



GENETICS · BIOMARKERS · EVIDENCE

CRACKING THE **CANCER** CASE

UNDERSTANDING GENETICS AND BIOMARKERS AS EVIDENCE

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FLORIDA CANCER DATA SYSTEM

September 9, 2026

CASE OBJECTIVES

WHAT THIS INVESTIGATION WILL UNCOVER

1

WHAT IS A BIOMARKER?

Define biomarkers and the role they play as biological evidence.

2

WHY BIOMARKERS MATTER

See how they drive precise, targeted treatment decisions.

3

THE SUSPECTS LOG

Investigate 13 Biomarker types, from genetic and protein to lipids and exosomes.

4

READING THE EVIDENCE

Trace HER2, p16, PSA, Oncotype DX and other biomarkers through reports and coding rules.

WHAT IS A BIOMARKER?

- Biomarkers are biological molecules found in tissues, blood and other body fluids that signifies a normal and abnormal process, or a disease or condition.
- It helps identify how the body reacts to treatment for a condition or disease.
- It is also called signature molecule or molecular marker.



WHY BIOMARKERS MATTER?

- Without biomarkers treatment decisions are less precise.
- With Biomarkers – we identify the tumor's unique characteristics , we choose targeted interventions, we improve outcomes



CASE FILE: TYPES OF BIOMARKERS

SUSPECTS LOG

CLUE #01
GENETICS

CLUE #02
PROTEIN

CLUE #03
METABOLIC

CLUE #04
LIPIDS

CLUE #05
LAMINS

CLUE #06
GALECTINS

CLUE #07
CARBOHYDRATE
ANTIGENS

CLUE #08
CELLS

CLUE #09
VIRUSES

CLUE #10
EXOSOMES

CLUE #11
SCREENING &
DIAGNOSTIC

CLUE #12
PROGNOSTIC

CLUE #13
PREDICTIVE

Mutations and Gene Alterations

- BRCA1/ BRCA2 mutations -breast/ ovarian cancer
- Kras mutations - colorectal ca
- EGFR -NSCLC
- Her2 amplification/ overexpression - breast and gastric

CLUE #01

GENETICS

TYPE OF BIOMARKER

Epigenetics

- RASSF1A, p16, BRCA1, NKX2-6, SPAG6, PER1, ITIH5, etc.
- Histone acetylation levels

Gene Expression Profiles

- Oncotype dx -Breast Ca
- MammaPrint -Breast Ca
- Decipher -Prostate ca

DNA

- p53, KRAS, APC, RAS, BRCA1/2, etc.
- Mismatch-repair gene mutations
 - Tumor DNA in circulation

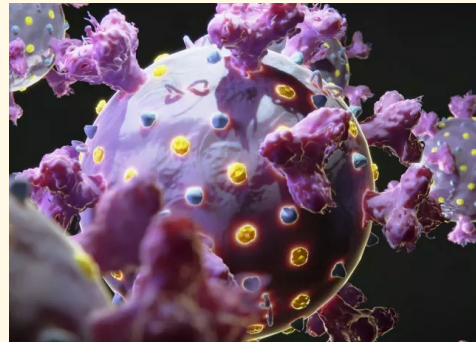
RNA

- Hsa circ 0013958 in lung adenocarcinoma
- Various microRNAs in different cancers

KRAS

KRAS is an oncogene (a gene that, when mutated or overexpressed, helps turn a normal cell into a cancer cell) .

Where do we find this in the records?
Pathology reports or clinical lab report



Coding Instructions

- Using a physician statement
- Kras analysis is commonly done in patients with metastatic disease .
- Kras often present in colorectal cancer
- If KRAS is positive and there is no mention of mutated codon , or mutated codon is not specified , code 4.

A codon is a three-letter word in the DNA instruction manual, and each word tells the cell which building block to add next when making a protein. A mutation is a typo in one of those words — the codon number just tells us which word had the typo.

Code	Description
0	Normal (wild type) Negative for mutations
1	Abnormal (mutated) in codon(s) 12, 13 and/or 61
2	Abnormal (mutated) in codon 146 only
3	Abnormal (mutated), but not in codon(s) 12, 13, 61, or 146
4	Abnormal (mutated), NOS, codon(s) not specified
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code 8 may result in an edit error.)
9	Not documented in medical record KRAS not assessed or unknown if assessed

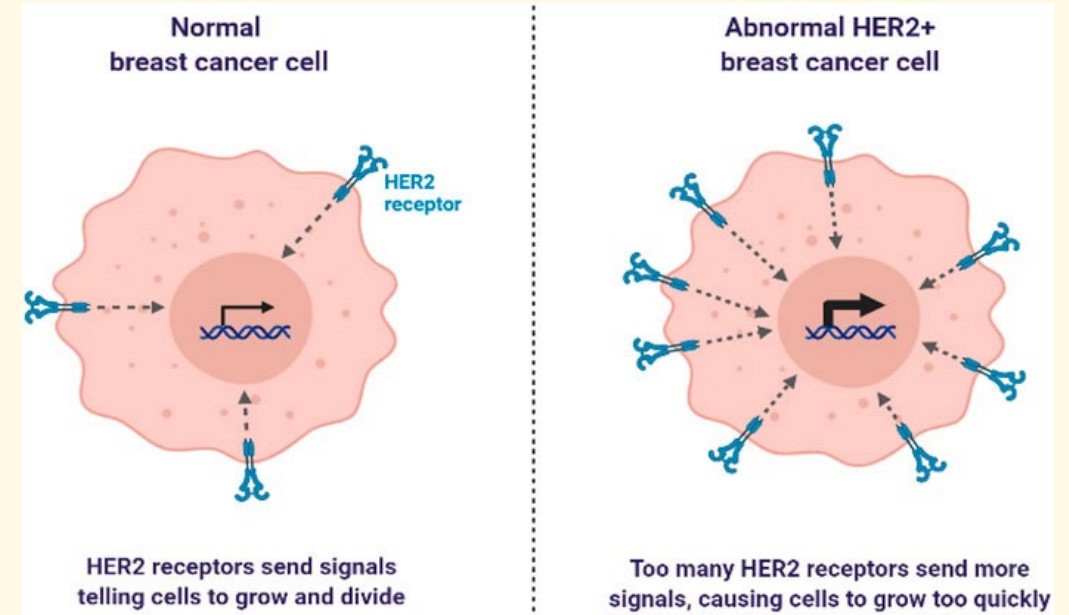
HER2

A subset of breast carcinomas (approximately 15% to 20%) overexpress human epidermal growth factor receptor 2 (HER2). The presence of HER2 overexpression in untreated patients is associated with worse prognosis in both node-negative and node-positive patients. Protein overexpression is usually due to HER2 gene amplification. The HER2 protein may also be referred to as ERBB2 and the HER2 gene may also be referred to as the ERBB2 gene.

