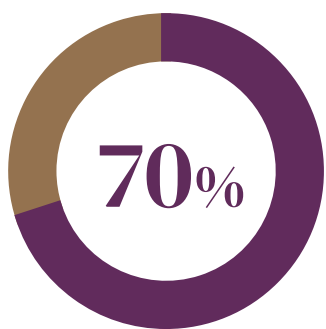
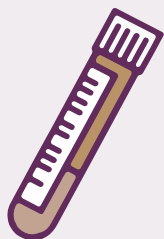


Understanding the Galleri[®] Test



Cancer screening saves lives, but **70%** of cancer deaths are caused by cancers without recommended screening tests.^{*1,2,3} The Galleri[®] multi-cancer early detection (MCED) test can help find these cancers.⁴

Galleri received FDA breakthrough designation in 2018. Galleri was launched commercially as a Laboratory Developed Test in 2021 under the Clinical Laboratory Improvement Amendment (CLIA) of 1988.



>500,000

Commercial Tests Completed



>380,000

Clinical Trial Participants

As of May 5, 2026

Among hundreds of cancer types, routine screening is only recommended for four cancers (colon, breast, cervical, and lung for those at high risk).³ Yet, only 14% of cancers in the US are detected by guideline-recommended screening tests.⁵ The goal of MCED is to find more cancers earlier, when they may be more treatable and potentially curable.

An annual blood test, **Galleri screens for 50+ cancer types, including many deadly cancers that currently lack screening options.**⁴

Galleri is the only available MCED test with demonstrated performance in patients being screened for cancer.^{**6,7} Galleri is **backed by a robust clinical evidence program**, with nearly 400,000 participants across multiple studies, including the NHS-Galleri trial, the first and only randomized controlled trial for an MCED test.^{8,9}

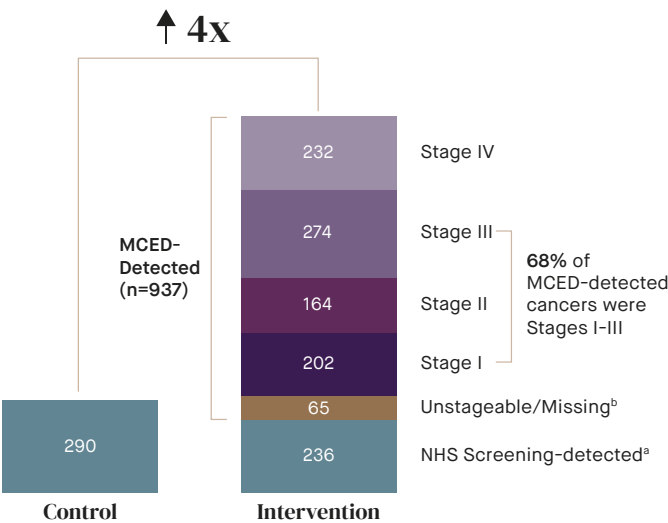
Galleri is the only MCED test clinically proven through a randomized controlled trial to increase earlier cancer detection and reduce Stage IV diagnoses — enabling more patients to have curative-intent treatment^{7,10}

The Galleri test reduced Stage IV diagnoses by 26% for a prespecified group of 12 deadly cancers*** in year 3 of annual testing.¹⁰



A statistically significant reduction was not observed in combined Stage III/IV diagnoses across three screening rounds for the 12 deadly cancers.¹⁰

When added to standard-of-care screening,^a the Galleri test increased cancer detection **fourfold** versus standard screening alone, with 2 out of 3 detected in Stages I-III.¹⁰



^a Includes NHS screening (UK) for breast, cervical, colorectal, and lung cancers.
^b Includes 10 unstageable cancers (no staging system exists) and 55 cancers with missing staging information.

