PATIENT INFORMATION:

# Paul Emmet Mederos

**Phone (H):** (833) 753-1851
**DOB:** 02/14/1963
**Gender:** Male **Age:** 62
**Patient ID:** 61386533

STATUS: **Final**

**Source:** Quest
**Collection Date:** 06/05/2025 03:16 PM UTC
**Time Reported:** 06/19/2025 02:23 AM UTC
**Received:** 06/19/2025 02:34 AM UTC
**Accession Number:** TZ636518X
**Lab Ref #:** 1360034

ORDERING PHYSICIAN:

# Lauren Jefferis, MD

600 Congress Avenue
Floor 14
Austin, TX, 78701

| Test | In Range | Out Of Range | Reference Range | Lab |
|---|---|---|---|---|
| **Galleri(R) (Performed/ Billed by GRAIL)** | Collected: 06/05/2025 03:16 PM UTC | | Received: 06/05/2025 03:17 PM UTC | |
| Galleri Results | SeeNote(s) | | | AJGA |

```
GALLERI NO PREDICTED SIGNAL ORIGIN
NO CANCER SIGNAL DETECTED
The Galleri test results report PDF document is the
official source of the test result and contains important
information regarding the Galleri test and the patient's
test results. Please read the official report for complete
results.
```

| | | | | |
|---|---|---|---|---|
| Galleri ID | GAL0CFCW7R | | | AJGA |
| **Enhanced PDF Report TZ636518X-1** | Collected: 06/05/2025 03:16 PM UTC | | Received: 06/05/2025 03:17 PM UTC | |
| Enhanced PDF Report TZ636518X-1 | **Paul Emmet Mederos - Enhanced PDF Report TZ636518X-1.pdf [See Appendix 1 for details]** | | | |

| | | |
|---|---|---|
| AJGA | GRAIL, Inc.<br>4001 E Nc 54 Hwy Assembly, Suite 1100, Durham, NC 27709-0101 | Dir: Daniel L Duncan MD |

Galleri®
Multi-cancer early detection

**Cover Page**

**MEDEROS, PAUL EMMET**

| Patient Information | Specimen Information | Client Information |
|---|---|---|
| **MEDEROS, PAUL EMMET**<br><br>**DOB: 02/14/1963 AGE: 62**<br>Gender: M<br>Phone: 833.753.1851<br>Patient ID: 61386533 | Specimen: TZ636518X<br>Requisition: 0056722<br>Lab Ref #: 1360034<br><br>Collected: 06/05/2025 / 11:16 EDT<br>Received: 06/06/2025 / 17:04 EDT<br>Reported: 06/18/2025 / 22:23 EDT | Client #: 73917267 MAIL992<br>JEFFERIS, LAUREN<br>FUNCTION HEALTH INC<br>600 CONGRESS AVE FL 14<br>AUSTIN, TX 78701-3263 |

**PERFORMING SITE:**

AJGA GRAIL INC, 4001 EAST NC 54 HIGHWAY ASSEMBLY SUITE 1100, DURHAM, NC 27709-0101 Laboratory Director: DANIEL L DUNCAN,MD, CLIA: 34D2231294

Galleri®

**PAUL EMMET MEDEROS**
GRAIL ID: GAL0CFCW7R

# Multi-Cancer Early Detection Test Report

### Patient

**Name:** PAUL EMMET MEDEROS
**Patient ID:** -
**DOB:** 14-FEB-1963
**Bio Sex:** Male

### Sample

**GRAIL ID:** GAL0CFCW7R
**Sample Type:** Whole Blood
**Report Date:** 18-JUN-2025 / 22:20 ET
**Collection Date:** 05-JUN-2025

### Ordering Provider

**Name:** Lauren Jefferis
**Location:** Quest Client 73917267
**Address:** 600 Congress Avenue Floor 14
Austin, TX 78701
**Phone:** 19363208708
**Fax:** -

## 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.**

## Talk to your healthcare provider about the following topics

### Continue routine cancer screenings

Discuss which screening tests are right for you. Screening is recommended for colon/rectum, breast, cervix, lung (for those at risk), and prostate cancers.

### Repeat testing with Galleri

Adding Galleri to annual wellness visits can improve the chances of finding cancer early when it is more treatable. Talk to your healthcare provider about whether annual testing with Galleri is appropriate for you.

a. PATHFINDER (NCT04241796)[1,2] was a prospective, interventional return of results study (n = 6,662) to assess the implementation of an early version of the Galleri test in a clinical setting. Participants were ≥ 50 years with and without additional cancer risk. A pre-specified reanalysis of blood samples (n = 6,578) was completed with the Galleri test.

