Galleri®

Multi-Cancer Early Detection Test Report

Patient

Name: Firstname Lastname
Patient ID: 1234567890
DOB: 01-JAN-1965
Bio Sex: Female

Sample

GRAIL ID: GRA-123456
Sample Type: Whole Blood
Report Date: 20-DEC-2024 / 18:54 ET
Collection Date: 08-DEC-2024

Ordering Provider

Name: Firstname Lastname, MD
Location: Clinical Office
Address: 123 Main Street, Suite 100
Anytown, CA 12345
Phone: (123) 456-7890
Fax: (123) 456-7899

Your Result

No Cancer Signal Detected

In a clinical study[a], on average 1 out of 100 people with a No Cancer Signal Detected result received a cancer diagnosis (NPV was 99%).

What this result means

The Galleri test looked for a DNA methylation signal associated with cancer in your blood sample and did not find a signal. Continue with routine cancer screening tests your healthcare provider recommends.

What this result does not mean

Although the Galleri test did not find a Cancer Signal in your blood, **this does not rule out the possibility of cancer.** The Galleri test does not detect all cancers and not all cancers can be detected in the blood.

This result does not predict whether you will develop cancer in the future.

Talk to your healthcare provider about the following topics

Continue routine cancer screenings

Discuss which screening tests are right for you. Screening is recommended for colon/rectum, breast, cervix, lung (for those at risk), and prostate cancers.

Repeat testing with Galleri

Adding Galleri to annual wellness visits can improve the chances of finding cancer early when it is more treatable. Talk to your healthcare provider about whether annual testing with Galleri is appropriate for you.

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a. PATHFINDER 2[1] is a prospective, single-arm, return-of-results trial designed to evaluate Galleri's performance, safety, and implementation in an intended-use population. The trial enrolled 35,878 adults aged 50 and older across healthcare systems in the U.S. and Canada who were eligible for routine, guideline-recommended screening and had no signs or symptoms raising clinical suspicion of cancer.

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Multi-Cancer Early Detection Test Report

What this screening test did

With the Galleri test, you took a step forward to better understand your health. The Galleri test allowed you to screen for a Cancer Signal shared by multiple cancers, many of which do not have recommended screening tests. Unlike single cancer screening, Galleri does not individually test for specific types of cancer. The Galleri test should be used in addition to routine cancer screening recommended by your healthcare provider.

- In order to deliver your results, the Galleri test studied more than 500,000 methylation sites in your DNA that are most informative for detecting the presence of a current Cancer Signal and predicting its origin in the body.
- As of September 2025, the Galleri test has been used by over 780,000 people, across 380,000 completed and ongoing study participants, and over 400,000 tests in clinical practice. In PATHFINDER 2, more than 7 times as many cancers were detected when the Galleri test was added to standard-of-care screening for breast, cervical, colorectal, and lung cancers[1].

For a full list of cancers that Galleri was able to detect, visit: **galleri.com/cancers**

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Do you have questions?

If you are a patient, please contact the healthcare provider who ordered this test if you have questions about Galleri or your test result. We are also here to help.

Give us a call at **833-694-2553** or email **customerservice@grail.com**

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About the Galleri® test

Test Description

The Galleri test is a qualitative, next-generation sequencing-based screening test that detects DNA methylation patterns on cell-free DNA (cfDNA) in whole blood. Cells in the body release cfDNA fragments into the bloodstream. This can include cancer cells. cfDNA from cancer cells has specific methylation patterns that can be recognized by Galleri as a Cancer Signal and contain information about the organ associated with the Cancer Signal. Methylation is a natural process that can change the activity of DNA. The test identifies DNA methylation patterns on cell-free DNA.

