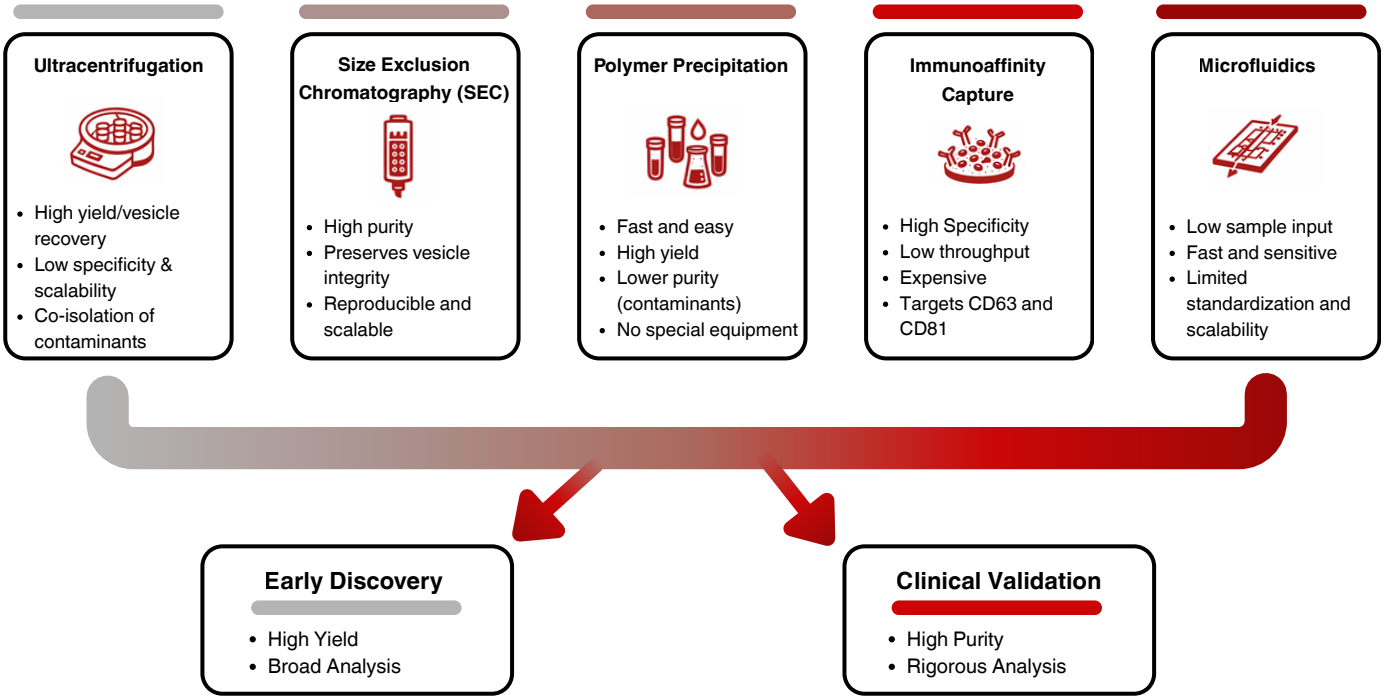
Versatile applications: Useful in oncology, cardiovascular disease, and immune monitoring

Traditional Liquid Biopsy ⟷ Exosome Liquid Biopsy

Traditional Liquid Biopsy	Exosome Liquid Biopsy
• Prone to degradation (cfDNA and RNA)	• High stability due to protective lipid bilayer
• Limited biological context with fragmented DNA and single analyte types	• Rich multiomic cargo reveals cell state
• Limited temporal resolution/monitoring ability	• High potential for longitudinal monitoring and disease progression
• Low sensitivity for early stage disease	• Higher potential sensitivity for early stage disease due to enriched cargo

SELECTING THE RIGHT ISOLATION METHOD

Exosome isolation methods vary widely in performance, and no single approach optimally balances purity, yield, scalability, and reproducibility [19]. mportantly, the choice of isolation method directly impacts downstream analyses. Lower-specificity methods may introduce contaminants that confound results, while highly selective approaches may bias biological interpretation [19]. As a result, higher-yield methods are typically used in early discovery to maximize analyte capture, whereas higher-purity, standardized methods are preferred in validation and clinical settings to ensure reliability and reproducibility [19,21].



DOWNSTREAM ANALYSES FOR EXOSOMES

Exosome-derived analytes can be measured using a range of analytical platforms, including proteomics (e.g., mass spectrometry, immunoassays), transcriptomics (e.g., RNA sequencing, qPCR), and targeted assays for specific proteins or nucleic acids [24,25]. These approaches enable comprehensive profiling of disease-relevant molecular signatures, supporting biomarker discovery, pathway analysis, and target engagement assessment.

The quality of such biomarker data depends on both the exosome isolation method and the analytical platform, requiring careful optimization and validation to ensure sensitivity, specificity, and reproducibility [19,24].

This is where access to multiplex immunoassays on machines like Luminex can make or break your study.

