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Ashkenazi Jewish descent.

Specific genetic variants in the BRCA1 and BRCA2 genes are associated with an increased risk of developing certain cancers, including breast cancer (in women and men) and ovarian cancer. These variants may also be associated with an increased risk for prostate cancer and certain other cancers. This test includes three genetic variants in the BRCA1 and BRCA2 genes that are most common in people of

BRCA1/BRCA2 (Selected Variants)

play+7cc1ce1057, we could **not determine** if you have the three genetic variants we tested.

This test is intended to detect two variants in the BRCA1 gene and one variant in the BRCA2 gene, but your result could not be determined.







This can be caused by random test error or other factors that interfere with the test. If you have a personal or family history of cancer, you should talk to a healthcare professional about other testing options.

How To Use This Test

This test does not diagnose cancer or any other health conditions and should not be used to make medical decisions. Results should be confirmed in a clinical setting before taking any medical action.

Please talk to a healthcare professional if cancer runs in your family, you think you might have cancer, or you have any concerns about your results.

Review the BRCA1/BRCA2 (Selected Variants) tutorial

See Frequently Asked Questions

See Scientific Details for complete Indications for Use statement and full list of Warnings, Precautions, and Limitations

Intended Uses

- Tests for three specific genetic variants: the 185delAG and 5382insC variants in the BRCA1 gene and the 6174delT variant in the BRCA2 gene. These variants are associated with an increased risk of developing certain cancers.
- · Provides information on whether a person's genetic result is associated with an increased risk for breast and ovarian cancer and may be associated with an increased risk for prostate cancer and certain other cancers.

Limitations

- Does not test for all possible variants in the BRCA1 and BRCA2 genes. More than 1,000 variants in these genes are known to increase cancer risk. Only three of those variants are included in this test.
- Does not test for variants in other genes linked to hereditary cancers.
- · Does not account for non-genetic factors, like environment and lifestyle, that influence overall cancer risk.

· The interpretation of your genetic result depends on the sex you reported in

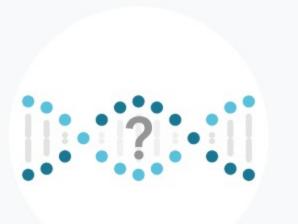
Important Ethnicities

your account settings.

- · The variants included in this test are most commonly found in people of Ashkenazi Jewish descent. In 23andMe customers of other ethnicities, between 0% and 0.1% of individuals has one of the three variants in this
- This test does not include the majority of BRCA1 and BRCA2 variants found in people of other ethnicities. Therefore, a "variants not detected" result is less informative for people with no Ashkenazi Jewish ancestry.

We could **not determine** if you have any of the three variants we tested linked to hereditary male breast cancer and prostate cancer.

If you have a personal or family history of cancer, consider talking with a healthcare professional about additional testing.



We could not rule out any of the three variants we tested.

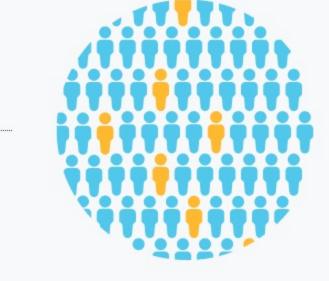
These three variants are most common in people of Ashkenazi Jewish descent and do not account for the majority of BRCA1 and BRCA2 variants in people of other ethnicities.

See Scientific Details

In the general population, about 1 in 9 men develops prostate cancer during his lifetime, and about 1 in 800 men develops male breast cancer.

Only a small percentage of these cancers are caused by the three genetic variants in this report. Your risk is influenced by many other factors, including lifestyle, family history, and other genetic factors.

See Scientific Details



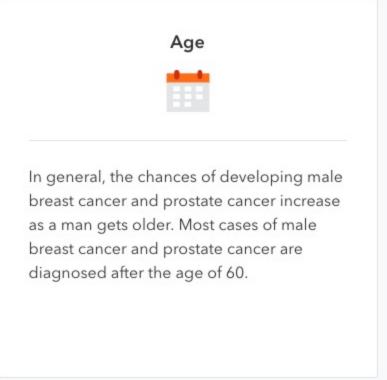


If you have a personal or family history of cancer, talk to a healthcare professional about other testing options.