Where do we find this in the records?

Pathology reports

/immunohistochemistry/FISH reports



HER2

Code	Description
0	HER2 is reported as negative or normal
1	HER2 is reported as positive or elevated
7	Test ordered, results not in chart
9	Not documented in medical record Cannot be determined (indeterminate) Borderline HER2 Overall Summary status not assessed or unknown if assessed

Coding Instructions

- Using a physician statement
- : In-situ and Invasive components present

If HER2 is positive on an in-situ component and HER2 is negative on all tested invasive components in the primary tumor, code HER2 as negative (code 0)

If in situ and invasive components present and HER2 only done on the in-situ component in the primary tumor, code unknown (code 9)

HER2 Positive and Oncotype

In some cases, the Oncotype DX report may include a quantitative HER2 result. However, this value from the OncotypeDx report should not be recorded in the registry.

The HER2 result recorded should be from the physician report based on the IHC and/or ISH as described for this element.

HER2 and in situ tumors

HER2 is not routinely done on pure in situ tumors (behavior /2); however, if you have an in-situ tumor and there are HER2 results, go ahead and record it. Otherwise, code 9

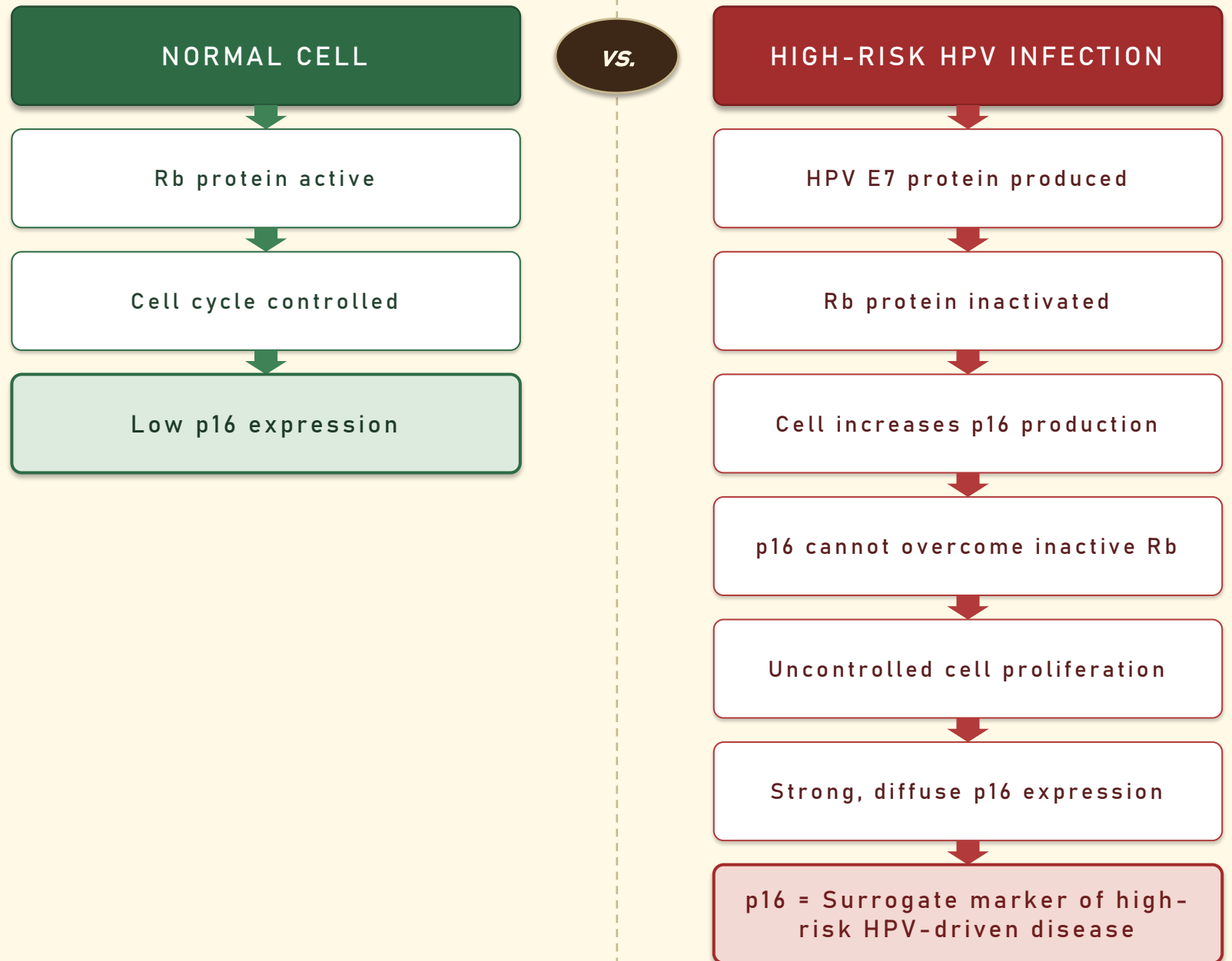
P16

This is a biomarker that is over-expressed in response to Human papilloma virus (HPV).

It is a surrogate marker for HPV disease

Where can it be found within the records?

Labs-Immunohistochemistry reports



P16

CODES

0	p16 Negative; Nonreactive
1	p16 Positive; Diffuse, Strong reactivity
8	Not applicable: Information not collected for this case (If this time is required by your standard setter, use of code 8 will result in an edit error).
9	Not tested for p16; Unknown
Blank	Diagnosis year prior to 2024

Code Notes:

See the SSDI Manual for coding instructions.

Anus schema added/ Please note for CCCR p16 for Cervix changed from
"." to RS* retroactive to 2021

P16

Positive - HPV-assoc.

Variable / uncertain

Negative - not HPV

WHERE p16 IS A RELIABLE HPV MARKER

Carcinoma Type	Typical p16 Status	Clinical Significance	Notes
Oropharyngeal SCC (OPSCC)	Positive (diffuse, strong staining)	Strong surrogate for transcriptionally active HPV; better prognosis and treatment response	p16 IHC is routinely used for staging (AJCC 8th ed.)
Cervical SCC	Usually strongly positive	Reflects high-risk HPV infection	Used diagnostically in pathology
Cervical Adenocarcinoma (HPV-assoc.)	Positive	Indicates HPV-associated subtype	Distinguishes HPV-associated from non-HPV adenocarcinomas
Anal SCC	Usually positive	Strong association with high-risk HPV	Often correlates with better chemoradiation response
Penile SCC (HPV-assoc. subtype)	Positive	Supports HPV-associated pathway	HPV-independent tumors are often p16 negative
Vulvar SCC (HPV-assoc.)	Positive	Distinguishes HPV-associated from differentiated pathway	HPV-independent tumors are frequently p16 negative
Vaginal SCC	Frequently positive	Often HPV-related	Less common tumor overall

P16

Positive - HPV-assoc.

