Galleri®
Multi-cancer early detection

What if we could detect cancer through a simple blood draw

Make the Galleri® test a part of your comprehensive, personalized patient care

Welcome to multi-cancer early detection

Improve the chances of detecting cancer early

Can detect a shared cancer signal across more than 50 cancer types, many of which lack recommended screening[1]

Complements recommended screening to improve the chances of early cancer detection

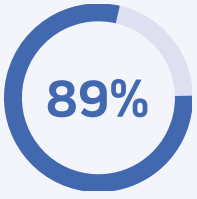
Predicts the cancer signal origin with high accuracy to help guide next steps to diagnosis[1]

Requires only a simple blood draw with results in 10 business days

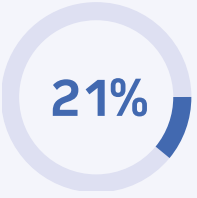
Based on SEER data, cancers that lack screening options drive the majority of cancer deaths

Today, the majority of cancers are found too late, when results are often deadly.[2] The earlier that cancer is diagnosed, the greater the chance of successful outcomes. Several cancer types, such as breast, colorectal, cervical, prostate and lung, can be detected through screening tests. However, the majority of cancer deaths each year are from cancers with no recommended screening.

Higher survival when cancer is detected early



5-year cancer-specific survival rate when cancer is **localized at diagnosis**[3]



5-year cancer-specific survival rate when cancer is **metastatic at diagnosis**[3]

Unscreened cancers cause the majority of cancer deaths

of cancer deaths due to cancers without recommended screening[4]

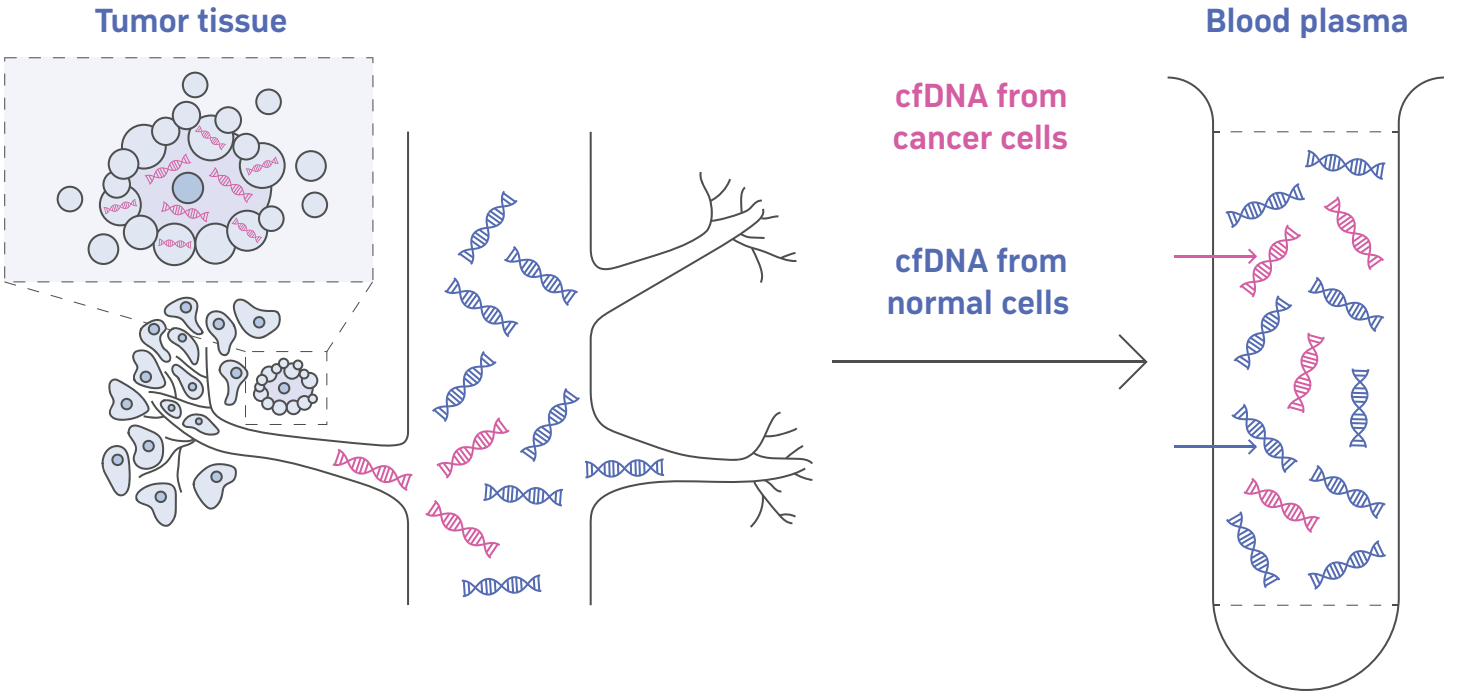
Early cancer signal can be found in the blood

