

# Patient + Provider Discussion Guide



Print and share this guide with your healthcare provider.

Talk to your provider about whether the Galleri<sup>®</sup> test is right for you.

## Who is the Galleri test for?

- The Galleri test is recommended for adults with an elevated risk for cancer, such as those age 50 and older.
- The Galleri test is available by prescription only.
- Use of the Galleri test is not recommended in individuals who are pregnant, 21 years old or younger, or undergoing active cancer treatment.

## Here are topics to discuss with your healthcare provider:

- The following lifestyle factors and health conditions may increase your risk for cancer. Check all that apply to you and discuss these with your provider

- |  |  |
|--|--|
| <input type="checkbox"/> Age 50 years or older                   | <input type="checkbox"/> Immunodeficiency  |
| <input type="checkbox"/> Cancer survivor                         | <input type="checkbox"/> Immunosuppressive therapies after organ transplant                                      |
| <input type="checkbox"/> Family history (parent, sibling, child) | <input type="checkbox"/> Increased BMI (Female $\geq 30$ kg/m <sup>2</sup> or Male $\geq 35$ kg/m <sup>2</sup> ) |
| <input type="checkbox"/> Genetic predisposition (e.g. BRCA)      | <input type="checkbox"/> Liver disease (Cirrhosis or chronic Hepatitis)  |
| <input type="checkbox"/> HPV infection                           | <input type="checkbox"/> Smoke or quit less than 10 years ago  |

- Share your concerns about cancer and why early detection is important to you
- Express your interest in the Galleri test and ask if it is right for you

## Pricing

Most health insurance companies do not cover the cost of the Galleri test. The cost varies depending on the healthcare practice or provider who orders your test. The list price for the Galleri test is \$949.

- You may be eligible for a 12-month, 0% interest, flexible payment plan. Call GRAIL Customer Service at 833-694-2553 to learn more.
- The Galleri test may be eligible for FSA or HSA coverage. Check with your plan to confirm eligibility.

**Important Safety Information:** 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.**

**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.

*See reverse page for healthcare provider information*

# Information for your healthcare provider



**Around 70% of cancer deaths** are caused by cancers without recommended screening.<sup>4,5</sup>



**Only 5 out of >100 known cancer types** have recommended screening options: breast, colorectal, cervical, lung (for those at risk), and prostate.<sup>4,6</sup>

## What is the Galleri test?

The Galleri multi-cancer early detection test screens for many of the deadliest cancers, including those with no recommended screening today.<sup>4,7,8</sup> Galleri identifies DNA shed by cancer cells into the bloodstream before symptoms appear<sup>9</sup> and can be taken annually. In the case of a Cancer Signal Detected result, the test will predict the most likely origin of the cancer signal, helping guide the diagnostic workup.<sup>9</sup> Visit [Galleri.com/50cancers](https://www.galleri.com/50cancers) to learn about what cancers the Galleri test screens for.

## 200,000+ tests completed, 11,000+ prescribing physicians across the US

Test performance validated through large-scale clinical studies with 20,000+ participants<sup>8,9</sup>



**2x the cancers detected**  
In a clinical study, adding the Galleri test to standard-of-care screening\* approximately doubled the number of cancers\*\* detected.<sup>9</sup>



**Low false positive rate** (1 in 200 people without cancer) helps minimize unnecessary diagnostic procedures to confirm cancer.<sup>8,9</sup>

\*Standard-of-care screening recommended by USPSTF (United States Preventive Services Task Force) for breast, cervical, colorectal, lung, and prostate cancer.

\*\*Cancers detected by the early version of the Galleri test that were confirmed by a diagnostic workup.

## There are two possible test results:

### ✓ No Cancer Signal Detected

This result means DNA fragments associated with cancer were not found in the blood sample. The test does not detect all cancers and not all cancers can be detected in the blood. This result does not completely rule out the possibility of cancer.

**Next steps:** Continue with routine cancer screenings.

### ! Cancer Signal Detected

This means DNA fragments often associated with cancer were found in the blood sample. This result will also include a prediction of the tissue type or organ associated with the cancer signal, called a **Cancer Signal Origin**.\*

**Next steps:** This result is not a cancer diagnosis and requires follow-up diagnostic testing, which may include lab work or imaging to confirm cancer.