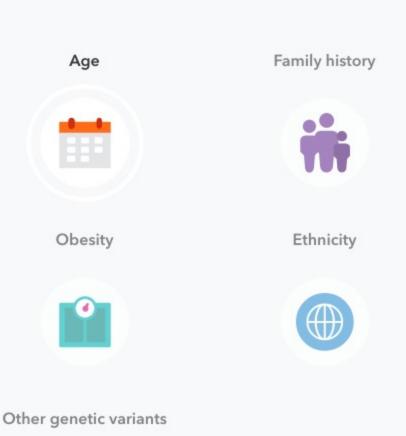
A genetic counselor can help you assess your overall cancer risk. Learn more about genetic counseling.

Lifestyle, family history, and other factors can also influence the chances of developing male breast cancer and prostate cancer.

Consult with a healthcare professional before making any major lifestyle changes.



See Scientific Details for more information



BRCA1 and BRCA2 variants are associated with an increased risk for several different cancers, including breast cancer (in women and men) and ovarian cancer. Variants in these genes may also be associated with an increased risk for prostate cancer, pancreatic cancer, and melanoma. The risk estimates below apply to BRCA1 and BRCA2 variants in general, including the three variants in this report.

About BRCA1/BRCA2-Related Cancers

Lifetime cancer risks

- . Men with a BRCA1 variant have a 1-2% chance of developing male breast cancer. They may also have an increased risk for prostate cancer and pancreatic cancer.
- . Men with a BRCA2 variant have a 7-8% chance of developing male breast cancer and an increased risk for prostate cancer. They may also have an increased risk for pancreatic cancer and melanoma.
- Women with a BRCA1 or BRCA2 variant have a greatly increased risk for breast and ovarian cancer, and may have an increased risk for pancreatic cancer and melanoma.

· See Scientific Details to learn more about these risks

When these cancers develop In general, the chances of developing cancer increase as a

person gets older. However, men with a BRCA1 or BRCA2 variant may develop earlier and more aggressive prostate cancer. Women with a BRCA1 or BRCA2 variant have an increased risk for early-onset breast cancer (before age 45) and multiple breast cancers. In addition, women with a BRCA1 variant may develop ovarian cancer at an earlier age.

How common are BRCA1 and BRCA2 variants?

BRCA1 or BRCA2 variant linked to hereditary male breast cancer and prostate cancer, although most of those variants are not included in this report. Among people of Ashkenazi Jewish descent, about 1 in 40 has a variant (usually one of the three variants in this report).

About 1 in 400 people in the general population has a



Screening and prevention Guidelines recommend that men with a BRCA1 or BRCA2

Screening guidelines for prostate cancer vary. Women with a BRCA1 or BRCA2 variant should be screened for breast cancer earlier and more often. However, there are

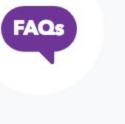
variant should be screened for male breast cancer.

currently no ovarian cancer screening tests that have been proven safe and effective. For women with a BRCA1 or BRCA2 variant, surgery and medication have been shown to be effective in reducing the risk of developing breast and ovarian cancer. Always consult with a healthcare professional before taking

any medical action.

Read more at: National Cancer Institute GeneReviews

Learn more about BRCA1/BRCA2-related cancers.



FAQs

See our Frequently Asked Questions for more information.

If you have a personal or family history of cancer, consult with a healthcare professional.



Learn more about cancer screening to help you and your doctor create a screening plan that's right for you.

Learn more

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Scientific Details Specific genetic variants in the BRCA1 and BRCA2 genes are associated with an increased risk of developing certain cancers, including breast cancer (in women and men) and ovarian cancer. These variants may also be associated with an increased risk for prostate cancer and certain other cancers. This test includes three genetic variants in the BRCA1 and BRCA2 genes that are most common in people of Ashkenazi Jewish descent.

BRCA1/BRCA2 (Selected Variants)

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Genetic variants in the BRCA1 and BRCA2 genes are associated with an

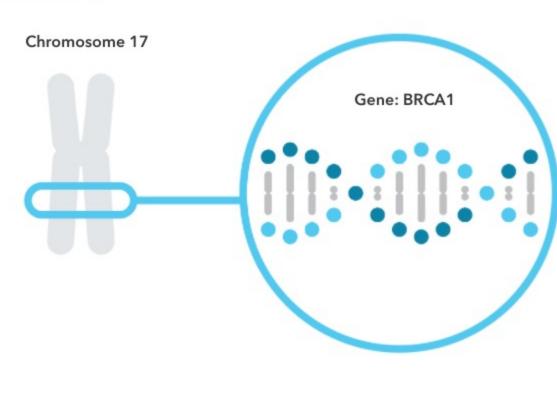
increased risk for certain hereditary cancers.