Variable / uncertain

Negative - not HPV

WHERE p16 IS NOT RELIABLE FOR HPV

Carcinoma Type	Typical p16 Status	Clinical Significance	Notes
Oral Cavity SCC	Usually negative; occasional positivity	p16 is not a reliable HPV marker	HPV-driven tumors are uncommon
Laryngeal SCC	Variable	Limited prognostic value	Does not reliably indicate HPV infection
Hypopharyngeal SCC	Variable	Limited role	HPV association is uncommon
Sinonasal SCC	Variable	Some HPV-related tumors are p16 positive	Confirmation with HPV-specific testing may be needed
Lung SCC	Variable; may be positive	p16 positivity is not evidence of HPV	Expression may occur via non-HPV mechanisms

Oncotype Diagnosis

It is a genomic test that predicts the risk of distant recurrence and likelihood of benefitting from chemotherapy for early-stage breast cancer.

Where do I find this within the records?
Oncotype dx breast recurrence Lab report or stated within the records

Oncotype DX Breast Recurrence Score® Report

EXACT SCIENCES

Node Negative

PATIENT, SAMPLE

Date of Birth: 01-Jan-1950

Gender: Female

Report Number: OR000123456-3260

Report Date: 11-Aug-2023

Specimen Source/ID: Breast/SP-16_0123456

Ordering Physician: Dr. First-Name I. Ordering-Physician-Last-Name

1

Recurrence Score® (RS) Result

32

Decision on individual treatment especially around the RS 25 cutoff may consider other clinical factors.

2

Distant Recurrence Risk at 9 Years

With TAM Alone

20%

95% CI (15%, 27%)

NSABP B-14

TAM = Tamoxifen
CI = Confidence Intervals

3

Group Average Absolute Chemotherapy (CT) Benefit*

RS 26-100 All Ages

>15%

95% CI (9%, 37%)

NSABP B-20

*For estimated CT benefit for individual RS results, see page 2.

Exploratory Subgroup Analysis for TAILORx and NSABP B-20:
Absolute CT Benefit for Distant Recurrence by Age and RS Result

Age	RS 0-10	RS 11-15	RS 16-20	RS 21-25	RS 26-100
>50 years	No CT Benefit (<1%)				>15% CT Benefit
≤50 years	No CT Benefit (<1%)	~1.6% CT Benefit	~6.5% CT Benefit	~6.5% CT Benefit	>15% CT Benefit

Quantitative Single-Gene Scores¹

10.2 ER Positive

6.4 PR Positive

8.4 HER2 Negative

1. ER Score based on quantitative ESR1 expression (estrogen receptor); PR Score based on quantitative PGR expression (progesterone receptor); HER2 Score based on quantitative ERBB2 expression.

GH004 Rev043

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Oncotype Diagnosis Breast Recurrence score

DCIS

Code	Description
000-100	Enter actual recurrence score between 0 and 100
XX6	Not applicable, invasive case
XX7	Test ordered, results not in chart
XX8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code XX8 will result in an edit error.)
XX9	Not documented in medical record Oncotype Dx recurrence score-DCIS not assessed or unknown if assessed

Oncotype Dx Recurrence Score-DCIS is a Registry Data Collection Variable in AJCC. It is a new data item for cases diagnosed 1/1/2018+.

INVASIVE

Code	Description
000-100	Enter actual recurrence score between 0 and 100
XX4	Stated as less than 11
XX5	Stated as equal to or greater than 11
XX6	Not applicable, in situ case
XX7	Test ordered, results not in chart
XX9	Not documented in medical record Oncotype Dx Recurrence Score-Invasive not assessed or unknown if assessed

Oncotype Dx Recurrence Score-Invasive is a Registry Data Collection Variable in AJCC. It is a new data item for cases diagnosed 1/1/2018+.

Oncotype Dx Risk Level

DCIS

0	Low risk (recurrence score 0-38)
1	Intermediate risk (recurrence score 39-54)
2	High risk (recurrence score greater than or equal to 55)
6	Not applicable: invasive case
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in medical record Oncotype Dx Risk Level-DCIS not assessed or unknown if assessed

INVASIVE

0	Low risk (recurrence score 0-17)
1	Intermediate risk (recurrence score 18-30)
2	High risk (recurrence score greater than or equal to 31)
6	Not applicable: DCIS case
7	Test done, results not in chart
8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in medical record Oncotype Dx Risk Level-Invasive not assessed or unknown if assessed

Oncotype Dx Recurrence Score-DCIS is a Registry Data Collection Variable in AJCC. It is a new data item for cases diagnosed 1/1/2018+.

Oncotype Dx Recurrence Score-Invasive is a Registry Data Collection Variable in AJCC. It is a new data item for cases diagnosed 1/1/2018+.

