



FAQs



Eligibility

Who	is	eligible	for	the
Galle	ri®	test?		

The Galleri test is available at no cost to all US-based employees enrolled on the health plan. Eligibility requirements:

- 50+ years of age
- 45-49 with certain risk factors
- Not currently pregnant
- Not undergoing active cancer treatment

Who is not eligible for the Galleri test?

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

Additionally, those who do not meet the eligibility criteria as stated by Klick will not be covered by the benefit.

What is covered in the Klick health benefit?

If you meet the eligibility criteria established by Klick in partnership with GRAIL (see "Who is eligible" question above), the full cost of the Galleri test is covered. The cost of the blood draw is also included if you visit a GRAIL partner lab.

I have a family member or friend interested in the Galleri test. Can they request the test?	Other family members or friends not eligible through the Klick benefit may learn more about the test on galleri.com. Those not eligible would be responsible for the cost of the test and PWNHealth provider services. Note: only the member requesting a Galleri test kit can take the test.
What information should I enter for my Access ID?	You will need to enter your Klick email address.
Will the Galleri test be covered if I request it through my primary healthcare provider?	No, employees must request the test online through GRAIL's patient portal where an independent telemedicine provider from PWNHealth will review your request and order the test if appropriate. When you request the test, you are given the option to enter your primary healthcare provider's contact information so your test result is automatically shared if a cancer signal is detected. If no cancer signal is detected, you can share the result with your provider, but we will not automatically send it.
I am not eligible for the Galleri test as a health benefit. Can I still request the test?	The Galleri test is currently available at no cost to eligible US-based Klick employees enrolled in a US Klick health plan(Aetna, UHC) and that also meet the eligibility criteria established by Klick in partnership with GRAIL (see "Who is eligible for the test" question above). If you are not eligible for this benefit but would still like to learn more about the test, visit galleri.com. Those not eligible would be responsible for the cost of the test and PWNHealth provider services.
Can I use my FSA/HSA to pay for the Galleri test?	If eligible through the Klick benefit you will not need to pay for the test using your flexible spending account (FSA) or health savings account (HSA). However, if you know someone interested in the Galleri test that is not eligible through Klick, they may be able to use pre-tax dollars in a flexible spending account (FSA) or health savings account (HSA) to pay for the Galleri test. Check with the FSA/HSA account administrator or insurance company to determine eligibility.
Are family members, such as parents and siblings, eligible for this benefit?	The Galleri test is available at no cost to eligible US-based Klick employees enrolled in a US Klick health plan (Aetna, UHC) and that also meet the eligibility criteria established by Klick in partnership with GRAIL (see "Who is eligible for the test" question above). Family members not eligible through Klick's benefit may learn more about the test on galleri.com. Those not eligible would be responsible for the cost of the test and PWNHealth provider services.

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As an eligible employee, is there a limit to the number of times I can request the test as part of this benefit?

As part of this benefit offering, eligible employees and their eligible dependents are each limited to one Galleri test over a 12 month period.

About the Galleri test

What is the Galleri test?	The Galleri test is a multi-cancer early detection test that detects a cancer signal across more than 50 types of cancer, many of which are not commonly screened for today, through a simple blood draw. The Galleri test does not diagnose cancer and not all cancers may be detected in the blood. The Galleri test is intended to be used in addition to, and not replace, other cancer screening tests your healthcare provider recommends.	
How can the Galleri test detect cancer in the blood?	The Galleri test looks for signals present in the blood that may be associated with cancer at the time of your blood draw. If a cancer signal is detected, the results can point to where in the body the cancer signal is coming from with high accuracy to help your healthcare provider guide next steps.	
I am not at risk for cancer nor do I have family history. Is the Galleri test really for me?	Family history is only one of many risk factors associated with cancer development. Other risk factors include eating habits, lifestyle, living or work environments, genetics, and many others. When you submit your test request, you may ask for a pre-test consultation of a PWNHealth provider to discuss whether the test is right for you. This option consultation is included in the benefit.	
What cancers does the Galleri test detect?	In a clinical validation study (CCGA3*), the Galleri test detected a cancer signal across more than more than <u>50 types of cancer</u> across all stages. *Circulating Cell-Free Genome Atlas (CCGA) sub-study	

