

# Patient Information Sheet for the Galleri<sup>®</sup> Multi-Cancer Early Detection Test

This document provides information about GRAIL's Galleri test. It should supplement any discussions with a healthcare provider regarding the purposes, benefits, risks, and limitations of the test. The test can only be ordered by licensed healthcare providers, and undergoing this test is your choice. We encourage you to ask any questions you may have about this test.

## Purpose of the Test

The Galleri test is a multi-cancer early detection (MCED) test to screen for cancer. Galleri is recommended for use in adults with an elevated risk for cancer, such as those aged 50 or older. The Galleri test is intended to be used in addition to, and not replace, other cancer screening tests your healthcare provider recommends.

The Galleri test can screen for many of the deadliest cancers before they become symptomatic, including those with no recommended screening tests today. Cancers growing in the body shed DNA into the bloodstream. Although there are many types of cancer, the DNA fragments act like a unique "fingerprint" of cancer. With this unique "fingerprint" of cancer, the Galleri test helps to provide direction to your healthcare provider on the potential cancer's origin, so that your provider can determine what additional tests are needed to confirm if cancer is present. The Galleri test does not diagnose cancer or measure your future risk of developing cancer.

## Testing Process and Results

GRAIL, the company that created and performs the Galleri test, will test your blood sample to look for DNA shed into the bloodstream that may have come from cancer. There are three possible results: Cancer Signal Detected, No Cancer Signal Detected, or Canceled. A Cancer Signal Detected result will include a Cancer Signal Origin, which predicts the tissue type or organ associated with the cancer signal. Around 1% of individuals over the age of 50 who are tested are expected to receive a Cancer Signal Detected result. This result is not a diagnosis of cancer. With this result, your healthcare provider will determine what additional tests are needed to confirm if cancer is present. These tests may include additional bloodwork, and/or imaging, endoscopic procedures, or biopsy. A test result of No Cancer Signal Detected does not rule out cancer. It is important that you continue to receive any cancer screening tests that your healthcare provider recommends as part of your usual medical care. Canceled reports are infrequent, but can occur if samples did not satisfy quality measures during processing.

GRAIL will provide your test results to your ordering healthcare provider and, if you or your provider have given GRAIL your email address, GRAIL also will provide your test results to you by email directly. In that case, please note that you may receive your results before your provider. If you are having trouble receiving or accessing your test results, you may contact GRAIL Customer Service at [833-694-2553](tel:833-694-2553) or [customerservice@grail.com](mailto:customerservice@grail.com).

## Limitations of the Test

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. The test is prescription (Rx) only.

## Laboratory/Test Information

The GRAIL clinical laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and accredited by the College of American Pathologists. 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. The GRAIL clinical laboratory is regulated under CLIA to perform high-complexity testing. The Galleri test is intended for clinical purposes.

## Disclosure and Use of Test Results & Health Information

Your Galleri test results and health information are confidential. Your test results and other health information will only be collected, used, or disclosed in compliance with the Health Insurance Portability and Accountability Act ("HIPAA"), as detailed in GRAIL's Notice of Privacy Practices ([Grail.com/hipaa](https://grail.com/hipaa)).

GRAIL may disclose your health information to:

- Your healthcare providers (or their designated representatives);
- Your health insurance company (if the Galleri test, or any follow-up diagnostic care, is paid for, partially or in full, by your health insurance company); and/or
- As otherwise described in GRAIL's Notice of Privacy Practices

You may also request your Galleri test results by contacting GRAIL Customer Service at **833-694-2553** or [customerservice@grail.com](mailto:customerservice@grail.com). However, given the complex nature of genetic testing, we strongly recommend that you obtain the clinical results directly from your healthcare provider and that you discuss test results with your healthcare provider.

## Secondary Data Uses

In compliance with HIPAA, GRAIL may de-identify your health information (including your test results and certain follow-up clinical information). "De-identification" means that all information that could be used to readily identify you, such as your name, address, and date of birth, is removed from your data so that the risk of identifying you is very low. GRAIL may use and disclose your de-identified information for the following: laboratory process and quality-related activities, product development and verification activities, and research and development activities. In order to accomplish these secondary uses, GRAIL may sometimes link multiple de-identified datasets, some of which may be collected from third party data sources, such as healthcare claims databases. Linked datasets will remain de-identified in accordance with HIPAA de-identification standards so the risk of identifying you remains very low. To the extent GRAIL uses identifiable data for research purposes, we would do so only in compliance with HIPAA and subject to review and approval by a committee responsible for ensuring the protection and privacy of research participants.

## Retention of Samples

By agreeing to the Galleri test, you release your rights to the biological samples collected and any results generated from the testing. GRAIL may choose to destroy the sample at the end of the testing process or retain it indefinitely. GRAIL may de-identify your blood sample and use such sample for the purposes described under "Secondary Data Uses" above, to the extent allowed by applicable law. You are not entitled to compensation for the use of your blood sample or rights to any products or discoveries resulting from use of your blood sample. If you do not want your leftover blood sample to be retained or used in the manner described in this document, you may request that your sample be destroyed by contacting the GRAIL Customer Service Department at **833-694-2553** or [customerservice@grail.com](mailto:customerservice@grail.com) within 60 days after you receive your Galleri test result.



Scan QR code  
above or visit  
[Grail.com/hipaa](https://grail.com/hipaa)

## Patient Acknowledgement

By requesting the Galleri test, I confirm that I have read this patient information sheet and any other information provided to me by GRAIL or the ordering healthcare provider, including the purpose, risks, benefits, and alternatives of this test. I have discussed any questions I may have with the ordering healthcare provider, and I understand that if I have any future questions or concerns related to this test, I will speak with the ordering healthcare provider. I understand that my leftover blood sample may be retained indefinitely by GRAIL unless I request its destruction. I hereby agree to take part in this testing. I understand that I will be given a copy of this form to keep for my records.