CLUE #02

PROTEIN

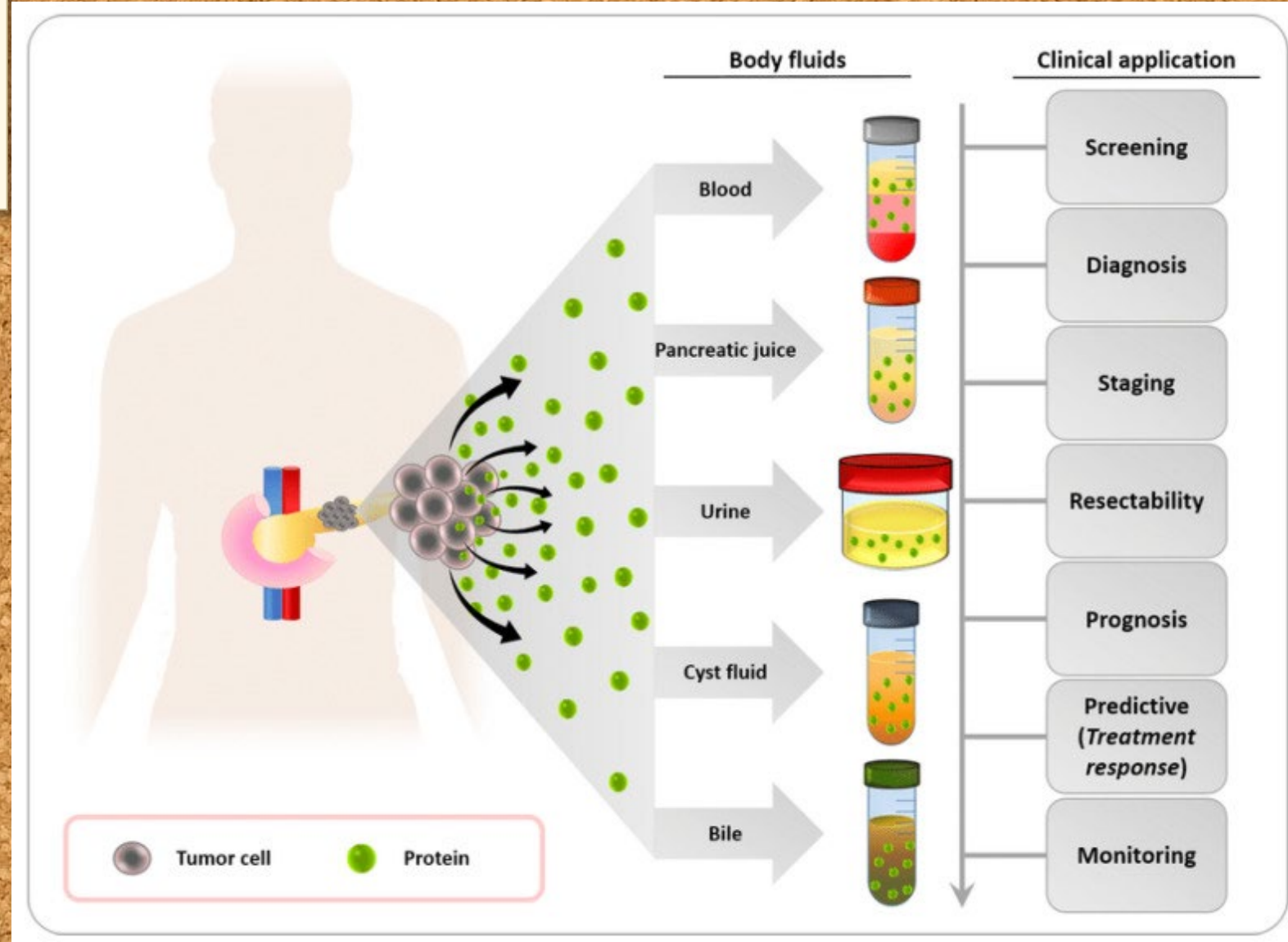
TYPE OF BIOMARKER

Protein Tumor Marker	Concentration in Healthy Individuals	Concentration in Cancer Patients
PROSTATE SPECIFIC Antigen (PSA)	< 4ng/ml	Elevated in Prostate cancer
Carcinoembryonic antigen (CEA)	< 3ng/ml	Elevated in many cancers including lung, colorectal and pancreatic cancer
Alpha fetoprotein	< 10ng/ml	Increased in hepatocellular carcinoma (hcc)
CA-125	<35 nu/ml	Elevated levels in ovarian and other gyn cancer
CA 19-9	< 37nu/ml	Elevated in pancreatic and other GI cancers
Human Chorionic Gonadotropin (hCG)	< 5 IU/L	Elevated ovarian and testicular ca
Human epidermal growth factor receptor (HER2)	Neg (score 0 or 1+)	Amplification or overexpression in HER2 – positive breast and gastric ca

CLUE #02

PROTEIN

TYPE OF BIOMARKER



PSA

PSA (Prostatic Specific Antigen) is a protein made by the prostate gland and is elevated in prostate cancer. This data item captures the PSA lab value — the most sensitive tumor marker for tracking disease progression and treatment response.

Where can I find this within the records?
Found in the Lab reports or within the notes

Code	Description
0.1	0.1 or less nanograms/milliliter (ng/ml) (Exact value to nearest tenth of ng/ml)
0.2-999.9	0.2 - 999.9 ng/ml (Exact value to nearest tenth of ng/ml)
XXX.1	1,000 ng/ml or greater
XXX.2	Lab value not available, physician states PSA is negative/normal
XXX.3	Lab value not available, physician states PSA is positive/elevated/high
XXX.7	Test ordered, results not in chart
XXX.9	Not documented in medical record PSA lab value not assessed or unknown if assessed

CASE NOTES · PSA CODING

- A physician statement of a pre-diagnosis PSA may be coded when no other information is available.
- A prognostic factor required for AJCC staging; it affects the stage group in most cases.
- If a Biopsy done record last PSA prior to and within 3 months of diagnostic biopsy. No / unknown biopsy: last PSA within 3 months of diagnosis or confirmatory testing (SSDI v3.3, cases 2018+).
- Adjusted PSA: A discrepancy between the PSA documented in the lab report and the PSA documented by the clinician may arise due to the clinician's adjusting the PSA value. Certain medications for benign prostatic hypertrophy (BPH) decrease the PSA. Further info check within NAACCR ssdi

CLUE #03

METABOLIC

TYPE OF BIOMARKER

NOTE

Metabolic alterations support cancer growth and provide biomarkers for diagnosis, prognosis, and treatment monitoring.

KEY BIOMARKERS

- Glycolysis: Lactate, GLUT1 (↑ glucose uptake)
- TCA cycle: Fumarate, Succinate, α-Ketoglutarate
- Lipid metabolism: Choline, FASN
- Amino acid metabolism: Glutamine, Serine, Glycine
- Nucleotide metabolism: Deoxythymidine (dTd)

METABOLIC IMAGING

- FDG-PET: Detects increased glucose metabolism
- MRS: Measures metabolites (choline, lactate)
- HP-MRI: Visualizes real-time metabolic pathways
- SPECT & DCE-MRI: Assess metabolism, blood flow, and angiogenesis

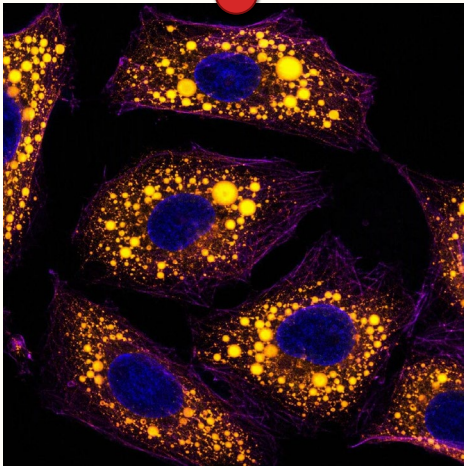
PROBES & CONTRAST

- Fluorescent probes
- MRI contrast agents
- PET tracers (FDG, FLT)
- Ultrasound contrast agents
- Near-infrared (NIR) probes

