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Stand up to Cancer:
MAGENTA
(Making **Gen**etic **T**esting **A**ccessible)

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Table of Contents

1. Objectives

To compare a standard approach to genetic counseling (telephone counseling both **pre-** and **post-genetic testing**) to three alternative approaches, all of which include online educational videos and online test results

1) **Pre-genetic testing** online educational video and **post-genetic testing** online test results report.
2) **Pre-genetic testing** online educational video and **post-genetic testing** online test results report with telephone genetic counseling.
3) **Pre-genetic testing** online educational video with telephone genetic counseling and **post- genetic testing** online test results report.

	Pre- Genetic Testing Education/Genetic Counseling	**Post- Genetic Testing Education/Genetic Counseling**
Arm A	Online educational video	Online Test Results Report
Arm B	Online educational video	Online Test Results Report + Telephone Genetic Counseling
Arm C (Standard)	Online educational video + Telephone Genetic Counseling	Online Test Results Report + Telephone Genetic Counseling
Arm D	Online educational video + Telephone Genetic Counseling	Online Test Results Report

A. Primary Objectives

1) To test the effects of online genetic education alone versus online genetic education with telephone genetic counseling on cancer-risk distress.

B. Secondary Objectives

1) To test the effects of online genetic education alone versus telephone genetic counseling with online genetic education on testing completion rates.
2) To evaluate the role of psychological and social variables in women's reactions to genetic testing for ovarian cancer risk with variable education strategies.
3) To consider the effects of variations of genetic education/counseling on genetic knowledge, satisfaction with the decision to undergo testing.

2. Rationale

The standard paradigm for cancer susceptibility genetic testing has been for patients to 1) be identified by their provider as being at high risk due to extensive family history or another diagnosis (e.g., breast cancer for ovarian cancer risk testing), and 2) attend in-person pre- and post- genetic test counseling sessions with a genetic counselor to prepare for testing and learn about the results. This time- and labor-intensive process has been found to deliver results in an appropriate and supportive environment where women can ask questions, receive reassurance, and facilitate family conversations after their own testing. However, due to the impracticality of this genetic testing model, many primary care providers or oncologists within the community are

ordering cancer susceptibility genetic testing with minimal to no levels of genetic counseling involvement. The current testing paradigm also places boundaries around the types of women willing to spend this time and effort receiving testing, as providers are required to act as gatekeepers to the testing process. In fact, in a recent study of over 11,000 women, two-thirds of insured women who underwent genetic testing for the *BRCA1* and *BRCA2* genes received no genetic counseling [1], calling into question the practicality of the current paradigm for in-person pre- and post-test genetic counseling. More open methods of accessing genetic testing and providing support are needed.

Two recently-published studies have identified telephone counseling as an equivalent method of providing pre- and post- test genetic counseling, genetic testing results, and support [2, 3]. These results, taken together with other studies that have used alternative approaches to in-person methods of delivering results and support to people undergoing genetic testing, indicate that using modern technology (i.e., telephone) to deliver an in-person service is not only possible, but also equivalent with respect to outcomes of cancer-related distress and completion of the genetic testing process. These studies have paved the way for testing and evaluating alternative methods of providing genetic testing support that would help to make genetic testing increasingly available to a wider audience.

We propose that we can deliver personal, risk-based genetic testing and results to women from the general public using the internet. Internet-based services offer several advantages over either in-person or telephone interventions. First, information can be accessed by participants and providers on their own schedules, at any location with internet access, and can be consumed at the pace and style that is best for individual preferences. If necessary, information and support can be re-reviewed if the patient does not remember the initial counseling session. Second, internet results can be shared more easily with family members, increasing access to potentially critical medical information to at-risk relatives. Third, delivery of information through the internet can be performed in a more efficient and cost-effective manner, reserving the limited in-person genetic counseling for individuals who need it the most, while providing support to the general public about basic medical and risk-based information. Finally, internet delivery can bring genetic testing to the patient in their home, eliminating a major barrier to testing (multiple visits to the provider) [4].These features make the internet a reasonable alternative to in-person or telephone counseling for providing genetic testing and risk-based information.

Evaluation for using this new technology to deliver genetic risk information widely and effectively is needed. Some scholars have predicted that use of the internet to deliver genetic risk knowledge will result in poor understanding or in lack of opportunity to feel satisfied with the process [5]. Others have expressed concern that internet delivery will increase confusing or negative reactions to risk information for women who learn about or receive results through this new modality. We selected a non-inferiority design to compare the effects of internet delivery of pre- and post- genetic testing education versus telephone genetic counseling separately, as the literature was not clear on this point.

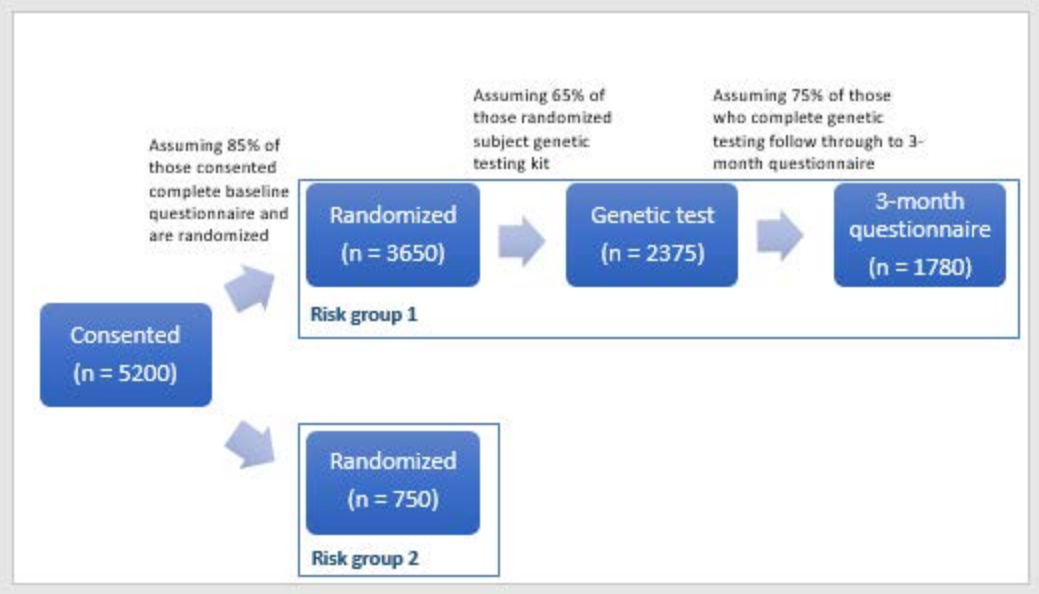
Commercially-available genetic testing panels are constantly evolving, as new mutations are identified and made clinically available. For genetic risk assessment, we will evaluate and provide feedback on 19 breast and ovarian cancer (OC) genes that have a clear relationship to cancer risk [6, 7]. The genes on this cancer panel will include: *ATM, BARD1, BRCA1, BRCA2, BRIP1, CDH1, CHEK2, EPCAM, MSH2, MSH6, MLH1, NBN, PALB2, PMS2, PTEN, RAD51C, RAD51D, TP53,* and *STK11*. Data on the mutation rate of these genes among affected individuals support a clinically-actionable risk.