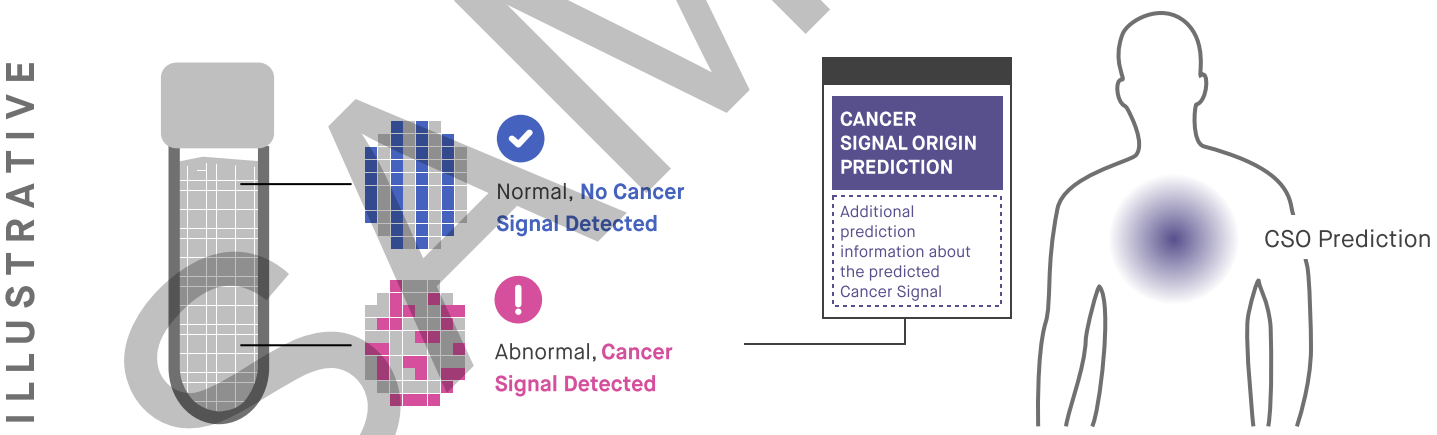
- **Galleri has been trained by the world's largest cancer DNA methylation database, created by GRAIL.** The process uses advanced technology and pattern recognition to detect a Cancer Signal and predict its Origin.
- **Galleri is intended for use in adults with an elevated risk of cancer (e.g., ≥ 50 years old).** The Galleri test does not detect a signal for all cancers and should be used in addition to routine cancer screening tests. When Galleri detects a Cancer Signal, a diagnostic evaluation by a qualified healthcare provider is required to establish a cancer diagnosis.

The Galleri test can be ordered by a healthcare provider only.

How the Galleri test works - visual explanation, not your test results.

1 Cancer Signal Detection

2 Cancer Signal Origin Prediction



In order to deliver your results, the Galleri test studied more than 500,000 methylation sites in your DNA that are most informative for detecting the presence of a current Cancer Signal and predicting its origin in the body. Galleri looks at methylation patterns to determine whether it comes from healthy (normal) or cancer (abnormal) cells.

If a Cancer Signal is detected, then Galleri compares the methylation pattern of the Cancer Signal to the patterns of 18 possible Cancer Signal Origin (CSO) predictions and reports the CSO prediction that has the strongest match. Additional prediction information may be reported in some cases.

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About the Galleri® test

Methods

The Galleri test is a qualitative, next-generation sequencing-based screening test that detects DNA methylation patterns on cell-free DNA (cfDNA) in whole blood. Cells in the body release cfDNA fragments into the bloodstream. The Limit of Detection (LOD95) of the Galleri test using abnormal coverage is 0.2 (abnormal coverage is the mean number of unique abnormal fragments observed per CpG in a sample).

This version of the Galleri test has been validated in a clinical validation analysis[2] using a subset from PATHFINDER[3] and Circulating Cell-free Genome Atlas (CCGA)[4,5] clinical studies. The Galleri test has 18 possible Cancer Signal Origin predictions: Anus; Bladder, Urothelial Tract; Bone and Soft Tissue; Breast; Cervix; Colon, Rectum; Head and Neck; Hematopoietic and Lymphoid Organs; Kidney; Liver, Bile Duct; Lung; Melanocyte-containing Tissues / Skin; Ovary; Pancreas, Gallbladder; Prostate; Stomach, Esophagus; Thyroid; and Uterus. Additional prediction information about the predicted Cancer Signal may be reported and may include one of the following possibilities: Human Papillomavirus (HPV) Associated Methylation Signal; Squamous Cell Signal of Head and Neck, Lung, and Esophagus; Neuroendocrine Signal; Female Reproductive Tract Signal; Lymphoid Lineage; Myeloid Lineage or Plasma Cell Lineage.

Clinical Trials

The following is data from clinical trials and is not your data. For more details, please visit **galleri.com/test-report**

- **Galleri Test Performance Characteristics in the PATHFINDER 2 Study[1]**
  PATHFINDER 2 is a prospective, interventional, multi-center study in North America evaluating the safety and performance of the Galleri test in participants at least 50 years old. Test performance reported here is based on the first 12 months of follow-up time for 25,000 participants. Galleri results from a prior version of the test[2] were returned to study investigators, and participants with Cancer Signal Detected results underwent targeted diagnostic evaluation guided by Cancer Signal Origin (CSO) predictions. Participants with No Cancer Signal Detected test results were encouraged to continue to follow their healthcare providers' cancer screening recommendations. Cancer status and utilization of guideline-recommended (routine) cancer screening tests are assessed on an annual basis for 3 years for all participants.