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Why is the Galleri test recommended to be used along with other cancer screening tests?	The Galleri test detects a cancer signal across more than 50 types of cancer; however, not all cancers may be detected in the blood. Recommended routine cancer screening tests such as colonoscopy or mammograms have been shown to reduce cancer deaths. The Galleri test is intended to be used in addition to and not replace these tests, and can help maximize the benefits of early cancer detection. Missing recommended screening or ignoring symptoms could lead to a delayed diagnosis of cancer.
What is the false positive rate of the Galleri test?	Based on data from our studies, the Galleri test has shown a low false-positive rate of 0.5% (detects a cancer signal when no cancer is present). This means that in approximately 200 people tested only 1 person would be expected to receive a false positive result.
What if I have been previously diagnosed with cancer, can I still take the Galleri test?	Someone who has previously had cancer can take the Galleri test as long as they completed treatment at least 3 years ago and are in remission. If you've had cancer in the past, we recommend talking with your doctor to determine if Galleri is right for you.
What happens if I get a false positive?	In the event that a diagnostic evaluation after a "cancer signal detected" result with Galleri does not confirm cancer, employees may be eligible for a complementary re-test with Galleri. The request for a re-test must be placed by the healthcare provider managing the employee's diagnostic evaluation. The re-test must be administered within 3-6 months after the initial Galleri test. To initiate a request for a re-test, the healthcare provider managing the employee's diagnostic evaluation should contact GRAIL Customer Service at 833-MY-GALLERI (833-694-2553) or customerservice@grail.com. Customer Service hours are Monday through Friday 5:00 AM - 5:00 PM PT.
What data supports the Galleri test?	The Galleri test development was supported by what is believed to be one of the largest clinical study programs in genomic medicine, with over 20,000 participants at more than 140 clinical study sites, including the Mayo Clinic, Dana-Farber Cancer Institute, Cleveland Clinic, Sutter Health, OHSU, Intermountain Healthcare, and U.S. Oncology Network. Please visit the Galleri clinical evidence page for more information.

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Is the Galleri test FDA approved?

The Galleri test has not been cleared or approved by the FDA. GRAIL's clinical laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and accredited by the College of American Pathologists (CAP). GRAIL's clinical laboratory is regulated under CLIA to perform high-complexity testing.

The Galleri test received FDA Breakthrough Device Designation in 2019.

Test process and blood draw

I submitted my test request. What happens next?

A healthcare provider from PWNHealth will review your request and clinical eligibility within one week. They will approve your request and order the test if appropriate.

If the PWNHealth provider approves your request, you will be shipped a Galleri collection kit and receive an email confirmation with instructions for how to schedule your blood draw.

When your collection kit arrives, you can <u>schedule a blood draw</u> appointment at one of GRAIL's partner labs, which is covered in this benefit. Test results will be ready in about 2 weeks after completing your blood draw.

Where can I get my blood drawn for the Galleri test?

If your Galleri test request is approved and your collection kit has arrived, you can <u>schedule a blood draw</u> appointment with one of GRAIL's partner labs at no cost to you.

What should I bring to my blood draw appointment?

Bring your unopened Galleri sample collection kit and your completed and printed 'Test Requisition Form' to your blood draw appointment.

To note, you will receive the following items if your eligibility for the Galleri test is approved.

- A collection kit will be mailed to you within one week after your request is approved. Do not break the quality seal on the collection kit. It should be opened by the lab technician who draws your blood sample.
- A completed Test Requisition Form will be emailed to you from GRAIL.
 Remember to print the form and bring it to your appointment.

What is my Test Requisition Form and where can I find it?

The Test Requisition Form is the ordering form the PWNHealth provider completes to order the test for you.

You will receive this document via an order confirmation email from GRAIL if the PWNHealth provider orders your test.

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Do I need to fast prior to the blood draw?	No preparation or fasting is required. Some lab technicians may ask if you have fasted (no eating or drinking), but this is not required for the Galleri test.
I received my Galleri sample collection kit. What happens next?	Please do not break the quality seal on the collection kit. it should be opened by the lab technician who draws your blood sample. Store the collection kit at room temperature until your blood draw appointment. The contents are sensitive to extreme temperatures. For example, avoid storing your collection kit in the trunk of your car. Your next step is to schedule a blood draw at a GRAIL partner lab.
What is inside the Galleri sample collection kit?	The collection kit includes instructions for the lab technician, two tubes for the blood sample, and packing materials to ensure the sample is safely shipped to GRAIL. Please do not break the quality seal on the collection kit. it should be opened by the lab technician who draws your blood sample.
How do I return the Galleri sample collection kit after my blood draw?	The lab technician who draws your blood will pack and ship your sample back to GRAIL for processing. Your sample will arrive at GRAIL 1 to 2 business days after your blood draw.
How much blood is needed for the Galleri test?	Approximately 1.5 tablespoons (or about 20 mL) of blood in two tubes typically from a vein in your arm.
I received my Galleri kit but no longer want to complete the test process. What should I do?	Please contact GRAIL Customer Service at customerservice@grail.com or 833-MY-GALLERI (833-694-2553) to let them know you will not be completing the test and discard of the kit.