\*GRAIL, Inc. Data on file: VV-TMF-59592

The Galleri test does not detect a signal for all cancers, and not all cancers can be detected in the blood. False positive and false negative results do occur. The Galleri test should be used in addition to healthcare provider recommended screening tests. See Important Safety Information on the previous page.

## If the Galleri test is right for your patient, to order:

### 1 Complete and fax the Cover Sheet and Test Requisition Form (TRF) to 650-999-9000

The specimen collection kit will be mailed directly to the patient. Please ensure the patient's mailing address is complete and accurate on the TRF.

### 2 Complete a blood draw, no fasting required

To schedule a blood draw with a GRAIL partner laboratory, patients can visit [Galleri.com/schedule](https://www.galleri.com/schedule)

### 3 Receive the results

The results will be faxed to you about two weeks after receiving the sample at the GRAIL laboratory.

Learn more:



[Galleri.com/hcp](https://www.galleri.com/hcp)  
[customerservice@grail.com](mailto:customerservice@grail.com)

833-MY-GALLERI  
(833-694-2553)

1. Surveillance, Epidemiology, and End Results (SEER) Program SEER\*Stat Database: Incidence - SEER Research Limited-Field Data, 21 Regs, 2020 Nov Sub (2000-2018) - Linked To County Attributes - Time Dependent (1990-2018) Income/Rurality, 1969-2019 Counties, National Cancer Institute, DCCPS, Surveillance Research Program, released 2021 Apr, based on the 2020 Nov submission. GRAIL Data on file GR-2023-0098 2. [GRAIL, LLC. Data on file: GA-2023-0205] 3. Cong Z, Ye X, Kurian AW. Elevated cancer risk among individuals with combinations of cancer-related risk factors: A large claims database analysis. American Society of Clinical Oncology (ASCO) [poster]; 2023 Jun 2-6. 4. US Preventive Services Task Force. A,B,C grade recommendations, cancer, screenings [cited 2023 Oct 23]. [https://www.uspreventiveservicestaskforce.org/uspstf/topic\\_search\\_results](https://www.uspreventiveservicestaskforce.org/uspstf/topic_search_results) 5. American Cancer Society. Estimated deaths per year in 2022. Cancer facts & figures 2022. <https://www.cancer.org/research/cancer-facts-statistics/all-cancer-facts-figures/cancer-facts-figures-2022.html> [GRAIL, LLC. Data on file: GA-2021-0065] 6. NIH, National Cancer Institute. What is cancer? [Updated 2021 Oct 11]. <https://www.cancer.gov/about-cancer/understanding/what-is-cancer> 7. American Cancer Society. Cancer facts & figures 2022. <https://www.cancer.org/research/cancer-facts-statistics/all-cancer-facts-figures/cancer-facts-figures-2022.html> [GRAIL, LLC. Data on file: GA-2021-0065] 8. Klein EA, Richards D, Cohn A, et al. Clinical validation of a targeted methylation-based multi-cancer early detection test using an independent validation set. Ann Oncol. 2021 Sep;32(9):1167-77. doi: 10.1016/j.annonc.2021.05.806 9. Schrag D, Beer TM, McDonnell CH, et al. Blood-based tests for multi-cancer early detection (PATHFINDER): a prospective cohort study. Lancet. 2023;402:1251-1260. doi: 10.1016/S0140-6736(23)01700-2

# Welcome

Thank you for choosing Galleri®, the first-of-its-kind multi-cancer early detection test.

## 1 Complete and fax this form

Please ensure the patient information, email, and address are correct and legible; the Galleri kit will be shipped to the patient.

