Understanding the Galleri® Test

Cancer screening saves lives, but **70%** of cancer deaths are caused by cancers without recommended screening tests.*1,2 The Galleri® multi-cancer early detection (MCED) test can help find these cancers.

Among the hundreds of cancer types, we routinely screen for about five cancers (colon, breast, cervical, lung, and prostate).[2]

With a simple blood draw, **Galleri detects 50+ types of cancer before symptoms appear — when they can be easier to treat and are potentially curable.**[3]

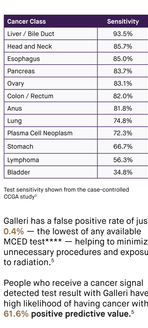
Galleri is the only available MCED test with demonstrated performance in patients being screened for cancer,** **Galleri has been rigorously studied in case-controlled and interventional studies, and has extensive real-world experience.**[3-5]

380,000+
Clinical Trial Participants

370,000+
Commercial Tests Completed
As of June 30, 2023

In PATHFINDER 2, the largest interventional MCED study conducted in the U.S., the Galleri test **increased the number of cancers detected more than seven-fold** when added to recommended screenings for breast, cervical, colorectal, and lung cancers in a broad asymptomatic population.[5]

Galleri approximately tripled the number of cancers detected when added to standard-of-care screening tests, which include prostate cancer, in addition to breast, cervical, colorectal, and lung screening.[5]



†MCED-detected refers to cancers diagnosed within 12 months following a positive MCED test result.

‡Screen-detected refers to cancer diagnosed following USPSTF grade A/B/C recommendations, which include screening for breast, cervical, colorectal, lung, and prostate cancers.

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Galleri Test Sensitivity for 12 Cancers Responsible for 2/3 Cancer Deaths in the U.S.

Galleri is especially sensitive to many of the deadliest cancers that are typically caught too late — like pancreatic, liver, and ovarian*** — and about half of Galleri-detected cancers are found at an early stage.[3,6] Galleri's ability to correctly identify individuals who actually have cancer (sensitivity) is **76.3%** for the 12 cancers responsible for two-thirds of U.S. cancer deaths, based on the case-controlled CCGA study.[3] The overall sensitivity in that study was 51.5%.[3]

Cancer Class	Sensitivity
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%
Lung	74.8%
Plasma Cell Neoplasm	72.3%
Stomach	66.7%
Lymphoma	56.3%
Bladder	34.8%

Test sensitivity shown from the case-controlled CCGA study[3]

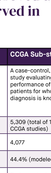
Galleri has a false positive rate of just **0.4%** — the lowest of any available MCED test**** — helping to minimize unnecessary procedures and exposure to radiation.[5]

People who receive a cancer signal detected test result with Galleri have a high likelihood of having cancer with a **61.6% positive predictive value.**[5]

When a cancer signal is found, **Galleri provides a cancer signal of origin with >90% accuracy** to help guide an efficient diagnostic work-up.[3]

How the Galleri Test Works

Cancer can stay hidden in the body for months or years, but many cancers leave clues in the blood — in the form of DNA released by the cancer cells — long before they cause symptoms.[4,6] The Galleri test detects cancer-specific patterns in this DNA that could indicate the presence of cancer, as well as its tissue or organ of origin in the body.



With Galleri, **>99% of results return with no cancer signal detected.** People who don't have cancer have a very low likelihood of receiving a cancer signal detected test result.[3]

Adding a multi-cancer early detection test, like the Galleri test, to recommended cancer screenings is a game changer for cancer detection, helping adults at elevated risk of cancer, such as those 50 and over, detect aggressive cancers earlier and giving them more control over their health.

Data from PATHFINDER 2 matched or improved upon PPV, cancer detection rate and CSO observed in PATHFINDER and CCGA trials.

