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Advancing Cancer Treatment and Care ▶ The Value of CANCER DIAGNOSTICS

Cancer diagnostics are a critical and transformative component of cancer prevention and cancer care. Cancer diagnostics can advance patient care and reduce health care costs by screening cancer in its early stages, enabling earlier interventions, reducing unnecessary or ineffective treatments, and guiding personalized treatments. Because of improved diagnostic tests, patients are receiving more effective cancer care and living fuller, longer lives. **#TestToTreatment**
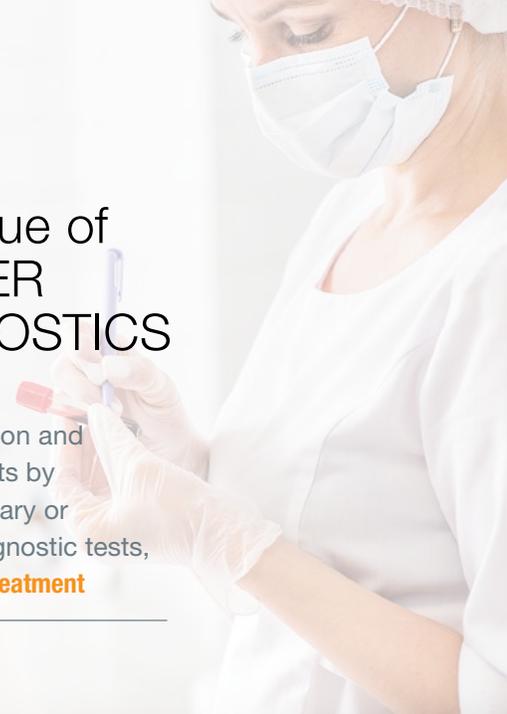
Advanced Diagnostic Tests are the Foundation of Personalized Medicine for Cancer Care

Advanced genetic sequencing technologies and the discovery of new biomarkers—that improve patient stratification and better predict outcomes, for example—have spurred further investment in research to understand the molecular mechanism of cancer. This knowledge is now yielding new diagnostic tests that are changing the cancer testing/treatment paradigm. New cancer companion diagnostics, for instance, have the potential to accelerate the development of new cancer treatments to fulfill unmet medical needs and further enable individualized and precise patient care.

Companion Diagnostics

Assessing a person's genomic makeup can serve as the basis of predicting their response to a potential treatment, tailoring therapy accordingly. For example, a cancer companion test can help a health care professional assess the aggressiveness and overall character of cancerous tumor, determining whether a therapeutic product—a drug, immunotherapy or combination therapy—would provide benefit to a patient, outweighing any potential serious side effects or risks. Specifically, in immunotherapy, diagnostics help clinicians understand the underlying biology of disease and whether the immune system has been activated by the tumor. Diagnostic markers guide whether preconditioning treatment may be required prior to immunotherapy to kick the immune system into action.

Diagnostic Test in Use:
From Risk Assessment to Therapy Selection and Beyond

Cancer diagnostics provide vital insights into patient health at every stage of cancer care, including:

➜ **RISK ASSESSMENT:** Diagnostic tests can be used to search for biomarkers that indicate an elevated risk of developing the corresponding cancer.

➜ **SCREENING:** Screening tests are used to look for a cancer when a person does not have symptoms and are normally applied to patients in the general population or patients at high risk of a certain cancer to identify the disease as early as possible.

➜ **DIAGNOSIS:** Tests for diagnosis are used to obtain a definitive diagnosis and determine the type of cancer.

➜ **STAGING & PROGNOSIS:** Staging or prognostic tests are used to assess the severity of the cancer and/or the risk of recurrence.

➜ **THERAPY SELECTION:** Many diagnostic tests can indicate which treatments and therapies may work most effectively or rule out those that are unlikely to work, for each patient.

➜ **MONITORING:** Monitoring tests can tell a patient and their doctor whether a treatment is working or provide information about the likelihood of recurrence.