Galleri®

**PAUL EMMET MEDEROS**
GRAIL ID: GAL0CFCW7R

# Multi-Cancer Early Detection Test Report

## What this screening test did

**With the Galleri test, you took a step forward to better understand your health.** The Galleri test allowed you to screen for a Cancer Signal shared by multiple cancers, many of which do not have recommended screening tests. Unlike single cancer screening, Galleri does not individually test for specific types of cancer. The Galleri test should be used in addition to routine cancer screening recommended by your healthcare provider.

- In order to deliver your results, the Galleri test studied more than 500,000 methylation sites in your DNA that are most informative for detecting the presence of a current Cancer Signal and predicting its origin in the body.
- The Galleri test development was supported by multiple rigorous clinical trials involving over 20,000 participants. In the CCGA clinical trial, the Galleri test was able to detect a signal shared across many cancers[4,5]. Among the cancers Galleri detected in this trial were cancers of the bladder, colon and rectum, esophagus, head and neck, liver, gallbladder, lung, lymphatic system, ovaries, pancreas, stomach, and many others.

For a full list of cancers that Galleri was able to detect, visit: **galleri.com/cancers**

**Do you have questions?**

If you are a patient, please contact the healthcare provider who ordered this test if you have questions about Galleri or your test result. We are also here to help.

Give us a call at **833-694-2553** or email **customerservice@grail.com**

**This page includes additional information about the Galleri test.**
*It does not include your own personal data and results.*

Galleri®

# About the Galleri® test

## Test Description

**The Galleri test is a qualitative, next-generation sequencing-based screening test that detects DNA methylation patterns on cell-free DNA (cfDNA) in whole blood.** Cells in the body release cfDNA fragments into the bloodstream. This can include cancer cells. cfDNA from cancer cells has specific methylation patterns that can be recognized by Galleri as a Cancer Signal and contain information about the organ associated with the Cancer Signal. Methylation is a natural process that can change the activity of DNA. The test identifies DNA methylation patterns on cell-free DNA.

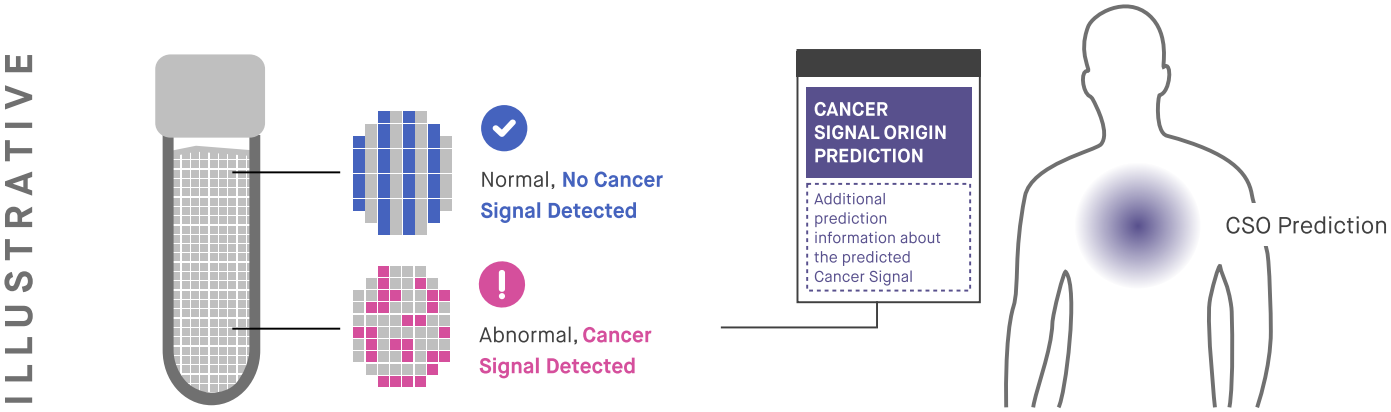
- **Galleri has been trained by the world's largest cancer DNA methylation database, created by GRAIL.** The process uses advanced technology and pattern recognition to detect a Cancer Signal and predict its Origin.
- **Galleri is intended for use in adults with an elevated risk of cancer (e.g., ≥50 years old).** The Galleri test does not detect a signal for all cancers and should be used in addition to routine cancer screening tests. When Galleri detects a Cancer Signal, a diagnostic evaluation by a qualified healthcare provider is required to establish a cancer diagnosis.

