

## **GALLERI (early cancer detection)**

### **A**

- Adrenal Cortical Carcinoma
- Ampulla of Vater
- Anus
- Appendix, Carcinoma

### **B**

- Bile Ducts, Distal
- Bile Ducts, Intrahepatic
- Bile Ducts, Perihilar
- Bladder, Urinary
- Bone
- Breast

### **C**

- Cervix
- Colon and Rectum

### **E**

- Esophagus and Esophagogastric Junction

### **G**

- Gallbladder
- Gastrointestinal Stromal Tumor
- Gestational Trophoblastic Neoplasms

### **K**

- Kidney

## L

- Larynx
- Leukemia
- Liver
- Lung
- Lymphoma (Hodgkin and Non-Hodgkin)

## M

- Melanoma of the Skin
- Merkel Cell Carcinoma
- Mesothelioma, Malignant Pleural

## N

- Nasal Cavity and Paranasal Sinuses Nasopharynx
- Neuroendocrine Tumors of the Appendix
- Neuroendocrine Tumors of the Colon and Rectum
- Neuroendocrine Tumors of the Pancreas

## O

- Oral Cavity
- Oropharynx (HPV-Mediated, p16+)
- Oropharynx (p16-) and Hypopharynx
- Ovary, Fallopian Tube and Primary Peritoneum

## P

- Pancreas, exocrine
- Penis
- Plasma Cell Myeloma and Plasma Cell Disorders
- Prostate

## S

- Small Intestine
- Soft Tissue Sarcoma of the Abdomen and Thoracic Visceral Organs
- Soft Tissue Sarcoma of the Head and Neck
- Soft Tissue Sarcoma of the Retroperitoneum
- Soft Tissue Sarcoma of the Trunk and Extremities
- Soft Tissue Sarcoma Unusual Histologies and Sites
- Stomach

## T

- Testis

## U

- Ureter, Renal Pelvis
- Uterus, Carcinoma and Carcinosarcoma
- Uterus, Sarcoma

## V

- Vagina
- Vulva

# Understanding the test report

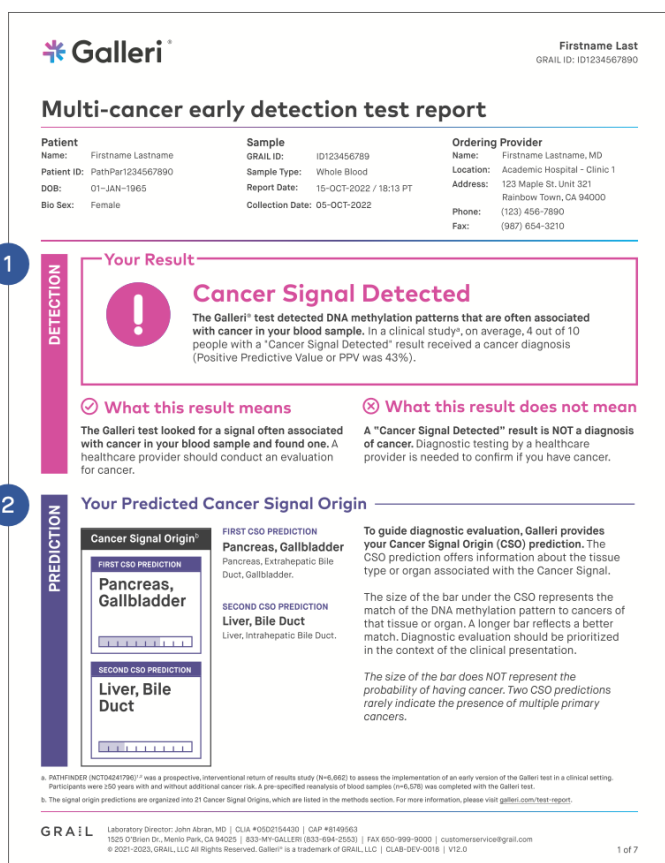
## Galleri® is a screening test for the detection of a signal shared by multiple cancers

When a cancer signal is detected, the Galleri multi-cancer early detection test also predicts the origin of the cancer signal. The Galleri test is intended to complement, not replace, recommended single cancer screening tests such as colonoscopy or mammography.

