

An opportunity for firefighters to go further with cancer screening

Firefighter occupational cancer is the #1 cause of line-of-duty deaths.¹



Cancers with recommended screenings

Lung
(at risk individuals)



Cervical

Colorectal

Breast

Prostate

Cancers without recommended screenings

Ureter

Bone

Kidney

Pancreas

Gastrointestinal Stromal Tumor

Melanoma

Liver/Bile-duct

Head & Neck
(Soft Tissue Sarcoma)

Testis

Uterus

Larynx

Plasma Cell Neoplasm

Soft Tissue Sarcoma
(4 additional types)

Lymphoma

Leukemia

Penis

Bladder

Ovary

Appendix

Gallbladder

Stomach

Mesothelioma

Oral Cavity

Small Intestine

Adrenal Cortical Carcinoma

Merkel Cell Carcinoma

Vulva

Anus

Esophagus

Vagina

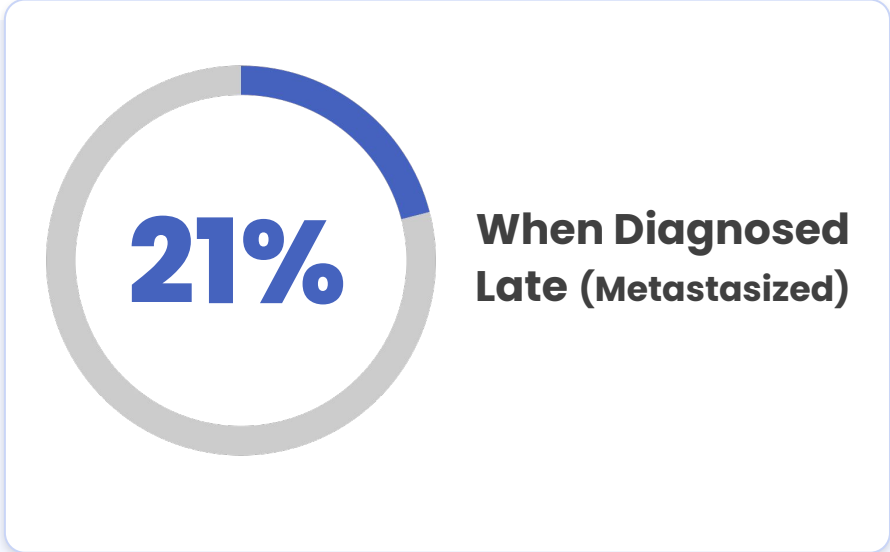
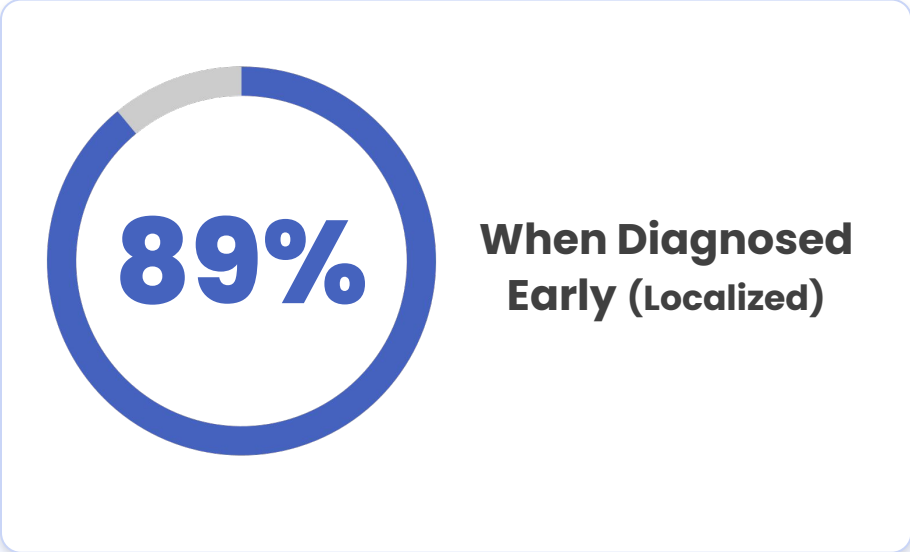
U.S. Preventive Services Task Force (USPSTF) grades A,B,C recommended cancer screening tests.

https://uspreventiveservicestaskforce.org/uspstf/topic_search_results?