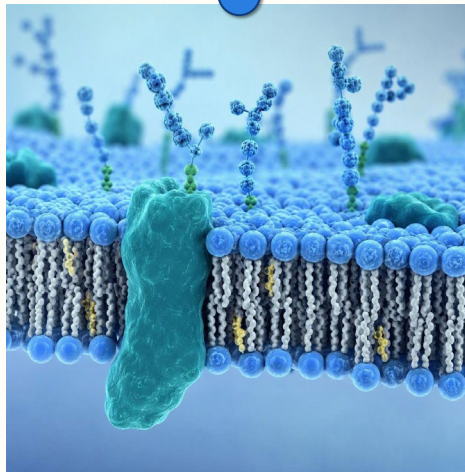
CLUE #04

LIPIDS

TYPE OF BIOMARKER



LIPID DROPLETS · CELL



PHOSPHOLIPIDS ·
MEMBRANE

LIPIDS AS BIOMARKERS

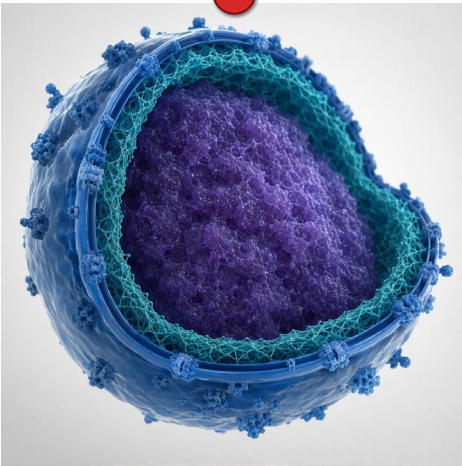
- Altered lipid metabolism is a hallmark of cancer, promoting tumor growth and metastasis.
- Key lipid biomarkers include ceramides (Cer), sphingomyelins (SM), phosphatidylcholines (PC), phosphatidylethanolamine (PE), and lysophosphatidylcholine (LPC).
- Abnormal lipid profiles are associated with breast, lung, pancreatic, and prostate cancers.
- Dysregulation of the PI3K/PTEN/Akt signaling pathway contributes to cancer progression.

Clinical Importance: Lipid biomarkers show promise for early diagnosis, prognosis, and monitoring of cancer progression.

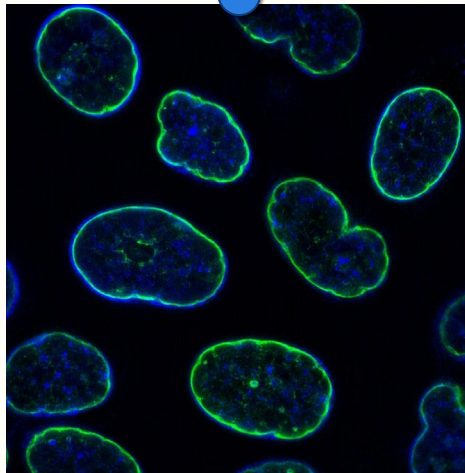
CLUE #05

LAMINS

TYPE OF BIOMARKER



LAMIN B1 · NUCLEUS



LAMIN A/C · LAMINA

LAMINS AS BIOMARKERS

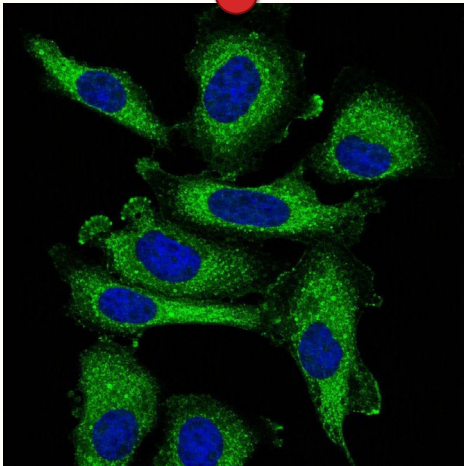
- Lamins (A/C, B1, C) are nuclear structural proteins involved in gene regulation, DNA repair, and cell growth.
- Abnormal lamin expression is linked to tumor progression, metastasis, and poor prognosis.
- Lamin B1 is often overexpressed in pancreatic, liver, and prostate cancers.
- Lamin A/C is commonly reduced in colorectal, breast, and neuroblastoma, promoting invasion and recurrence.

Clinical Importance: Lamin expression patterns are promising diagnostic, prognostic, and therapeutic biomarkers for multiple cancer types.

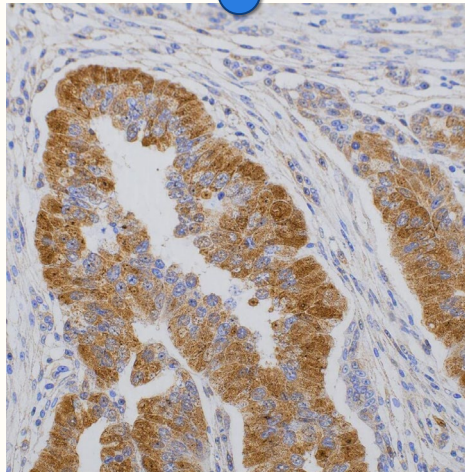
CLUE #06

GALECTINS

TYPE OF BIOMARKER



GALECTIN-3 · TUMOR
STROMA



GALECTIN-1 · TUMOR TISSUE

GALECTINS AS BIOMARKERS

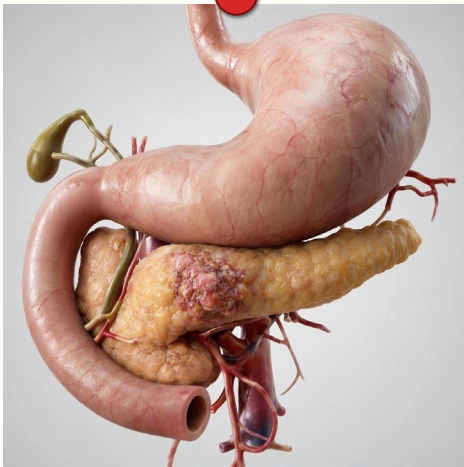
- Galectins are beta-galactoside-binding proteins driving tumor growth, angiogenesis, invasion, metastasis, and immune regulation.
- Galectin-3 is overexpressed in triple-negative breast, metastatic prostate, and pancreatic cancer, marking tumor aggressiveness.
- Galectin-1 is increased in most reproductive, gastrointestinal, respiratory, urinary, thyroid, and skin cancers, tracking disease progression.
- Galectin-7 expression is subtype-specific, raised in breast, thyroid, and laryngeal tumors and reduced in skin, cervical, and gastric cancers.