## The Galleri Test Results Report provides the following information

### 1 The presence or absence of a cancer signal

### 2 The predicted Cancer Signal Origin(s)



**Galleri®**  
Firstname Last  
GRAIL ID: ID1234567890

**Multi-cancer early detection test report**

Patient	Sample	Ordering Provider
Name: Firstname Lastname	GRAIL ID: ID123456789	Name: Firstname Lastname, MD
Patient ID: PathPat1234567890	Sample Type: Whole Blood	Location: Academic Hospital - Clinic 1
DOB: 01-JAN-1965	Report Date: 15-OCT-2022 / 18:13 PT	Address: 123 Maple St. Unit 321 Rainbow Town, CA 94000
Bio Sex: Female	Collection Date: 05-OCT-2022	Phone: (123) 456-7890 Fax: (987) 654-3210

**1 DETECTION**

**Your Result**

**Cancer Signal Detected**

The Galleri® test detected DNA methylation patterns that are often associated with cancer in your blood sample. In a clinical study\*, on average, 4 out of 10 people with a "Cancer Signal Detected" result received a cancer diagnosis (Positive Predictive Value or PPV was 43%).

**What this result means**

The Galleri test looked for a signal often associated with cancer in your blood sample and found one. A healthcare provider should conduct an evaluation for cancer.

**What this result does not mean**

A "Cancer Signal Detected" result is NOT a diagnosis of cancer. Diagnostic testing by a healthcare provider is needed to confirm if you have cancer.

**2 PREDICTION**

**Your Predicted Cancer Signal Origin**

**Cancer Signal Origin**

**FIRST CSO PREDICTION**  
Pancreas, Gallbladder

**SECOND CSO PREDICTION**  
Liver, Bile Duct

**THIRD CSO PREDICTION**  
Liver, Bile Duct

To guide diagnostic evaluation, Galleri provides your Cancer Signal Origin (CSO) prediction. The CSO prediction offers information about the tissue type or organ associated with the Cancer Signal.

The size of the bar under the CSO represents the match of the DNA methylation pattern to cancers of that tissue or organ. A longer bar reflects a better match. Diagnostic evaluation should be prioritized in the context of the clinical presentation.

The size of the bar does NOT represent the probability of having cancer. Two CSO predictions rarely indicate the presence of multiple primary cancers.

\* A REFINER (NCT04247902) was a prospective, interventional return of results study (N=6,682) to assess the implementation of an early version of the Galleri test in a clinical setting. Participants were 550 years with and without additional cancer risk. A pre-specified analysis of blood samples (N=4,576) was completed with the Galleri test.  
b. The signal origin predictions are organized into 21 Cancer Signal Origins, which are listed in the methods section. For more information, please visit [galleri.com/test-report](https://galleri.com/test-report).

**GRAIL** Laboratory Director: John Abram, MD | CLIA #0502154430 | CAP #149563  
1525 O'Brien Dr., Menlo Park, CA 94025 | 833-MY-GALLERI (833-694-2553) | FAX 650-999-9000 | customerservice@grail.com  
© 2021-2023, GRAIL, LLC All Rights Reserved. Galleri® is a trademark of GRAIL, LLC | CLAB-02V-0018 | V12.0

1 of 7

### 3 Next steps - considerations for healthcare providers (Cancer Signal Detected)

### 4 Additional information about the Galleri test, including test performance in clinical trials

#### Note:

The Galleri Test Results Report may indicate that the test has been Canceled, Amended, or Corrected with the reason noted in the comments section.

If you have questions about the Galleri Test Results Report, please contact GRAIL Customer Service **833-694-2553** and ask to speak with a Medical Information Specialist.

## Types of results

### No Cancer Signal Detected

If DNA methylation patterns that are often associated with cancer are not detected in the patient's blood sample, then a "No Cancer Signal Detected" result will be reported.