Early diagnosis can improve 5-year cancer survival rate¹

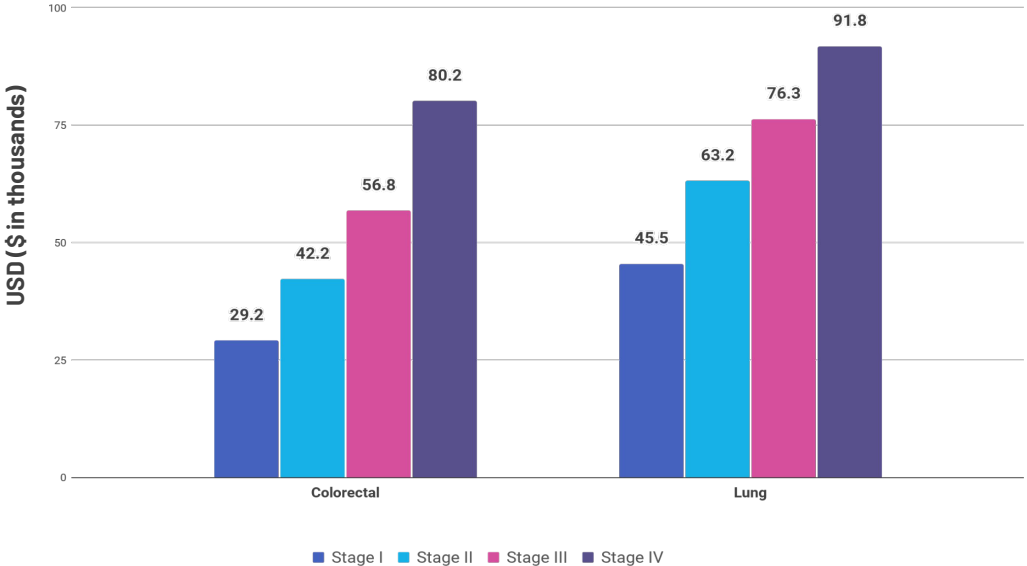
5-year survival rates (cancer-specific across all cancers¹)



¹“Early/Localized” includes invasive localized tumors that have not spread beyond organ of origin, “Late/Metastasized” includes invasive cancers that have metastasized beyond the organ of origin to other parts of the body.

Cancer treatment also costs less when diagnosed in earlier stages

Cost of Medical Care by Cancer and Stage^{1*} (Net Year 1)



Treatment of early stage cancer costs up to **7 times less** than late stage cancer²

*Estimates of net direct costs of medical care were calculated as total cost for cases minus total cost for controls, for year 1 by each cancer site, stage, and age <65 y group. All estimates are presented in thousands.



INTRODUCING

Galleri[®]

multi-cancer early detection

- **Screens for** a signal shared by **50+ types of cancer**^{1,2}
- **Predicts origin of the cancer signal** to guide next steps to diagnosis
- Access via a **simple blood draw**

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 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 looks for a signal associated with active cancer and does not predict future genetic risk for cancer. Galleri should be used in addition to healthcare provider recommended screening tests.

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. Amin MB, et al. (Eds). *AJCC Cancer Staging Manual* (8th edition). Springer International Publishing: American Joint Commission on Cancer; 2017.

Galleri was built on a strong network of clinical study institutions



GRAIL has and continues to conduct multiple studies with over 300,000 participants enrolled to-date as part of its clinical development program



Galleri was made commercially available in June 2021.

