Cancer biomarker types and clinical applications

By Rajasri Chandra, MS, MBA

The National Cancer Institute defines a biomarker as a biological molecule found in blood, other body fluids, or tissues that indicates if a process, or a condition or a disease such as cancer is normal or abnormal. A biomarker is also called a molecular marker or signature molecule.[1] Cancer biomarkers are classified in different ways based on their use (See **Figure 1**).

Cancer biomarkers are used to:[3,4]

- Assess patients in multiple clinical settings to identify, estimate risk of disease, screen for occult primary cancers, distinguish benign from malignant type, characterize one type of malignancy from another type (for example, BRCA1 germline mutation for breast and ovarian cancer[5] and prostate-specific antigen (PSA) for prostate cancer[6])
- Determine prognosis and predict chance of survival or recurrence for patients who have been diagnosed with cancer (for example, 21 gene in Oncotype Dx for breast cancer[8])
- Monitor status of the disease
- Inform individualized treatment plans (for example, immunohistochemistry for various cancers[7] and KRAS mutations in Exon 2, 3 and 4 for colorectal cancer[9])
- Detect recurrence or determine response or progression to therapy (for example, 22 gene in Decipher Prostate[10] and cancer antigen 15-3 (CA 15-3) and carcinoembryonic antigen (CEA) for breast cancer[11])
- Anticipate and manage negative medication reactions

Cancer biomarkers based on the type of biomolecules

Cancer biomarkers can be broadly categorized into their biological nature

Cancer biomarker types and clinical applications

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LEARNING OBJECTIVES

Upon completion of this article, the reader will be able to:

1. Define how cancer biomarkers are used and list their types or biomolecules.
2. Discuss how genetic and epigenetic biomarkers are used and the latest emerging tests in this category.
3. Discuss the advantages and disadvantages of protein biomarkers and the mechanisms of action related to testing for them.
4. Discuss the mechanisms and types of metabolic biomarker testing to aid in cancer care.

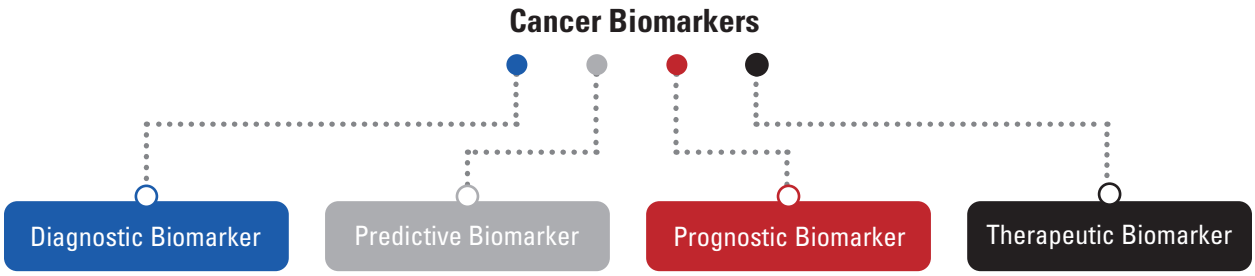

Figure 1. Based on their use, cancer biomarkers can be broadly classified as shown.[2]

— genetic, epigenetic, transcriptomic, proteomic, and metabolic.[3]

Genetic biomarkers

Genetic biomarkers for cancer are specific genes, gene mutations, or gene expression patterns that can indicate the presence and stage of cancer or the potential for cancer development. Gene mutations and gene alterations can provide valuable information about the underlying genetic changes driving the development and progression of cancer. **Table 1** provides a few examples of gene mutation– and gene alteration–based cancer biomarkers. Gene expression profiles provide insights into tumor behavior, prognosis, and treatment response. **Table 2** provides a few examples of gene expression profile–based cancer biomarkers.

DNA as a cancer biomarker

Cancer cells release nucleic acids, freely or associated with other structures such as vesicles into body fluids, including blood. Among these nucleic acids, circulating tumor DNA (ctDNA) has emerged as a minimally invasive biomarker for cancer.[19] Circulating tumor DNA (ctDNA) has now emerged as a very promising noninvasive biomarker for cancer diagnosis, prognosis, and therapeutic monitoring, providing significant potential for real-time insights into tumor dynamics.[20] The circulating tumor DNA (ctDNA) is a key component of liquid biopsy tests. **Table 3** provides examples of a few FDA-approved liquid biopsy ctDNA tests.

