



INNOVATIONS

A blood test to detect cancer? Some patients are using them already.



(Photo illustration by Chelsea Kyle for The Washington Post)



By Marlene Cemons

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When her husband was undergoing cancer treatment, Cindy Perez of Southwest Ranches, Fla., learned about a new blood test that could help find early cancers. The 50-year-old said she felt fine, but her husband urged her to take the test anyway.

To her surprise, the blood test — called Galleri — came back positive. Scans revealed a small tumor in her groin and a diagnosis of [mantle cell lymphoma](#), a rare but aggressive form of cancer. She was treated and now, two years later, she's in remission. "For me, the test was a miracle," she said. "A real big miracle."

Many experts believe that such tests, which analyze substances in the blood that might indicate cancer, represent a remarkable new chapter in cancer detection. The tests may be especially useful finding "silent" cancers — such as pancreatic or ovarian cancer — which often don't cause symptoms until the disease is advanced and more difficult to treat.

"It opens up a whole new world," said Eric Klein, a scientist at the health-care company [Grail](#) who developed [Galleri](#), a multi-cancer detection test. "It's the unmet need we face in cancer."

Finding early cancer 'signals'

These new cancer detection blood tests — about 20 are in various [stages of development](#) — measure cancer "signals," which are biological substances shed by cancers such as fragments of tumor DNA. Some can even identify the organ or tissue involved.

Technological and scientific advances in recent years, including discoveries in tumor biology, machine-learning tools and the ability to recognize circulating DNA and other substances in the blood, have made these new tests possible, experts said.

Some tests focus on one cancer, such as Guardant Health's Shield test, which looks for colorectal cancer. Others screen for multiple cancers, including Grail's Galleri and Exact Sciences' Cancerguard, whose forerunner CancerSeek was developed and studied by researchers at the Johns Hopkins Sidney Kimmel Cancer Center.

Delfi's FirstLook lung cancer test identifies patterns of DNA fragments in the blood that have been shed by dying cells unique to lung cancer and uses machine learning to distinguish those who probably have lung cancer from those who don't,

Innovations

according to Peter Bach, Delfi's chief medical officer.

"There are certain cancers where we know for sure that finding them early will save a lot of lives, and lung cancer is the biggest cancer problem we have today," Bach said.

The tests don't diagnose cancer — a positive result will probably lead to additional imaging tests or biopsies.

Experts say the tests aren't yet ready to replace standard-of-care screening tests such as colonoscopy, mammography or Pap smear but are meant to complement them.

One [study](#) of Galleri, for example, found the test predicted the cancer location with 88 percent accuracy. A [study](#) of the Delfi lung cancer test reported more than 90 percent accuracy, and a [study](#) of [Guardant Health's Shield](#) showed an 83 percent accuracy in identifying patients with colon cancer.

While these findings are promising, experts warned of drawbacks. So far, there's no evidence that finding cancer via a blood test translates to longer survival and fewer deaths, or even a cure, experts said.

"People want to believe there is one test that can pick up all the different kinds of cancers, and if it's negative, they can go on their way," said [Lori Minasian](#), deputy director of the National Cancer Institute's division of cancer prevention. "But it's not that simple."

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Elusive targets for early detection

Several experts pointed out that multi-cancer detection tests don't find every cancer at its earliest stage, in part because certain cancers spread quickly.

"It depends on the cancer," said [William Grady](#), medical director of the gastrointestinal cancer prevention program at the Fred Hutchinson Cancer Center in Seattle and one of the scientists who studied Guardant's colon cancer test.

For example, he said, brain cancer frequently is an elusive target for early detection. "These tests are not effective for brain cancer because brain cancer spreads rapidly, even when early and very small, so it is not often curable even at an early stage," he said.

Much remains unclear about how and when various cancers secrete the telltale substances detected by the new blood tests, and whether these markers show up early or often enough to make a difference in life expectancy.

Still, some patients who took the Galleri test are convinced it saved their lives.

In 2022, after Valerie Caro's positive Galleri test, an MRI found "an angry gallbladder" that needed to come out, she said. Caro, 56, a real estate broker from Flagstaff, Ariz., was asymptomatic, but a small malignant tumor was among the gallstones. After treatment, she said she is now cancer-free.