The Galleri® test works by analyzing methylation patterns of cell-free DNA (cfDNA) in the bloodstream using next-generation sequencing (NGS) and machine-learning algorithms. All cells—cancer and non-cancer—shed DNA into the bloodstream.

Methylation is a process used by cells to regulate gene expression. cfDNA can carry cancer- and tissue-specific information in its methylation patterns.

Different cancers shed DNA into the bloodstream at different rates. The proportion of cfDNA from cancer cells in the blood tends to increase as cancer progresses.

The greater the proportion of cfDNA from cancer cells in a sample, the stronger the cancer signal and the more likely it is to be detected by the Galleri test.



Prediction of the Cancer Signal Origin helps direct diagnostic workup

The DNA methylation patterns also provide information about the Cancer Signal Origin(s). When a cancer signal is detected, the Galleri test predicts the origin of the signal with high accuracy to help guide the next steps to diagnosis.*

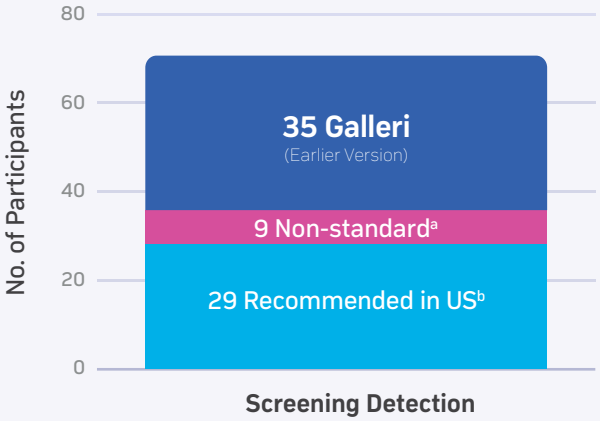
*Galleri does not detect all cancers. False positive and false negative results can occur. In the Circulating Cell-free Genome Atlas sub-study (CCGA3), a prospective, case-controlled, observational study that included cancer (n=2823) and noncancer (n=1254) participants without a history of cancer, Cancer Signal Origin (CSO) prediction accuracy was 88.7% for cancer participants with a cancer signal detected.

Galleri® test performance

The Galleri test complements recommended cancer screenings

Screening with the early version of Galleri more than **doubled the number** of cancers[§] detected by standard-of-care (SoC)[†] screening alone.[‡]

Cancers Identified Within One Year of Galleri Testing: Participants with Cancers Detected by Screening.[8]



(a) 3 thyroid and 6 melanoma

(b) breast, cervical, colorectal, lung, and prostate cancer

[§]Cancers detected by the early version of Galleri that were confirmed by diagnostic workup

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

[‡]The PATHFINDER study was conducted with an earlier version of Galleri

Minimizes false positives and predicts Cancer Signal Origin (CSO) with high accuracy (in true positives)

99.5%
Specificity[1,8]

A low false-positive rate of 0.5% helps minimize unnecessary diagnostic procedures.

88%
CSO Accuracy**

In predicting the top 2 CSOs among true positive participants, helping guide diagnostic workup[8]

In study participants with cancer (true positives), when a cancer signal was detected by Galleri, the first or second predicted CSO was accurate 88% of the time.