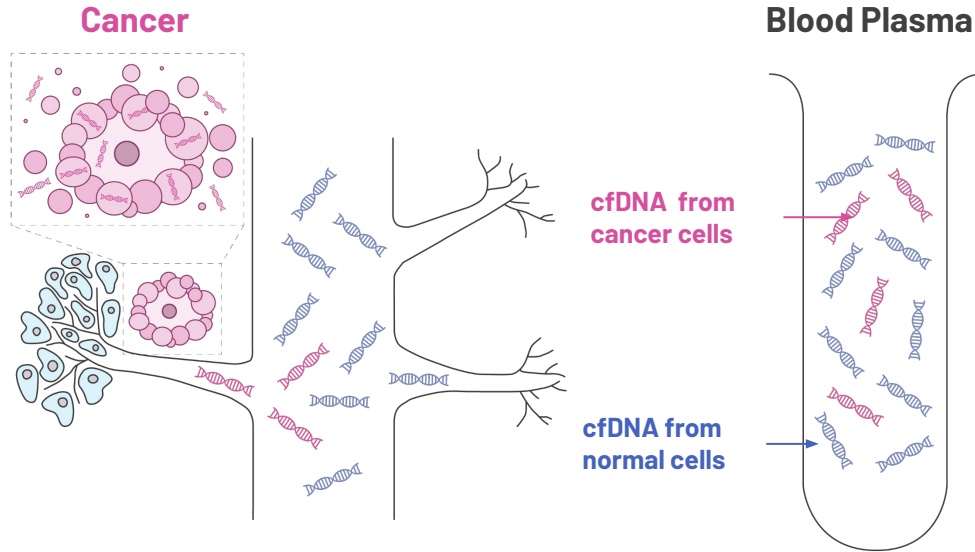
Clinical Study Institutions



Memorial Sloan Kettering
Cancer Alliance



Cancers growing in the body shed DNA into the bloodstream



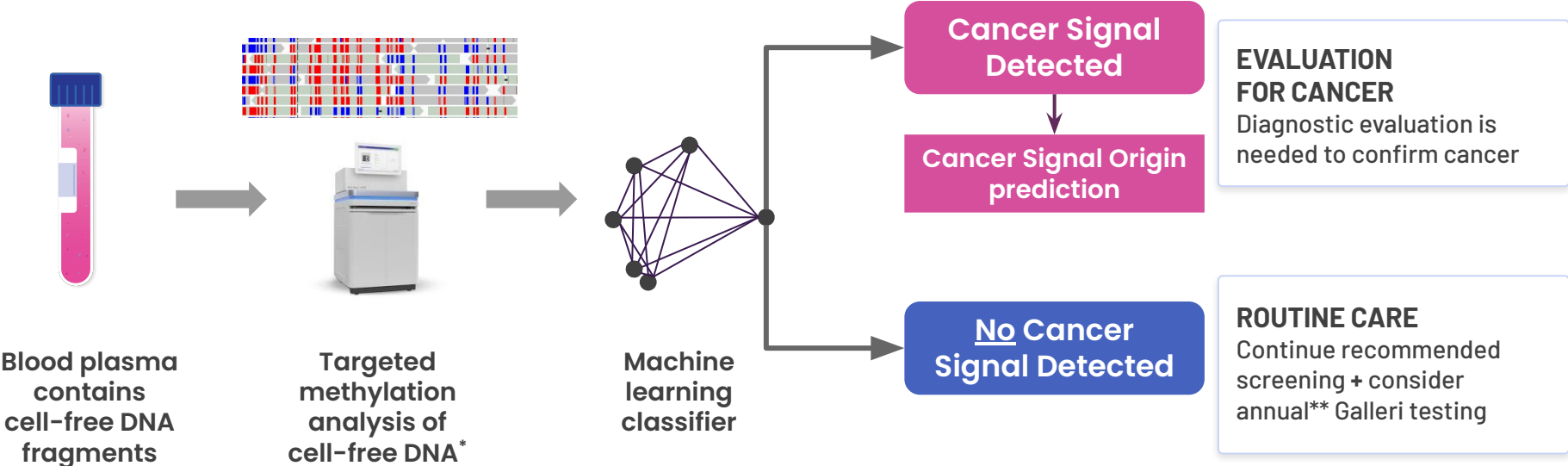
[See how the technology works](#)

Cell-free DNA (cfDNA): fragments of DNA - from healthy cells and cancer cells - that can be found in the bloodstream

DNA methylation: epigenetic mechanism by which methyl groups are attached to DNA, potentially modifying the function of genes

Methylation patterns in cancer: Certain DNA methylation patterns suggest the presence of cancer

Galleri looks for a unique “fingerprint” of cancer by analyzing methylation patterns on cell-free DNA



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 result do occur. Gallerie should be used in addition to healthcare provider recommended cancer screening tests.

