Preologi Is providing you with a Galleri® Multi-Cancer Early Detection Test, which is manufactured by GRAIL and conducted by the GRAIL laboratory, located in the United States.

What is the Galleri® Test?

The Galleri® test is a multi-cancer early detection test to screen for cancer. The Galleri® test is recommended for use in adults with an elevated risk of cancer, such as those aged 50 years or older. The Galleri® test does not detect all cancers and should be used in addition to routine cancer screening tests recommended by healthcare providers.

This may also include individuals with a personal history of cancer, smokers or former smokers, and anyone wishing to take a proactive approach to their health. Your Preologi clinician will help assess whether the test is appropriate for you.

If you have had a past history of cancer, you must undergo all recommended post-cancer surveillance tests and follow-ups as recommended by their oncologists.

Test and Follow up Results

Preologi, or your clinical provider, will collect a blood sample from you. This sample will then be sent to GRAIL laboratories in the US to test your blood sample to look for DNA shed into the bloodstream[1]. There are 3 possible results: Cancer Signal Detected, No Cancer Signal Detected or Cancelled and results can be expected in 14 working days.

Receiving a "Cancer Signal Detected" result is not a cancer diagnosis. It means the test has found a signal that may be associated with cancer. Preologi's clinical team, or your clinical provider (depending on who ordered the test), will contact you promptly, explain the result clearly, and arrange appropriate follow-up diagnostic investigations to determine whether cancer is present. Our team will support you through this process.

A "No Cancer Signal Detected" result means that the test did not find a cancer signal in your blood at the time of testing. This can be a reassuring result, but it cannot guarantee you are cancer-free – some cancers may not yet shed detectable DNA. This result does not predict whether you will develop cancer in the future. Specific tumor biology also means that some cancers, such as thyroid cancer, are not well detected using this technique. It should be taken in context alongside other health information, not as a definitive all-clear.

Galleri® may produce false positive or false negative results. A false positive result occurs when Galleri® indicates cancer signal detected and there is no cancer diagnosed within a pre-specified follow up period. A false negative result occurs when Galleri® indicates no cancer signal detected and the individual is diagnosed with cancer within a pre-specified follow up period.

A Cancelled report is infrequent but can occur if samples did not satisfy quality measures during processing.

[1]Please see GRAIL privacy notice for further information on test and data processing.
This can be found by contacting our team through enquiries@preologi.com

Limitations of the Galleri® Test

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 professionals 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. 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.

Performance of sequential Galleri tests has not been evaluated.

The Galleri® test can be ordered by a healthcare professional.

Cancelling your Galleri® Test and Refund

Cancellations can be accommodated provided that your blood sample has not yet been dispatched to GRAIL laboratories for analysis.

If you change your mind about proceeding with the Galleri® test, please contact Preologi as soon as possible by emailing enquiries@preologi.com so that we can cancel your test before your sample enters the testing process.
Refunds can be provided if your blood sample has not yet been sent to GRAIL laboratories. Once your sample has been dispatched for analysis, the testing process cannot be stopped, and a refund will not be possible.

Preologi is only responsible for refunding patients from whom Preologi has directly received payment. Preologi will not issue refunds where payment has been collected by a third party. If you purchased your Galleri test via a clinical provider, please contact your provider directly to arrange a refund.

Patient Name (print):

Date:

Signature:

Your approval of the terms and conditions indicates that you have agreed and acknowledged the information in this document.