The genetic testing services will be provided by Color Genomics (https://getcolor.com), a company that already provides high-quality, online genetic testing and education at affordable cost to the general public. However, the relative acceptability of this type of online education in comparison to a more traditional method of genetic counseling has not been established yet. We will use Color Genomics' testing platform to test our hypothesis that online education with supportive phone counseling on an as-needed basis when requested by the participant is equivalent (not inferior) to mandatory pre- and post- genetic test counseling.

3. Study Design

There will be up to 5200 participants consented to allow for a total of 3650 participants in risk group 1 and 750 in risk group 2 to be randomized through REDCap into one of four arms. Participants will be randomized to one of the four arms after the baseline questionnaire is completed.

- **Arm A:** Pre- genetic testing online educational video and post- genetic testing online test results report with approximately 1100 participants.
- **Arm B:** Pre- genetic testing online educational video and post- genetic testing online test results report with telephone genetic counseling with approximately 1100 participants.
- **Arm C:** Pre- genetic testing online educational video with telephone genetic counseling and online test results report with telephone genetic counseling with approximately 1100 participants. Arm C is the control arm.
- **Arm D:** Pre- genetic testing educational video with telephone genetic counseling and post- genetic testing online test results report with approximately 1100 participants.



Every participant in this study will have access to a genetic counselor by phone at any time throughout the study. A study phone number and email address is provided to all participants. If the genetic counselor providing the phone counseling believes that the participant is very distressed, the genetic counselor will refer the participant to a local provider based on their needs,

as is standard clinical practice.

A. Participant's study experience

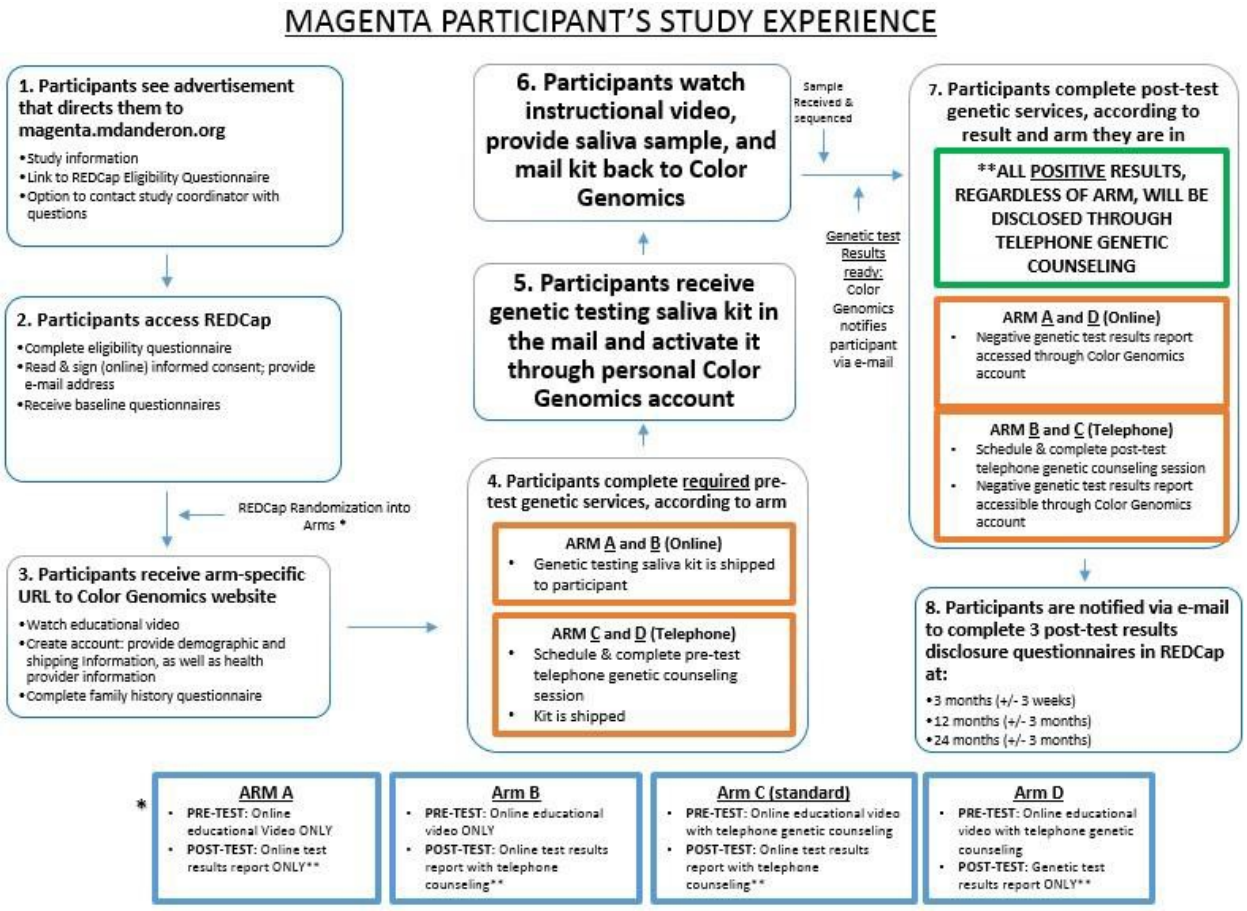


Figure 1 details a participant's experience in the study

B. Recruitment

Advertising for the study: In order to randomize 3650 women in risk group 1 and 750 in risk group 2, we will need to attract between 7,000- 10,000 women to the MAGENTA website (magenta.mdanderson.org). Recruiting efforts will be carried out through:

- Clinical settings: We will provide IRB approved flyers to clinical sites to catch interest of women who might be eligible and interested (Appendix A)
- Recruiting partners, including (but not limited to) advocacy groups and Genetic Counseling Organizations: Advocacy groups and Genetic Counseling Organizations that wish to participate will be provided with the IRB recruitment material, including the IRB approved flyer and blogs, press releases or social media advertisement material (Appendix C).