* Targeted probes pull out fragments matching regions of interest. Adapted from Liu MC, et al. *Ann Oncol.* 2020;31(6):745-759.
** Annual testing with Galleri provides the opportunity to detect more cancers early, when there may be more treatment options

Galleri is supported by robust clinical data, helping with the #1 ranked medical fear for Americans: cancer¹

RELIABLE

0.5%

false positive rate²

(found in study participants without cancer)

TARGETED

76.3%

sensitivity

(in cancers responsible for 2 of 3 US cancer deaths;³
Overall test sensitivity was 51.5%)

ACTIONABLE

89%

accuracy²

(in predicting cancer signal origin,
found in study participants with cancer)

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

*The group of cancers responsible for two-thirds of annual US cancer deaths included anus, bladder, colon/rectum, esophagus, head and neck, liver/bile-duct, lung, lymphoma, ovary, pancreas, plasma cell neoplasm, and stomach.

In the Circulating Cell-free Genome Atlas sub-study (CCGA3), a prospective, case-controlled, observational study that included cancer (n=2823) and non-cancer (n=1254) participants without a history of cancer, a Cancer Signal Origin (CSO) prediction accuracy was 88.7% for cancer participants with a cancer signal detected

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.

1. MedicareAdvantage.com. [What Medical Condition Are You Most Afraid Of?](#) Published May 5, 2021. 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. 3. Amin MB, et al (Eds). AJCC Cancer Staging Manual (8th edition). Springer International Publishing: American Joint Commission on Cancer; 2017.

Galleri was able to detect a signal shared across 50+ cancer types in clinical studies – including 45 cancer types without recommending screening

Breast	Cervical	Colorectal	Lung	Prostate
<ul style="list-style-type: none"> Adrenal Cortical Carcinoma Ampulla of Vater Anus Appendix, Carcinoma Bile Ducts, Distal Bile Ducts, Intrahepatic Bile Ducts, Perihilar Bladder, Urinary Bone Esophagus and Esophagogastric Junction Gallbladder Gastrointestinal Stromal Tumor Gestational Trophoblastic Neoplasms Kidney Larynx Leukemia 	<ul style="list-style-type: none"> Liver Lymphoma (Hodgkin and Non-Hodgkin) Melanoma of the Skin Merkel Cell Carcinoma Mesothelioma, Malignant Pleural Nasal Cavity and Paranasal Sinuses Nasopharynx Neuroendocrine Tumors of the Appendix Neuroendocrine Tumors of the Colon and Rectum Neuroendocrine Tumors of the Pancreas Oral Cavity Oropharynx (HPV-Mediated, p16+) Oropharynx (p16-) and Hypopharynx Ovary, Fallopian Tube and Primary Peritoneum Pancreas, exocrine Penis 	<ul style="list-style-type: none"> Plasma Cell Myeloma and Plasma Cell Disorders 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 Testis Ureter, Renal Pelvis Uterus, Carcinoma and Carcinosarcoma Uterus, Sarcoma Vagina Vulva 		

Galleri does not detect all cancers and all cancers cannot be detected in the blood.

**In an analysis of employer claims,
Galleri had the potential to detect**

98%

**of cancer types
via a shared cancer signal¹**

(Data from employees aged 50+)

The Galleri test does not detect a signal for all cancers and not all cancers can be detected in the blood.

Sensitivity varies by cancer type^{1,2}

Since Galleri detects DNA shed into the blood by developing cancers, **the more aggressive the cancer, the more likely it is to be detected**

- Galleri demonstrated 76.3% sensitivity rates¹ in cancers responsible for $\frac{2}{3}$ of cancer deaths³ and this goes over 80% for the most serious cancers

Galleri is a screening test and does not diagnose cancer. Diagnostic testing is needed to confirm cancer.

¹ Klein E. et al. Ann Oncol. 2021;32(9):1167-77.

² Chen X et al. Clin Cancer Res. 2021;27(15):4221-4229.

³ U.S. Mortality Data 1969-2016 (www.seer.cancer.gov); based on 2015-2016. American Cancer Society. Cancer Facts & Figures 2021.