The Galleri test does not detect a signal for all cancers, and not all cancers can be detected in the blood. A Galleri result of "No Cancer Signal Detected" does not rule out cancer. The Galleri test does not determine a patient's genetic cancer risk. Patients should be advised to continue participating in recommended cancer screening programs at the appropriate intervals. Adding Galleri to annual wellness visits can improve the chances of finding cancer early.

### Cancer Signal Detected

If DNA methylation patterns often associated with cancer are detected in the patient's blood sample, then a "Cancer Signal Detected" result will be reported.

To guide diagnostic evaluation, Galleri provides one or two Cancer Signal Origin (CSO) predictions. The size of the bar under the CSO represents the match of the DNA methylation pattern to cancers of that tissue or organ. A longer bar reflects a better match. A test result of "Cancer Signal Detected" requires confirmatory diagnostic evaluation by medically established procedures (e.g., imaging) to confirm cancer. Diagnostic evaluation should be prioritized in the context of the clinical presentation.

Among clinical study<sup>1</sup> participants diagnosed with cancer following a "Cancer Signal Detected" result, the first CSO prediction was accurate 84% of the time, while the first and second CSO predictions were accurate 88% of the time.

In some cases, the Galleri test may detect a cancer signal, but diagnostic evaluation may not result in a cancer diagnosis. This could mean that cancer is not present or testing was not able to detect cancer, possibly because the cancer is located in a different part of the body.

A complimentary retest may be requested under certain circumstances. Please contact GRAIL Customer Service **833-694-2553** for more information.

## Frequently asked questions

### Which cancers can the Galleri test detect?

In the Circulating Cell-free Genome Atlas (CCGA) Sub-Study 3,<sup>2</sup> the Galleri test detected a signal shared by 50+ cancer types as defined by the American Joint Committee on Cancer classification system. To see the cancer types detected by a shared signal with the Galleri test, please visit [Galleri.com/cancers-detected](https://www.galleri.com/cancers-detected). Sensitivities by cancer class for the Galleri test from the CCGA3 study are shown in the 'Clinical Trials' section of the test report.

### Which Cancer Signal Origins does the Galleri test report?

A Galleri "Cancer Signal Detected" test result includes a prediction of one or two of 21 possible Cancer Signal Origins: anus; bladder/urothelial tract; bone and soft tissue; breast; cervix; colon/rectum; head and neck; kidney; liver/bile duct; lung; lymphoid lineage; melanocytic lineage; myeloid lineage; neuroendocrine cells of lung or other organs; ovary; pancreas/gallbladder; plasma cell lineage; prostate; stomach/esophagus; thyroid gland; and uterus.

### Is Cancer Signal Origin the same as cancer type?

No. When the Galleri test detects a cancer signal, it predicts one or two of 21 Cancer Signal Origins based on distinct DNA methylation data that reflect the biology and the tissue type or organ associated with the cancer signal. The predicted "Cancer Signal Origin(s)" is provided to help guide the diagnostic evaluation needed to confirm the presence of cancer and determine the cancer type.

### What is the positive predictive value of the Galleri test?

In a clinical study<sup>1</sup>, on average, 4 out of 10 people with a "Cancer Signal Detected" result received a cancer diagnosis. The Positive Predictive Value or PPV was 43%. See Positive Predictive Value in the 'Clinical Trials' section of the test report for details.

#### 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.



**Galleri.com**  
customerservice@grail.com



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



**1525 O'Brien Drive**  
Menlo Park, CA 94025

#### References:

1. 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.
2. 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):1167-1177. doi: 10.1016/j.annonc.2021.05.806.

The PATHFINDER Study (NCT04241796) was a prospective, interventional, return of result study to examine use of an early version of Galleri (n=6621) in clinical practice. Participants were adults ≥50 years of age with and without additional cancer risk factors. Participant samples were also tested with Galleri.

The Circulating Cell-free Genome Atlas (CCGA) Study (NCT02889978) was a prospective, case-control, observational study designed to determine whether a screening test could detect a cancer signal and predict signal origin for multiple cancers. CCGA3 was a sub-study that included cancer (n=2823) and non-cancer (n=1254) participants without a history of cancer.