- MD Anderson Resources: We will utilize the MD Anderson Twitter account for advertisement of the study with the IRB pre-approved template.

In addition, the University of Washington collaborator, Deborah Bowen, PhD, will assist the MD Anderson MAGENTA team with review and analysis of recruitment methods and trends.

MAGENTA website: Study and contact information will be available for interested individuals in the MAGENTA website at http://magenta.mdanderson.org. (Screenshots available in Appendix D). A video on the website will also detail the overview of the study (Script and final video on Appendix E). They will be invited to complete the MAGENTA eligibility questionnaire in REDCap.

C. Eligibility Questionnaire

A potential participant's eligibility will assessed through a public eligibility questionnaire administered through REDCap. Prior to completing it, potential participants will acknowledge a consent statement for collection of eligibility information through REDCap. This statement clarifies that the answers provided do not guarantee enrollment in the study.

Participants who consent will be taken directly to the eligibility questionnaire (Appendix F). Those who don't consent will be thanked for their consideration and exit REDCap.

The eligibility criteria for the study is summarized below.

Inclusion criteria

Participants must meet each of the following four criteria:

1) Age 30 or older
2) Have access to a healthcare provider and be willing to share genetic results with that provider
3) Have at least one ovary
4) Have a valid United States mailing address for receipt of saliva kit

Additionally, participants must also meet any one of the following six criteria:

5) Diagnosed with breast cancer at age 45 or younger
6) Diagnosed with triple negative (negative for estrogen receptor, progesterone receptor and not Her2 amplified) breast cancer at 60 or younger
7) Have one blood relative with a mutation in *BRCA1, BRCA2, BRIP1, PALB2, RAD51C, RAD51D, BARD1, MSH2, MSH6, MLH1*, or *PMS2*
8) Have one relative with ovarian cancer
9) Have at least 2 relatives with breast cancer on the same side of the family, one of which is ≤50 years of age
10) Have one male relative with breast cancer

Exclusion criteria

1) Personal history of ovarian cancer
2) Unable to read, speak, and understand English
3) Unable to provide informed consent
4) Unwilling to complete baseline and follow-up questionnaires
5) Unable to access the internet
6) Previous genetic testing or counseling regarding cancer risk
7) Previous bone marrow transplant
8) Previous blood transfusion (7 days prior to genetic testing)
9) Active hematologic malignancy (cancer that begins in blood-forming tissue, such as leukemia or lymphoma)

The data obtained from eligibility criteria for those who are ineligible (or do not provide consent) may be used to determine 1) which recruitment method has been most successful in recruiting eligible participants, 2) from which geographic area have individuals been recruited from through the zip codes they entered and 3) potential eligibility criteria that is excluding interested patients. There is minimal to no risk to participants from providing this information.

D. Informed Consent

Based on the potential participant's answers to the eligibility questionnaire, those who qualify for the study will be immediately informed of their eligibility, and presented with the option to complete the online informed consent within REDCap.

In order to complete the online consent, participants must provide their name and email address, as well as create a unique username and password. Participants will then be emailed a link to the online consent and will need to use the information they provided in order to access the online consent form, as a method of verifying their identity before signing the electronic consent.

After reading the informed consent, participants will be asked to answer 5 comprehension questions regarding information found in the informed consent. Individuals may not sign the informed consent unless all the comprehension questions have been answered correctly.

This process follows the FDA draft guidance on electronic consent and has been reviewed and approved by the MDACC compliance team and the Information Security team.

If they agree to participate, they will electronically sign the informed consent and will be advised to save or print a copy of their signed consent form. (Appendix G).

We anticipate that it will take approximately two years to accrue the 3650 randomized participants in risk group 1 needed.

E. Baseline Questionnaires

After consenting to the study, participants will be asked to provide and confirm their e-mail address. Prior to arm assignment, participants will be emailed a link to complete their baseline questionnaires via REDCap (see Section 4). The study coordinator will be notified when a

participant has completed the baseline questionnaires, in order to proceed to the arm assignment phase.

F. Arm Assignment

We expect to randomize 3650 participants in risk group 1 in order to achieve the sample size needed for our primary outcome. Participants will be randomized equally to one of 4 study arms with the randomization stratified by risk group, as defined below. Our primary interest is in risk group 1, and the study is designed around this risk group.

After completing the baseline questionnaire, participants will be automatically randomized to one of the four arms using REDCap's randomization feature (participants will not be informed of which arm they are in). Participants will then receive an e-mail message via REDCap with the arm-specific link inside the Color Genomics website. The study specific link also contains a unique Color Genomics promotional code that can only be used once. This allows the study to ensure that each link is only used by the intended participant and tracks the number of Color Genomics kits utilized and purchased by the study.

Participants will have 30 days from randomization to proceed to the Color Genomics website and create an account. If this is not completed within 30 days, then their promotional code for testing via the study will expire.

For current participants who were not previously notified that their promo codes/ ability to move forward with genetic testing will expire, they will be sent the following email message:

"Dear MAGENTA participant, while you have completed the baseline questionnaire, you have not ordered your kit from Color Genomics. If you are having difficulty with this step, please respond to this email with your questions. You will have 2 weeks from today to order your kit. If your kit is not ordered in 2 weeks, you will no longer be able to proceed with testing as part of this study."

These study-specific URLs will direct participants to a secure Color Genomics website where they will create a password-secured account and provide contact and shipping information. Each study arm will have a different website interface, customized to the characteristics of the study arm.

All four study arms will receive the same basic educational content before undergoing genetic testing, consisting of an online, educational video delivered on the Color Genomics website. Selected participants will also receive telephone counseling, which will be provided by trained genetic counselors from Color Genomics.