Pre-specified cancers that cause 2/3 of cancer deaths in the US

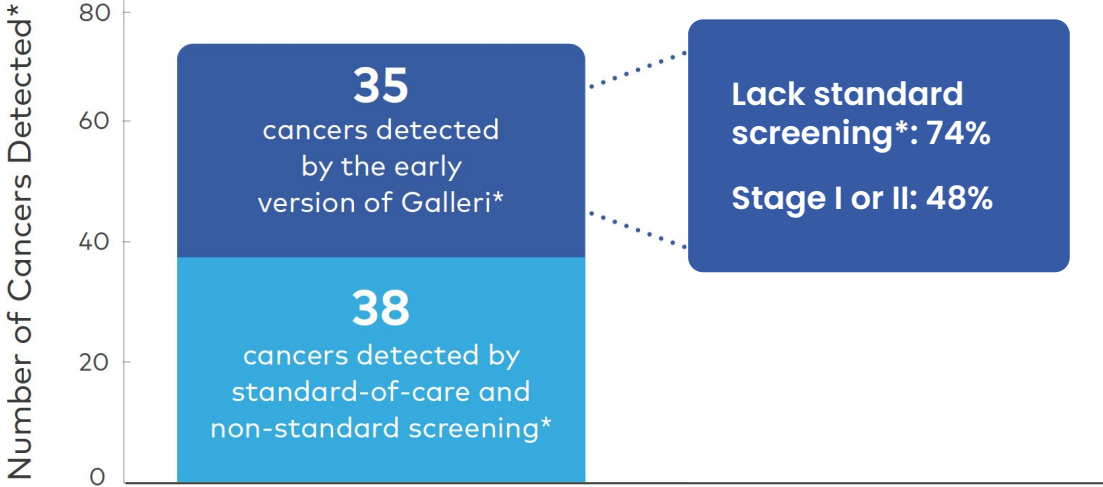
Other cancers

Cancer Classes ¹	Sensitivity ¹ , proportion of true positives
Liver/Bile-duct	93.5%
Head and Neck	85.7%
Esophagus	85.0%
Pancreas	83.7%
Ovary	83.1%
Colon/Rectum	82.0%
Anus	81.8%
Cervix	80.0%
Urothelial Tract	80.0%
Lung	74.8%
Plasma Cell Neoplasm	72.3%
Gallbladder	70.6%
Stomach	66.7%
Sarcoma	60.0%
Lymphoma	56.3%
Other	50.8%
Melanoma	46.2%
Lymphoid Leukemia	41.2%
Bladder	34.8%
Breast	30.5%
Uterus	28.0%
Myeloid Neoplasm	20.0%
Kidney	18.2%
Prostate	11.2%
Thyroid	0.0%

Maximize the chances of early cancer detection

Adding MCED to standard-of-care screening approximately doubled the number of cancers detected*

These include cancers without existing guideline recommended screening¹ and early-stage cancers



* Cancers detected refer to cancers confirmed by diagnostic workup after screening with the early version of Galleri or standard and non-standard screening. Standard-of-care or standard screening refers to USPSTF (United States Preventive Services Task Force) recommended screening for breast, cervical, colorectal, lung and prostate cancers. Cancers detected by non-standard screening refers to those that lack USPSTF screening recommendations, such as thyroid and melanoma.

Modeled data shows adding Galleri to recommended screening could result in a 50% reduction in late-stage cancer incidence¹

This stage shift from late to earlier stages shows the potential for a

**26%
reduction**

in 5-year cancer-related mortality,¹ when adding an earlier version of Galleri to usual care.

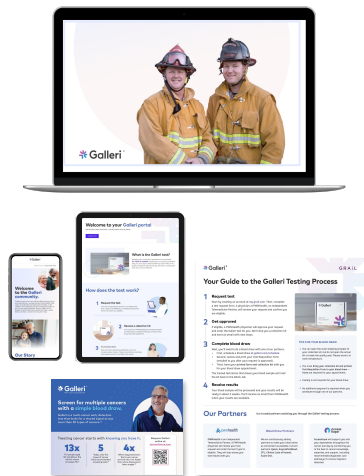
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Late stage defined as stages III + IV. MCED results based upon fast tumor growth model. Usual care represents real-world cancer diagnostic processes (e.g., screening, incidental detection, symptomatic workup) as captured by SEER. Data on stage-specific incidence and 5-year survival of all invasive cancers in people aged 50-79 years diagnosed between 2006-2015. Performance of MCED test in a state-transition model (interception model) when added to usual care.