- Fax the completed Test Requisition Form (TRF) with cover sheet to this number:  
**650-999-9000**

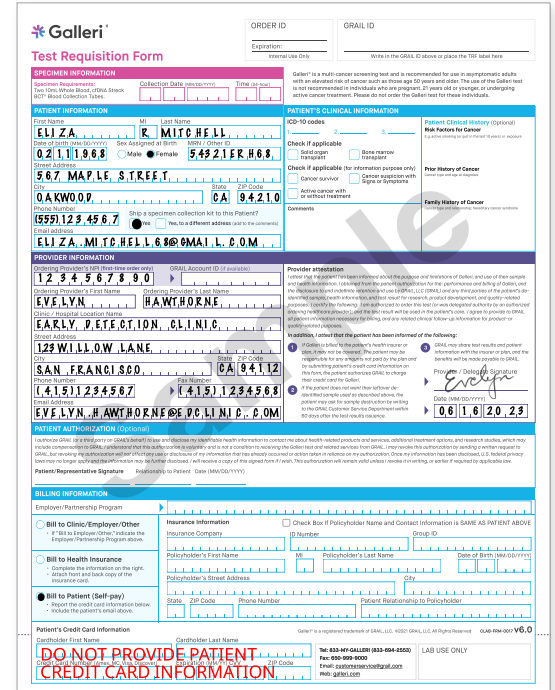
## 2 Expect a fax confirmation

Once we receive your order and verify your information, we will fax you a confirmation and your patient will receive a kit within a week.

- Your test order is not placed until you receive a confirmation from us.

## What to know

- GRAIL partners with labs nationwide for blood draw services. Your patient will be given information about convenient scheduling options when the collection kit arrives ([Galleri.com/schedule](http://Galleri.com/schedule)).
- **The list price of the test is \$949.** Blood draw services are included in the price of the test when a Galleri-contracted site is used. We do not currently bill to insurance, please select 'Bill to Patient (Self-Pay)' on the Test Requisition Form.
- Your patient will be billed directly, once their sample has been processed and the results are made available. **Please DO NOT provide a patient's credit card information.** We will work with your patient directly to collect this information securely.
- Results will be sent to you via FAX to the number indicated on the TRF about 2 weeks from when the sample is received at our lab.




## Reminder

Your patient is required to bring a completed TRF with them to their blood draw appointment.

We will send them a copy of the completed TRF via email. **Please ensure the patient email address is correct on the form.**

## Contact GRAIL Customer Service



Galleri.com  
customerservice@grail.com



833-MY-GALLERI  
(833-694-2553)



FAX:  
650-999-9000

## Fax Cover

Fill in the blank fields below, and fax it along with the fully completed Test Requisition Form (TRF) to GRAIL Customer Service at 650-999-9000.

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**Date:**

**Number of Pages (including cover sheet):**

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### Recipient Information

**To:** GRAIL Customer Service

**FAX Number:** 650-999-9000

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### Sender Information

**From:**

**Re:** New Provider Galleri Order via Discussion Guide

**FAX Number:**

**Phone Number:**

**Message:**

**CONFIDENTIAL INFORMATION ENCLOSED**

STATEMENT OF CONFIDENTIALITY: This facsimile message contains private, privileged, and confidential information intended only for the sole use of the intended individual or entity named above. If the reader of this message is NOT the intended recipient, you are hereby notified that any review, use, dissemination, distribution, sharing, disclosure, or copying of this communication is strictly prohibited. If you are not the intended recipient, please immediately notify us by telephone at 650-771-9752 and destroy the original message. Thank you.



# Test Requisition Form

ORDER ID

Expiration:

Internal Use Only

GRAIL ID

Write in the GRAIL ID above or place the TRF label here

## SPECIMEN INFORMATION

### Specimen Requirements:

Two 10mL Whole Blood, cfDNA Streck BCT® Blood Collection Tubes.

Collection Date (MM/DD/YYYY)

Time (24-hour)

Galleri® is a multi-cancer screening test and is recommended for use in asymptomatic adults with an elevated risk of cancer such as those age 50 years and older. The use of the Galleri test is not recommended in individuals who are pregnant, 21 years old or younger, or undergoing active cancer treatment. Please do not order the Galleri test for these individuals.