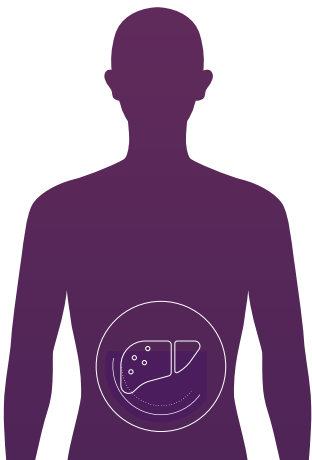
Detailed results from the [NHS-Galleri trial](#)

People who receive a Cancer Signal Detected test result with Galleri have a high likelihood of having cancer with a 60.3% positive predictive value.¹¹



The Galleri test has the lowest false positive rate among MCED tests**** (0.4%) and the ability to predict Cancer Signal Origin with >90% accuracy, helping guide efficient diagnostic evaluation.¹¹

Cancer Signal Origin accuracy >90%



Detailed results from the [PATHFINDER 2 trial](#)

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.^{4,6,11} Galleri’s ability to correctly identify individuals who actually have cancer (sensitivity) is **76.3%** for the group of 12 cancers responsible for two-thirds of U.S. cancer deaths, based on the case-controlled CCGA study.⁴ The overall sensitivity in that study was 51.5%.⁴

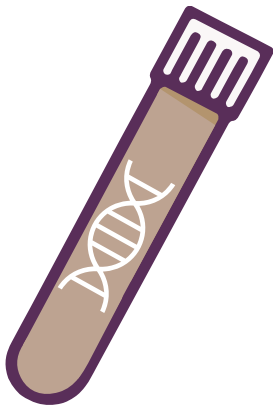
Cancer Class	Sensitivity
Liver / Bile Duct	93.5%
Head and Neck	85.7%
Esophagus	85.0%
Pancreas	83.7%
Ovary	83.1%
Colon / Rectum	82.0%
Anus	81.8%
Lung	74.8%
Plasma Cell Neoplasm	72.3%
Stomach	66.7%
Lymphoma	56.3%
Bladder	34.8%

Test sensitivity shown from the case-controlled CCGA study⁴

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 — before they cause symptoms.^{6,12} The Galleri test detects cancer-specific patterns in this DNA that could indicate the presence of cancer, as well as predict 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.¹¹



Adding annual Galleri testing to recommended screening **helps detect more cancers earlier**, when more patients can benefit from curative-intent treatment.¹⁰

Galleri Has Delivered Consistent Performance Across Studies.^{4,6,10,11}

	NHS-Galleri ¹⁰	PATHFINDER 2 ¹¹	PATHFINDER ⁶	CCGA Sub-Study ⁴
Description	A prospective, randomized, controlled study in patients presenting for screening without clinical suspicion of cancer conducted in partnership with the NHS in England.	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	142,924	35,878	6,662	5,309 (total of 15,254 across CCGA studies)
Analysis set size	142,250	32,007	6,621	4,077
Positive Predictive Value	52.0% (aggregate) 58.0% (at 1st screening round)	60.3%	43.1%	44.4% (modeled)
Sensitivity for the 12 cancers that cause 2/3 of cancer deaths***	Episode sensitivity: 54.7%	Episode sensitivity: 69.8%	Not reported	Test sensitivity: 76.3%
Overall Sensitivity	Episode sensitivity: 30.7% (aggregate)	Episode sensitivity: 39.3%	Not reported	Test sensitivity: 51.5%
False Positive Rate	0.45%	0.40%	0.5%	0.5%
CSO Accuracy	92.5% (in predicting the top two Cancer Signal Origins)	91.3% (in predicting the top two Cancer Signal Origins)	88% (in predicting the top two Cancer Signal Origins)	88.7%
Cancer Detection Rate	0.48%	0.54%	0.38%	N/A
More information	Fact Sheet	Fact Sheet	Fact Sheet	Fact Sheet

Cancer Types Detected by Galleri^{4,13}

Cancer types detected by Galleri in the CCGA study.⁴
Highlighted cancers also have USPSTF screening guidelines.

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 screenings³
- Cancer for which there is USPSTF grade C recommended screening³
- Cancers for which there are no USPSTF grade A/B/C recommended screenings³

*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 12 cancer types include anus, bladder, colorectal, esophagus, head and neck, liver/bile duct, lung, lymphoma, myeloma/plasma cell neoplasm, ovary, pancreas, stomach. The NHS-Galleri trial was designed to first assess the primary objective in these 12 cancers. Had that data reached statistical significance, the primary objective would have been assessed in all routinely staged cancer types other than prostate, and then in all stageable cancers.

****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.

*****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

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.

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