Clinical Importance: Circulating galectins carry diagnostic, prognostic, and therapeutic value, best combined with other biomarkers.

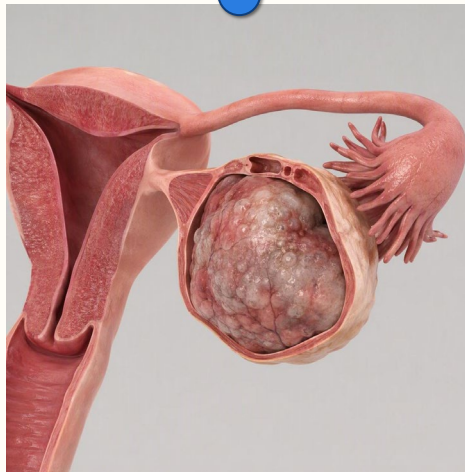
CLUE #07

CARBOHYDRATE ANTIGENS

TYPE OF BIOMARKER



CA19-9 · GI TRACT



CA-125 · OVARIAN

CARBOHYDRATE ANTIGENS AS BIOMARKERS

- CA19-9: Biomarker for pancreatic and gastrointestinal cancers.
- CA-125 (MUC16): Used to detect, monitor treatment, and identify recurrence in ovarian cancer (limited specificity).
- CEA (Carcinoembryonic Antigen): Elevated in colorectal, gastric, breast, ovarian, and lung cancers; useful for prognosis and disease monitoring.

Clinical Importance: Carbohydrate antigen biomarkers support cancer diagnosis, prognosis, treatment monitoring, and recurrence detection.

CEA Pretreatment Lab Value

CEA

CEA (Carcinoembryonic Antigen) CEA is a nonspecific tumor marker that has prognostic significance for colon and rectum cancer.

Where can I find it within the records?
Lab reports

Codes:

0.0	0.0 nanograms/milliliter (ng/ml) exactly
0.1-9999.9	0.1-9999.9 ng/ml (Exact value to nearest tenth in ng/ml)
XXXX.1	10,000 ng/ml or greater
XXXX.7	Test ordered, results not in chart
XXXX.8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code XXXX.8 may result in an edit error.)
XXXX.9	Not documented in medical record CEA (Carcinoembryonic Antigen) Pretreatment Lab Value not assessed or unknown if assessed

CEA (Carcinoembryonic Antigen) Pretreatment Lab Value is a Registry Data Collection Variable in AJCC

CEA

CEA is a glycoprotein that is produced by adenocarcinomas from all sites as well as many squamous cell carcinomas of the lung and other sites. CEA may be measured in blood, plasma or serum. CEA is a prognostic marker for adenocarcinomas of the appendix, colon and rectum and is used to monitor response to treatment

CEA Pretreatment Interpretation

Codes:

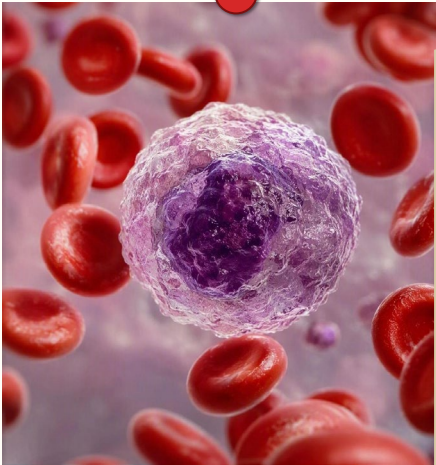
0	CEA negative/normal; within normal limits
1	CEA positive/elevated
2	Borderline
3	Undetermined if positive or negative (normal values not available) AND no MD interpretation
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case (If this data item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in medical record CEA (Carcinoembryonic Antigen) Pretreatment Interpretation not assessed or unknown if assessed

CEA (Carcinoembryonic Antigen) Pretreatment Lab Value is a Registry Data Collection Variable in AJCC

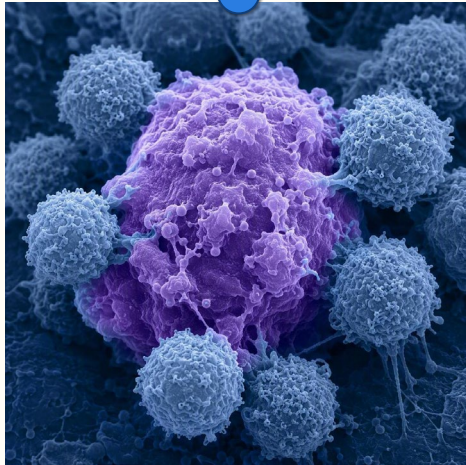
CLUE #08

CELLS

TYPE OF BIOMARKER



TUMOR CELLS (CTCs)



T-CELLS / TILs

CELLS AS CANCER BIOMARKERS

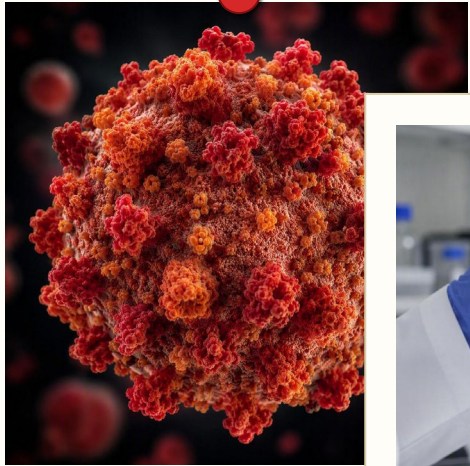
- Circulating Tumor Cells (CTCs): Present in the bloodstream; useful for early detection of metastasis, prognosis, and monitoring treatment response.
- Immune Cells: Tumor-infiltrating lymphocytes (TILs) and regulatory T cells (Tregs) reflect the tumor immune environment and help predict survival and response to immunotherapy.
- Cancer Stem Cells (CSCs): Self-renewing cells responsible for tumor initiation, recurrence, and metastasis; identified by markers such as CD44, CD24, CD133, EpCAM, and ALDH1.

Clinical Significance: Cell-based biomarkers support cancer diagnosis, prognosis, personalized treatment selection, and disease monitoring.