For an overview of the participant's experience in Color Genomics, according to arm, refer to the following appendices: Arm A (Appendix H), Arm B (Appendix I), Arm C (Appendix J), and Arm D (Appendix K).

G. Pre- Genetic Testing Process

All participants, regardless of arm assignment, must watch an online educational video about hereditary cancers and genetic testing by Color Genomics (Script on Appendix L). This video will provide an explanation of hereditary cancer genes on the Color Genomics panel including their characteristics, inheritance patterns, associated cancer risks, and an overview of the possible results. After watching the video, the participants will provide their shipping information, the name and contact information for their local physician, as well as their personal and family history information.

The remainder of the pre- genetic testing process will differ based on study arm assignment.

- Participants in **Arms A and B** will be provided with the option to speak with a genetic counselor, if they have additional questions or concerns; if they do not choose to speak with a genetic counselor, they may proceed to genetic testing.

- Participants in **Arms C and D** will be required to make an appointment with a genetic counselor who will provide telephone pre-test genetic counseling. Only after completing telephone genetic counseling can these participants proceed to genetic testing.

Pre-test telephone genetic counseling will include a review of the participant's personal and family history, and an explanation of hereditary cancer genes on the Color Genomics panel, including their characteristics, inheritance patterns, and associated cancer risks. The genetic counselor will also review the risks, benefits and limitations of genetic testing, as well as the possible results and their implications for the participant and her family members. The participant will have ample opportunity to have all of her questions addressed by the genetic counselor. The pre-test genetic counseling telephone sessions will be documented with a written report and saved within the participant's REDCap data base (Appendix M). A copy of this document will also be provided to the participant.

H. Genetic Testing Process

After completing the pre- genetic testing process, participants will be mailed an FDA-approved saliva collection kit (ORAgene-Dx) from Color Genomics. Dr. Elizabeth Swisher, a co-investigator of the study and overall PI for the Stand Up to Cancer Grant, will serve as the ordering physician for the genetic test in all states except New York. She is a gynecologic oncologist at the University of Washington. Dr. Douglas Levine (study collaborator) will serve as the ordering physician for genetic testing in the state of New York.

Before providing a saliva sample, the participant must log into her account and activate her kit by entering the unique code provided on the kit's bar code. This step helps ensure that the individual providing the saliva sample is the appropriate participant. An instructional video (Script in Appendix N) will inform participants how to provide an adequate specimen and send it back to Color Genomics using a pre-paid shipping package. Once at Color Genomics, DNA is sequenced for the 19 hereditary cancer genes as is standard in their commercially available test. Testing takes 6-8 weeks to complete.

Participants will have 30 days from the day it is ordered to return their kit to Color Genomics. If their kit is not returned within 30 days, then their kits will expire.
For current participants who were not previously notified that kits will expire, they will be sent a notification that their kits will be expiring in 2 week. They will be sent the following email message:
"Dear MAGENTA participant, you have completed the baseline questionnaire and ordered your color kit. However, you have not sent your sample back. Please return within 2 weeks. If your kit is not received by Color Genomics in 2 weeks, it will no longer be active. "

For current participants who have not completed their pre-test counseling and were not previously notified that promo codes and kits will expire will be sent the following email message:

"Dear MAGENTA participant, you have completed your baseline questionnaire but have not scheduled your pre-test genetic counseling. You have 2 weeks to schedule the appointment. Please log in to your Color Genomics account to schedule the appointment or call (844) 352-6567. Please email magenta@mdanderson.org if you have questions.

I. Post- Genetic Testing Process and Results Disclosure

Once results are available, the participant will receive an email from Color Genomics informing her that she may log in to her account to view her results. Participants will have the opportunity to save and print their results from the Color Genomics website.

After the participant has received her results, a report of the participant's genetic test results will be provided to the healthcare provider she listed in her account. This report will include information regarding the meaning the test results and the participant's empiric cancer risks (based on the personal and family history provided).

For Participants with Negative Test Results:

- Participants in **arms A and D** will receive their results online and will be given the option to schedule an appointment with a genetic counselor to discuss their test results.

- Participants in **arms B and C** must make an appointment and initiate a post- test telephone genetic counseling session with the genetic counselor before they can receive their results.

Post- test telephone genetic counseling will include (but are not limited to): disclosure and review of the genetic test results, the implications of these results for the participant and her family, as well as the participant's residual cancer risks and recommended screening management guidelines based on the National Comprehensive Cancer Network (NCCN) criteria. The genetic counselor will also review with the participant the importance of sharing the genetic test results with her family members, and recommendations for genetic testing for relatives. Participants will also be given resources for additional information regarding hereditary cancer syndromes. The post-test genetic counseling telephone sessions will be documented with an individualized

written report and saved within the participant's record in the REDCap database. A copy of this document will also be provided to the participant.

For Participants with Positive Test Results

All participants with a deleterious mutation in one or more genes, regardless of study arm, must make an appointment to complete a post- genetic test telephone counseling session with the genetic counselor in order to receive their results. Once a post-test telephone genetic counseling session has been initiated, participants will be given access to their genetic test results. (Sample positive report is provided in Appendix P)

Post- test telephone genetic counseling (but are not limited to): disclosure and review of the genetic test results, the implications of these results for the participant and her family, as well as a discussion of the participant's cancer risks and recommended medical management guidelines based on NCCN criteria for the participant. The genetic counselor will also review with the participant the importance of sharing the genetic test results with her family members, and recommendations for genetic testing for other family members. Participants will be given resources for additional information regarding hereditary cancer syndromes and information regarding resources local to the participant. The post- test genetic counseling telephone sessions will be documented with an individualized written report and saved within the participant's record in the REDCap data base. A copy of this document will also be provided to the participant.

We will attempt to schedule a post- test telephone genetic counseling call three times with each participant with a deleterious mutation in one or more genes. If a participant does not respond to schedule the call within one week after the third attempt, we will deliver her results online with a note to please call and schedule a counseling session. We can verify electronically when participant has accessed her results through her account.

J. Post- Genetic Test Results Disclosure Questionnaires

Participants will be e-mailed a link to complete their questionnaires through REDCap at 3 months (+/- 1 month), 12 months (+/- 3 months) and 24 months (+/- 3 months) after results disclosure (see Table 1).

