Galleri®
Multi-cancer early detection

GRAIL

# Understanding Positive Predictive Value (PPV)

## The importance of PPV for interpreting Galleri® Cancer Signal Detected results

### What Is PPV?

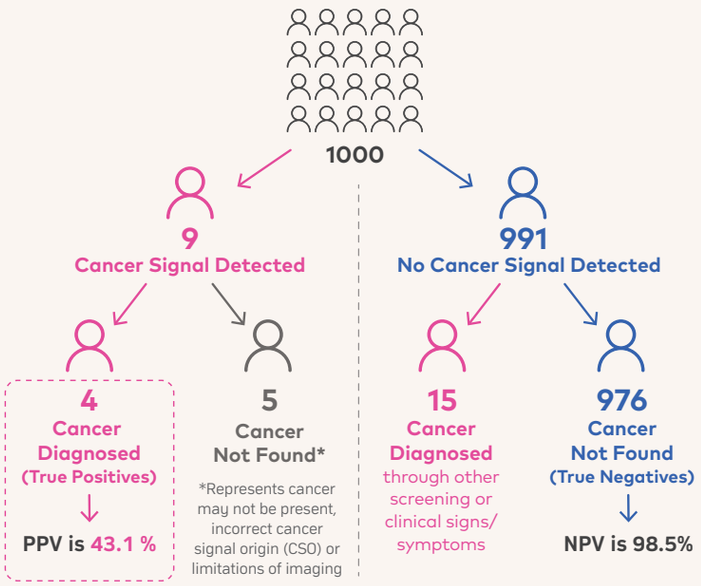
PPV represents the number of individuals who receive a Cancer Signal Detected test result who had cancer diagnosed. It can help guide the discussion on the implications and appropriate next steps.

### What Does That Mean?

Galleri's PPV is 43.1% meaning that **about 4 out of 10** individuals with a "Cancer Signal Detected" result are expected to have a **confirmed cancer diagnosis** following diagnostic work-up.

**PPV for the Galleri Test is: 43.1%**

**A sample of asymptomatic individuals ages 50-79 years taking the Galleri test**



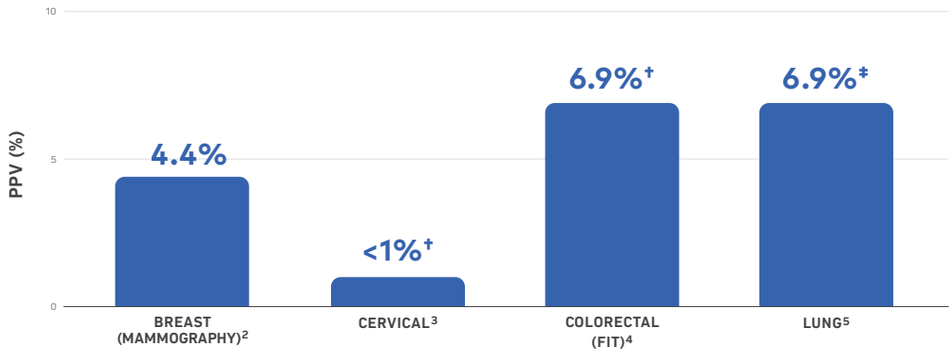

In the PATHFINDER study[1], out of 6,578 participants tested with Galleri, 58 had a Cancer Signal Detected result. Of these, 25 had a cancer diagnosed. 25/58 = 43.1%

## PPV of Single Cancer Screening Tests

**Current standard-of-care screening tests** for individual cancers have PPVs in the range of 1-10%.

The Galleri test should be used in addition to recommended single cancer screenings.

There has been no head-to-head PPV comparison of Galleri to these standard-of-care screening tests.




See Important Safety Information on reverse

†Pre-cancerous lesions were excluded. ‡Based on previous USPSTF recommendations of adults 55–80 years with a 30 pack/year smoking history. **1** Schrag D, et al. Presentation at European Society for Medical Oncology (ESMO) Congress; September 9-13, 2022 **2** USPSTF. 2016. Lehman, et al. Radiology. 2017;283(1):49-58. **3** Kim, et al. JAMA. 2018;320(7):706-714. **4** Imperiale T, et al. N Engl J Med 2014;370:1287-1297. **5** Pinsky, et al. Ann Intern Med. 2015 Apr 7;162(7): 485–491. Data on file. GA-2021-0069.

## 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 theCollege 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.

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