Launching in 2016 as a Laboratory Developed Test at our Certified CLIA Laboratory

exosomedx

PLASMA-BASED SOLID TUMOR MUTATION PANEL

ExoDx®
Solid Tumor

exoRNA- and cfDNA-Based, Highly Sensitive Mutation Detection of Actionable Mutations in Most Significant Cancer Pathways

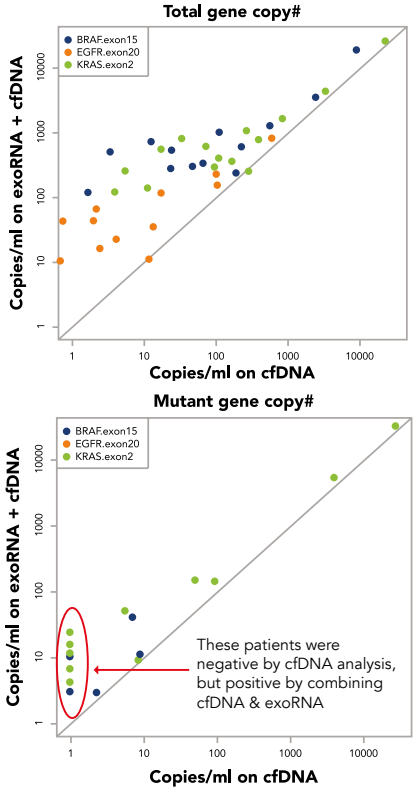
In 2016, we are launching our plasma-based actionable mutation panel, focused on mutations most relevant in solid tumors, for use by pharma companies in clinical development.

PLASMA-BASED MUTATION DETECTION

26 Genes, 1000 Mutations, Most Significant Cancer Pathways

Exosome Diagnostics' blood-based solid tumor mutation panel covers 26 of the most important genes and 1000 associated mutations in the most significant pathways of cancer, including EGFR/MAPK and PI3K. The panel utilizes our unique exosome-based technology platform to simultaneously isolate and analyze exosomal RNA (exoRNA) and cell-free DNA (cfDNA), two biologically distinct sources of circulating nucleic acids. Combining exoRNA and cfDNA in a single step enables our panel to achieve ultra-sensitive detection of rare cancer mutations.

SOLID TUMOR MUTATION PANEL PERFORMANCE



In a clinical cohort of 16 colorectal patients, KRAS mutations went undetected in many patients when analyzed with cfDNA alone. In comparison, combining exosomal RNA and cfDNA increased sensitivity and successfully detected the mutation in patients who were negative by cfDNA analysis.

GENES COVERED IN OUR SOLID TUMOR MUTATION PANEL

BRAF • NRAS • PIK3CA • MEK1 • KRAS • EGFR
KIT • PDGFRA • EML4-ALK • ROS1 • RET
HER-2/NEU; ERBB2 • ALK • AKT1 • ARv7 • PTEN
DH2 • mTOR • TP53 • NOTCH1 • Hedgehog
FGFR3 • NTRK1 • TSC1 • TSC2 • CDKN2A

KEY BENEFITS

- Analyzes stable, high-quality exoRNA plus cfDNA for highly sensitive mutation detection
- Covers 26 of the most important genes and 1000 associated mutations
- Detects most actionable mutations with clear clinical relevance; EGFR, MAPK, and PI3K pathways
- Eliminates need for tissue samples as a plasma-based test
- Enables rapid eligibility identification and patient stratification for clinical trials
- Allows longitudinal and serial molecular monitoring throughout clinical trial process
- Can utilize fresh or frozen/archived plasma samples
- Does not require special shipping or storage provisions
- Employs expert analysis from CLIA-certified lab

FACT SHEET

ABOUT EXOSOME DIAGNOSTICS

Exosome Diagnostics is focused on developing and commercializing revolutionary, biofluid-based diagnostics to deliver personalized, precision healthcare that improves lives. We aim to deliver comprehensive and dynamic molecular insights to transform how cancer and other serious diseases are detected, diagnosed, treated, and monitored.

FOR MORE INFORMATION

Companies interested in Exosome Diagnostics' pharma services and solid tumor panel for clinical development should contact **bd@exosomedx.com**.

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EXOSOME DIAGNOSTICS' PHARMA SERVICES

Partnering with Pharma for Biomarker Discovery, Clinical Validation, and Development of Companion Diagnostics

We work in partnership with pharma companies to advance the development of therapeutics and overcome challenges in clinical trials and the drug approval process by supporting biomarker discovery and companion diagnostics. By utilizing our best-in-class technology to isolate exosomes and extract both RNA and DNA from biofluids, we can help assess biomarker status without using historical tissue or requiring a biopsy. Our expertise supporting the development of companion diagnostics can help in clinical trial recruitment and support therapy selection for patients.

BENEFITS OF WORKING WITH EXOSOME DIAGNOSTICS

We have the only platform that allows exploration and validation of RNA and DNA from biofluids.

Our technology can help pharma and research organizations use biofluids to discover, detect, and validate biomarkers – which facilitates safer and more effective drug dosing and selection, and reduces the risk of adverse effects.

Our technology can support faster clinical validation by using any biofluids (urine, blood, and cerebrospinal fluids) instead of requiring tissue.

We have leading experts in personalized medicine and exosome science on our team and a dedicated, certified CLIA laboratory.

A TO D PROGAM

We are proud to offer a new program to partner with academic and clinical researchers, the "Academic Bench to Diagnostic Assay (A to D) Program." This program is designed to utilize our developmental and regulatory expertise to bring assays developed by researchers from the academic bench to the clinical diagnostics laboratory. Exosome Diagnostics' A to D program will help provide the expertise needed to address the challenges of advancing tests into the clinic:

- Navigation of the regulatory approval process
- Assistance with reimbursement
- Implementing a commercialization plan
- Leverages ExoDx's patented exoRNeasy research kits (marketed by QIAGEN) with the benefit of working with Exosome Dx for the addition of cell free DNA for increased sensitivity of rare mutations when necessary.

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