	PATHFINDER 2[5]	PATHFINDER[6]	CCGA Sub-study 3[3]
Description	An interventional, clinical, return-of-results study in patients presenting for screening without clinical suspicion of cancer, a study population that reflects the intended use population	An interventional, clinical, return-of-results study in patients presenting for screening without clinical suspicion of cancer, a study population that reflects the intended use population	A case-control, observational study evaluating the performance of Galleri in patients for whom cancer diagnosis is known
Overall Enrollment size	35,878	6,662	5,309 (total of 15,254 across CCGA studies)
Analysis set size	23,161*****	6,621	4,077
Positive Predictive Value	61.6%	43.1%	44.4% (modeled)
Sensitivity for the cancers that cause 2/3 of cancer deaths	Episode sensitivity: 73.7%	Not reported	Test sensitivity: 76.3%
Overall Sensitivity	Episode sensitivity: 40.4%	Not reported	Test sensitivity: 51.5%
False Positive Rate	0.4%	0.5%	0.5%
CSO Accuracy	91.7%	88% (in predicting the top two Cancer Signal Origins)	88.7%
Cancer Detection Rate	0.57%	0.38%	N/A
More information	Fact Sheet	Fact Sheet	Fact Sheet

Cancer Types Detected by Galleri[3,7]

Highlighted cancers also have screenings with USPSTF guidelines.
Cancers types detected by Galleri in the CCGA study.[7]

Cancer Types
Adrenal Cortical Carcinoma
Ampulla of Vater
Anus
Appendix, Carcinoma
Bile Ducts, Distal
Bile Ducts, Intrahepatic
Bile Ducts, Perihilar
Bladder, Urinary
Bone
Breast
Cervix
Colon and Rectum
Esophagus and Esophagogastric Junction
Gallbladder
Gastrointestinal Stromal Tumor
Gestational Trophoblastic Neoplasms
Kidney
Larynx
Leukemia
Liver
Lung
Lymphoma (Hodgkin and Non-Hodgkin)
Melanoma of the Skin
Merkel Cell Carcinoma
Mesothelioma, Malignant Pleural

Cancer Types Continued...
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
Plasma Cell Myeloma and Plasma Cell Disorders
Prostate
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

Cancers for which there are USPSTF grade A/B recommended screenings†

Cancer for which there is USPSTF grade C recommended screening†

Cancers for which there are no USPSTF grade A/B/C recommended screenings†

*Assumes screening is available for all prostate, breast, cervical, and colorectal cancer cases and 43% of lung cancer cases (based on the estimated proportion of lung cancers that occur in screen-eligible individuals older than 40 years).

**The Galleri test's key performance metrics were derived from the outcomes of an interventional clinical study of patients presenting for screening without clinical suspicion of cancer, a study population that reflects the intended-use population.

***The overall sensitivity in study participants with pancreatic cancer was 83.7% (61.9% for stage I, 60.0% stage II, 85.7% stage III, 95.9% stage IV). The overall sensitivity in study participants with liver/bile duct cancer was 93.5% (100% for stage I, 70.0% stage II, 100% stage III, 100% stage IV). The overall sensitivity in study participants with ovarian cancer was 83.1% (50.0% for stage I, 80.0% stage II, 87.1% stage III, 94.7% stage IV).[3]

****Test performance metrics do not represent results of a head-to-head comparative study. Separate studies have different designs, objectives, and participant populations, which limits the ability to draw conclusions about comparative performance.

***** Performance analyzable cohort from a pre-specified initial analysis of the ongoing PATHFINDER 2 study.

Important Safety Information
The Galleri test is recommended for use in adults with an elevated risk for cancer, such as those age 50 or older. The test does not detect all cancers and should be used in addition to routine cancer screening tests recommended by a healthcare provider. The Galleri test is intended to detect cancer signals and predict where in the body the cancer signal is located. Use of the test 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
The GRAIL clinical laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and accredited by the College of American Pathologists. 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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3. 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 Sep;32(9):1167-77. doi: 10.1016/j.annonc.2021.05.806

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5. Nadarajah N, McDonnell C, Kurbegov D, et al. Safety and Performance of a Multi-Cancer Early Detection (MCED) Test in an Intended-Use Population: Initial Results from the Registrational PATHFINDER 2 Study. ESMO 2025. Presentation LBA64.

6. Hall MP, Aravanis AM. The Galleri Assay. In: *Current Cancer Research*. 2023:633-664. doi: 10.1007/978-3-031-22903-9_25

7. Liu MC, Oxnard GR, Klein EA, et al. Sensitive and specific multi-cancer detection and localization using methylation signatures in cell-free DNA. *Ann Oncol*. 2020 Mar 30;31(6):745-59. doi: 10.1016/j.annonc.2020.02.011

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