RNA as a cancer biomarker

RNA molecules, including messenger RNA (mRNA), microRNA (miRNA), long non-coding RNA (lncRNA), and circular RNA (circRNA), are emerging as promising cancer biomarkers due to their dynamic nature and potential for non-invasive detection in bodily fluids. Their levels can indicate the presence, stage, and progression of various cancers, providing valuable information for early diagnosis, prognosis, and treatment monitoring. Like circulating tumor DNA, RNAs are also detected in liquid biopsy tests. That said, RNA-based liquid biopsy tests are not yet that prevalent as DNA-based liquid biopsy tests. Researchers at the University of Chicago for the first time used RNA modifications to develop a liquid biopsy test for colorectal cancer that was more sensitive than DNA-based liquid biopsy test.[24]

Epigenetics as a cancer biomarker

Epigenetic changes including DNA methylation, histone modifications, nucleosome positioning, and non-coding RNAs, particularly microRNAs are essential for normal gene expression and proper cellular functioning. Any disruption of this mechanism results in a change in gene function and eventually development of cancer. Hence detection of aberrant epigenetic patterns can serve as biomarkers for early detection, prognosis, and potential targets for therapeutic intervention.[25] **Table 4** provides examples of a few epigenetics biomarkers for cancer.

Protein as cancer biomarker

Protein biomarkers are specific proteins present in biological fluids (such as blood, urine, or saliva) or tissues that provide valuable information about the presence and progression of cancer.[32] A

Genetic biomarker	Cancer type	Use
BRAF V600E mutation	Melanoma[12]	To guide targeted therapy selection
EGFR mutation (Exon 19 deletion, L858R point mutation in Exon 21)	Non-small-cell lung cancer[13]	Increases sensitivity to EGFR inhibitors
KRAS mutations in Exon 2, 3 and 4	Colorectal cancer[9]	To guide targeted therapy selection
BRCA1/BRCA2	Breast/ovarian cancer[14]	To inform risk of cancer and guide therapy selection
HER2/neu amplification/ overexpression	Bladder, breast, ovarian, pancreatic, stomach[15]	To inform treatment decisions
IDH1/IDH2	Glioma[16]	To diagnose and inform treatment decisions

Table 1. Gene mutation– and gene alteration–based cancer biomarkers.

Assay name	Cancer type	Number of genes	Use
Oncotype Dx[8]	Breast cancer	21 genes	To predict the likelihood of breast cancer recurrence and guide treatment decisions for early-stage, hormone-receptor-positive breast cancer.
MammaPrint[17]	Breast cancer	70 genes	Prognostic and predictive diagnostic test that assesses the risk of recurrence.
Decipher Prostate[10]	Prostate cancer	22 genes	To predict the likelihood of disease recurrence after prostate surgery and guide decisions regarding adjuvant therapy.
ColoPrint[18]	Colon cancer	18 genes	Aids in determining prognosis and guides on treatment decisions.

Table 2. Gene expression profile–based cancer biomarkers.

Test name	Cancer type	Genes involved	Use
Cobas EGFR Mutation Test v2[21]	Non-small-cell lung cancer (NSCLC)	EGFR Exon 19 deletions, L858R, T790M	Companion diagnostic for NSCLC
Guardant360 CDx[22]	Non-small-cell lung cancer (NSCLC)	74 genes and EGFR Exon 19 deletions, L858R, T790M	Tumor profiling and companion diagnostics for NSCLC
FoundationOne Liquid CDx[23]	Non-small-cell lung cancer (NSCLC), prostate cancer, breast cancer, solid tumors, colorectal cancer	311 genes	Companion diagnostics for targeted therapy

Table 3. FDA-approved liquid biopsy ctDNA tests.

majority of the tumor markers are either protein or peptides. Tumor biomarkers have revolutionized cancer diagnostics as they are non-invasive and can be used for the following:[33]

- Screening and early detection of cancer
- Aid in the diagnosis of cancer
- Determine response to therapy
- Prognostic indicator of disease progression
- Indicate relapse during follow-up period

That said, tumor markers also have disadvantages as below:

- They have very low concentrations or may not be present for early-stage cancer.
- Not standardized as proteins and/or modified proteins; may vary among individuals, between cell types, and even within the same cell under different stimuli or different disease states.
- Tumor markers may be present even in noncancerous conditions, hence not very specific for cancer.

