EML4-ALK is a gene fusion found in approximately 3 - 5% of all patients with NSCLC. The current testing standard for EML4-ALK is FISH from a tissue biopsy. FISH has been shown to lack sensitivity and is generally acknowledged to miss the mutation in a significant number of patients (up to 60 percent) [The Oncologist, February 26, 2015]. In addition, access to tissue in NSCLC patients is sometimes not available. ExoDx Lung(ALK) helps serve this population who otherwise could not be tested.

**KEY BENEFITS**

- Analyzes stable, high-quality exoRNA to detect EML4-ALK mutation with high sensitivity
- Detects with high specificity distinct fusion transcripts (v1, v2, v3a, b, c); increasingly important for treatment selection
- Allows longitudinal monitoring to determine molecular response to therapy and molecular relapse
- As a plasma-based test it enables molecular analysis without the need for tissue
- Overcomes challenges of tissue sample scarcity and heterogeneity
- Can utilize fresh or frozen/archived plasma samples
- Does not require special shipping or storage provisions
- Employs expert analysis from CLIA-certified lab with 5 day turn around time on results
WHAT ARE EXOSOMES?

- Messengers released by all living cells into biofluids, such as plasma/serum, urine, cerebrospinal fluid, and saliva, as an active process of cellular communication
- Contain RNA, including mRNA, microRNA, IncRNA, and other RNA species, as well as DNA and proteins, from their cell of origin
- Broad utility throughout care continuum: detection, diagnosis, treatment, and monitoring

OUR SOLUTION:

Plasma-Based, Highly Sensitive, exoRNA + cfDNA-Based Mutation Detection

ExoDx Lung(EGFR) and ExoDx Lung(T790M) isolate and analyze both exoRNA and cell-free DNA (cfDNA) from plasma.

ExoDx Lung(T790M), now available, is a blood plasma test that provides sensitive detection of the T790M resistance mutation that arises in 50 to 60 percent of NSCLC patients being treated with EGFR inhibitor therapies. The test can enable assessment by serial blood draw, monitoring patients for development of resistance while on EGFR inhibitor therapy.

ExoDx Lung(EGFR), available in 2016, is a blood plasma test that can detect the EGFR activating mutations and the T790M resistance mutation without the need for a biopsy. The presence of EGFR activating mutations means that patients are more likely to respond to EGFR inhibitor therapies. The EGFR T790M mutation causes cancer cells to develop resistance to many EGFR inhibitor therapies.

EGFR T790M Liquid Biopsy Positive Agreement with Tissue

<table>
<thead>
<tr>
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<th>Sensitizing EGFR mutations</th>
<th>EGFR T790M mutation</th>
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<tbody>
<tr>
<td>ALL STAGES</td>
<td>81% (17/21)</td>
<td>75% (12/16)</td>
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Data demonstrating our solid tumor panel’s ability to detect activating and acquired resistance (AR) mutations on exoRNA and cfDNA co-isolated from 21 plasma samples of lung cancer patients. Concordance with tissue was 17/21 (81%) for activating mutations, and 12/16 (75%) for AR mutations.

KEY BENEFITS

- Analyze stable, high-quality exoRNA + cfDNA in a single step; enable ultra-sensitive detection of the low-abundance EGFR T790M mutation
- Allow monitoring of patients for development of the EGFR T790M resistance mutation while on TKI therapy
- Detect EGFR T790M resistance mutation ahead of radiographic evidence of disease progression
- Enable molecular analysis without the need for tissue
- Enable non-invasive molecular assessment for advanced-stage patients
- Can utilize fresh or frozen/archived plasma samples
- Does not require special shipping or storage provisions
- Employ expert analysis from CLIA-certified lab with 5 day turn around time on results

ExoDx Lung(T790M) Now Available!
ExoDx Lung(EGFR) Coming Soon

Addressing the Unmet Need in EGFR T790M Resistance Mutation Detection

EGFR T790M is a resistance mutation that arises in 50 to 60 percent of NSCLC patients being treated with a tyrosine kinase inhibitor, or TKI. Currently, the only method for assessing EGFR T790M is a tissue biopsy, which is sub-optimal in an advanced-stage patient population. Patients are rarely positive for EGFR T790M at diagnosis. Assessing for resistance is only done at time of progression on an EGFR inhibitor.