**CSO = Cancer Signal Origin

43.1% PPV[8]

PPV = Positive Predictive Value, is the proportion of people with a "Cancer Signal Detected" test result who will have a confirmed cancer diagnosis following diagnostic work-up.

Detects deadly cancers with a high sensitivity***

76.3%
Sensitivity[1]

in 12 Pre-Specified Deadly Cancers (51.5% Overall Sensitivity)

12 pre-specified deadly cancers that are responsible for 2/3 of cancer deaths per year include[1,6]:

Anus, Bladder, Colon/rectum, Esophagus, Head and neck, Liver/bile duct, Lung, Lymphoma, Ovary, Pancreas, Plasma cell neoplasm, Stomach

***The Circulating Cell-free Genome Atlas (CCGA) Study (NCT02889978) is 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.[1]

Using the Galleri® test in your practice

Convenient ordering and actionable results

The Galleri test **should be used in addition to guideline-recommended cancer screenings such as mammography, colonoscopy, PSA, or cervical cancer screening**. It is recommended for use in adults with an elevated risk of cancer, such as those aged 50 or older. Not recommended in individuals who are pregnant, 21 years or younger, or those undergoing active cancer treatment.

Ordering options

» Online via Provider Portal
» With a paper Test Requisition Form (TRF)

Sample collection

» In your office
» Through reference labs

Results reporting + next steps

» Test results released to provider via Provider Portal or fax within **10 business days** from receipt of sample in lab

No Cancer Signal Detected

Continue routine recommended screening and consider annual* Galleri testing

Cancer Signal Detected + Top Predicted Cancer Signal Origin(s)

Further cancer evaluation through diagnostic work-up

*Annual testing with Galleri provides the opportunity to detect more cancers early. Modeled data suggests that adding Galleri to annual wellness visits can improve the chances of finding cancer early, when it is more treatable.

The Galleri test does not detect all cancers. False positive and false negative results do occur. 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.

Determine if Galleri® is right for your patients

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.**

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.

Learn more at:

Galleri.com
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1. 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. **2**. Siegel RL, Miller KD, Fuchs HE, Jemal A. Cancer Statistics, 2021. CA Cancer J Clin. 2021 Jan;71(1):7 – 33. **3**. Surveillance, Epidemiology, and End Results (SEER) Program (www.seer.cancer.gov) SEER*Stat Database: Incidence - SEER 18 Regs Research Data, Nov 2018 Sub. Includes persons aged 50-79 diagnosed Noone AM, Howlader N, Krapcho M, et al. (eds). SEER Cancer Statistics Review, 1975-2015, National Cancer Institute, Bethesda, MD, http://seer.cancer.gov/csr/1975_2015/, based on November 2017 SEER data submission, posted to the SEER website April 2018. **4**.Among individuals 50-79 years old. Assumes screening is available for all prostate, breast, cervical, and colorectal cancer cases and 43% of lung cancer cases (based on estimated proportion of lung cancers that occur in screen-eligible individuals older than 40 years). Estimated deaths per year in 2021 from American Cancer Society Cancer Facts and Figures 2021. Available at: http://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2021/cancer-facts-and-figures-2021.pdf. Data on file GA-2021-0065. **5**. Noone AM, Howlader N, Krapcho M, et al. (eds).SEER Cancer Statistics Review, 1975–2015, National Cancer Institute, Bethesda, MD, http://seer.cancer.gov/csr/1975_2015/, based on November 2017 SEER data submission, posted to the SEER website April 2018. **6**. U.S. Mortality Data 1969-2016 (www.seer.cancer.gov); based on 2015-2016. **7**. American Cancer Society. Cancer Facts & Figures 2021. Atlanta: American Cancer Society; 2021. **8**. Schrag D, et al. Presentation at European Society for Medical Oncology (ESMO) Congress; September 9-13, 2022. The PATHFINDER Study was conducted with an earlier version of Galleri.

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