The different types of protein biomarkers are as follows:

- Oncofetal antigens
- Tumor-associated antigens
- Hormones and hormone receptors
- Enzymes and isoenzymes
- Serum and tissue proteins
- Cancer stem cells

Mechanisms behind cancer-related protein biomarkers

Cancer cells undergo several molecular and genetic changes that result in the overproduction, alteration, or loss of normal proteins. These changes result in new proteins or modified versions of existing proteins that are released into the bloodstream or other bodily fluids, which act as diagnostic or prognostic biomarkers. Some key mechanisms include the following:

- Overexpression of growth factors: Cancer cells often overproduce growth factors, leading to uncontrolled cell proliferation.
- Loss of tumor suppressor proteins: Tumor suppressor proteins, such as p53, are often mutated or down regulated in cancer cells, contributing to uncontrolled cell growth.
- Altered post-translational modifications: Changes in protein modifications such as phosphorylation, glycosylation, or cleavage can produce altered protein isoforms detectable in blood samples. **Table 5** provides

Epigenetic cancer marker	Cancer type	Use
GSTP1 –methylation[26]	Prostate cancer	Diagnostic and prognostic biomarker. GSTP1 methylation is frequently observed in prostate cancer tissue but is rare in normal prostate tissue.
BMP3 and NDRG4 methylation[27]	Colorectal cancer (CRC)	Hypermethylation is an indicator for early detection and diagnosis for CRC.
SHOX2 and PTGER4 methylation[28]	Lung cancer	Increased methylation of SHOX2/PTGER4 promoter is an indicator for lung cancer development.
TWIST1, OTX1 and ONECUT2[29]	Bladder cancer	Hypermethylation of TWIST1, OTX1 and ONECUT2 genes indicate presence and progress of bladder cancer.
BRACA1 methylation[30]	Breast and ovarian cancer	BRACA1 methylation is a therapeutic biomarker. When methylated the cancer cells become vulnerable to chemotherapy particularly platinum-based drugs and PARP inhibitors.
MGMIT methylation[31]	Glioblastoma	MGMT promoter methylation is a therapeutic marker, particularly in glioblastoma, as it indicates a tumor's sensitivity to alkylating chemotherapy agents like temozolomide.

Table 4. Epigenetics biomarkers for cancer.

Protein biomarker	Cancer type	Clinical application
Prostate-specific antigen (PSA)	Prostate cancer	Early screening, monitoring treatment response
Carcinoembryonic antigen (CEA)	Colorectal cancer, others	Diagnosis, monitoring recurrence
HER2/neu	Breast cancer	Prognostic marker, guides HER2-targeted therapy
Alpha-fetoprotein (AFP)	Liver cancer, germ cell tumors	Diagnosis of hepatocellular carcinoma (HCC)
CA-125	Ovarian cancer	Early detection, monitoring response
EGFR	Non-small-cell lung cancer	Prognostic marker, guides EGFR-targeted therapy
BCR-ABL fusion protein	Chronic myelogenous leukemia (CML)	Diagnosis, treatment monitoring
Cyclin D1	Breast, prostate, lymphoma	Prognosis, identifies tumor progression

Table 5. Protein biomarkers for cancer.

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examples of a few protein biomarkers for cancer.[32]

Metabolic biomarkers

Cancer has an effect on metabolic pathways and causes alterations in metabolites resulting in inappropriate proliferation of cancer cells and adaptation to the tumor microenvironment. The aberrant metabolites play pivotal roles in tumor formation and metastasis and thus serve as potential biomarkers for personalized cancer therapy.[34] **Table 6** provides a few examples of metabolic biomarkers for cancer.[3]

Due to the risk of false positive or negative results, it is advisable to combine a test for a cancer biomarker with another method such as tissue biopsy or endoscopy to improve the effectiveness of screening for cancer.[36,37] A study showed that the combined detection of alpha-fetoprotein (AFP) with cell-free DNA (cfDNA) can improve the specificity of hepatocellular carcinoma (HCC) diagnosis to 94.4%, which was superior to that of AFP alone in terms of higher sensitivity and better clinical correlation.[38]