The Galleri test is part of a comprehensive, guided experience

1

Awareness & Education



2

Galleri Onsite Event

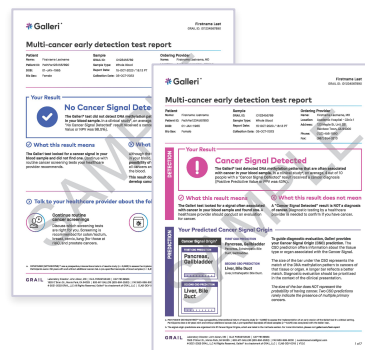
Test requires a prescription by a physician. If approved, blood draw is conducted onsite by a phlebotomist.



3

Return of Results to Provider

(and return of results to firefighter within about 2-3 weeks of receipt of blood sample at GRAIL Laboratory)



Sample Test Reports

4

“Cancer Signal Detected” Support



Based on a clinical study of people ages 50 to 79 around 1% are expected to receive a cancer signal detected result. After diagnostic evaluation, around 40% of these people are expected to have a confirmed cancer diagnosis.¹



There is no upfront investment, charge for unused test kits, or implementation fee

Cost of Test

Firefighters: **\$649**

(billable only if test results are returned)



+ Wraparound Support (optional)

Included

- **Phlebotomy support only** (if individual works through their own ordering provider)
- **Full wrap-around support** (includes phlebotomy and ordering provider)

+ Implementation & Client Support Services

Included

- Department communications
- Custom landing page and online ordering configuration
- GRAIL Care Navigation
- Reporting
- Account management



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 a signal for 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.



Thank you!



In clinical studies,
**Galleri® detected a signal shared
by 50+ cancers, including
45 cancers that do not have
recommended screening**

Galleri should be used in addition to healthcare provider recommended screening tests.

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<https://www.galleri.com/the-galleri-test/types-of-cancer-detected>

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American Joint Commission on Cancer; 2017

United States Preventive Services Task Force (USPSTF) recommended cancer screening.

https://uspreventiveservicestaskforce.org/uspstf/topic_search_results?



US-GA-2300293-1
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Ureter Bone **Kidney** Pancreas
Gastrointestinal Stromal Tumor
Melanoma
Liver/Bile-duct **Lung** **Head & Neck**
(at risk individuals) (Soft Tissue Sarcoma)
Testis Uterus Lymphoma
Plasma Cell Neoplasm Larynx
Cervical **Colorectal**
Leukemia Penis Bladder
Appendix Gallbladder
Stomach Soft Tissue Sarcoma
(4 additional types)
Breast **Prostate**
Small Intestine Merkel Cell Carcinoma
Ovary Anus Vagina
Vulva Adrenal Cortical Carcinoma Oral Cavity
Mesothelioma **Esophagus**

External recognition for the Galleri test



The Atlantic

2022 Breakthroughs of the Year





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US-GA-2300293-1
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(at risk individuals) (Soft Tissue Sarcoma)
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Ovary Anus Vagina
Vulva Adrenal Cortical Carcinoma Oral Cavity
Mesothelioma **Esophagus**

Appendix



The Galleri test has seen increasing market traction since our commercial launch in June 2021

100,000+

tests completed across
GRAIL's key channels

As of June 12, 2023¹

7,100+

prescribing physicians
across the US

As of June 12, 2023¹



Eligibility Criteria for the Galleri Test

1



Individuals age

50
& above

This option is based on age groups that were included in clinical trials studying the safety and effectiveness of Galleri.

2



Individuals age

40-49

with certain
risk factors

This option includes the 50+ age group, plus adults ages [40-49, your choice] with certain risk factors, based on scientific data supporting elevated risk for cancer in this age group; Galleri has not been studied in individuals under 50.

