

# The True Liquid Biopsy

## REVOLUTIONARY, BIOFLUID-BASED DIAGNOSTICS TO ADVANCE PERSONALIZED CARE

At Exosome Diagnostics, we are focused on developing and commercializing revolutionary, biofluid-based diagnostics to deliver personalized, precision healthcare that improves lives. The first applications of our proprietary, exosome-based platform will be in cancer with the launch of several liquid biopsies for mutation detection, screening, and drug-resistance monitoring. We are also exploring the potential of our diagnostics for other serious diseases beyond oncology. Our breakthrough molecular diagnostics have the potential to deliver on the promise of personalized healthcare, guiding treatment decisions precisely and in real time along the entire patient care continuum.

### EXOSOME DIAGNOSTICS LIQUID BIOPSIES: *Leveraging Exosomal RNA to Reveal Insights about Cancer*

Our liquid biopsies currently in development leverage the rich molecular information found in exosomal RNA (exoRNA). Exosomes are important cell messengers carried within all biofluids, including plasma, urine, cerebrospinal fluid, and saliva, and contain RNA, DNA, and proteins from their cell of origin.

We analyze stable, high-quality exoRNA to detect cancer mutations, such as gene arrangements and splice variants, which are difficult or impossible to detect utilizing circulating DNA analysis. We are the first and only company that can simultaneously isolate and analyze exoRNA + cell-free DNA (cfDNA) in a single step, adding the circulating DNA fraction to enhance rare mutation detection.

### OUR DIAGNOSTICS: A Transformational Impact on Patient Care and Outcomes





# LAUNCHING THE FIRST EXOSOME-BASED LIQUID BIOPSIES

ExoDx™  
Lung(ALK)

Now Available!

## Blood-Based ALK and T790M Lung Cancer Liquid Biopsies



- Analyzes RNA and DNA to detect ALK and T790M mutations at various points throughout treatment, including late-stage disease when tissue biopsy is impractical
- Enables more informed decisions about drug selection or clinical trial participation

## Blood-Based Solid Tumor Mutation Panel



- Focuses on the EGFR, MAPK and PI3K activation pathways, and analyzes mutations on both RNA and DNA
- Covers 26 of the most actionable genes and approximately 1000 associated mutations; initially available to pharma as a clinical development tool

## Urine-Based Prostate Cancer Liquid Biopsy



- Uses a proprietary algorithm that integrates a three-gene signature on exoRNA to help identify men who are least likely to have high-grade prostate cancer
- Large clinical validation study completed (NPV = 91%)
- Overall goal and utility of test: to reduce the number of unnecessary biopsies without missing men who do need to be treated

## Broad Future Clinical Utility beyond Oncology



- Will focus on disease areas where genetic testing is beneficial, but access to tissue is difficult or impossible
- Neurological, endocrine and cardiovascular disease, among others

## COMPREHENSIVE MOLECULAR ANALYSIS CAPABILITY AND VERSATILE CLINICAL UTILITY

Given the rise in molecularly targeted therapies, molecular diagnostics are a critical component to inform the most appropriate treatment approaches both at treatment onset and throughout the course of care. Unlike most current molecular tests, our diagnostics do not rely on analyzing tissue. Instead, they can extract molecular information from exosomes carried in biofluids. Uniquely, our technology also offers the flexibility to simultaneously isolate and analyze both high-quality exosomal RNA (exoRNA) and cell-free DNA (cfDNA) from plasma, maximizing the opportunity for biofluid-based mutation detection of low-abundance, rare mutations, and delivering a superior detection rate versus cfDNA-only analysis.

## COLLABORATING WITH THE MEDICAL AND SCIENTIFIC COMMUNITY

We collaborate with leading clinicians and researchers in our therapeutic areas of focus to understand challenges with the current diagnostic paradigm, and to determine how our exosome-based platform can help address unmet needs. We are working with top academic medical institutions, hospitals, community-based practices, and advocacy groups to conduct clinical validation of our diagnostics in development and early research into future diagnostic approaches.

We have also initiated the “Academic Bench to Diagnostic Assay (A to D) Program,” a partnership program designed to enable academic and clinical researchers to utilize our developmental and regulatory expertise to bring promising assays they have developed into the clinic so that these innovations can directly benefit patients.

### Key Advantages of Our Biofluid-Based, Exosome- Enabled Diagnostics

Combine RNA and DNA analysis;  
can utilize fresh or frozen/archived  
biofluid samples

Do not rely on analyzing tissue samples

Biofluids more readily accessed (vs. an  
invasive surgical procedure)

Enable a comprehensive understanding  
of molecular makeup; a tissue sample  
may not reflect the heterogeneity of all  
cells in a tumor

Leverage routine sample handling to  
easily fit into clinical lab workflow

Enhance access to cost-effective  
diagnostics and healthcare

Enable more informed, individualized  
treatment decisions



## STRATEGIC PARTNERSHIPS TO ACCELERATE ADOPTION

### Promega:

- OEM Manufacturing for Clinical Sample Concentrator Class I Devices

### QIAGEN:

- Global Manufacturing, Sales, Marketing, and Distribution for Research Kits

### Eli Lilly and Company:

- Clinical Partnership for Biomarker Discovery and CDx Validation

## CLINICAL PARTNERSHIPS TO EXPLORE DIAGNOSTIC POTENTIAL

**Lung Cancer** (Addario Lung Cancer Medical Institute)

**Parkinson's Disease** (Michael J. Fox Foundation)

**Alzheimer's Disease** (University of California, San Diego; VU University Medical Center, Amsterdam)

**Prostate Cancer** (Prostate Cancer Foundation)

**Neurological Disorders** (NASA)

## ENABLING BIOPHARMA TO ENHANCE THE R&D PROCESS

We are a leader in collaborating with biopharma, helping companies leverage exosome-based science to enhance the R&D process, from biomarker discovery through validation, and the development of sophisticated companion diagnostics (CDx) to maximize the potential of targeted therapies.

Biopharma companies continue to rapidly advance the development of molecularly targeted therapies. Biomarker strategies are incorporated into virtually every R&D process, but sourcing tissue to identify biomarkers can lead to delays in clinical trial recruitment and complicate clinical study design and implementation. By offering biopharma companies biofluid-based solutions for clinical trials, we overcome these tissue-related obstacles.

### Key Advantages for Biopharma

Isolate and extract RNA and DNA to assess biomarker status without historical tissue or requiring a biopsy; other liquid biopsy technologies cannot analyze RNA

Offer enhanced freedom with clinical trial design

Provide access to virtually unlimited supply of molecular information via biofluids

Accelerate enrollment

Shorten study duration

Reduce overall clinical study costs

Potentially increase time on patent life

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Driving Innovation. Personalizing Healthcare. Improving Lives.