4. Questionnaires

All participants will complete surveys at baseline (prior to pre-genetic testing process) and at 3 months, 12 months and 24 months after receiving their results. To complete each survey each participant will receive an email with a request to complete the survey and a link to the survey. The request will remind women of the study and the follow-ups and will ask them to complete the survey within 7 days. Three reminder emails will be sent to each woman at one, two and three weeks after the initial email was sent, if they have not completed the survey. The study coordinator may also provide questionnaire reminders to participants via phone call. If the participant prefers, the coordinator may read the questionnaires over the phone to record the participant answers. After 30 days (for 3 month time point) or 90 days

(for 12 month and 24 month time-point) without completion of the questionnaires, the participant will be considered lost to follow-up. A date and time stamp will be automatically captured in REDCap when a questionnaire is completed. Table 1 lists the survey instruments for the study and the time points in which they are given.

Table 1. Questionnaires

			TIMEPOINTS			
	Outcome	**# of Questions**	**Baseline (prior to pre-genetic testing process)**	**3 months post-results disclosure**	**12 Months post-results disclosure**	**24 Months post-results disclosure**
Impact of Events Scale (IES) [8.9]	Cancer Risk Distress	15	X	X	X	X
Satisfaction with Decision (SWD) [10]	Decisional Satisfaction Concerns	6		X	X	X
Multidimensional Impact of Cancer Risk Assessment (MICRA) [11]	Genetic Testing Concerns	21		X	X	X
Generalized Anxiety Disorder Scale (GAD-7) [12]	Anxiety	9	X	X	X	X
Patient Health Questionnaire (PHQ-8) [13]	Depression	8	X	X	X	X
Decision Regret Scale [14]	Decisional Regret	5		X	X	X
Veterans RAND 12-Item Survey (VR-12) [15]	Quality of Life	12	X	X	X	X
Behavioral Risk Surveillance Study Measures [16]	Surveillance Behaviors	13	X	X	X	X
General Knowledge about HBOC [17]	Genetics Knowledge	9	X	X	X	X
Demographics		9	X			
Total Number of Questions		**107**	**76**	**99**	**99**	**99**

Each of these scales is relatively short (Appendix O-X). There are up to 108 questions, and it should take no more than 20 minutes for study participants to complete the questionnaires.

5. Distress Plan

The distress plan may be triggered during either the telephone genetic counseling session or by the responses to the questionnaires.

A. Distress detected by genetic counselor:

During the telephone counseling session, the genetic counselor will assess how the participant is handling the information based on the participant's responses. This is based on good clinical judgment. A genetic counselor generally ask questions such as "How are you feeling about this information?", "Do you feel that you have a support system?", and "How do you think you will feel if you were to test positive?" If the genetic counselor is concerned about the participant's responses, he/she will also determine whether Dr. Lu and/or the study co-chairs should be notified. These procedures will be documented by the genetic counselor in the genetic counseling note. If, after speaking with the genetic counselor, Dr. Lu and/or the study co-chairs feels the participant needs to be referred to her local physician (this is the physician that the participant indicated is their local provider when creating their Color Genomics account), Dr. Lu and/or the study co-chairs will call the participant's local provider to inform him/her of the situation within 72 hours of the genetic counselor's telephone counseling session (or if the local healthcare provider is unavailable, this will be communicated with the provider covering for them). Dr. Lu and/or the study co-chairs will also contact the participant to recommend that she contact her local provider. The participant will be given the website *www.psychologytoday.com* as a resource. The study investigators (PI and/or study co-chairs) contact with the participant and her physician will be documented within REDcap; this will be considered source documentation. The genetic counselors are very experienced in working with high-risk patients and presenting genetic test results. Based on their clinical experience, these situations are extremely rare events.

B. Distress detected by questionnaire responses:

The cutoff scores for distress REDCap message are: A score between > 9 to < 20 on the PHQ- 8 or a score of equal to or greater than 15 on the GAD-7. If any of these scores are detected for a participant, REDCap will immediately display a message to the participant with the following: "Based on your responses to this questionnaire, we recommend that you call your local healthcare provider for mental health resources. Additional resources are also available at: www.psychologytoday.com".

The cutoff scores for notification of distress: A response of ≥ 20 on the PHQ-8. If a participant indicates a response of ≥ 20 on the PHQ-8, REDCap will immediately display the following message to the participant: "If you feel that you may harm yourself, please contact your local healthcare provider, call 911 or go to your nearest emergency room. National Suicide Prevention Lifeline: 1-800-273-8255. Hours: 24 hours, 7 days a week Languages: English, Spanish Website: www.suicidepreventionlifeline.org". In addition, if the participant indicates a response of ≥ 20 on the PHQ-8, REDCap will immediately notify the MAGENTA email account (this email account is monitored by the study coordinator and other team members), as well as Dr. Lu and/or

the study co-chairs email accounts. The email will indicate the participant has exceeded the cutoff score for a specific questionnaire and will include the participant's name, questionnaire score, contact information and a time stamp. Within 72 hours Dr. Lu and/or the study co-chairs will contact the participant to inform her about the questionnaire response and recommend that the participant to follow-up with her local physician. The participant will be given the website *www.psychologytoday.com* as a resource. If Dr. Lu and/or the study co-chairs feel that it is indicated, participant's physician will be contacted to inform him/her that the participant's questionnaire results suggest that the participant should seek follow-up consultation for distress. (If the local healthcare provider is unavailable, this will be communicated with the provider covering for them). Dr. Lu and/or the study co-chairs will also inform the genetic counselor on the study and document this information in REDCap; this will be considered source documentation.

6. Statistical Considerations

Given a total of 5200 subjects consented, we expect ≈ 85% to complete the baseline questionnaire. We therefore expect to randomize 3650 participants in risk group 1 in order to achieve the sample size needed for our primary outcome, given that around 65% will follow through to complete the genetic testing, and, of those subjects, 75% will complete the 3-month questionnaire. 750 subjects will be randomized from risk group 2 and included in the analysis for the secondary outcome. Participants will be randomized equally to one of 4 study arms with the randomization stratified by risk group, as defined below. Our primary interest is in risk group 1, and the study is designed around this risk group.