This report includes two variants in the BRCA1 gene and one variant in the BRCA2 gene. These three variants do not account for the majority of the BRCA1 and BRCA2 variants in the general population. More than 1,000 variants in these genes are known to increase cancer risk.

BRCA2

BRCA1

The BRCA1 gene contains instructions for making a protein that helps repair damaged DNA. The BRCA1 protein also helps control the process of cell division. Through both of these functions, the BRCA1 protein acts as a tumor suppressor, preventing cells from growing and dividing too rapidly. Certain variants in the BRCA1 gene disrupt the protein's function. This can lead to a buildup of DNA errors, and can cause normal cells to become cancer cells. Read more at Genetics Home Reference



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Variants Detected View All Tested Markers

Your result for the three genetic variants we tested could not

be determined.

| Marker Tested | Your Genotype* | Additional Information |
|---|----------------|--|
| 185delAG Gene: BRCA1 Marker: rs386833395 | Not determined | Biological explanation Typical vs. variant DNA sequence(s) Percent of 23andMe customers with variant References [1, 12, 23, 36, 40, 42, 59, 60, 67, 97, 98, 103, 104, 116] ClinVar³ |
| 5382insC Gene: BRCA1 Marker: rs80357906 | Not determined | Biological explanation Typical vs. variant DNA sequence(s) Percent of 23andMe customers with variant References [1, 12, 40, 42, 53, 59, 79, 97, 98, 99, 104, 108, 116, 120] ClinVar |
| 6174delT Gene: BRCA2 Marker: rs80359550 | Not determined | Biological explanation Typical vs. variant DNA sequence(s) Percent of 23andMe customers with variant References [1, 12, 18, 23, 38, 40, 42, 43, 59, 82, 85, 97, 98, 102, 104, 116] ClinVar |

²³andMe always reports genotypes based on the 'positive' strand of the human genome reference sequence (build 37). Other sources sometimes report genotypes using the opposite strand.

from both parents. This may impact how these variants are passed down.

This test cannot distinguish which copy you received from which parent. This test also cannot determine whether multiple variants, if detected, were inherited from only one parent or

Test Interpretation

This report provides risk estimates for several cancers associated with BRCA1 and BRCA2 variants. In most cases, these estimates represent a general risk for individuals with any BRCA1 or BRCA2 variant, not the specific risk estimates associated with the three variants in this report. This test does not take into account non-genetic factors that influence a person's overall risk for these cancers.

or during their lifetime (for men).

Cancer type

Ovarian

Breast (female)

Lifetime risk Health Risk Estimates The risk estimates shown below represent the proportion of people expected to develop a given Risk estimates are based on clinical studies cancer during their lifetime. Estimates for the general population are based on observed cancers that identify an association between a among people in the United States. Estimates for men and women with a BRCA1 or BRCA2 variant are

> General population

12.4%

1.3%

needed to understand the risk for people with this result. For some cancers, numerical risk estimates are

Numerical risk estimates are not available for

people who have both a BRCA1 and a BRCA2 variant. An interpretation of "increased risk" is provided to people with this result. It is likely

that their risk is at least as high as the risk for people with just one variant. More research is

genotype and a health condition.

not available. Consider talking to a healthcare professional if you have any concerns about your results.

References [30, 54, 59, 61, 111, 112]

BRCA2 variant **BRCA1** variant 45-85% 45-85% 10-27% 39-46%

Breast (male) 0.12% 1-2% 7-8% Prostate 11.6% May have an increased risk Increased risk 1.6% Pancreatic May have an increased risk May have an increased risk Melanoma 2.2% Research ongoing May have an increased risk See risk estimates by ethnicity for the general population

based primarily on studies of people of European and Ashkenazi Jewish descent. Estimates for people with a BRCA1 or BRCA2 variant represent the risk of developing cancer by the age of 70 (for women)

The three genetic variants in this report are associated with an increased risk for male breast cancer. They may also be associated with an increased risk for prostate cancer, pancreatic cancer, and melanoma.

References

[16, 64, 70, 80, 92,

96, 117]

[33, 44, 111]

[33, 87, 100]

[13, 39, 117]

[31, 55, 68]

Other Factors

Other Factors

However, other factors besides the genetic variants in this report can influence your chances of developing these cancers.

