YOUR GUIDE IN THE FIGHT

Biomarkers

A FIGHT COLORECTAL CANCER™ Resource

BIOMARKERS:
A Game-Changer for Treatment Options

Just as astronomers using telescopes have discovered galaxies millions of miles away, scientists armed with microscopes have discovered that inside of cancer tumors lie a variety of different markers, called "biomarkers."

Tumor biomarkers can inform both doctors and patients about what makes up a tumor or body fluids. **What this means to a patient is that their biomarkers can provide insight and information into their treatment because not all colorectal cancers are the same.**

Some colorectal cancers respond to immunotherapy, but not to chemotherapy, or vice versa. **All patients should ask about their tumor's biomarkers. Knowing your tumor's biomarkers provides game-changing information.**

Some biomarkers tell what kind of cancer you have; others tell if your tumor will respond well or poorly to certain treatments.

Biomarkers can give clues about how your tumor may behave in the future, about dosing decisions, and they can also give an idea as to whether cancer is still circulating in your body once treatment ends. For example, knowing what side of the colon your cancer is on is a biomarker.

Knowing your tumor's biomarkers is incredibly important when you're planning treatment.

"I think the biomarker tests allowed me to have the best treatment and the least side effects for me, so that I could remain cancer-free for 10 years plus."

PAM ALLEN
Stage III Colon Cancer Survivor

"Having my biomarkers tested gave me and my medical team a better understanding of my course of treatment. Knowledge is power in the fight against cancer."

JOE BULLOCK
Stage IIIb Colorectal Cancer Survivor

[Scientific] ▪ DEFINITION

Biomarkers (short for "biological markers") **are characteristics of the body that you can measure from bodily fluids or tissue.**

When you are newly diagnosed, it's hard to remember everything your healthcare team is telling you.

But this is the best time to ask about biomarkers and biomarker testing.

Biomarker testing may be referred to as tumor, molecular, mutation, or genomic testing. Biomarker testing is NOT the same as GENETIC testing for an inherited mutation or for inherited cancer risk. Genetic testing is often a blood and/or saliva test that involves a genetic counseling team and outlines your family health history, not your tumor.

The actual biomarker test is performed on a small amount of tissue (obtained during a biopsy) from a patient's tumor, or by drawing a blood sample. The tissue or blood sample is sent to a lab for testing. Once a biopsy or blood sample is collected, it is analyzed by a specialized laboratory. The laboratory supplies a report to your doctor based on information provided about your tumor.

Often, your doctor will request biomarker testing without you realizing it. So it's always good to ask about your results before making treatment decisions.

PRE-SURGERY BIOMARKER TIP

Before surgery, ask your doctor about biomarker testing and confirm your tumor tissue will be analyzed and a biomarker report will be provided to you.

? *I've Already Had Surgery: Is It too Late to Find out My Biomarkers?*

If your surgery is behind you, and you're unsure if you had biomarker testing, ask your doctor to pull up the pathology report from your tumor biopsy and review it for biomarkers.

Then be sure to have your doctor communicate their findings to you. If you don't understand what the findings or report means, ask your doctor to explain in a way that you do understand.

Don't be embarrassed to ask questions. Asking questions is one of the best ways to advocate for yourself because you obtain answers, and gain knowledge and experience.

? *What If My Doctor Didn't Test Me?*

If biomarker testing was not done on your tumor, the hospital where your surgery was performed should have a piece of your tumor in a tissue bank, and you can still request biomarker testing be performed on your tumor.

If you had one biomarker tested but need more tests run, you can use the saved tissue. If your tissue wasn't saved, discuss next steps with your doctor.

DON'T FORGET!

Biomarker testing is NOT the same as GENETIC testing for an inherited mutation or for inherited cancer risk.

How **Biomarker Testing** Works

STEP 1	STEP 2	STEP 3	STEP 4	STEP 5
Request Testing	Biopsy	Testing	Results	Personalized Treatment (Based on your biomarkers)

Why **Biomarker Testing Is Important**

To recommend the best ***personal*** treatment path, it's helpful for your treatment team to understand what's causing your cancer on a molecular level. **This starts with biomarker testing.**

Your tumor's biomarkers can show game-changing information about your cancer by showing DNA alterations in your tumor.

Biomarkers can give clues about how your tumor may behave in the future, how it may respond to different treatments, and give an idea as to whether cancer is still circulating in your body once treatment ends.