*The Galleri test can be ordered by a healthcare provider only.*

**How the Galleri test works** - visual explanation, not your test results.

### 1 Cancer Signal Detection

### 2 Cancer Signal Origin Prediction




In order to deliver your results, the Galleri test studied more than 500,000 methylation sites in your DNA that are most informative for detecting the presence of a current Cancer Signal and predicting its origin in the body. Galleri looks at methylation patterns to determine whether it comes from healthy (normal) or cancer (abnormal) cells.

If a Cancer Signal is detected, then Galleri compares the methylation pattern of the Cancer Signal to the patterns of 18 possible Cancer Signal Origin (CSO) predictions and reports the CSO prediction that has the strongest match. Additional prediction information may be reported in some cases.

**This page includes additional information about the Galleri test.**
*It does not include your own personal data and results.*

Galleri®

# About the Galleri® test

## Methods

The Galleri test is a qualitative, next-generation sequencing-based screening test that detects DNA methylation patterns on cell-free DNA (cfDNA) in whole blood. Cells in the body release cfDNA fragments into the bloodstream. The Limit of Detection (LOD95) of the Galleri test using abnormal coverage is 0.2 (abnormal coverage is the mean number of unique abnormal fragments observed per CpG in a sample).

This version of the Galleri test has been validated in the subset of PATHFINDER[2] and Circulating Cell-free Genome Atlas (CCGA)[5] clinical studies in a clinical validation analysis[3]. Overall specificity and sensitivity of the Cancer Signal Detected result were maintained and accuracy of Cancer Signal Origin prediction was improved compared to the prior test version[1,4]. The Galleri test has 18 possible Cancer Signal Origin predictions: Anus; Bladder, Urothelial Tract; Bone and Soft Tissue; Breast; Cervix; Colon, Rectum; Head and Neck; Hematopoietic and Lymphoid Organs; Kidney; Liver, Bile Duct; Lung; Melanocyte-containing Tissues / Skin; Ovary; Pancreas, Gallbladder; Prostate; Stomach, Esophagus; Thyroid; and Uterus. Additional prediction information about the predicted Cancer Signal may be reported and may include one of the following possibilities: Human Papillomavirus (HPV) Associated Methylation Signal; Squamous Cell Signal of Head and Neck, Lung, and Esophagus; Neuroendocrine Signal; Female Reproductive Tract Signal; Lymphoid Lineage; Myeloid Lineage or Plasma Cell Lineage.

## Clinical Trials

**The following is data from clinical trials and is not your data.** For more details, please visit **galleri.com/test-report**

- **Galleri Test Performance Characteristics in the PATHFINDER Study[1,2]**
  The prospective PATHFINDER study enrolled 6,662 participants without clinical suspicion of cancer at enrollment. Participants were men and women at least 50 years old recruited into two cohorts. One cohort included participants with additional cancer risk (history of smoking, prior cancer with treatment completed > 3 years ago, or genetic cancer predisposition). The other cohort included participants without additional cancer risk. Participants who received a Cancer Signal Detected result from an early version of the Galleri test underwent a diagnostic evaluation to assess whether they had cancer. Later, blood samples were reanalyzed with a previous version of the Galleri test: 58 of 6,578 participants had a Cancer Signal Detected result. All participants were followed for 12 months to assess cancer status.

  At the end of the study, 121 participants had a cancer diagnosis, including 73 with cancers detected by screening: 35 with a Cancer Signal Detected result from an early version of the Galleri test, 29 with cancers detected by recommended USPSTF screening, and 9 with cancers detected by other cancer screening. The early version of the Galleri test almost doubled the number of cancers detected by screening. A subset of PATHFINDER study including 1893 participants with no cancer diagnosis and completed 12 month follow-up was included in the 2024 clinical validation analysis of this test version[3].

- **Galleri Test Performance Characteristics in the CCGA sub-study[4,5]**
  CCGA was a prospective, case-control, observational study, and CCGA3 a pre-specified sub-study of 2,823 cancer participants (cases) and 1,254 non-cancer participants (controls). Participants were men and women aged 20 years and older (81% 50 years or older) without a prior history of cancer. Cancer participants were enrolled after diagnosis (or with a high suspicion of cancer) before any cancer treatment.

  In this CCGA3 sub-study, the Galleri test detected a shared Cancer Signal shared across more than 50 types of cancer (defined by the American Joint Committee on Cancer[6]). A subset of CCGA3 study including 944 cancer participants was included in the 2024 clinical validation analysis of this test version[3].