Risk Group 1

1. Women with a personal and/or family history that increases the likelihood of carrying an ovarian cancer (OC) gene: (a) one relative with OC, (b) one male relative with breast cancer, (c) at least two relatives with breast cancer (BC) on the same side of the family, one of which was diagnosed at age ≤ 50 years, (d) personal history of triple negative BC diagnosed at age ≤ 60 years or any BC diagnosed at age ≤ 45 years. We expect to randomize 3650 participants in this risk group.

Risk Group 2

2. Relatives of individuals with deleterious mutations in OC genes. We expect to randomize 750 participants in this risk group.

We will use descriptive statistics to summarize the demographic characteristics of participants in each of the four study arms.

A. Primary Outcome: Impact of Event Scale (IES)

Table 2. Number of Participants in Risk Group 1 with IES Scores before and after Testing

		Post- genetic testing Education/Counseling		
		Report	Report + Phone	Total
Pre- genetic testing Education/Counseling	Video	445 (A)	445 (B)	890
	Video + Phone	445 (D)	445 (C)	890
	Total	890	890	1780

NOTE: All participants with positive results will have telephone counseling regardless of study arm.

We expect that 3650 participants randomized will be in Risk Group 1. Of these 3650 participants, we expect ≈ 2375 to complete the genetic testing (i.e., 65% of subjects randomized), and 1780 to complete the study (i.e., 75% of subjects who completed the genetic testing) by responding to the follow-up questionnaires.

A sample size of 445 participants with primary outcome available on each of the 4 study arms described in the table above with baseline and 3-month assessments will yield 93% power to reject each of the following null hypotheses with a 1-sided significance level of 0.0083. We use a Bonferroni correction to the usual 1-sided significance level of 0.025 (i.e., 0.025 ÷ 3 = 0.0083) to preserve our overall 1-sided significance level at 0.025 since we will test 3 hypotheses. With 93% power for each hypothesis we will have 93% × 93% × 93% = 80% power to reject all 3 null hypotheses. We assume that stress about the risk of getting cancer is measured with the Impact of Event Scale (Horowitz et al. 1979), that the scores for the pre- and post- genetic test phone counseling arm (arm C) will be similar to those reported in (Schwarz et al. 2014), a standard deviation of 15.3, and a non-inferiority margin of 4 points as suggested by Schwarz et al. We will test each of the 3 alternative hypotheses against the single null hypothesis, as shown below. Here μ is the mean stress score, and study arm C is the control arm.

$$H_0: \mu_K - \mu_C \geq 4$$

$$H_{1A}: \mu_A - \mu_C < 4$$

$$H_{1B}: \mu_B - \mu_C < 4$$

$$H_{1D}: \mu_D - \mu_C < 4$$

We will conduct an interim analysis of efficacy and futility using the method of Lan and DeMets (1983) [18] with O'Brien-Fleming (1979) [19] stopping boundaries once half the participants have been enrolled and completed the 3 month assessment. The nominal significance level for the interim analysis of efficacy will be 0.0002, the nominal significance level for the interim analysis of

futility will be 0.3285, and the significance level for the final analysis will be 0.0082. We will conduct these interim analyses for each alternative hypothesis stated above. This sample size calculation was performed using East 5.4 (Copyright © 2010, Cytel Inc., Cambridge, MA).

Once the study is complete we will construct 99.17% one-sided confidence intervals for differences in mean cancer stress scores for study arms A, B, and D compared with study arm C within risk group 1, and if the upper bound of the confidence interval is < 4 we will reject the null hypothesis stated above and conclude that the study arm is not inferior to study arm C. We will conduct a similar analysis with risk groups 1 and 2 combined. An evaluable participant will be any participant that has completed the Impact of Events scale at the baseline and 3 month post-results disclosure time points. We expect that approximately 20% of participants who completed the genetic testing will not complete both the baseline and the 3-month assessments of the Impact of Events scale.

We will conduct the analysis of the primary outcome on the "intent-to-treat" population of all evaluable participants as randomized. As a supporting analysis we will also conduct the analysis of the primary outcome on the "as treated" population of all evaluable participants, according to the study arm they actually completed. Note that those participants with positive results will speak with a genetic counselor by phone. If such a participant was randomized to study arm A, tests positive, then speaks with a genetic counselor by phone, they are in effect completing study arm B. Similarly, a participant may move from study arm D to study arm C.

B. Secondary Outcomes:

Table 3. Number of Participants Randomized

		Post- genetic testing Education/Counseling		
		Report	Report + Phone	Total
Pre- genetic testing Education/Counseling	Video	1100 (A)	1100 (B)	2200
	Video + Phone	1100 (D)	1100 (C)	2200
	Total	2200	2200	4400

NOTE: All participants with positive results will have telephone counseling regardless of study arm.

One secondary outcome is the "completion" rate, defined as a participant progressing through the entire process from pre- genetic testing education/counseling to receiving her test results and post- genetic testing education/counseling. However, for our secondary outcome we will test only 2 hypotheses, as stated below.

$$H_{01}: \pi_{pre-test\ video+phone} - \pi_{pre-test\ video} \geq 6\%$$
$$H_{11}: \pi_{pre-test\ video+phone} - \pi_{pre-test\ video} < 6\%$$

and

$$H_{02}: \pi_{post-test\ report+phone} - \pi_{post-test\ report} \geq 6\%$$
$$H_{12}: \pi_{post-test\ report+phone} - \pi_{post-test\ report} < 6\%$$

where π is the "completion" rate.

A sample size of 2200 participants with pre-genetic testing video + pre-test telephone genetic counseling (arms C+D) and 2200 participants with pre-genetic testing video education (arms A+ B) will yield 97.7% power with a 1-sided significance level of 0.0125 to reject the null hypothesis H_{01} stated above. We assume that the "completion" rate with pre- genetic testing video + pre-test telephone genetic counseling will be 33% [2] and a non-inferiority margin of 6%.

Once the study is complete we will construct a 98.75% one-sided confidence interval for the difference in completion rates for pre-genetic testing video + pre-test telephone genetic counseling and pre-genetic testing video education, and if the upper bound of the confidence interval is < 6% we will reject null hypothesis H_{01} stated above and conclude that pre- genetic testing video based education is not inferior to pre- genetic testing video + pre-test telephone genetic counseling.

We will test hypothesis H_{02} stated above in the same manner. With 97.7% power to reject each null hypothesis we will have 97.7% × 97.7% = 95.5% power to reject both null hypotheses.

