Test Result Report options

Galleri®

The Galleri® test screens your blood sample for signs of cancer that may be active in your body.[1] There are two possible results No Cancer Signal Detected and Cancer Signal Detected.

No Cancer Signal Detected

Your Result

No Cancer Signal Detected

In a clinical study[a], on average, fewer than 2 out of 100 people with a No Cancer Signal Detected result received a cancer diagnosis (Negative Predictive Value was 98.5%).

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.

Cancer Signal Detected
with Cancer Signal Origin

DETECTION

Your Result

Cancer Signal Detected

In a clinical study[a], on average, 4 out of 10 people with a Cancer Signal Detected result received a cancer diagnosis (Positive Predictive Value was 43%).

What this result means

The Galleri test looked for a DNA methylation signal associated with cancer in your blood sample and found a signal. A healthcare provider should conduct a diagnostic evaluation for cancer.

What this result does not mean

A Cancer Signal Detected result is NOT a cancer diagnosis. Diagnostic evaluation by a healthcare provider is needed to confirm if you have cancer.

PREDICTION

Your Predicted Cancer Signal Origin

To help guide diagnostic evaluation, the Galleri test provides a prediction about the most likely organ(s) associated with the Cancer Signal. The Signal Origin predictions are organized into 18 Cancer Signal Origins, which are listed in the methods section.

CANCER SIGNAL ORIGIN PREDICTION

Pancreas, Gallbladder

What is included: Pancreas, Extrahepatic Bile Duct, Gallbladder.

Cancer Signal Detected
with Cancer Signal Origin and additional information

PREDICTION

Your Predicted Cancer Signal Origin

To help guide diagnostic evaluation, the Galleri test provides a prediction about the most likely organ(s) associated with the Cancer Signal. The Signal Origin predictions are organized into 18 Cancer Signal Origins, which are listed in the methods section.

CANCER SIGNAL ORIGIN PREDICTION

Head and Neck

What is included: Oropharynx, Hypopharynx, Nasopharynx, Larynx, Lip and Oral Cavity (including Oral Tongue), Nasal Cavity, Paranasal Sinuses, Major Salivary Glands.

FOR HEALTHCARE PROVIDERS

Additional prediction information:

Squamous Cell Signal of Head and Neck, Lung and Esophagus

If the diagnostic evaluation based on the predicted Cancer Signal Origin does not lead to a cancer diagnosis, consider expanding the diagnostic evaluation to other organs possibly affected (Head and Neck, Lung, Esophagus).

A small number of samples will not yield a result due to a variety of reasons including but not limited to failed quality metrics and insufficient volume.

Test Result Report options

Galleri®

While the Galleri test is a powerful tool, it cannot detect all cancers. Not all cancers shed the same amount of DNA into the bloodstream, which makes some more likely to be detected than others. Some cancers shed little or no DNA into the bloodstream, which makes them unlikely to be detected through a blood test, for example brain, skin, and early breast and prostate cancers.

Sensitivity by cancer class[1]

The proportion of people with cancer who received a Cancer Signal Detected result

Cancer Classes[4]	Sensitivity[4], 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[e]	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%)

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).

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.

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 Sep;32(9):1167–77.

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