

# Patient + Provider Discussion Guide



Print this guide to help start the conversation and share your interest in the Galleri<sup>®</sup> test with your healthcare provider.

## Who is the Galleri test for?

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 is intended to be used in addition to, and not replace, other cancer screening tests your healthcare provider recommends.



**Age is the biggest risk factor for cancer.** In fact, adults over age 50 are 13 times more likely to have cancer compared to people under the age of 50.

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

- Share your concerns about cancer and why early detection is important to you
- If over the age of 50, discuss your increased risk of cancer
- Discuss your family history and any other risk factors for cancer
- Express your interest in the Galleri test and ask if it is right for you

## Pricing

Remember, 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.

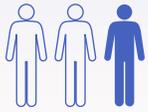
You may be able to use your flexible spending account (FSA) or health savings account (HSA) to pay for the test. Check with your benefit administrator or insurance provider to determine eligibility.

**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:** GRAIL’s clinical laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and accredited by the College of American Pathologists (CAP). 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. The Galleri test is intended for clinical purposes.

# Information for your healthcare provider

## Detecting cancer at early stages increases the likelihood of successful treatment



More than 1 out of 3 individuals will develop cancer in their lifetime.<sup>1</sup>



Around 70% of cancers deaths are from cancers without recommended screening options<sup>2</sup>



Only 5 out of 100+ known cancer types have recommended screening tests.<sup>3</sup>

### What is the Galleri test?

Galleri is a multi-cancer early detection (MCED) test that looks for a signal shared by more than 50 types of cancer through a simple blood draw.<sup>4</sup> Most of these cancers have no recommended screening and often go unnoticed until symptoms appear. Adding the Galleri test to recommended cancer screening increases the chance of early cancer detection and may lead to successful treatment.<sup>5</sup> The Galleri test looks for a signal associated with active cancer and does not predict future genetic risk for cancer. The test detects DNA methylation patterns from tumor-derived cell-free DNA (cfDNA). For a full list of cancers diagnosed with a Galleri Cancer Signal Detected result, visit: [Galleri.com/50cancers](https://galleri.com/50cancers).

### A new era of cancer screening is here

**20,000+**  
clinical study participants

Test performance supported by large clinical studies.<sup>4,5</sup>

**2x more cancers detected**

In a clinical study Galleri approximately doubled the number of screen-detected cancers.<sup>5</sup>

**Low false positive rate**

0.5% (1 in 200 people) minimizes unnecessary diagnostic procedures to confirm cancer.<sup>4,5</sup>

### There are two possible test results:

#### ✓ No Cancer Signal Detected

The Galleri test looked for a cancer signal and did not find one  
This result does not completely rule out the possibility of cancer.  
Continue with routine recommended cancer screening tests.

#### ! Cancer Signal Detected

The Galleri test detected a signal associated with cancer. This result will also include one or two predictions of the tissue type or organ associated with the cancer signal, called "Cancer Signal Origins."  
This result requires follow-up diagnostic testing to confirm cancer. This is not a cancer diagnosis, diagnostic tests should be ordered to confirm cancer.

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. See Important Safety Information on prior page.

### If the Galleri test is right for your patient, start ordering with these 3 steps:

1

#### Complete and fax the Cover Sheet and Test Requisition (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.

At your office or at one of our partner laboratories. At no additional cost, patients can visit [Galleri.com/schedule](https://galleri.com/schedule) to schedule a blood draw.

3

#### Receive the results

Results will be shared with you about 2 weeks after the sample is received at the GRAIL laboratory via fax.

Learn more:



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



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

1. American Cancer Society. Lifetime Risk of Developing or Dying From Cancer. <https://www.cancer.org/cancer/risk-prevention/understanding-cancer-risk/lifetime-probability-of-developing-or-dying-from-cancer.html>. 2. American Cancer Society. Cancer Facts & Figures 2022. Atlanta: American Cancer Society; 2022 <https://www.cancer.org/research/cancer-facts-statistics/all-cancer-facts-figures/cancer-facts-figures-2022.html>. Data on file GA-2021-0065. 3. American Cancer Society. Cancer Facts & Figures 2022. Atlanta: American Cancer Society; 2022 <https://www.cancer.org/research/cancer-facts-statistics/all-cancer-facts-figures/cancer-facts-figures-2022.html>. Data on file GA-2021-0065. 4. 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;32(9):1167-77. DOI:<https://doi.org/10.1016/j.annonc.2021.05.806>. 5. Schrag D, McDonnell CH, Naduld L, et al. PATHFINDER: A Prospective Study of a Multi-Cancer Early Detection Blood Test. Presentation at European Society of Medical Oncology (ESMO) Congress September 9-13, 2022; Paris, France. [https://grail.com/wp-content/uploads/2022/09/Schrag\\_9030\\_ESMO-2022\\_Pathfinder-Main\\_Proffered-Paper-Oral-Presentation.pdf](https://grail.com/wp-content/uploads/2022/09/Schrag_9030_ESMO-2022_Pathfinder-Main_Proffered-Paper-Oral-Presentation.pdf).

# 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**

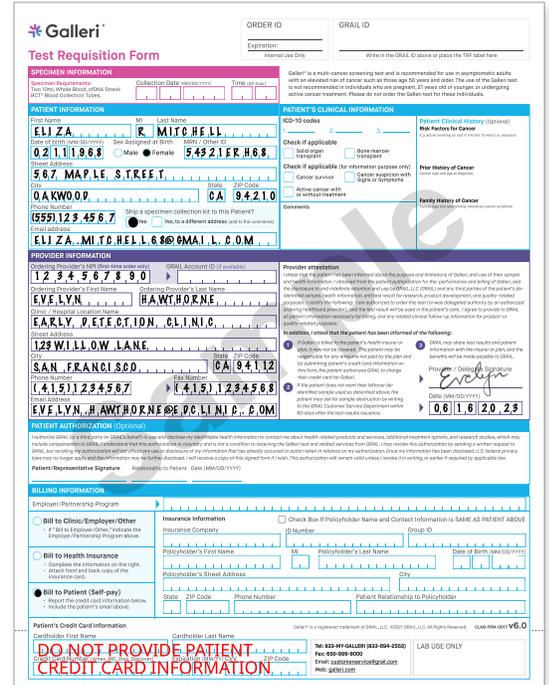
## 2 Expect a fax confirmation

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)

MM DD YYYY HH MM

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 MRN / Other ID

Street Address

City State ZIP Code

Phone Number Ship a specimen collection kit to this Patient?

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:

- 1. 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.
2. 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.
3. 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

Bill to Health Insurance

Bill to Patient (Self-pay)

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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