We will use descriptive statistics and boxplots to summarize the scores on each of the questionnaires at each assessment time for each study arm. We will similarly summarize the change from baseline in scores. To evaluate the role of psychological and social variables in women's reaction to genetic testing for ovarian cancer risk with variable education strategies, we will use regression methods to model scores (and changes from baseline) of the IES as a function of study arm, risk group, time, and scores (and changes from baseline) of the MICRA, GAD-7, PHQ-8, VR-12, and BRSS. We will also use regression methods to model scores of the SWD and DRS as functions of study arm, risk group, and time to understand the effects of variations in genetic education/counseling on satisfaction with decision. To assess the impact on genetics knowledge of variations in genetic education/counseling we will use regression methods to model scores (and changes from baseline) of the "General Knowledge about Hereditary Breast and Ovarian Cancer (HBOC)" questionnaire as a function of study arm, risk group, and time.

We will conduct all secondary analyses on the "intent-to-treat" and "as treated" populations of all participants randomized.

7. Financial Considerations

All study procedures and measures will be provided to participants free of charge, paid for by research dollars. This includes use of website, study sample collection, genetic panel testing, returning results via email to the participant and to the provider, and all genetic counseling as per the study protocol. Any subsequent follow-up, treatment, or preventive activities will be paid for by the participant and /or by health insurance.

8. Data and Protocol Management

Study data will be collected and managed using REDCap (Research Electronic Data Capture) electronic data capture tools hosted at MD Anderson. [20] REDCap (www.project-redcap.org) is a secure, web-based application with controlled access designed to support data capture for research studies, providing: 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless downloads to common statistical packages; and 4) procedures for importing data from external sources. REDCap (https://redcap.mdanderson.org) is hosted on a secure server by MD Anderson Cancer Center's Department of Research Information Systems & Technology Services. REDCap has undergone a Governance Risk & Compliance Assessment by MD Anderson's Information Security Office and found to be compliant with HIPAA, Texas Administrative Codes 202-203, University of Texas Policy 165, federal regulations outlined in 21CFR Part 11, and UTMDACC Institutional Policy #ADM0335.

Study data will also be sent from Color Genomics to MD Anderson and imported into REDCap. This data will include the personal and family health information completed on the Color Genomics website, as well as the participant's genetic test results and zip code.

Those having access to the data include the study principal investigator (PI) and research team personnel. Users are authenticated against MD Anderson's Active Directory system. The application is accessed through Secure Socket Layer (SSL). All protected health information (PHI) will be removed from the data when it is exported from REDCap for analysis. All dates for a given participant will be shifted by a randomly generated number between 0 and 364, thus preserving the distance between dates. Dates for each participant will be shifted by a different randomly generated number.

Following publication study data will be archived in REDCap. Since study data may be useful for future research studies performed under separate IRB approved protocols, study data will be archived indefinitely in REDCap. Since REDCap is a secure electronic database with controlled access, and because identifiers may be needed to link study data to data from other sources under future IRB approved protocols, participant identifying information will be retained in the archived database.

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Protocol Appendices

Appendix	Description
A	Magenta Recruitment Flyer
B	List of Recruitment Partners Via Facebook
C	Study emails to partcipants
D	MAGENTA website
E	Informational Video Script
F	Eligibility Questionnaire
H	Color Genomics interface Arm A
I	Color Genomics interface ArmB
J	Color Genomics interface Arm C
K	Color Genomics interface Arm D
L	Color Genomics Pre-Genetic Testing Educational Video
M	Genetic Counseling Documentation Template
N	How to provide a saliva sample script
O	Impact of Events Scale Questionnaire
P	Satisfaction with Decision Questionnaire
Q	Multidimensional Impact of Cancer Risk Assessment (MICRA) Questionnaire
R	GAD-7 Questionnaire
S	PHQ-8 Questionnaire
T	Decisional Regret Scale Questionnaire
U	VR-12 Questionnaire
V	BRFSS Surveillance Questionnaire
W	HBOC Knowledge
X	Demographic Questionnaire
Z	Eligibility Questionnaire (ineligible)
XXX	Magenta newsletter
YYY	Recruitment Materials

magenta

making genetic testing accessible

Background:

Genetic testing can help identify individuals who are at increased risk to develop ovarian cancer. People who have a genetic mutation identified by genetic testing can take steps to prevent cancer.

Eligible participants must:

- Be English-speaking women over the age of 30
- Live in the U.S.
- Have a personal or family history of breast cancer OR family history of ovarian cancer
- Be willing to share their genetic test results with local healthcare provider

Additional eligibility criteria is available at magenta.mdanderson.org

Purpose of study:

Through this study we hope to make genetic testing more accessible by studying the use of online genetic testing services alone vs telephone genetic counseling with online genetic education. Study participation will last about 2 years.

Study Procedures:

- Saliva Sample for Genetic Testing through Color Genomics
- Online genetic education video
- Phone Genetic Counseling (depending on study arm)
- Quality-of-Life Questionnaires

For more information:

Please visit magenta.mdanderson.org
or contact us at 713-745-7877 or email magenta@mdanderson.org

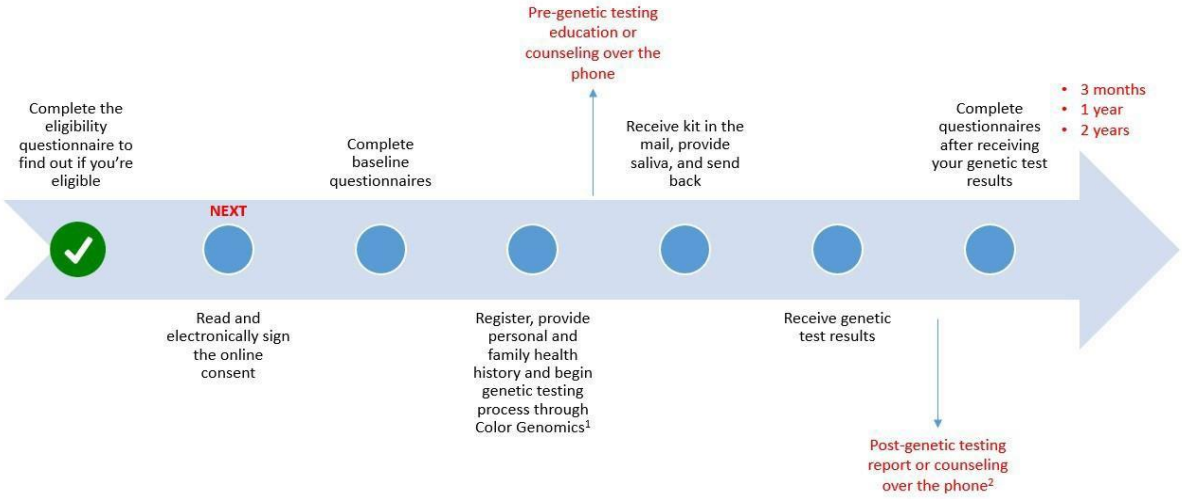
THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center
Making Cancer History®

