

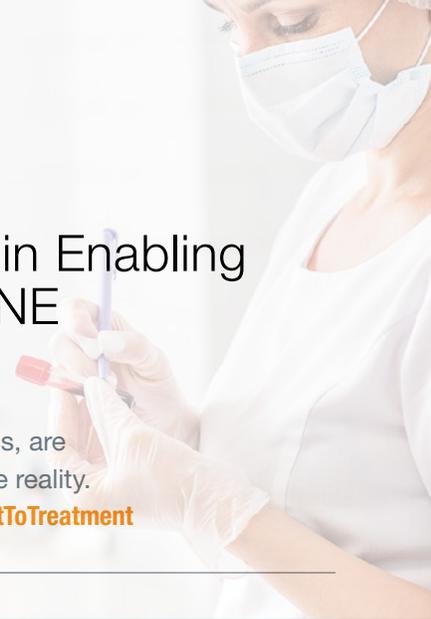


From Test to Treatment ▶ The Value of Diagnostics in Enabling PERSONALIZED MEDICINE

Personalized medicine is the ability to tailor medical treatment to reduce side effects and improve outcomes based on understanding the genetic makeup of an individual patient.

Advances in molecular diagnostics and other diagnostic technologies, including data analytics, are the drivers that allow individualizing treatments such as targeted immunotherapies to become reality.

Personalized medicine is changing the way we think about, identify, and manage health. **#TestToTreatment**



Advanced diagnostic tests are the foundation for personalized medicine

Innovative diagnostic tests precisely measure biological signs called biomarkers. Biomarkers indicate if processes in the human body are functioning normally or if an abnormal condition or disease exists, allowing doctors to better understand how this affects their patient. By combining the data from molecular and other diagnostic tests with an individual's medical history and current clinical symptoms, healthcare providers can develop targeted management and/or prevention plans. Tailoring treatments to the needs of an individual rather than applying standard treatments determined by broader populations has been shown to improve patient quality of life and outcomes. Such therapy reduces cost from overtreatment with ineffective therapies and avoidance of adverse events.

Advanced Diagnostics Allow Doctors to Deliver

- ✓ **The right treatment:** Molecular and other tests, including companion diagnostics, help improve outcomes by allowing doctors to make a precise diagnosis and tailored treatment decisions to avoid ineffective therapies.
- ✓ **To the right patient:** Genetic profiling tests allow doctors to assess a patient's potential responsiveness to available treatment options, including identifying appropriate clinical trials.
- ✓ **In the right dose:** Pharmacogenomic testing helps us understand how a patient's genetic variations can influence their responses to medications and help pinpoint optimal dosing.
- ✓ **At the right time:** Diagnostic tests enable doctors to make safer and more effective patient management and treatment decisions at a faster pace.





Example: Diagnostics have enabled breakthroughs in immunotherapy for certain cancer patients

Genetic profiling tests can detect whether there is a high amount of instability in a patient's tumor, commonly referred to as microsatellite instability-high or MSI-H. Patients with MSI-H solid tumors are more likely to benefit from drugs developed for cancer immunotherapy (medicines that work with a patient's immune system). This discovery led to a groundbreaking FDA approval for a "pan-tumor" immunotherapy based on a common biomarker across different types of tumors—marking a shift toward treating cancers based on their tumor genetics rather than their site of origin in the body¹.