**This page includes additional information about the Galleri test.**
*It does not include your own personal data and results.*

Galleri®

# About the Galleri® test

## Clinical Trials (Continued)

**Galleri Test Performance**

| Metrics | PATHFINDER[1,2] | | CCGA3[4,5] | |
|---|---|---|---|---|
| | Rate (95% CI) | Details | Rate (95% CI) | Details |
| Positive Predictive Value (PPV) | 43.1% (31.2–55.9%) | 25 participants had cancer diagnosed among 58 participants with Cancer Signal Detected results. | 44.4% (28.6–79.9%) | Projected estimate adjusted for SEER incidence and stage distribution in the 50-79 years age group.[7,c] |
| Negative Predictive Value (NPV) | 98.5% (98.2–98.8%) | 6,216 participants had no cancer diagnosed among 6,311 participants with No Cancer Signal Detected results who completed a 12-month follow-up. | 99.4% (99.4–99.5%) | Projected estimate adjusted for SEER incidence and stage distribution in the 50-79 years age group.[7,c] |
| Specificity (true negative rate) | 99.5% (99.3–99.6%) | 6,216 participants had accurate No Cancer Signal Detected results among 6,249 participants with no cancer diagnosis who completed a 12-month follow-up. | 99.5% (99.0–99.8%) | 1,248 non-cancer participants had accurate No Cancer Signal Detected results among 1,254 non-cancer participants. |
| False Positive Rate[b] | 0.5% (0.4–0.7%) | 33 participants had false Cancer Signal Detected results among 6,249 participants with no cancer diagnosis who completed a 12-month follow-up. | 0.5% (0.2–1.0%) | 6 non-cancer participants had false Cancer Signal Detected results among 1,254 non-cancer participants. |

- **Positive Predictive Value:** The proportion of people with Cancer Signal Detected results diagnosed with cancer.
- **Negative Predictive Value:** The proportion of people with No Cancer Signal Detected results without a cancer diagnosis.
- **Specificity:** The proportion of people without cancer who received No Cancer Signal Detected results. True negative rate.
- **False Positive Rate:** The proportion of people without cancer who received Cancer Signal Detected results.
- **95% Confidence Interval (CI):** A range of values that you can be 95% certain contains a true parameter of interest.

b. False Positive Rate is equal to (1 - Specificity).

c. Extrapolation of the Positive Predictive Value (PPV) and Negative Predictive Value (NPV). Results were adjusted by Surveillance, Epidemiology, and End Results Program (SEER) incidence rates and stage distribution for those aged 50-79 years to align with intended use population.[4]

**This page includes additional information about the Galleri test.**
*It does not include your own personal data and results.*

Galleri®

# About the Galleri® test

## Clinical Trials (Continued)

**Galleri Test Performance: Sensitivity**

| Metrics | CCGA3[4,5] | |
|---|---|---|
| | Rate (95% CI) | Details |
| **Sensitivity: Cancers responsible for 2/3 of cancer deaths in the US[8]** | **76.3%** (74.0–78.5%) | 1,040 cancer participants received Cancer Signal Detected results among 1,363 participants with cancers responsible for 2/3 of all cancer deaths in the US. |

**Notes**

Sensitivity was not evaluated in the PATHFINDER study[1] because the cancer status was unknown for all participants at the time of the blood draw.

CCGA3[4,5] enrolled participants with a cancer diagnosis. Therefore, the cancer status was known.

**Galleri Test Performance: Accuracy**

| Metrics | Data on File[3] | |
|---|---|---|
| | Rate (95% CI) | Details |
| **Cancer Signal Origin (CSO) Prediction** | **93.4%** (90.7–95.4%) | 413 participants had correct CSO prediction of 442 participants with cancer and Cancer Signal Detected results. |
| **Additional Prediction Information** | **93.0%** (88.2–96%) | 160 participants had correct Additional Prediction Information of 172 participants with cancer and Cancer Signal Detected results who also had an additional prediction. |

- **Sensitivity:** The proportion of people with cancer who received Cancer Signal Detected results. True positive rate.
- **Accuracy: Cancer Signal Origin (CSO) Prediction[d]:** The proportion of correctly predicted CSO among study participants with a Cancer Signal Detected test result and cancer diagnosis.
- **Accuracy: Additional Prediction Information:** The proportion of correctly predicted additional information among study participants with a cancer diagnosis who received a Cancer Signal Detected test result with an additional information return.

d. In a 2024 analysis[3], overall specificity and sensitivity of Cancer Signal Detected were maintained and Cancer Signal Origin Prediction Accuracy was improved.

**This page includes additional information about the Galleri test.**
*It does not include your own personal data and results.*

Galleri®

# About the Galleri® test

## Clinical Trials (Continued)

**Cancer Signal detection for various cancer classes in the CCGA3 sub-study[4]**

| 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%) |

e. Other cancers include: Adrenal (n = 1), ampulla of Vater (n = 1), Brain (n = 6), 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).