Cancer Diagnostic Technologies

In order to help health care professionals accurately diagnose and monitor the specific biology of a patient's cancer and make personalized treatment decisions, there are several different types of diagnostic tests that may be used, including:

➜ **HISTOLOGY-BASED TESTS:** Histology-based tests involve a variety of staining or hybridization technologies aiding in the microscopic analysis of a sample of cells (tissues and fluids) from patients to determine whether the cells are abnormal and cancerous.

➜ **CLINICAL CHEMISTRY:** Clinical chemistry testing is used to detect abnormal amounts of molecular substances in the blood, urine or body tissues of some patients with certain types of cancer. Various types of molecules, such as nucleic acids (DNA/RNA), proteins or hormones, can serve as biomarkers.

➜ **NUCLEIC ACID–BASED TESTING:** Nucleic acid–based tests are used to evaluate the gene mutations in a sample of tumor tissue from a patient. The tests can identify genes that have developed abnormal functions and drive the growth of a tumor. Next-Generation Sequencing is a key enabling technology to allow genomic testing to move from single plex (single gene) to multiplex (multiple genes) simultaneously.

➜ **DIAGNOSTIC IMAGING:** Diagnostic imaging involves visualization of abnormal masses (tumors) using machines that create images. Examples of diagnostic imaging include x-rays, ultrasound, computed tomography (CT) scans, positron emission tomography (PET) scans and magnetic resonance imaging (MRI).

➜ **MOLECULAR DIAGNOSTICS:** Tests designed to specifically identify the presence of causative agents of cancer and are used to determine risk. Examples include HPV (cervical cancer), EBV (lymphomas), and HCV (liver cancer).

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Examples of Common Cancer Diagnostics

Breast Cancer Diagnostics

The **mammogram** is commonly used to screen for breast cancer. If the doctor finds an area of concern on a mammogram, **additional imaging tests** such as breast ultrasound or MRI scans may be used to further evaluate that abnormality. A breast **biopsy**, the only definitive way to make a diagnosis of breast cancer, will then be used to determine whether the sample cells are cancerous.

New **genetic tests** use DNA analysis to identify harmful mutations in breast cancer susceptibility genes (BRCA1 and BRCA2). The tests help people who are likely to have an inherited mutation based on family history to understand their cancer risk.

Cervical Cancer Diagnostics

Cervical cancer was once a leading cause of cancer death for women in the United States. But with the use of the **Papanicolaou screening test** and testing for and vaccination against the human papilloma virus (HPV), the cervical cancer death rate has decreased significantly. Nevertheless, it is estimated that about 13,170 new cases of invasive cervical cancer will be diagnosed in the United States in 2019.[1] Most cervical cancers are a result of a previous HPV infection and the **HPV test** is used to identify the high-risk HPV infections most likely to lead to cervical cancer. If cancer is detected, the doctor may use **body CT, body MRI, chest x-ray or PET scan** to help determine whether the cancer has spread. Detection of precancerous lesions can allow for treatment to prevent cancer. Early detection of cancer leads to improved patient outcomes.

Colorectal Cancer Screening

Colorectal cancer almost always develops from **precancerous polyps** (abnormal growths) in the colon or rectum. Colorectal screening tests can find precancerous polyps so that they can be removed before they turn into cancer. Screening tests can also find colorectal cancer early when treatment works best. These tests range from **prescription tests** that can be administered at home, to **colonoscopy** exams.

Melanoma Skin Cancer Tests

Diagnostic tests can help identify a melanoma and determine if it has spread to other areas of the body. For certain advanced melanomas, **advanced genetic diagnostic testing** which examines mutations in certain genes is critical in helping to determine personalized targeted therapy options.

Tests for Prostate Cancer

The **prostate-specific antigen** (PSA) test helps detect abnormal amounts of PSA, a substance that's produced by the prostate gland, and screens prostate cancers at the earliest stages. If a screening test indicates an abnormality, **imaging tests** such as ultrasound, MRI, or prostate biopsy will be used to determine definitively if there is prostate cancer and the level of aggressiveness of the cancer cells.

1 Key Statistics for Cervical Cancer, The American Cancer Society, accessed January 7, 2019
https://www.cancer.org/cancer/cervical-cancer/about/key-statistics.html

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.

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