CLUE #09

VIRUSES

TYPE OF BIOMARKER



HBV / HCV → HCC



ctDNA ASSAY

VIRUS-ASSOCIATED CANCERS & BIOMARKERS

- HBV is the leading viral cause of hepatocellular carcinoma (HCC) by inducing genomic instability; HCV contributes to 12–17% of cases.
- HPV is the primary cause of cervical cancer and is also linked to oropharyngeal, anal, penile, vulvar, vaginal, and other cancers.
- HPV biomarkers (E6/E7 antibodies and HPV-derived ctDNA) support diagnosis, treatment monitoring, and early detection of recurrence.
- EBV DNA in blood is a valuable biomarker for Hodgkin lymphoma and nasopharyngeal carcinoma, aiding diagnosis, prognosis, and recurrence monitoring.
- HTLV-1 is associated with specific forms of leukemia.
- Overall: Viral biomarkers have significant clinical value for diagnosis, prognosis, treatment monitoring, and recurrence detection in virus-associated cancers.

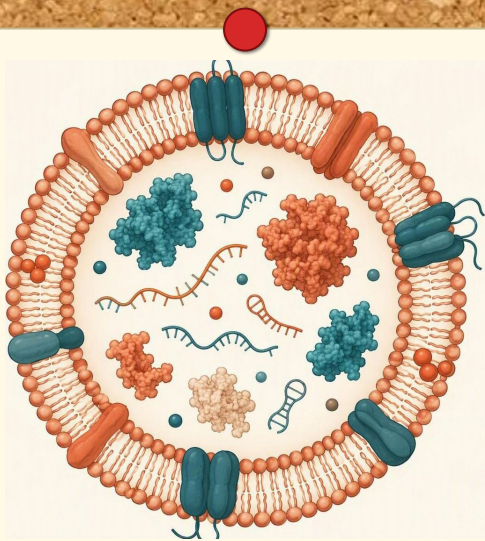
CLUE #10

EXOSOMES

TYPE OF BIOMARKER

NOTE · EXOSOMES AS CANCER BIOMARKERS

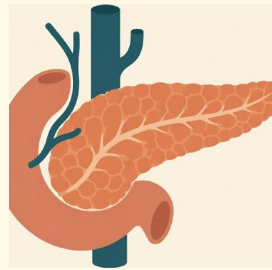
- Exosomes (30–150 nm) are extracellular vesicles released by normal and tumor cells, carrying proteins, RNA, lipids, and metabolites.
- Present in blood, urine, saliva, and other body fluids — ideal non-invasive (liquid biopsy) biomarkers.
- Tumor-derived exosomes (TEXs) promote tumor growth, angiogenesis, invasion, metastasis, and drug resistance.



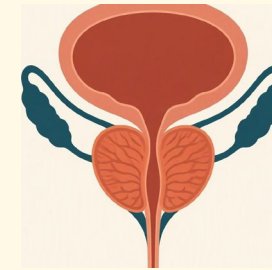
EXOSOME

Extracellular vesicle, 30–150 nm

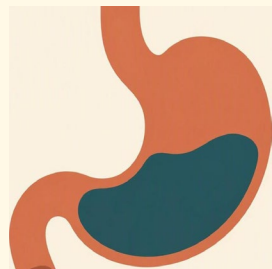
KEY EXOSOMAL BIOMARKERS · CANCER MAP



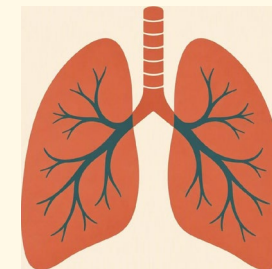
GPC-1, CKAP4
→ Pancreatic cancer



miR-375, miR-1290
→ Prostate cancer



CEBPA-AS1
→ Gastric cancer



miR-21, miR-105
→ Lung, breast, and metastatic cancers

CLUE #11

SCREENING & DIAGNOSTIC

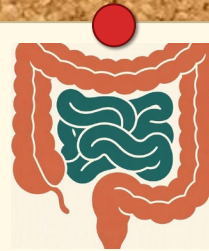
TYPE OF BIOMARKER

NOTE · SCREENING & DIAGNOSTIC

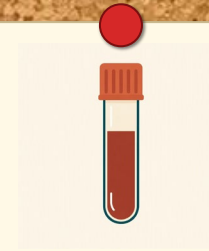
Purpose: enable **early cancer detection** for timely diagnosis and treatment.



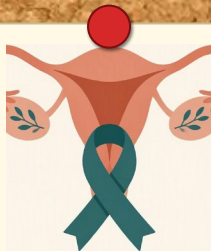
PSA
Prostate cancer



FOBT
Colorectal cancer



CEA
Colorectal & others



CA-125
Ovarian cancer



HPV test
Cervical cancer



Mammography
Breast cancer

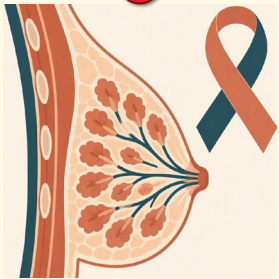
CLUE #12

PROGNOSTIC

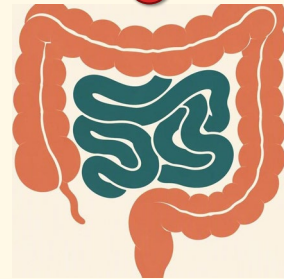
TYPE OF BIOMARKER

CASE NOTE · PROGNOSTIC BIOMARKERS

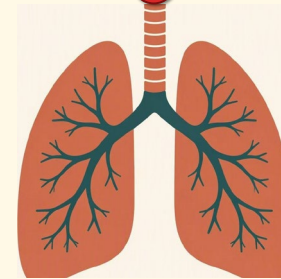
Purpose: predict disease progression, recurrence, and patient survival.



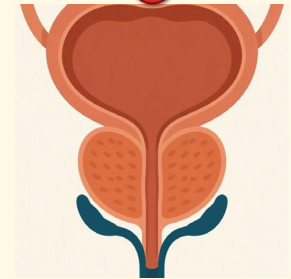
Breast cancer
ER/PR, HER2, Ki-67



Colorectal cancer
MSI, CEA, BRAF



Lung cancer
EGFR, ALK, PD-L1



Prostate cancer
PSA, Gleason score

KI-67

Ki-67 (MIB-1) (Proliferative Index) is a marker of cell proliferation. A high value indicates a tumor that is proliferating more rapidly. Codes and coding instructions for this data item are site-specific.