Endnotes

- 1 FDA, 2017. *FDA approves first cancer treatment for any solid tumor with a specific genetic feature*. [Online] Available at: <https://www.fda.gov/news-events/press-announcements/fda-approves-first-cancer-treatment-any-solid-tumor-specific-genetic-feature>
- 2 Waks AG and Winer EP, "Breast Cancer Treatment: A review," *JAMA*. Jan 2019; 321(3): 288-300.
- 3 2009 Gastrointestinal Cancers Symposium (GICS). *GICS 2009: Huge Cost Savings From KRAS Testing in Metastatic Colorectal Cancer*, January 2009. Available at: <http://www.medscape.com/viewarticle/586946>
- 4 LaSala A, Bower BB, et al., "Integrating Genomic Based Information into Clinical Warfarin (Coumadin®) Management: An Illustrative Case Report," *Conn Med*. Aug 2008; 72(7): 399-403. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3696193/>
- 5 Digkila A and Michielin O, "The cutting edge of metastatic melanoma therapy," *Melanoma Manag*. Sep 2016; 3(3): 217-229. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6094682/>
- 6 Politi K and Herbst RS, "Lung Cancer in the Era of Precision Medicine," *Clin Cancer Res*. May 2015; 21(10): 2213-2220. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4505624/>
- 7 Kris MG, Johnson BE, Berry LD, et al. "Using Multiplexed Assays of Oncogenic Drivers in Lung Cancers to Select Targeted Drugs," *JAMA*. May 2014; 311(19):1998-2006. Available at: <https://jamanetwork.com/journals/jama/fullarticle/1872815>
- 8 Dean L, "Abacavir Therapy and HLA-B*57:01 Genotype," 2015 Sep 1 [Updated 2018 Apr 18]. Medical Genetics Summaries [Internet]. Bethesda (MD): National Center for Biotechnology Information (US); 2012-. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK315783/>



Personalized Medicine is Transforming Patient Care in Many Disease Areas



Breast Cancer

12% of women in the U.S. will be diagnosed with breast cancer over the course of their lifetime—with over **250,000 new cases** diagnosed in 2017. Diagnostic tests utilize varying technologies to identify which of the major subtypes of breast cancer a patient has and enables doctors to design **optimal treatment strategies** for each individual patient leading to **improved outcomes**².



Metastatic Colorectal Cancer

Routine testing of patients with metastatic colorectal cancer for the KRAS mutation before initiating treatment with epidermal growth-factor receptor (EGFR) inhibitors would save patients from having to undergo ineffective therapy—and result in **\$604 million** in annual health care cost **savings**³.



Stroke

If genetic testing were performed for every patient before starting treatment with Warfarin, a commonly prescribed anticoagulant, it is estimated that **17,000 strokes could be prevented** while avoiding 85,000 serious bleeding events annually—**saving over \$1 billion** in healthcare spending⁴.



Metastatic Melanoma

Metastatic Melanoma is an aggressive cancer with a 5-year survival rate of 15-20%. Advanced genetic testing led to the discovery that 40% of patients have a mutation in the BRAF gene and 20% have a mutation in their NRAS gene. **Targeted treatment** of these specific genetic alterations has shown **high response rates** and impressive survival benefits over conventional chemotherapies⁵.



Lung Cancer

Multiple studies have demonstrated that the majority (60–70%) of lung cancers possess genetic biomarkers that could be treated with targeted therapies. Patients matched to **targeted therapies** based on molecular diagnostic testing had **better survival** than those who were not matched^{6,7}.



HIV/AIDS

Abacavir is a medication used to treat HIV/AIDS. While well-tolerated in most patients, it can cause serious hypersensitivity reactions in others. A strong link was discovered between hypersensitivity to Abacavir and a rare form of the HLA-B gene. Using **genetic tests** to screen patients for this HLA-B gene allows doctors to use a personalized medicine approach, selecting the **safest treatment** for each patient⁸.



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About AdvaMedDx

AdvaMedDx, a division of the Advanced Medical Technology Association (AdvaMed), represents *in vitro* diagnostics (IVD) companies. Our member companies produce advanced IVD tests and technologies that allow early detection of disease, facilitate evidence-based medicine, improve patient health and healthcare, and enable personalized medicine. Further, leveraging innovative IVDs can lower overall healthcare costs. AdvaMedDx is the only advocacy organization exclusively addressing policy issues facing diagnostic manufacturers in the United States and abroad.