• AT LEAST ONE of the following:

- Cancer survivor who was diagnosed at least 5 years ago, *excluding basal and squamous cell carcinoma of the skin*
- Currently smokes or quit smoking less than 10 years ago

Risk factors that have an elevated risk for some cancer types but need additional evidence to quantify the risk:

- Cirrhosis or chronic Hepatitis B or C Infection
- Infection with certain strains of HPV (e.g. HPV 16 or 18)
- Known hereditary cancer syndrome:
Confirmation and documentation of a gene mutation associated with increased cancer risk (e.g., Li-Fraumeni syndrome, Hereditary Breast and Ovarian Cancer syndrome [BRCA1/2], Lynch syndrome, CHEK2)

OR

• AT LEAST TWO of the following:

- First degree relative with cancer, *excluding basal and squamous cell carcinoma of the skin*
- History of HIV infection
- Current use of immunosuppressive therapies after organ transplantation

BMI:

- Female ≥ 30 kg/m²
- Male ≥ 35 kg/m²



Galleri should be used in addition to healthcare provider recommended screening tests, such as mammography, colonoscopy, lung cancer screening (for those at risk), PSA, or cervical cancer screening.

US-GA-2200231-3 CONFIDENTIAL & PROPRIETARY

PATHFINDER study at the European Society for Medical Oncology (ESMO) Congress 2022 reinforces Galleri's clinical support

6,578

patients aged 50 years or older
(in the study)

Also featured in:

**POPULAR
SCIENCE**

**The
Guardian**

Adding the Galleri Multi-Cancer Early Detection (MCED) screening to standard of care screening **more than doubled the number of cancers detected**

(Early version of Galleri)

Participants reported **high satisfaction and low negative psychological impact** with MCED Screening

(Early version of Galleri)

40% of the Galleri-detected new cancers were stage I or II

(Early version of Galleri)

The Galleri-predicted Cancer Signal Origin (CSO) had **88% accuracy*** and enabled **targeted diagnostic workups**

(Current version of Galleri)

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.

*In the PATHFINDER study, Cancer Signal Origin (CSO) prediction accuracy was 88% for participants with a cancer diagnosis among study participants with "Cancer Signal Detected" test result.

<https://www.popsci.com/health/blood-test-detect-cancer-early-stage/>

<https://www.theguardian.com/science/2022/sep/11/galleri-blood-test-multiple-cancers-before-clear-symptoms-study>

Schrag D, 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.

Receiving a “No Cancer Signal Detected” result could be very meaningful to employees*

76%

of market research respondents agree it would **help to address one of their top health anxieties**^{*1}

A Galleri result of No Cancer Signal Detected does not rule out cancer. The Galleri test is intended to be used in addition to, and not replace, other cancer screening tests such as mammography, colonoscopy, lung cancer screening (for those at risk), PSA, or cervical cancer screening.

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 subjective effect of Galleri results on anxiety was not studied in clinical studies. Market research conducted by Ipsos Group S.A. Study demographics included 1,000 respondents who were full-time employees working at companies with at least 3000 employees: 15% of sample aged 65+, 70% of sample aged 50-64; 15% aged under 50 with cancer risk factors. Respondents were a representative mix across gender, region, race, ethnicity.

†Defined as individuals who have:

At least one of these risk factors: cirrhosis or chronic Hepatitis B or C infection, infection with certain strains of HPV (e.g., 16 or 18), known hereditary cancer syndrome, had cancer at least 3 years ago, and/or are current smokers or quit smoking less than 10 years ago, OR At least two of these risk factors: documented genetic predisposition to cancer, first degree relative with cancer, HIV, use immunosuppressive therapies after organ transplantation, diabetes, and/or high BMI (i.e., ≥30 for females and ≥35 for males).

1. % Selecting Somewhat or Strongly Agree, 5-point scale. Base: All Respondents (n=1000), Q330: “Now, please imagine that after using Product X you have received a ‘No cancer signal detected’ result. To what extent do you agree or disagree with the following statement: Receiving a ‘No cancer signal detected’ result would help to address one of my top health anxieties.”

Ipsos Market Research Grail Data on File: GA-2023-0102.

“...This sounds awesome and would help with my peace of mind, even understanding the limitations of it...”²

- Market research respondent, employee, male, 50 years old



2. Q200: “Please share your initial impressions of Product X in as much detail as possible. Feel free to comment on positive and/or negative aspects from your point of view. Include any questions you have about how the testing process works.”

GRAIL Market Research Data on File: GA-2022-0089.

