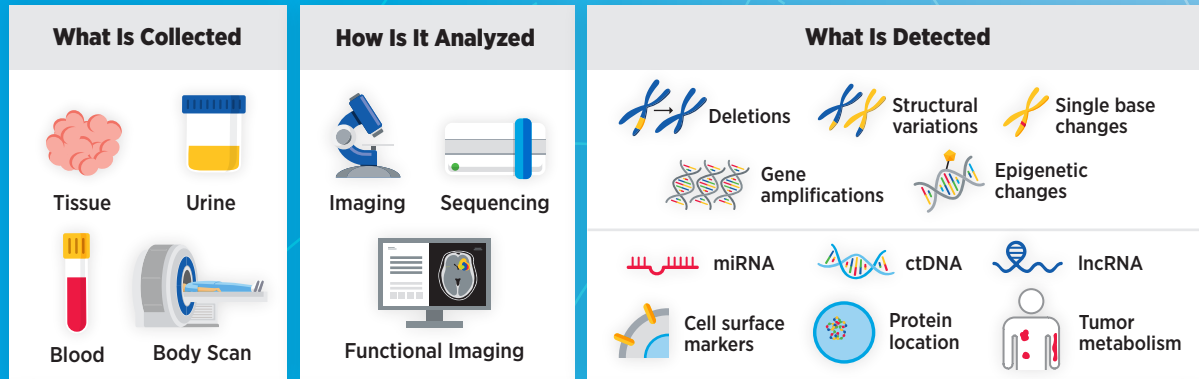









BIOMARKERS AND THEIR USE IN CANCER SCIENCE AND MEDICINE



Use of Biomarkers in Cancer Research and Care: Selected Examples

BIOMARKER TYPE	CANCER TYPE	WHAT IS TESTED/HOW	CLINICAL PURPOSE
 Risk Assessment	Breast cancer	A 70-gene panel (MammaPrint)/DNA sequencing	To evaluate risk of recurrence
 Diagnostic	Prostate cancer	PSMA (Ga 68 PSMA-11)/Radiography	To diagnose metastatic prostate cancer
 Monitoring	Leukemia	Immunoglobulin rearrangements (clonoSEQ)/DNA sequencing	To monitor minimal residual disease in leukemia
 Prognostic	Breast and Prostate cancers	A 17-gene signature (OncotypeDX)/DNA sequencing	To assess the aggressiveness of cancer and to help manage treatment
 Predictive	Multiple cancer types	MSI-H/dMMR/DNA sequencing	To guide treatment and identify those at high risk of cancer recurrence after initial treatment
 Response	Multiple cancer types	Nucleic acid sequences from patient's tumor (e.g., cfDNA) or proteins produced by tumors (e.g., CEA)	To assess treatment response and guide next course of action
 Safety	AML	IDH1/2 mutations/DNA sequencing	To determine what therapy will be safe for patients

According to the FDA, a biomarker is a defined characteristic that is measured as an indicator of normal and/or abnormal biological processes, or to determine responses to a therapeutic intervention. Molecular, histological, and physiological characteristics are all considered different types of biomarkers. Changes in structure, function, and/or location of all major types of molecules—DNA, RNA, and proteins—can be monitored using biomarkers.

Biomarkers are measurable in biological materials such as tissues, cells, and/or bodily fluids using a variety of techniques depending on the nature of the biomarker. The FDA uses the **Biomarkers, EndpointS** and other **Tools** (BEST) glossary to characterize biomarkers into seven categories that include risk assessment, diagnosis, monitoring, prognosis, prediction, responsiveness, and safety.