[54, 101, 111] Age People with multiple risk factors may have a higher risk of developing cancer. Like most cancers, the risk of developing male breast cancer and prostate cancer increases with age. For the average man in the U.S., the risk of Consult with a healthcare professional before developing prostate cancer by age 50 is 1 in 500. That number rises to 1 in

This is not a complete list of other factors.

making any major lifestyle changes.

of 60. In general, the risks for pancreatic cancer and melanoma also increase with age. Family history [33, 39, 44, 68, 90, 96] Most men who develop male breast cancer and prostate cancer don't have a family history of these cancers. However, men who have cases of

with cancer at an earlier age. This increased risk is likely due to shared

genetic and non-genetic factors. A family history of pancreatic cancer and melanoma also increases a person's risk for those cancers. Obesity Being overweight increases a man's chances of developing male breast cancer. The association between obesity and prostate cancer is less clear. However, some studies have found that men who are overweight are more likely to develop aggressive forms of prostate cancer. Obesity is also associated with a higher risk for pancreatic cancer. These increased risks may be due to differences in hormone levels in men who are overweight.

9 by age 80. Most cases of male breast cancer are diagnosed after the age

male breast cancer or prostate cancer in their family are more likely to develop these cancers themselves. A family history of female breast or ovarian cancer is also associated with an increased risk for male breast cancer and prostate cancer. The risk is even greater in families with more than one affected family member and in families with members diagnosed

Ethnicity African-American men have a greater risk of developing prostate cancer than men of other ethnicities. In the U.S., more than 1 in 7 African-

Other genetic variants More than 1,000 variants in the BRCA1 and BRCA2 genes have been linked to hereditary cancers. Variants in other genes can also increase a man's risk for male breast cancer and prostate cancer. In some cases, risk is increased to levels similar to the risk conferred by BRCA1 and BRCA2

Conditions such as liver cirrhosis, which can be caused by drinking too

The increase in cancer risk is thought to be due to a decrease in

much alcohol, can increase the chances of developing male breast cancer.

testosterone and an increase in estrogen in the body. Liver cirrhosis may

cancer. The effect of smoking on the risk of developing prostate cancer is

less clear. Smoking is also a major risk factor for pancreatic cancer,

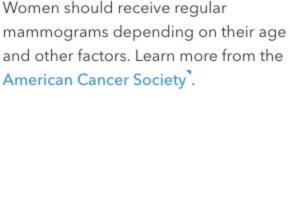
American men develops prostate cancer by the age of 80, compared to 1 in 9 men of European descent. African-American men are also more likely to develop prostate cancer at an earlier age. This difference may be due to

a combination of genetic and lifestyle factors.

also increase the risk for pancreatic cancer. Smoking Smoking is associated with an increased risk of dying from prostate

Liver disease

accounting for about 25% of all cases. Smoking does not appear to increase the risk for male breast cancer. Cancer Screening Guidelines



organizations may differ in their recommendations.

The 23andMe Personal Genome Service (PGS) uses qualitative genotyping to detect select clinically

reporting of the 185delAG and 5382insC variants in the BRCA1 gene and the 6174delT variant in the

developing prostate cancer. The three variants included in this report are most common in people of

general population. The test report does not describe a person's overall risk of developing any type of

Ashkenazi Jewish descent and do not represent the majority of the BRCA1/BRCA2 variants in the

BRCA2 gene. The report describes if a woman is at increased risk of developing breast and ovarian cancer, and if a man is at increased risk of developing breast cancer or may be at increased risk of

Breast cancer

Keep in mind that you could still have a BRCA1 or BRCA2 variant not included in this report that could affect your cancer risk. In that case, different screening and prevention actions may be recommended. Consult with a healthcare professional to learn

Men should talk with their doctor about

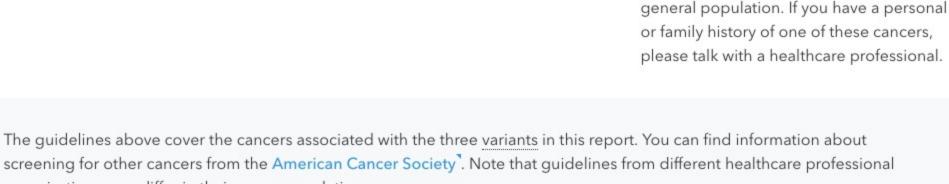
the benefits and risks of prostate cancer

screening. Learn more from the American

Prostate cancer

Cancer Society'.