## PATIENT INFORMATION

First Name  MI  Last Name

Date of birth (MM/DD/YYYY)  Sex Assigned at Birth  Male  Female MRN / Other ID

Street Address

City  State  ZIP Code

Phone Number  Ship a specimen collection kit to this Patient?  Yes  Yes, to a different address (add to the comments)

Email address

## PATIENT'S CLINICAL INFORMATION

ICD-10 codes  
1.  2.  3.

Check if applicable  
 Solid organ transplant  Bone marrow transplant

Check if applicable (for information purpose only)  
 Cancer survivor  Cancer suspicion with Signs or Symptoms

Active cancer with or without treatment

Comments

Patient Clinical History (Optional)  
**Risk Factors for Cancer**  
E.g. active smoking (or quit in the last 10 years) or exposure

**Prior History of Cancer**  
Cancer type and age at diagnosis

**Family History of Cancer**  
Cancer type and relationship; hereditary cancer syndrome

## PROVIDER INFORMATION

Ordering Provider's NPI (first-time order only)  GRAIL Account ID (if available)

Ordering Provider's First Name  Ordering Provider's Last Name

Clinic / Hospital Location Name

Street Address

City  State  ZIP Code

Phone Number  Fax Number

Email Address

### Provider attestation

I attest that the patient has been informed about the purpose and limitations of Galleri, and use of their sample and health information. I obtained from the patient authorization for the: performance and billing of Galleri, and the disclosure to and indefinite retention and use by GRAIL, LLC (GRAIL) and any third parties of the patient's de-identified sample, health information, and test result for research, product development, and quality-related purposes. I certify the following: I am authorized to order this test (or was delegated authority by an authorized ordering healthcare provider); and the test result will be used in the patient's care. I agree to provide to GRAIL all patient information necessary for billing, and any related clinical follow-up information for product-or quality-related purposes.

### In addition, I attest that the patient has been informed of the following:

- If Galleri is billed to the patient's health insurer or plan, it may not be covered. The patient may be responsible for any amounts not paid by the plan and by submitting patient's credit card information on this form, the patient authorizes GRAIL to charge their credit card for Galleri.
- If the patient does not want their leftover de-identified sample used as described above, the patient may ask for sample destruction by writing to the GRAIL Customer Service Department within 60 days after the test results issuance.
- GRAIL may share test results and patient information with the insurer or plan, and the benefits will be made payable to GRAIL.

Provider / Delegate Signature

Date (MM/DD/YYYY)

## PATIENT AUTHORIZATION (Optional)

I authorize GRAIL (or a third party on GRAIL's behalf) to use and disclose my identifiable health information to contact me about health-related products and services, additional treatment options, and research studies, which may include compensation to GRAIL. I understand that this authorization is voluntary and is not a condition to receiving the Galleri test and related services from GRAIL. I may revoke this authorization by sending a written request to GRAIL, but revoking my authorization will not affect any use or disclosure of my information that has already occurred or action taken in reliance on my authorization. Once my information has been disclosed, U.S. federal privacy laws may no longer apply and the information may be further disclosed. I will receive a copy of this signed form if I wish. This authorization will remain valid unless I revoke it in writing, or earlier if required by applicable law.

Patient/Representative Signature  Relationship to Patient  Date (MM/DD/YYYY)

## BILLING INFORMATION

Employer/Partnership Program

**Bill to Clinic/Employer/Other**  
• If "Bill to Employer/Other," indicate the Employer/Partnership Program above.

**Bill to Health Insurance**  
• Complete the information on the right.  
• Attach front and back copy of the insurance card.

**Bill to Patient (Self-pay)**  
• Report the credit card information below.  
• Include the patient's email above.

**Insurance Information**  Check Box If Policyholder Name and Contact Information is SAME AS PATIENT ABOVE

Insurance Company  ID Number  Group ID

Policyholder's First Name  MI  Policyholder's Last Name  Date of Birth (MM/DD/YYYY)

Policyholder's Street Address  City

State  ZIP Code  Phone Number  Patient Relationship to Policyholder

## Patient's Credit Card Information

Cardholder First Name  Cardholder Last Name

Credit Card Number (Amex, MC, Visa, Discover)  Expiration (MM/YY) CVV  ZIP Code

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