Methods of detection of cancer biomarkers

The traditional method for detection of cancer has been the detection of tissue biopsy and cytology to examine tissue and imaging techniques like positron emission tomography scan (PET Scan), computed tomography scan (CT Scan) and magnetic resonance imaging (MRI) to assess tumors. However, the various cancer biomarkers can be detected using a variety of methods, including immunoassays (like ELISA) for proteins; molecular techniques such as polymerase chain reaction (PCR), real-time quantitative PCR (qRT-PCR), digital PCR (dPCR), microarrays, and next-generation sequencing (NGS) for genetic alterations; mass spectrometry to identify proteins and metabolites; and advanced biosensors and nanomaterial-based methods for rapid, highly sensitive detection. The non-invasive liquid biopsy technique that detects circulating tumor cells (CTC), cell-free DNA (cfDNA) extracellular vesicles (EV), or circulating tumor DNA (ctDNA) in body fluids has also become very promising in detecting cancer biomarkers.

Conclusion

Despite the emergence of various newer techniques and technological advancements, on average, 1,700 deaths

Metabolite	Sample type	Cancer type
Glucose metabolism		
Glucose	Serum/plasma ↑	Kidney cancer
	Serum/plasma ↓	Diffuse large lymphoma
	Urine ↓	Prostate cancer
Pyruvate	Serum/plasma ↑	Esophageal cancer, non-small cell lung cancer
	Urine ↑	Prostate cancer
Lactic acid	Serum/plasma ↑	Osteosarcoma
	Serum/plasma ↓	Kidney cancer
	Urine ↑	Prostate cancer, renal cell carcinoma
Myoinositol	Serum/plasma ↑	Prostate cancer
	Serum/plasma ↓	Kidney cancer, lung cancer
	Urine ↑	Renal cell carcinoma, pancreatic cancer
Amino acid metabolism		
Glutamic acid	Serum/plasma ↑	Hepatocellular carcinoma, osteosarcoma, pancreatic cancer, small cell lung cancer, kidney cancer, esophageal squamous cell carcinoma
	Serum/plasma ↓	Pancreatic cancer, prostate cancer, colorectal cancer, epithelial ovarian cancer
	Urine ↑	
Glutamine	Serum/plasma ↑	Esophageal squamous cell carcinoma, prostate cancer, epithelial ovarian cancer
	Serum/plasma ↓	Lung cancer, pancreatic cancer, pan-cancer
Leucine	Serum/plasma ↓	Kidney cancer, small cell lung cancer
	Urine ↑	Prostate cancer
	Saliva ↓	Oral squamous cell carcinoma
Valine	Urine ↑	Prostate cancer
	Saliva ↓	Lung cancer, thyroid cancer
Glycine	Serum/plasma ↓	Kidney cancer, endometrial cancer, esophageal cancer
	Urine ↓	Esophageal cancer
Nucleotide metabolism		
Hypoxanthine	Serum/plasma ↑	Esophageal squamous cell carcinoma, breast cancer
	Serum/plasma ↓	Esophageal squamous cell carcinoma
Inosine	Plasma ↓	Pancreatic cancer, esophageal squamous cell carcinoma
	Saliva ↑	Oral squamous cell carcinoma
Uracil	Serum ↑	Lung adenocarcinoma
	Serum ↓	Breast cancer
	Saliva ↑	Oral squamous cell carcinoma, lung cancer
Lipid metabolism		
Palmitic acid	Serum/plasma ↑	Non-small cell lung cancer, pancreatic cancer
	Serum/plasma ↓	Lung cancer, gastric cancer
Linoleic acid	Serum/plasma ↓	Esophageal squamous cell carcinoma, colorectal cancer, gastric cancer
Glycocholic acid	Serum/plasma ↑	Colon cancer, hepatocellular carcinoma, pancreatic cancer
Estradiol	Serum ↑	Serum ↑
	Serum ↑	Breast cancer
Others		
Hippuric acid	Urine ↓	Prostate cancer, renal cell carcinoma, bladder cancer

Table 6. Metabolic biomarkers for cancer.

occur daily from cancer in the United States.[39] Hence, the fight against cancer is still not over. Artificial intelligence (AI) has revolutionized various fields including healthcare, and it can help to reshape how we understand, diagnose, and treat patients. By using emerging multi-omics technology in combination with AI, we hope to provide personalized treatment to cancer patients and save lives in ways that were never possible before.

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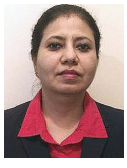

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