Cancer screening can help detect certain cancers at an earlier stage, when they may be more treatable. The guidelines below apply to people with an average risk of developing cancer. These guidelines may help you and your doctor create a screening plan that's right for you.



Warnings, Precautions, and

This test should not be used to make

medical decisions. Results should be

This test does not cover all variants that

of a variant tested does not rule out the

· Other factors, such as environmental and

confirmed in a clinical setting before taking

could increase risk for cancer.* The absence

presence of other genetic variants that may

cancer in the future.

any medical action.

impact cancer risk.

There are currently no specific screening

pancreatic cancer, or melanoma. Although

against screening for ovarian cancer in the

recommendations, guidelines advise

guidelines for male breast cancer,

there are some conflicting

Test Details

Limitations relevant variants in genomic DNA isolated from human saliva collected from individuals ≥18 years with the Oragene Dx model OGD500.001 for the purpose of reporting and interpreting genetic health This test does not diagnose cancer or any risks, including the 23andMe PGS Genetic Health Risk Report for BRCA1/BRCA2 (Selected Variants). other health conditions and cannot The 23andMe PGS Genetic Health Risk Report for BRCA1/BRCA2 (Selected Variants) is indicated for determine your overall risk of developing

cancer, and the absence of a variant tested does not rule out the presence of other variants that may be cancer-related. This test is not a substitute for visits to a healthcare provider for recommended screenings or appropriate follow-up and should not be used to determine any treatments.

Special Considerations Genetic testing for BRCA1 and BRCA2 variants in the general population is not currently recommended by any healthcare professional organizations.

Indications for Use

- depends on family history and other factors. **Test Performance Summary** Clinical Performance [48, 50, 56, 57, 62, 71, 89, 93, 94, 108, 115, 116] The variants included in this report represent a very small subset of all those associated with breast, ovarian, and prostate cancer. The three variants tested are associated with an increased risk of developing these cancers. However, some people who have these variants do not develop cancer. In

This number is expected to be higher among individuals of Ashkenazi Jewish descent.

addition, most cases of these cancers are not caused by inherited genetic variants.

- About 1 in 40 people of Ashkenazi Jewish descent is expected to have one of the three variants in this report. These three variants are much less common in people of other ethnicities. In 23andMe three variants in this report.
- mutations in your sample may interfere with the performance of this test. The effects of the interfering mutations on the performance of this test have not been studied. For more details on the analytical performance of this test, refer to the package insert.

lifestyle risk factors, may affect your risk of developing cancer. This test does not Cancer risk associated with a BRCA1 or BRCA2 variant varies from person to person. Exact risk

 The three variants in this report account for more than 90% of cancer-related BRCA1 and BRCA2 variants among people of Ashkenazi Jewish descent. These three variants account for a much smaller proportion of cancer-related BRCA1 and BRCA2 variants found in people of other ethnicities.

Approximately 5-10% of breast cancer cases, 10-15% of ovarian cancer cases, and 15-20% of male

breast cancer cases are known to be caused by inherited variants in the BRCA1 and BRCA2 genes.

customers of other ethnicities, between 0% and 0.1% of individuals (up to 1 in 1,000) has one of the **Analytical Performance**

Accuracy was determined by comparing results from this test with results from sequencing. Greater

than 99% of test results were correct. The 95% confidence interval was 83.9% to 100%. While unlikely, this test may provide false positive or false negative results. It is possible that the presence of certain

test is for you.

account for those factors, and does not test for variants in other genes linked to hereditary cancers.

· Your ethnicity may affect how relevant this

This test is intended to provide you with

with your doctor or other healthcare professional. This device is not intended for prenatal testing.

· This test should not be used to assess the

presence of genetic variants that may

impact response to medications.

genetic information to inform conversations

 This test is not intended to detect the presence of deterministic variants in autosomal dominant diseases or conditions. This test is not a substitute for visits to a

healthcare professional for recommended

screenings. Consult with a healthcare

professional if you have any questions or concerns about your results or your current state of health. Some people feel a little anxious after getting genetic health risk results. This is

normal. If you feel very anxious, you should

speak to your doctor or a genetic counselor.

See the Package Insert for more details on use and performance of this test. * Variants not included in this test may be rare, may not be available on our genotyping platform, or may not pass our testing standards.

