GALLERI® MULTI-CANCER EARLY DETECTION TEST

DESCRIPTION

The **Galleri® Multi-Cancer Early Detection (MCED)** test is an innovative blood test designed to look for a signal associated with many types of cancer - even before symptoms develop. Unlike traditional screening tests that typically check for a single type of cancer, the Galleri test is designed to detect a shared cancer signal across more than 50 types of cancer with a single blood draw.

Many cancers do not have recommended routine screening tests and are often diagnosed only after symptoms appear. The Galleri test is intended to complement - not replace - recommended cancer screenings such as mammograms, colonoscopies, Pap tests, PSA testing, and lung cancer screening when appropriate.

This test does not diagnose cancer. A Cancer Signal Detected result requires follow-up testing to confirm if cancer is present. It does not detect all cancers and not all cancers can be detected in the blood. A healthcare provider should interpret your results in the context of your medical history and any additional testing that may be needed.

Early detection can make a meaningful difference for many cancers. The Galleri test offers a proactive approach to looking for a cancer signal with a simple blood draw, providing another tool to help you take control of your health.

Important Safety Information from GRAIL:

The Galleri test is recommended for use in adults with an elevated risk for cancer, such as those aged 50 or older. The Galleri test does not detect all cancers and should be used in addition to routine cancer screening tests recommended by a healthcare provider. Galleri is intended to detect cancer signals and predict where in the body the cancer signal is located. Use of Galleri is not recommended in individuals who are pregnant, 21 years old or younger, or undergoing active cancer treatment.

Results should be interpreted by a healthcare provider in the context of medical history, clinical signs and symptoms. A test result of “No Cancer Signal Detected” does not rule out cancer. A test result of “Cancer Signal Detected” requires confirmatory diagnostic evaluation by medically established procedures (e.g. imaging) to confirm cancer.

If cancer is not confirmed with further testing, it could mean that cancer is not present or testing was insufficient to detect cancer, including due to the cancer being located in a different part of the body.

False-positive (a cancer signal detected when cancer is not present) and false-negative (a cancer signal not detected when cancer is present) test results do occur. Rx only.

Test Details:

This test detects small fragments of DNA from cancer cells that are released into the bloodstream.

WHO SHOULD CONSIDER THIS TEST?

The **Galleri® multi-cancer early detection (MCED)** test may be appropriate for adults with an increased risk of cancer, including individuals who:

- Are age 50 or older
- Have a family history of cancer
- Have certain lifestyle or environmental risk factors
- Want to be proactive about their health in addition to recommended cancer screenings

WHY IS THIS TEST IMPORTANT?

The **Galleri® multi-cancer early detection (MCED)** test screens for multiple cancers with a single blood sample, including many without recommended routine screening tests

CAN I TAKE THIS TEST IF I AM UNDER 50 YEARS OLD?

Yes. The Galleri test may be appropriate for customers aged 40 or older with a family history of cancer or certain lifestyle or environmental risk factors. It is important to note that test performance has not been evaluated in all age populations and may vary in customers under 50 years old.

HOW DOES THIS TEST WORK?

Cancer cells release small fragments of DNA into the bloodstream. The Galleri test analyzes these DNA fragments using advanced technology and artificial intelligence to look for patterns that may indicate the presence of cancer.

If a cancer signal is detected, the test can also predict where in the body the signal most likely originated, helping your healthcare provider determine the most appropriate next steps for additional evaluation.

WHAT CANCERS CAN THIS TEST DETECT?

In clinical studies, this test was able to detect a signal shared by more than 50 types of cancer. This includes many of the deadliest cancers that currently lack other screening options. See the list of cancers that the Galleri test is able to detect.

WHAT DOES MY RESULT MEAN?

Your results will report one of two findings:

- **No Cancer Signal Detected:** No cancer signal was identified in your blood sample. This does **not** rule out cancer since the test cannot detect a signal for all cancers, and not all cancers can be detected in the blood. You should continue all recommended cancer screening tests based on your age and risk factors.
- **Cancer Signal Detected:** A cancer signal was identified. This does **not** mean you have cancer, but additional diagnostic testing is recommended. The report also provides the predicted Cancer Signal Origin to help guide follow-up care with your healthcare provider.

HOW OFTEN SHOULD I TAKE THIS TEST?

Cancer can be unpredictable. The Galleri test can be taken annually and added to your yearly wellness visits. Ask your healthcare provider when would be the best time to schedule your next test.

CAN I TAKE THIS TEST IF I'VE HAD CANCER BEFORE?

Yes. As long as you completed cancer treatment three or more years ago, you can take the Galleri test.

IS THIS A DIAGNOSTIC TEST?

No. While the test provides important information, results should only be used to help you and your healthcare provider determine if additional diagnostic testing is required if you receive a Cancer Signal Detected result.

IS THIS TEST FDA-APPROVED?

No. The Galleri test was developed and its performance characteristics were determined by GRAIL. The Galleri test has not been cleared or approved by the Food and Drug Administration. GRAIL's clinical laboratory is regulated under CLIA to perform high-complexity testing.

WHAT KIND OF SAMPLE IS REQUIRED?

This test requires a blood sample.

WHAT DO I NEED TO DO TO PREPARE?

No special preparation or fasting is required. However, drinking plenty of water prior to any blood draw procedure is recommended.

IS A DOCTOR'S ORDER REQUIRED?

Yes. However, at Any Lab Test Now we can provide the doctor's order at no additional cost. We can also accept your doctor's order if you have one.

DO I NEED TO MAKE AN APPOINTMENT?

No. You can walk in for same-day testing. We make it easy by offering work-friendly store hours.

HOW LONG WILL IT TAKE TO GET MY RESULTS?

Testing is typically completed within 14 days of the lab receiving your sample.

IF I HAVE QUESTIONS ABOUT MY RESULTS, WHO SHOULD I CONTACT?

We recommend that you share your results with your healthcare provider.

Website test descriptions and all associated information are provided through the Any Lab Test Now Product Management Team, in conjunction with the Medical Professionals Committee and Dr. Ekan Essian, MD, Corporate Medical Director.