MESSENGERS OF DISEASE

Exosome cargo provides a dynamic snapshot of disease biology by reflecting the molecular state of the cells they originate from. The proteins, mRNA, and miRNA packaged within exosomes can reveal key processes such as tumor progression and metastasis in cancer, inflammation and immune activation in autoimmune disorders, and cellular stress or damage in cardiovascular disease. Because this cargo is both stable and tissue-specific, it enables deeper insight into disease mechanisms, act as predictive biomarkers, supports patient stratification, and allows for real-time monitoring of therapeutic response. [26]

Cargo	Disease	Insight
miRNA-22 miRNA-320a miRNA-423-5p	Cardiovascular	Prognosis of systolic heart failure
miR-21-5p miR-126-3p	Asthma	Level of lung function decline
miR-142-3p	Pulmonary Fibrosis	Diffusing capacity and alveolar levels of CO2
miR486-1-5p	Pre-eclampsia	Early Diagnosis
miR-200b miR-200c	Lung Cancer	Early Detection
miR-375	Bone Marrow Metastatic Disease	Disease Progression

HOW CROs ACCELERATE EXOSOME PROGRAMS

As a CRO, SBH Sciences offers a fully integrated, end-to-end exosome research platform built to accelerate biomarker discovery and de-risk translational programs for our partners. Our capabilities combine scientific rigor, operational scalability, and regulatory readiness to support both exosome based biomarker discovery and clinical utility:

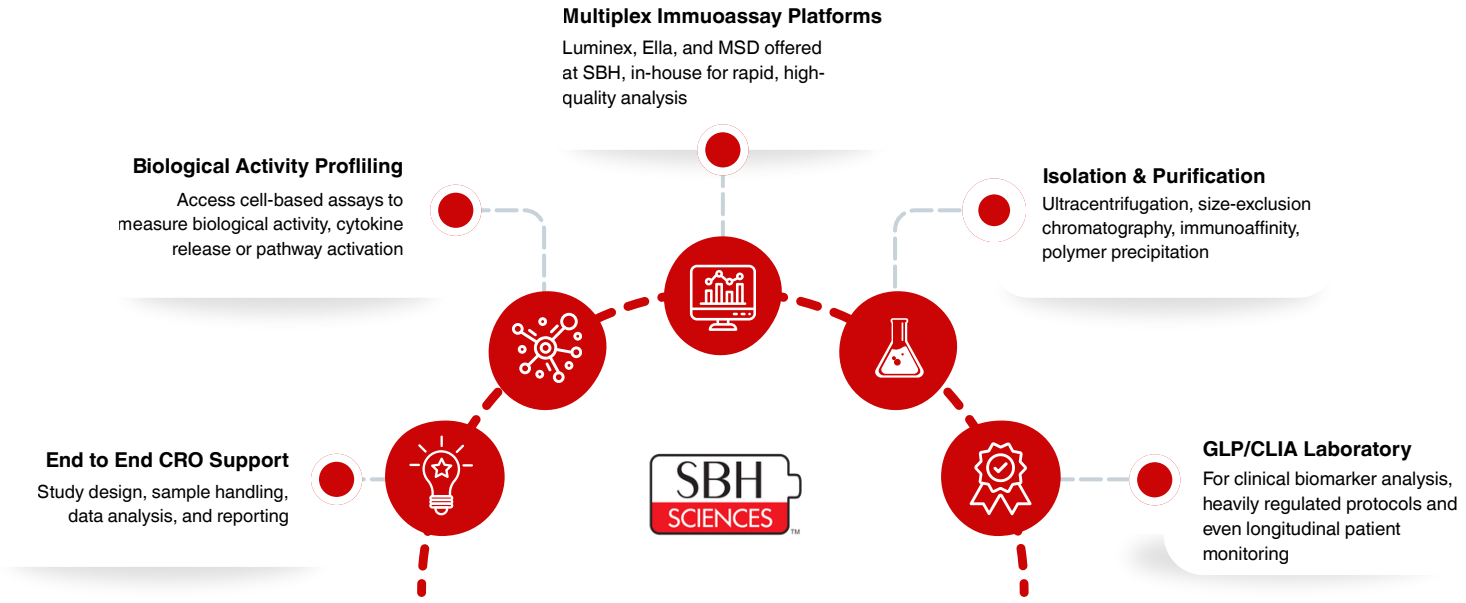
Optimized exosome isolation workflows delivering high yield, reproducibility, and consistency across studies, ensuring assay robustness and reducing variability.

Tissue specific immunoaffinity-based enrichment technologies to selectivy capture tissue and cell type–specific exosome populations (such as liver, muscle), enabling analysis of tissue specific biomarkers in biofluid samples.

High-sensitivity downstream analysis platforms (protein and RNA) designed to enable detection of low-abundance exosome analytes and their utility for biomarker assay development.

GCLP-compliant and CLIA-certified laboratory infrastructure, enabling seamless transition from discovery to clinical biomarker assays, including support for regulated studies and longitudinal patient monitoring.

As a CRO partner, we work closely with our clients to design fit-for-purpose studies, mitigate technical risk, and accelerate timelines. We actively collaborate with academic institutions and industry partners to deliver high-quality, reproducible exosome biomarker data that can drive decision-making in preclinical, translational, and clinical programs, and advance precision medicine strategies.



To learn more about leveraging exosomes for precision biomarker discovery, contact SBH Sciences and start a conversation with our scientific team.

www.sbhsciences/exosome-services

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ABOUT SBH SCIENCES

SBH Sciences is a contract research organization (CRO) based in Natick, MA specializing in biomarker discovery, cytokines, immunoassays, and translational research services. With over 28 years of experience and partnerships with more than 350 biotech and pharmaceutical companies, SBH supports end-to-end biomarker programs from early discovery through clinical validation. Our expertise spans multiplex platforms, including in-house Luminex, Ella, and MSD systems, and is backed by a CLIA- and GLP-compliant laboratory to ensure high-quality, reproducible data for precision medicine applications.

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