



# NEWS RELEASE

## FOR IMMEDIATE RELEASE

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### **Foundation Medicine Receives CLIA Certification for its Genomic Sequencing Laboratory**

CAMBRIDGE, Mass. – February 1, 2012 – [Foundation Medicine, Inc.](#), a molecular information company that brings comprehensive cancer genome analysis to routine clinical care, today announced certification from the U.S. Department of Health and Human Services' Centers for Medicare and Medicaid Services (CMS) under the Clinical Laboratory Improvement Amendments (CLIA) of 1988 for its genomic sequencing laboratory in Cambridge, Massachusetts. This certification follows receipt of a Massachusetts State license and allows the company to accept clinical samples from most U.S. states.

“Foundation Medicine has been dedicated to exceptional standards of operational performance from day one, and that quality commitment was evident in our clinical laboratory certification process,” said Kevin Krenitsky, M.D., chief operating officer of Foundation Medicine. “CLIA certification is a critical step that enables us to accept and report on clinical samples as we scale for full commercial launch later this year.”

Foundation Medicine achieved Massachusetts State licensing in October 2011, enabling the company to begin processing clinical samples from most states. The company has begun accepting clinical samples and expects to commercially launch its fully informative genomic profile for all patients with solid tumors in mid-2012.

Mandated by the Code of Federal Regulations (CFR 42 Part 493.2), the CMS manage and conduct inspections of CLIA laboratories. The regulation was enacted to ensure consistent, accurate, and reliable clinical test results reporting from laboratories across the country used for the diagnosis, treatment, and/or prognosis of disease in human subjects. CLIA applies to all clinical laboratories operating in the U.S. and its territories and encompasses more than 200,000 clinical testing sites.

### **About Foundation Medicine’s Comprehensive Cancer Genomic Test**

Foundation Medicine’s [comprehensive cancer genomic test](#) uses next-generation sequencing to analyze routine clinical specimens (i.e., small amounts of formalin fixed, paraffin embedded tumor tissue) for all classes of genomic alterations (point mutations, copy number alterations, insertions/deletions, and select rearrangements) in approximately 200 cancer-related genes. The test is optimized for clinical-grade analysis of tumor tissues, overcoming multiple complexities (such as purity, ploidy, and clonality) inherent to tumor genomes. Results are designed to serve

as a helpful decision-support tool for physicians to evaluate cancer treatment approaches tailored to each patient's [molecular subtype](#). Each patient report is reviewed and annotated by a molecular oncologist and consists of scientific and medical literature relevant to that patient's genomic alterations and includes information on targeted therapies and clinical trials supported by scientific and medical research.

### **About Foundation Medicine**

Foundation Medicine is dedicated to improving cancer care through the development of comprehensive cancer diagnostics that will help physicians inform treatment decisions based on an individual patient's molecular cancer subtype. Foundation Medicine's first laboratory developed test, based on a next-generation sequencing platform, is designed to accommodate a broad landscape of cancer genome information and a growing repertoire of targeted treatments and clinical research opportunities. Foundation Medicine's test will assist physicians to make prompt and informed determinations about the best cancer treatments and clinical trial options for each patient, taking into account each patient's unique cancer-associated alterations alongside publicly available scientific and medical information. The company's founding advisors are world leaders in genome technology, cancer biology and medical oncology; they, alongside clinicians, biotech and molecular diagnostics industry leaders, are working to harness emerging technologies to develop unparalleled tests that will identify and interpret an ever-growing set of actionable genomic alterations, truly enabling personalized cancer medicine. For more information, please visit the company's website at [www.foundationmedicine.com](http://www.foundationmedicine.com).

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