

Advancing Personalized Medicine in Cancer

Genzyme Genetics is one of the largest providers of cancer testing services in the United States, offering extensive medical expertise and an advanced menu of testing services to help doctors diagnose and effectively treat patients with cancer.

Industry Challenge: Breaking away from “Trial and Error Medicine”

There is a critical need for more advanced diagnostic testing in the treatment of cancer and other diseases:

- In 2005, U.S. drug spending totaled more than \$250 billion,ⁱ yet 50 percent of drugs were shown not to be efficacious as prescribedⁱⁱ
- The pipeline for new oncology medications is increasingly based on genetically engineered compounds targeted to specific molecular alterations which need to be identified to maximize the therapeutic benefit of these medications.
- While research, development and spending for oncology medications is dramatically increasing, U.S. diagnostics spending has consistently decreased since 1984ⁱⁱⁱ
- Adverse drug reactions are the 6th leading cause of death in the United States^{iv}

Genzyme’s Solution: Bridging the Gap between Diagnostics and Therapeutics

Genzyme Genetics addresses the need for developing better diagnostic tests and more personalized cancer treatment by focusing on an innovative pipeline of new products and services to help physicians select the appropriate therapies for their patients and monitor their patients on therapy. Genzyme Genetics offers complex diagnostic testing and consultative diagnostic pathology services for patients with many types of cancer, including breast cancer, colorectal cancer, lung cancer, leukemia and lymphoma.

- In 2006 and 2007, Genzyme launched eight new personalized diagnostic cancer-related tests, including one for B-cell chronic lymphocytic leukemia, a disease for which Genzyme also offers a therapy.

Genzyme is a leading provider of many complex diagnostic tests and services including consultative diagnostic pathology, hematopathology, cancer cytogenetics, flow cytometry immunophenotyping, fluorescence in situ hybridization (FISH), immunohistochemistry (IHC), PCR-based mutation analysis and gene sequencing.

Oncology: Genzyme Helps Doctors Accurately Test for and Treat Cancer

A Growing Lung Cancer Portfolio

According to the American Lung Association, close to 342,000 Americans die of lung disease every year, making it the leading cause of cancer death in the U.S.

- Genzyme Genetics offers three lung cancer tests including the epidermal growth factor receptor (EGFR) Mutation Analysis, KRAS Mutation Analysis, and EGFR Amplification by FISH assays. Genzyme holds the exclusive worldwide diagnostic rights to use of the EGFR gene mutations in testing for non-small cell lung cancer (NSCLC) tumors.

ⁱ Feb. 2005 PriceWaterhouseCoopers report titled Personalized Medicine: the Emerging Pharmaceutical Revolution.

ⁱⁱ Nov. 2005 Thomas Weisel Partners report titled Beneficiaries of Personalized Medicine and Market Update.

ⁱⁱⁱ The Pharmacogenomics Journal (Vol 6, pg 16-, Pharmacogenetics and the concept of individualized medicine.

^{iv} Molecular Diagnostics and Personalized Medicine 2003, Drug and Market Development August 2003.

Helping Women Battle Breast Cancer

According to the American Cancer Society, approximately 178,480 women in the United States will be found to have invasive breast cancer in 2007 and approximately 40,460 women will die from the disease this year.

- Genzyme Genetics' expert staff, including more than 25 full-time pathologists, reviews nearly 20 percent of newly diagnosed cases of breast cancer and performs ancillary testing used by their treating physicians to make important treatment decisions.

The Fight Against Leukemia and lymphomas

According to the National Cancer Institute, it is estimated that 44,240 men and women will be diagnosed with and 21,790 men and women will die of leukemia in 2007.

- Genzyme Genetics' expert staff reviews more than 10 percent of leukemias and lymphomas diagnosed in the U.S. each year and performs important diagnostic services and ancillary testing related to hematopathology, ordered by both client pathologists and hematologist/oncologists.

Genzyme Genetics: Personalized Medicine Cancer Testing Overview

<u>Cancer Subtypes</u>	<u>Associated Tests</u>	<u>Current Approved Therapies</u>
AML (acute myeloid leukemia)	FLT3 Mutation Analysis	Multiple chemotherapy agents
APL (acute promyelocytic leukemia)	PML-RARA Analysis	Trisenox® (arsenic trioxide), ATRA/tretinoin, anthracyclines
Breast	ER/PR	Tamoxifen
Breast	HER-2 by IHC and FISH	Herceptin® (trastuzumab), Tykerb® (lapatinib ditosylate)
CLL (chronic lymphocytic leukemia)	CLL-MRD IgVh Mutation Analysis p53 Abnormalities	Multiple therapies such as Campath® (Alemtuzumab), Cytoxan® (Cyclophosphamide), Fludara® (Fludarabine) and Leukeran® (Chlorambucil)
CML (chronic myelogenous leukemia)	ABL Kinase Mutation Analysis; BCR-ABL	Gleevec® (imatinib), Sprycel® (dasatinib), Tassigna® (nilotinib)
Colorectal cancer	EGFR pharmDx	Erbix® (cetuximab), Vectibix® (panitumumab)
Colorectal cancer	UGT1A1 Molecular Assay	Camptosar® (Irinotecan)
MDS (myelodysplastic syndrome)	5q Deletion Analysis	Dacogen® (decitabine), Revlimid® (Lenalidomide), Vidaza® (5-azacytidine).
MPD (myeloproliferative disorders)	JAK2 Mutation Analysis	Agrylin® (anagrelide), Hydrea® (hydroxyurea)
NSCLC (non-small cell lung cancer)	EGFR Amplification ; EGFR Mutation Analysis; KRAS Mutation Analysis	Erbix® (cetuximab), Tarceva® (erlotinib)

Genzyme Genetics employs more than 1,500 employees including an extensive team of medical and scientific experts in the areas of pathology, hematopathology and genetics who interpret results for physicians and patients. The business also employs the largest nationwide network of genetic counselors. Providing broad access to their innovative testing services, Genzyme Genetics has more than 475 national and regional contracts with managed care organizations throughout the U.S.

To learn more about the cancer testing capabilities of Genzyme Genetics, please visit www.genzymegenetics.com or call Sarah Millerick at (617) 768-6438.

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