

Dear Healthcare Provider,

There might be questions from your patients about the Galleri® test and times when you need to provide information to help educate them. Please find the following content organized by subject to help guide the discussion with your patients.

### **What is the importance of early detection?**

- Finding cancer early is important to provide care when there may be more treatment options and potential for better outcomes.<sup>1</sup>
- The vast majority of cancers show no symptoms until later stages, when treatment options may be limited.<sup>2</sup>
- Today, there are 5 recommended cancer screening tests that together only account for 1 in 4 diagnosed cancers in patients over 50 years of age.<sup>3,4</sup>
- Roughly 3 out of 4 of cancer deaths are caused by cancers without recommended screening tests.<sup>5,6</sup>
- When cancers are diagnosed early before they have had a chance to spread, the overall 5-year survival rate is 4x higher than when diagnosed in later stages.<sup>1,7</sup>
- The most important cancer is the one that you or your loved one may have - and treating it starts with knowing you have it.

### **What is Multi-Cancer Early Detection?**

- Multi-cancer early detection enables you to proactively screen for a signal shared by many cancers at once, increasing the chances of finding cancer early.

### **What is the Galleri test and what are the benefits?**

- The Galleri test screens for a signal shared by multiple cancers, many without recommended screening.
- In a clinical study the Galleri test was able to detect a signal shared by more than 50 types of cancer.<sup>8,9</sup>
- Test benefits:
  1. Early cancer detection
    - a. Early detection can provide care when there may be more treatment options and potential for better outcomes. The Galleri test detects a cancer signal shared by many cancers that are not commonly screened for today, to allow for earlier treatment.<sup>9</sup>
  2. Testing with ease
    - a. The Galleri test can be incorporated into a wellness healthcare visit through a simple blood draw.
  3. Actionable results
    - a. If a cancer signal is detected, the results predict where in the body the cancer is coming from to help guide your next steps.

### **Who can benefit from the Galleri test?**

- The Galleri test is recommended for use in adults with an elevated risk for cancer, such as those aged 50 or older. It is intended to be used in addition to and not replace other cancer screening tests your healthcare provider recommends.
- Age is the biggest risk factor in developing cancer. People aged 50 and above have a 13x increased risk for cancer compared to younger adults.<sup>10</sup>

### **How does the Galleri test work?**

All cells, healthy and cancer cells, contain DNA. The DNA from cancer cells is different from the DNA of healthy cells. As cells grow through their lifecycle and die, DNA is released into the bloodstream. The Galleri test can tell the difference between DNA from cancer cells and DNA from healthy cells.

### **How can Galleri tell cancer DNA from healthy DNA?**

Galleri was trained using a database that contains DNA from thousands of different cancer patients and healthy patients. This training uses advanced technology that allows Galleri to identify a cancer signal and then predict where the cancer signal originated in the body.<sup>11</sup>

It is important to know that:

- Galleri is a screening test and does not diagnose cancer. Diagnostic testing is needed to confirm cancer.
- The Galleri test looks for active cancer and does not predict your future genetic risk for cancer. It should be used in addition to guideline-recommended cancer screenings such as mammography, colonoscopy, PSA, or cervical cancer screening.
- The Galleri test does not detect all cancers and not all cancers can be detected in the blood. False positive and false negative results do occur.

### **Where can I learn more?**

- Call GRAIL customer service (833) 694-2553
- [www.galleri.com](http://www.galleri.com)
- [Facebook](#), [YouTube](#), [Linkedin](#) and [Twitter](#)
- See [Important Safety Information](#)

### 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 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.

### REFERENCES

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<https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2021/cancer-facts-and-figures-2021.pdf>
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6. Estimated deaths per year in 2022 from American Cancer Society Cancer Facts and Figures 2022. Available at: <http://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2022/cancer-facts-and-figures-2022.pdf>. Data on file GA-2021-0065
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10. Data source: U.S. Cancer Statistics Working Group. U.S. Cancer Statistics Data Visualizations Tool, based on 2019 submission data (1999-2017): U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and National Cancer Institute; [www.cdc.gov/eancer/dataviz](http://www.cdc.gov/eancer/dataviz), released in June 2020.
11. Liu MC, Oxnard GR, Klein EA, et al. for 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.

## **SAMPLE COPY FOR NEWSLETTER, WEBSITE OR BLOG POST**

Today, most cancers are diagnosed too late. When cancer is detected in its early stages, there may be more treatment options and potential for better outcomes.

That's why we're excited to offer the Galleri® multi-cancer early detection test\* to our patients.

Galleri is the first of its kind multi-cancer early detection test that screens for a signal shared by multiple [dozens of] cancers, many without recommended screening tests. In a clinical study the test was able to detect a signal shared by more than 50 types of cancer with a simple blood draw.

It is important to know that:

- Galleri is a screening test and does not diagnose cancer. Diagnostic testing is needed to confirm cancer.
- The Galleri test looks for active cancer and does not predict your future genetic risk for cancer.
- The Galleri test does not detect all cancers and not all cancers can be detected in the blood. False positive and false negative results do occur.

Learn more about the Galleri test at [galleri.com](https://galleri.com) or watch a [short video here](#).

Take control of your health and call us to make an appointment. Our healthcare providers can determine if the test may be right for you.

\*The Galleri test is recommended for use in adults with an elevated risk for cancer, such as those aged 50 or older. It is intended to be used in addition to, and not replace, other cancer screening tests.

[galleri.com/safety-information](https://galleri.com/safety-information)