Get **Resources**

Knowledge is a powerful tool in your fight against colorectal cancer. Treatment planning for patients has been dramatically changed thanks to better understanding biomarkers. For more information, visit *FightCRC.org/Biomarker* or scan the QR code.

Paying for Testing

While it is important to know your biomarkers, it's also important to know who will cover the cost of biomarker testing.

Some biomarker testing is covered by Medicare, and some states have enacted laws requiring testing to be covered by private insurance.

Knowing which test(s) your healthcare team would like to perform can help you prepare to speak to an insurance representative about coverage for your specific biomarker testing.

Questions to **Ask Your Insurance:**

1. **Is prior authorization required for my biomarker test to be covered by insurance?**
2. **Are there any pre-approved biomarker tests that are covered by my insurance plan?**
3. **Do you require biomarker tests to be performed by specific companies or labs in order to be covered?**

My **BIOMARKER** Passport

Biomarker testing may help you and your doctor choose a cancer treatment plan specifically designed for you. Knowing your biomarkers is especially important for metastatic colorectal cancer patients and for patients looking for clinical trials. Biomarker testing will help you obtain the responses to fill out the card, but if you need additional help with the questions on this card, ask your healthcare team.

Tumor Biomarker Information Card

FIGHT COLORECTAL CANCER™

Carrying this card will allow you to quickly reference important factors about your cancer when speaking to your medical team and searching for treatment options, such as clinical trials.

_____
Last Name First Name

_____/_____/_____
Biomarker Testing Date Cancer Type Stage

_____
Where my tumor tissue is stored

My biomarker and other important factors of my cancer are:

☐ KRAS _____	☐ BRAF _____	☐ Tumor Side: __L __R	☐ HER2
☐ NRAS _____	☐ BRAF V600E	☐ TRK Fusions	☐ DPD
☐ KRAS wild-type	☐ PIK3CA	(NTRK1, NTRK2, or	☐ _____
☐ NRAS wild-type	☐ MSI-High	NTRK3)	☐ _____

I Know My Tumor's Biomarkers. ***Now What?***

Biomarker test reports may have different layouts, formats, or organization depending on who runs your test. But all test reports should include the following information:

- Patient and doctor information
- Primary diagnosis
- Treatment (therapy) association/ relevant treatments for each biomarker
- Relevant biomarkers
- Additional results (other biomarkers that may not be relevant to this cancer)

If you're just now choosing treatment, use your newly acquired biomarker testing results to make a plan. There are specific treatments that can target colorectal cancer with certain biomarkers. These treatments are called "targeted therapy" and "immunotherapy," and some biomarkers indicate which tumors are more or less likely to respond to a specific treatment or treatments.

For example, immunotherapy has been shown to be an effective treatment option with more positive outcomes for colorectal cancer patients with tumors that have microsatellite instability (often abbreviated MSI or MSI-H, where H refers to "High") when compared with chemotherapy.

If biomarker testing reveals that you are positive for a certain biomarker (positive means your tumor has the marker), **your doctor can choose treatments that work to attack the specific biomarker your tumor has.** Alternatively, biomarker testing can also inform your doctor about which treatments to avoid, since some biomarkers do not respond to certain drugs.

For example, we know that for tumors with the KRAS biomarker, chemotherapy treatments such as cetuximab (Erbitux®) and panitumumab (Vectibix®) may not be effective.

More Information

Learn more about each biomarker and important factors for making treatment decisions at ***FightCRC.org/Biomarker***

Sample ***Biomarker Report***

PATIENT

TUMOR TYPE
Colon adenocarcinoma (CRC)

REPORT DATE

ORDERED TEST #

PATIENT	PHYSICIAN	SPECIMEN
DISEASE Colon adenocarcinoma (CRC)	ORDERING PHYSICIAN	SPECIMEN SITE
NAME	MEDICAL FACILITY	SPECIMEN ID
DATE OF BIRTH	ADDITIONAL RECIPIENT	SPECIMEN TYPE
SEX	MEDICAL FACILITY ID	DATE OF COLLECTION
MEDICAL RECORD #	PATHOLOGIST	SPECIMEN RECEIVED

Companion Diagnostic (CDx) Associated Findings

GENOMIC FINDINGS DETECTED	FDA-APPROVED THERAPEUTIC OPTIONS
KRAS wildtype (codons 12 & 13)	Erbitux® (Cetuximab)
KRAS/NRAS wildtype (codons 12, 13, 59, 61, 117, & 146 in exons 2, 3, & 4)	Vectibix® (Panitumumab)
Tumor Mutational Burden (TMB) ≥ 10 Muts/Mb	Keytruda® (Pembrolizumab)

OTHER ALTERATIONS & BIOMARKERS IDENTIFIED

Results reported in this section are not prescriptive or conclusive for labeled use of any specific therapeutic product. See ***professional services*** section for additional information.