"I don't like to think about what would have happened if this had been discovered later," she said.

Some employers now offer the tests

The Food and Drug Administration has not cleared any of the tests for final approval, but they are available as "lab-based" tests under federal regulations that permit their use in certain settings. The tests are not covered by Medicare or other insurance.

Nevertheless, some medical practices and employers now provide them. Any patient with a doctor's prescription can get a Galleri test, which costs \$949. Princeton University has been offering Galleri to eligible employees for free in a pilot program. Guardant's colon cancer test, which costs \$895, is also available, though not all doctors have access to it yet, the company said.

Later this year, Exact Sciences plans to make its test available on a limited basis, said Tom Beer, the company's chief medical officer for multi-cancer early detection.

Susan Johns, 75, a retired Medicare counselor from Hegins, Pa., took a test as part of a CancerSeek study in 2018. After a positive test, scans revealed leiomyosarcoma in her uterus. After a hysterectomy, doctors believed they got it all, she said.

"I don't know how aggressive it would have been," she said. "But I have one grandchild and I was able to see him graduate from high school. I'm looking forward to his college graduation — and later to my great-grandkids."

Not a replacement for traditional cancer screening

Studies show the rates of false positive and negatives are low among the new cancer blood tests. As with conventional screening, one concern is that a false positive could prompt anxiety and more invasive and costly tests, while a false negative could result in a misguided sense of security and lead patients to forgo proven conventional screening, experts say.

For instance, a blood test may not be as reliable as a colonoscopy at finding precancerous polyps or early cancers, in part because early cancers may shed less DNA. Grady, the Fred Hutchinson researcher,

said that in studies, the Guardant test detected just 13 percent of people with advanced polyps, 71 percent of Stage 1 cancers and 100 percent of Stage 2 and 3 cancers.

But for patients who resist conventional screenings, the tests may be useful. Dennis Barnes, 55, a pharmaceutical compliance lawyer from Raleigh, N.C., was reluctant to go through the unpleasant bowel-cleaning preparation needed for a screening colonoscopy.

Instead, he took Guardant Health's colon cancer blood test two years ago, which, to his relief, was negative. He's being tested again this month. "I knew being an African American man made my risk higher, but the thought of a colonoscopy was not very appealing," he said. When his doctor mentioned the blood test, "I jumped at it," he said.

Finding out if the blood tests save lives

The National Cancer Institute recently announced the creation of the Cancer Screening Research Network, a clinical trials network of nine hubs coordinated by the Fred Hutchinson Cancer Center. The goal is to design and ultimately sponsor a clinical trial to evaluate the benefits and risks of the new blood tests and to find out if using them reduces deaths, Minasian said.

Later this year, the network will launch a pilot study with 24,000 participants in advance of a potential larger randomized controlled trial. "We do see these tests as promising," Minasian said. "The challenge now is to better understand the technology and harness it in a way that we know saves lives."

The endpoint of such a trial "should be whether people who have taken the test survive longer," said N. Jewel Samadder, co-director of precision oncology at the [Mayo Clinic Comprehensive Cancer Center](#) in Phoenix, who has been a consultant for Caris Life Sciences, which is also designing a multi-cancer blood test. "It means nothing if these tests don't lead to better survival."

The tests probably are several years away

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from widespread use because so many questions remain unanswered, such as whether use of the tests should be based on age, risk factors or family history. It's also unclear how frequently people should take the blood tests.

“Will we see these as part of a routine physical exam? We are not there yet, not at all,” Samadder said. “Will we get there? That is the hope.”

Jonathan, 69, of San Diego readily agreed three years ago to his doctor’s suggestion that he take the Grail blood test. His annual checkup — routine lab work and physical — had been normal, so he was surprised when the test came back positive. (He asked that his full name not be used to protect his medical privacy.)

After further checks, doctors found cancer in a lymph node under his right armpit, a form of Hodgkin lymphoma. After radiation and chemotherapy, he currently is cancer-free. If he hadn’t taken the blood test, “where would I be now?” he said. “Who knows? But it wouldn’t have gone away.”

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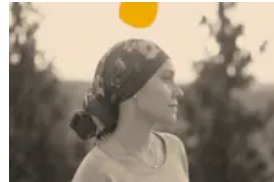
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