**This page includes additional information about the Galleri test.**
*It does not include your own personal data and results.*

Galleri®

# About the Galleri® test

## Warnings, Precautions, and Limitations

The Galleri test performance may be subject to the collection, storage, and transportation of blood samples. The test is not intended for other sample types. Any sample handling outside of the suggested procedures may affect test performance.

Use of the Galleri test is not recommended in individuals who are pregnant, 21 years old or younger, or undergoing active cancer treatment.

A Cancer Signal Detected result is not a diagnosis of cancer. The results of the Galleri test must be confirmed by diagnostic evaluation recommended by qualified healthcare providers following standard medical practice. These results should be interpreted in the context of the individual's clinical risk factors. Diagnostic decisions are the responsibility of the treating physician. A No Cancer Signal Detected result does not eliminate the possibility that cancer is present or will occur in the future. Individuals who receive a No Cancer Signal Detected result should continue with all recommended cancer screening options at intervals appropriate for the individual. The Galleri test should not replace, supersede, or otherwise alter the use or frequency of standard-of-care cancer screening or detection modalities.

The Galleri test does not detect a signal for all cancers. Cancers evaluated in the CCGA3 sub-study[4] are listed at galleri.com/test-report

The test performance in cancer classes not observed in CCGA3[5] and PATHFINDER[1] is unknown. If a Cancer Signal Detected result is returned, the Galleri test also reports a CSO prediction, which must be confirmed by diagnostic evaluation. In some cases, the Galleri test may produce a Cancer Signal Detected result, but diagnostic evaluation may not confirm a cancer diagnosis. This could mean that the individual has cancer that is difficult to identify by the selected diagnostic evaluation, that the individual has cancer but it is located elsewhere, or that the individual does not have cancer and the Galleri test result is a false positive.

Sensitivity and Cancer Signal Origin accuracy observed in cancer participants from the case-control CCGA3 sub-study[4] may be higher than in the general screening population because the Cancer Signal may be stronger in cancers detected by standard medical practice.

Performance of sequential Galleri tests has not been evaluated.

*The Galleri test can be ordered by a healthcare provider 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 (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. The GRAIL clinical laboratory is regulated under CLIA to perform high-complexity testing. The Galleri test is intended for clinical purposes.

## References


1. Schrag D, Beer TM, McDonnell CH, et al. Blood-based tests for multi-cancer early detection (PATHFINDER): a prospective cohort study. Lancet. 2023;402:1251-1260. doi: 10.1016/S0140-6736(23)01700-2.
2. The PATHFINDER Study: Assessment of the Implementation of an Investigational Multi-Cancer Early Detection Test Into Clinical Practice (NCT04241796). www.clinicaltrials.gov/ct2/show/NCT04241796
3. GRAIL, Inc. Data on file: VV-TMF-59592 on clinical validation analysis in a subset of CCGA3 study including 944 cancer participants and a subset of PATHFINDER study including 1893 non-cancer participants.
4. 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.
5. The Circulating Cell-free Genome Atlas Study (NCT02889978). www.clinicaltrials.gov/ct2/show/NCT02889978
6. Amin MB, et al. (Eds.). AJCC Cancer Staging Manual (8th edition). Springer International Publishing: American Joint Commission on Cancer; 2017.
7. SEER Stat Database: Incidence - SEER 18 Regs Research Data, Nov 2017 Sub. Includes persons aged 50+ diagnosed 2006-2015. GRAIL. Data on file.
8. American Cancer Society. Cancer Facts & Figures 2021. Atlanta: American Cancer Society; 2021.


## Publications


- Liu MC, Oxnard GR, Klein EA, et al. CCGA Consortium. Sensitive and specific multi-cancer detection and localization using methylation signatures in cell-free DNA. Ann Oncol. 2020;31(6):745-759. doi: 10.1016/j.annonc.2020.02.011.
- 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.
- Jamshidi A, Liu MC, Klein EA, et al. Evaluation of cell-free DNA approaches for multi-cancer early detection. Cancer Cell. 2022;40(12):1537-1549.e12. doi: 10.1016/j.ccell.2022.10.022.
- Schrag D, Beer TM, McDonnell CH, et al. Blood-based tests for multi-cancer early detection (PATHFINDER): a prospective cohort study. Lancet. 2023;402:1251-1260. doi: 10.1016/S0140-6736(23)01700-2.



Laboratory Director: Daniel Duncan, MD | CLIA #34D2231294 | CAP #9151388
4001 E NC 54 Hwy Assembly, Suite 1100, Durham, NC 27709 | 833-MY-GALLERI (833-694-2553) | FAX 650-999-9000 | customerservice@grail.com