Microsatellite status MSI-High §
Tumor Mutational Burden 47 Muts/Mb §
ASXL1 G646fs*12
ATR I774fs*5
BCOR E623*
BCORL1 P1681fs*20
BRCA2 T3033fs*29
CREBBP R1446C
CTNNB1 R449C
CUL3 R733*
ERBB3 V104M
HNF1A P291fs*51
MAP2K1 (MEK1) K57N
MLH1 Q445*
MLH1 E663D
MLL2 A2205fs*59
MLL2 P648fs*283
MSH3 K383fs*32
MSH6 R361H
MSH6 F1088fs*5
PDGFRB V823I
SPEN A2251fs*102
SPEN R806fs*14
SPEN I1052fs*40

Genomic Findings Detected are the biomarkers identified in your tumor.

FDA-Approved Theraputic Treatment Options are the FDA-approved drugs that are known to be effective against your identified biomarkers.

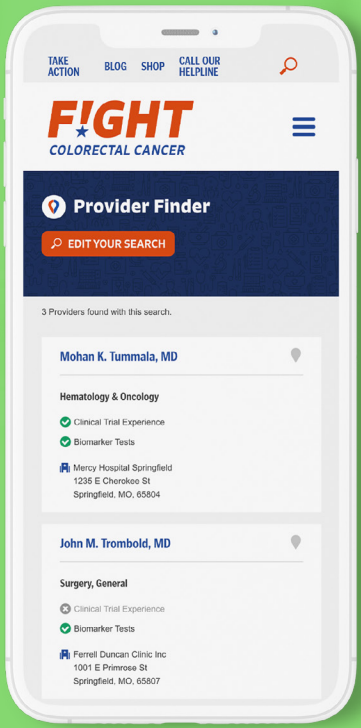
Other Alterations and Biomarkers Identified are additional biomarkers identified in your tumor that may not have a known FDA-approved drug yet, as well as other important factors about your cancer that may play a role in making treatment decisions.

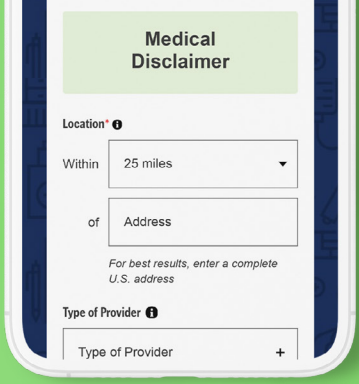
DEFINITION

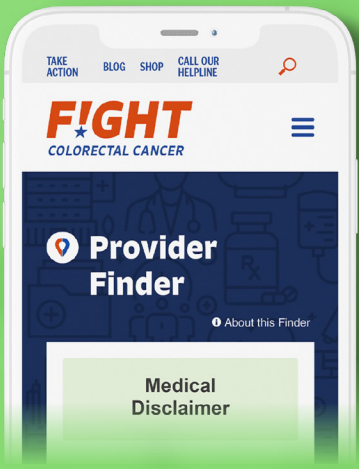
You may see the term "wild-type" on your report.

Wild-type means that there is no mutation (or is "negative" for the mutation) in the biomarker.

For example KRAS wild-type means a tumor ***does not*** have a KRAS mutation.







SEARCHING FOR *Biomarker Testing?*

Fight CRC's Provider Finder is a digital tool that can help patients find and connect with oncologists, gastroenterologists, and surgeons with experience in biomarker testing.

The Provider Finder suggests providers who are actively seeing and treating colorectal cancer patients around the country based on factors such as:

* geographic accessibility.
* biomarker testing experience.
* colorectal cancer patients volume.
* clinical trial experience.
* whether they have a strong referral network to support interdisciplinary care pathways.

SCAN HERE *to learn more*

Search at ***ProviderFinder.FightCRC.org***

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