Where can I find it within the records?
Pathology reports or search within the records

Codes:

0.0-100.0	0.0 to 100.0 percent positive: enter percent positive
XXX.4	Ki-67 stated as less than 3%
XXX.5	Ki-67 stated as 3%-20%
XXX.6	Ki-67 stated as greater than 20%
XXX.7	Test done, actual percentage not stated
XXX.8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code XXX.8 will result in an edit error.)
XXX.9	Not documented in medical record Ki-67 (MIB-1) not assessed or unknown if assessed

It was a new data item for breast cases diagnosed 1/1/2018+. It will apply to neuroendocrine tumors (NET) of the gastrointestinal tract (AJCC Chapters 29 – 34) for cases diagnosed 1/1/2021+

MSI

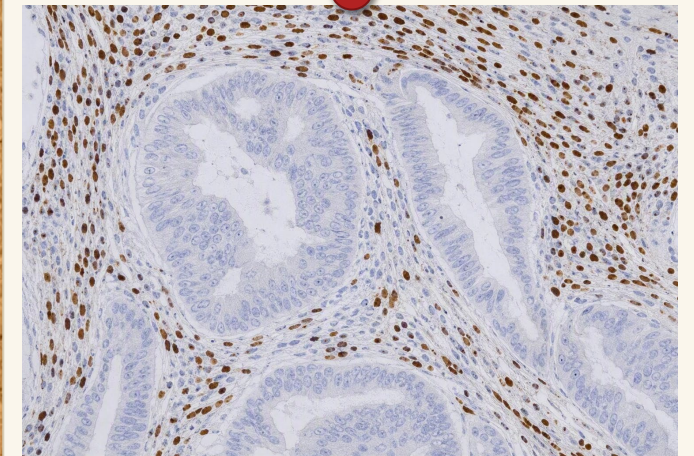
NOTE · MSI TESTING

The microsatellite instability (MSI) test is a genetic test performed on tumor tissue to look for differences in length of certain non-functioning sections of DNA. Knowing whether cancer is microsatellite instability high may help plan the best treatment.

Found within Immunology or genetic test reports

Codes:

0	Microsatellite instability (MSI) stable; microsatellite stable (MSS); negative, NOS AND/OR Mismatch repair (MMR) intact, no loss of nuclear expression of MMR proteins MMR proficient (pMMR or MMR-P)
1	MSI unstable low (MSI-L)
2	MSI unstable high (MSI-H) AND/OR MMR-D (dMMR or MMR-D), loss of nuclear expression of one or more MMR proteins, MMR protein deficient)
8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code 8 may result in an edit error.)
9	Not documented in medical record MSI-indeterminate MSI-equivocal Microsatellite instability not assessed or unknown if assessed



MMR IHC · COLORECTAL TUMOR

PD-L1

The absence or presence of PD-L1 expression determines if the tumor will respond to treatment with a targeted inhibitor (immunotherapy). PD-L1 is done for Non-small cell lung cancers (NSCLC).

Where can I find it within the records?
Pathology reports or search within the records

Codes:

0.0	No PD-L1 expression identified Tumor Proportion Score (TPS) = 0%
0.1-100.0	0.1-100.0 PD-L1 expression Tumor Proportion Score (TPS) = 0.1%-100.0%
XXX.2	PD-L1 expression absent AND Tumor Proportion Score (TPS) stated as negative
XXX.3	PD-L1 expression present AND Tumor Proportion Score (TPS) stated as low
XXX.4	PD-L1 expression present AND Tumor Proportion Score (TPS) stated as high/positive
XXX.7	Test ordered, results not in chart
XXX.8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 8 will result in an edit error)
XXX.9	Not documented in medical record No microscopic confirmation of tumor PD-L1 cannot be determined PD-L1 not assessed or unknown if assessed
Blank	NA - Diagnosis year is prior to 2025

It is a new data item for cases diagnosed 1/1/2025+.

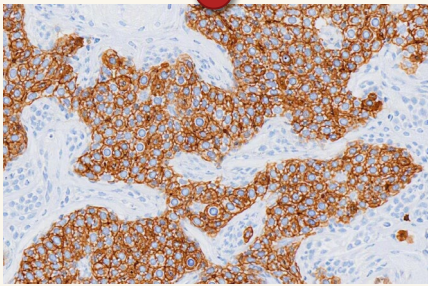
CLUE #13

PREDICTIVE

TYPE OF BIOMARKER

NOTE · PREDICTIVE BIOMARKERS

Purpose: predict which patients are most likely to benefit from specific therapies, enabling **personalized treatment**.



HER2 IHC · BREAST



TARGETED THERAPY

Biomarker	Cancer Type	Targeted Therapy
HER2	Breast	HER2-targeted therapy such as trastuzumab
EGFR	NSCLC	EGFR tyrosine kinase inhibitors like gefitinib
ALK	NSCLC	ALK inhibitors like crizotinib
MSI-H/dMMR	Colorectal	Immunotherapy like pembrolizumab
BRAF V600E	Melanoma	BRAF/MEK inhibitors like dabrafenib and trametinib
Low ERCC1	NSCLC	Platinum chemotherapy

EGFR

Epidermal growth factor receptor (EGFR) mutational analysis is performed for patients with advanced **non-small cell lung cancer (NSCLC)** to identify patients with certain activating mutations in the EGFR gene which are sensitive to tyrosine kinase inhibitors.

Codes:

0	Normal EGFR negative, EGFR wild type Negative for mutations, no alterations, no mutations (somatic) identified, not present, not detected
1	Abnormal (mutated)/detected in exon(s) 18, 19, 20, and/or 21
2	Abnormal (mutated)/detected but not in exon(s) 18, 19, 20, and/or 21
4	Abnormal (mutated)/detected, NOS, exon(s) not specified
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case If this information is required by your standard setter, use of code 8 may result in an edit error.
9	Not documented in medical record EGFR not assessed or unknown if assessed
Blank	Diagnosis year is prior to 2021

EGFR mutational analysis is recommended by treatment guidelines for patients with advanced lung cancer as a prognostic marker and factor in determining appropriate therapy. It is a new data item for cases diagnosed 01/01/2021+

CASE CLOSED

THE VERDICT: BIOMARKERS AND GENETICS CRACK THE CANCER CASE

- ✓ Biomarkers are the biological evidence — measurable signals of what disease is doing.
- ✓ The suspects log runs 13 clue (biomarkers) types — genetic, protein, metabolic, lipids, galectins, exosomes and more.
- ✓ Reading them takes the case from screening to diagnosis, prognosis and therapy choice.
- ✓ HER2, p16, PSA, Oncotype DX and other biomarkers turn suspicion into targeted, correctly coded action.

SOLVED



CASE CLOSED · QUESTIONS WELCOME

THANK YOU

QUESTIONS, SECOND OPINIONS, AND FOLLOW-UP EVIDENCE WELCOME

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[The Florida Cancer Data System Home Page](#)