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Test results and privacy

How long does it take to return my Galleri test results?	It takes about 2 weeks after your blood draw to receive your test results from the PWNHealth provider that ordered your test. Your result should be available to the PWNHealth provider who ordered your test within 10 business days (Mon-Fri excluding holidays) from the time your sample is received at GRAIL. Your sample will arrive at the lab 1 to 2 business days after your blood draw.
How do I cancel my test order if I no longer want to receive my results?	If you no longer wish to receive your Galleri results, please contact PWNHealth to request a cancellation at gc@pwnhealth.com or 888-494-7333. If you are unable to reach PWNHealth or require further assistance, please contact GRAIL Customer Service at customerservice@grail.com or 833-694-2553.
What does it mean if I receive a "Cancer Signal Not Detected" result?	This means that no cancer signal was found. However, not all cancers can be detected by the Galleri test. Continue with all routine screening tests that your healthcare provider recommends. Missing routine screenings or ignoring symptoms can lead to a delayed diagnosis of cancer. PWNHealth also offers optional post-test counseling to discuss your result, which is included in your benefit.
What does it mean if I receive a "Cancer Signal Detected" result?	This means that there is a suspicion of cancer, and additional tests are needed to see if you have cancer. The PWNHealth provider who ordered your test will share this result with you and what it may mean. When you request the test, you are given the option to enter your primary healthcare provider's contact information so your test result is automatically shared if a cancer signal is detected. If you do not have a primary healthcare provider, PWNHealth will partner with Include Health to help you find one in your area. The Galleri test can point to where in the body the cancer is coming from to help your primary healthcare provider guide next steps. Your primary healthcare provider will order appropriate follow-up testing to determine if cancer is present.

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Why are additional tests needed when the Galleri test detects a cancer signal?

Galleri is a screening test that detects cancer signals in blood. When a signal is detected, the Galleri test also indicates where in the body the signal is coming from with high accuracy.

The Galleri test is not a diagnostic test. Additional tests ordered by your primary healthcare provider are needed to confirm if cancer is present which may include blood work or imaging.

What happens if I get a false positive?

In the event that a diagnostic evaluation after a "cancer signal detected" result with Galleri does not confirm cancer, employees may be eligible for a complementary re-test with Galleri.

The request for a re-test must be placed by the healthcare provider managing the employee's diagnostic evaluation. The re-test must be administered within 3-6 months after the initial Galleri test. To initiate a request for a re-test, the healthcare provider managing the employee's diagnostic evaluation should contact GRAIL Customer Service at 833-MY-GALLERI (833-694-2553) or customerservice@grail.com. Customer Service hours are Monday through Friday 5:00 AM - 5:00 PM PT.

Why should I take the Galleri test in the future if a cancer signal is not detected?

The Galleri test is looking for the presence of cancer at the time your blood is drawn, but you may develop cancer in the future. The test does not measure your risk of developing cancer in the future and it does not detect all cancers.

Can you share my Galleri test result with my primary healthcare provider?

Yes, when you request the test, you are given the option to enter your primary healthcare provider's contact information so your test result is automatically shared if a cancer signal is detected.

We will not automatically share a No Cancer Signal Detected result, but we encourage you to share it with your primary healthcare provider.

Who can see my test result?

The PWNHealth provider that orders the test will receive your test result and share it with you. Your test result and medical information are confidential and access is limited to individuals who need the information for a specific purpose.

For example:

- If a cancer signal is detected, your test result will be shared with your primary healthcare provider (if you gave their contact information) so they can guide your next steps
- If a cancer signal is detected, your test result may be shared with AccessHope so they can consult with your primary healthcare provider and specialists, and advise on standard diagnostic care pathways

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Who is AccessHope?	When it comes to treating cancer, every moment matters, so getting expert care should be as easy as possible. AccessHope connects you and your local treating doctor to expertise from renowned National Cancer Institute (NCI)-Designated Comprehensive Cancer Centers for expert cancer support.
Is my test result shared with my employer?	Your employer only receives de-identified and aggregated information across all employees and will not receive individual results.
Will my Galleri test results impact my premiums?	If you receive a "Cancer Signal Detected" result from the Galleri test, and follow-up diagnostic testing confirms a cancer diagnosis, it will not impact your premiums through Klick. Existing cancer or cancer that is in remission would need to be disclosed in most insurance applications. This does not necessarily mean that new policy applications would be declined or require higher premiums.
Will my Galleri test results impact my insurability for other insurance products?	If you receive a "Cancer Signal Detected" result from the Galleri test, and follow-up diagnostic testing confirms a cancer diagnosis, it will not impact your other insurance products, like life insurance, through Klick. Existing cancer or cancer that is in remission would need to be disclosed in most insurance applications. This does not necessarily mean that new policy applications would be declined or require higher premiums.

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 "Cancer Signal Not 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 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.