- **Galleri Test Performance Characteristics in the CCGA sub-study[4,5]**
  CCGA was a prospective, case-control, observational study, and CCGA3 a pre-specified sub-study of 2,823 cancer participants (cases) and 1,254 non-cancer participants (controls). Participants were men and women aged 20 years and older (81% 50 years or older) without a prior history of cancer. Cancer participants were enrolled after diagnosis (or with a high suspicion of cancer) before any cancer treatment.

  In this CCGA3 sub-study, the Galleri test detected a shared Cancer Signal shared across more than 50 types of cancer (defined by the American Joint Committee on Cancer[6]). A subset of CCGA3 study including 944 cancer participants was included in the 2024 clinical validation analysis of this test version[2].

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About the Galleri® test

Clinical Trials (Continued)

Galleri Test Performance

PATHFINDER 2 performance was established using a prior version of Galleri. A statistical approach known as non-inferiority was used to show the current version of the test is comparable to the prior version[2].

Metrics	PATHFINDER 2[1]	
	Rate (95% CI)	Details
Positive Predictive Value (PPV)	61.6% (54.9–67.8%)	133 participants had cancer diagnosed among 216 participants with Cancer Signal Detected results.
Negative Predictive Value (NPV)	99.1% (99.0–99.3%)	22,749 participants had no cancer diagnosis among 22,945 participants with No Cancer Signal Detected results who completed a 12-month follow up.
Specificity	99.64% (99.55–99.71%)	22,749 participants had accurate No Cancer Signal Detected results among 22,832 participants with no cancer diagnosis who completed a 12-month follow-up.
False Positive Rate[b]	0.36% (0.29–0.45%)	83 participants had Cancer Signal Detected results among 22,832 participants with no cancer diagnosis who completed a 12-month follow-up.
Proportion of cancers detected in Stage I and II	53.5%	38 Stage I and 23 Stage II cancers were detected. 74% of Stage I-II cancers do not have recommended screening options.
Proportion of cancers detected in Stage I, II, and III	69.3%	38 Stage I, 23 Stage II, and 18 Stage III cancers were detected.

- **Positive Predictive Value:** The proportion of people with Cancer Signal Detected results diagnosed with cancer.
- **Negative Predictive Value:** The proportion of people with No Cancer Signal Detected results without a cancer diagnosis.
- **Specificity:** The proportion of people without cancer who received No Cancer Signal Detected results.
- **False Positive Rate:** The proportion of people without cancer who received Cancer Signal Detected results.
- **95% Confidence Interval (CI):** A range of values that you can be 95% certain contains a true parameter of interest.

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b. False Positive Rate is equal to (1 - Specificity).

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Clinical Trials (Continued)

Galleri Test Performance: Sensitivity

Metrics	CCGA3[4,5]	
	Rate (95% CI)	Details
Test Sensitivity: Cancers responsible for 2/3 of the cancer deaths in the US[7]	**76.3%** (74.0–78.5%)	1,040 cancer participants received Cancer Signal Detected results among 1,363 participants with cancers responsible for 2/3 of all cancer deaths in the US.
Test Sensitivity: Overall	**51.5%** (49.6–53.3%)	1,453 cancer participants received Cancer Signal Detected results among 2,823 participants with cancer across cancer classes and stages.
Metrics	**PATHFINDER 2[1]**	
Episode Sensitivity: Cancers responsible for 2/3 of the cancer deaths in the US	**73.7%** (65.6–80.4%)	98 participants received Cancer Signal Detected results among 133 participants with cancers diagnosed within 12 months that are responsible for 2/3 of all cancer deaths in the US.
Episode Sensitivity: Overall	**40.4%** (35.3–45.8%)	133 participants received Cancer Signal Detected results among 329 participants with cancer diagnosed within 12 months.

Note: Test sensitivity was evaluated in CCGA3 where participants' cancer status was known at the time of testing. In PATHFINDER 2, episode sensitivity was assessed, as participants' cancer status was unknown and diagnoses occurred within 12 months of the blood draw, allowing assessment of the test's performance in a true screening setting.

Galleri Test Performance: Accuracy

Metrics	PATHFINDER 2[1]	
	Rate (95% CI)	Details
Cancer Signal Origin (CSO) Prediction	**91.7%** (85.8–95.3%)	122 participants had correct first CSO prediction of 133 participants with cancer and Cancer Signal Detected results.

- If detected, this version of the Galleri test will also provide Additional Prediction Information that further contextualizes the CSO Prediction.
- **Sensitivity:** The proportion of people with cancer who received Cancer Signal Detected results.
- **Accuracy: Cancer Signal Origin (CSO) Prediction[c]:** The proportion of correctly predicted CSO among study participants with a Cancer Signal Detected test result and cancer diagnosis.