1. Abeliovich D et al. (1997). "The founder mutations 185delAG and 5382insC in BRCA1 and 6174delT in BRCA2 appear in 60% of ovarian cancer and 30% of

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4. American Cancer Society. "Breast Cancer in Men." Retrieved March 5, 2018, from https://www.cancer.org/cancer/breast-cancer-in-men.html." 5. American Cancer Society. "Breast Cancer." Retrieved March 5, 2018, from https://www.cancer.org/cancer/breast-cancer.html.

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- 10. Anderson KN et al. (2014). "Reproductive risk factors and breast cancer subtypes: a review of the literature." Breast Cancer Res Treat. 144(1):1-10." See all references 💙

Change Log

Your report may occasionally be updated based on new information. This Change Log describes updates and revisions to this report.

Date Change BRCA1/BRCA2 (Selected Variants) report created. April 9, 2018

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6. American Cancer Society. "Melanoma Skin Cancer." Retrieved March 5, 2018, from https://www.cancer.org/cancer/melanoma-skin-cancer.html." 7. American Cancer Society. "Ovarian Cancer." Retrieved March 5, 2018, from https://www.cancer.org/cancer/ovarian-cancer.html.



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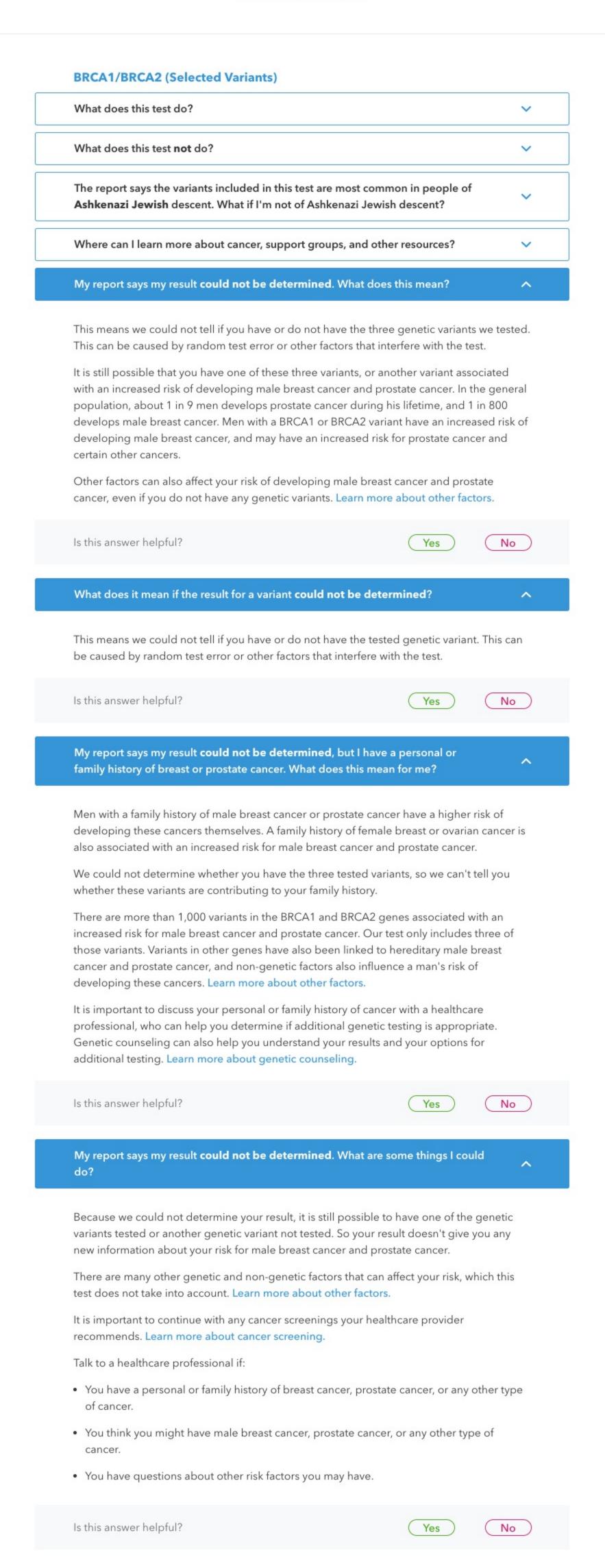
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BRCA1/BRCA2 (Selected Variants)

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Frequently Asked Questions

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Have more questions? Check out our Customer Care Help Center.