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c. In a 2024 analysis[2], overall specificity and sensitivity of Cancer Signal Detected were maintained and Cancer Signal Origin prediction accuracy was improved.

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About the Galleri® test

Clinical Trials (Continued)

Cancer Signal detection for various cancer classes in the CCGA3 sub-study[5]

Note: PATHFINDER 2 was not powered to measure individual cancer type sensitivity.

Cancer Classes[5]	Sensitivity[5], proportion of true positives	95% Confidence Interval (CI)
Liver, Bile Duct	93.5%	(82.5–97.8%)
Head and Neck	85.7%	(77.8–91.1%)
Esophagus	85.0%	(76.7–90.7%)
Pancreas	83.7%	(76.6–89.0%)
Ovary	83.1%	(72.2–90.3%)
Colon, Rectum	82.0%	(76.2–86.7%)
Anus	81.8%	(61.5–92.7%)
Cervix	80.0%	(60.9–91.1%)
Urothelial Tract	80.0%	(49.0–94.3%)
Lung	74.8%	(70.3–78.7%)
Plasma Cell Neoplasm	72.3%	(58.2–83.1%)
Gallbladder	70.6%	(46.9–86.7%)
Stomach	66.7%	(48.8–80.8%)
Sarcoma	60.0%	(42.3–75.4%)
Lymphoma	56.3%	(48.9–63.5%)
Other[d]	50.8%	(38.4–63.2%)
Melanoma	46.2%	(23.2–70.9%)
Lymphoid Leukemia	41.2%	(28.8–54.8%)
Bladder	34.8%	(18.8–55.1%)
Breast	30.5%	(26.7–34.6%)
Uterus	28.0%	(21.6–35.5%)
Myeloid Neoplasm	20.0%	(5.7–51.0%)
Kidney	18.2%	(11.8–26.9%)
Prostate	11.2%	(8.5–14.6%)
Thyroid	0.0%	(0.0–21.5%)

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d. Other cancers include: Adrenal (n = 1); ampulla of Vater (n = 1); Brain (n = 1); Choriocarcinoma (n = 1); Mesothelioma (n = 7); Non-Melanoma Non-Basal Cell Cancer / Squamous Cell Carcinoma Skin Cancer (n = 2); Penis (n = 1); Small Intestine (n = 13); Testis (n = 6); Vagina (n = 2); Vulva (n = 7); and other / unspecified (n = 10).

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About the Galleri® test

Warnings, Precautions, and Limitations

The Galleri test performance may be subject to the collection, storage, and transportation of blood samples. The test is not intended for other sample types. Any sample handling outside of the suggested procedures may affect test performance.

Use of the Galleri test is not recommended in individuals who are pregnant, 21 years old or younger, or undergoing active cancer treatment.

A Cancer Signal Detected result is not a diagnosis of cancer. The results of the Galleri test must be confirmed by diagnostic evaluation recommended by qualified healthcare providers following standard medical practice. These results should be interpreted in the context of the individual's clinical risk factors. Diagnostic decisions are the responsibility of the treating physician. A No Cancer Signal Detected result does not eliminate the possibility that cancer is present or will occur in the future. Individuals who receive a No Cancer Signal Detected result should continue with all recommended cancer screening options at intervals appropriate for the individual. The Galleri test should not replace, supersede, or otherwise alter the use or frequency of standard-of-care cancer screening or detection modalities.

The Galleri test does not detect a signal for all cancers. Cancers evaluated in the CCGA3 sub-study[5] are listed at galleri.com/test-report

The test performance in cancer classes not observed in CCGA3[5] and PATHFINDER 2[1] is unknown. If a Cancer Signal Detected result is returned, the Galleri test also reports a CSO prediction, which must be confirmed by diagnostic evaluation. In some cases, the Galleri test may produce a Cancer Signal Detected result, but diagnostic evaluation may not confirm a cancer diagnosis. This could mean that the individual has cancer that is difficult to identify by the selected diagnostic evaluation, that the individual has cancer but it is located elsewhere, or that the individual does not have cancer and the Galleri test result is a false positive.

Sensitivity and Cancer Signal Origin accuracy observed in cancer participants from the case-control CCGA3 sub-study[5] may be higher than in the general screening population because the Cancer Signal may be stronger in cancers detected by standard medical practice.

Performance of sequential Galleri tests has not been evaluated.

The Galleri test can be ordered by a healthcare provider 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 (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. The GRAIL clinical laboratory is regulated under CLIA to perform high-complexity testing. The Galleri test is intended for clinical purposes.

References

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