Appendix B

Facebook Recruitment Partners

Category	Group	Facebook Followers
SU2CDream Team OVCA Dream Team Partners	SU2C	1,288,686
	Ovarian Cancer Research Fund (OCRF)	35,764
	Ovarian Cancer National Alliance (OCNA)	30,545
	National Ovarian Cancer Coalition (NOCC)	28,973
	Facing our Risk of Cancer Empowered (FORCE)	15,801
	American Association for Cancer Research (AACR)	34,975
	Minnesota Ovarian Cancer Alliance	3,282
Breast Cancer Organizations	Lynn Sage Foundation	6,296
	Living Beyond Breast Cancer	59,607
	Susan G. Komen (national)	849,678
	Susan G. Komen -Minnesota	5,077
	Bright Pink	48,912
	Sharsheret	6,069
	Breast Cancer Research Foundation	48,964
Hereditary Breast and Ovarian Cancer Groups	Lynn Cohen Foundation	1,548
	Pink and Blue: Colors of Heredity Cancer (movie page)	8,434
	Decoding Annie Parker	4,867
Health Care Institutions	Lorie Cancer Center	2,877
	Fred Hutchinson	16,790
	Dana Farber	183,819
	Mayo Clinic	728,961
Ovarian Cancer Groups	Teal Toes	16,585
	Marsha Rivkin Center for Ovarian Cancer Research	711
Young Adult Cancer Org.	Stupid Cancer	311,947
African American Breast Health Org.	Sisters Network	9,420
	National Society of Genetic Counselors	2,865

1. ***MAGENTA STUDY: Read and Sign the Online Informed Consent Document (E-mail that participants receive to complete the informed consent)***



[1] Color Genomics owns and operates a CLIA licensed and CAP-accredited laboratory in California, U.S.A. that will be performing the genetic testing.
[2] All participants with a positive test result will receive genetic counseling over the phone

Dear [MAGENTA participant],

Click on the link below to open the Informed Consent for the MAGENTA study. Please review it and decide whether you would like to participate in the MAGENTA study. For more information, visit our study website. [Hyperlink to magenta.mdanderson.org]

To log into the consent, use the username and password you created. If you have problems logging in, please contact us at magenta@mdanderson.org.

Sincerely,

The MAGENTA Team

You may open the survey in your web browser by clicking the link below:

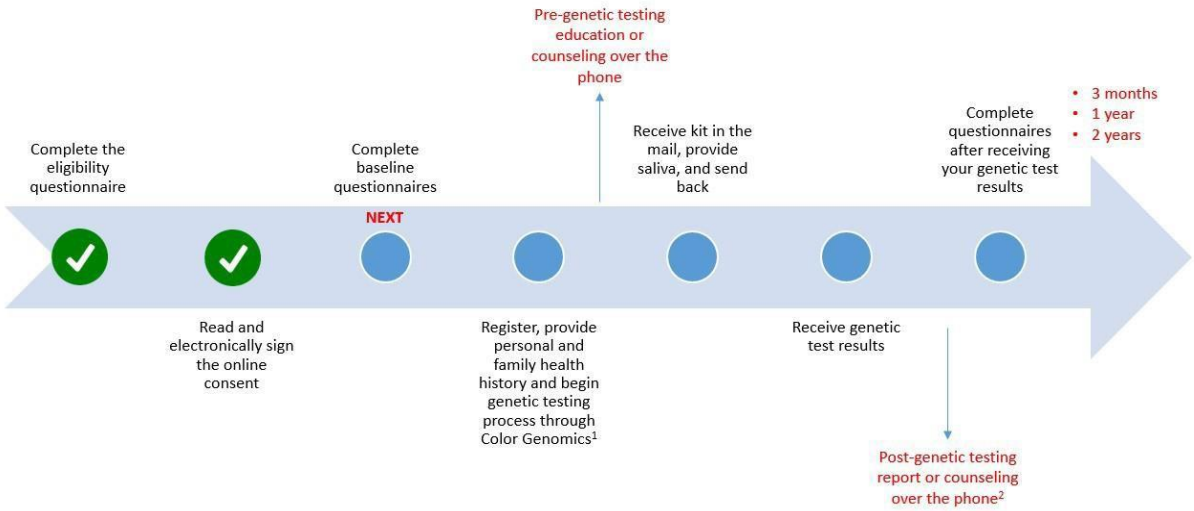
[Hyperlink to MAGENTA Consent Form]

If the link above does not work, try copying the link below into your web browser.

[URL to REDCap]

This link is unique to you and should not be forwarded to others.

2. ***MAGENTA STUDY: Complete Your Baseline Questionnaires (E-mail that participants receive to complete baseline questionnaire)***



[1] Color Genomics owns and operates a CLIA licensed and CAP-accredited laboratory in California, U.S.A. that will be performing the genetic testing.
[2]All participants with a positive test result will receive genetic counseling over the phone

Dear [MAGENTA participant],

Congratulations! You are now part of MAGENTA.

The link below will take you to a baseline questionnaire we would like you to complete as part of your participation in the MAGENTA study. Your answers will help us evaluate the effectiveness of providing genetic testing and support to high-risk women using this method. It should take you about 20 minutes to complete.

You may receive e-mail reminders like this one if you have not completed them.

Note: You will not be able to begin the genetic testing process until these have been completed

To log into the baseline questionnaires, use the username and password you created. If you have problems logging in, please contact us at magenta@mdanderson.org.

Sincerely,

The MAGENTA Team

You may open the survey in your web browser by clicking the link below:

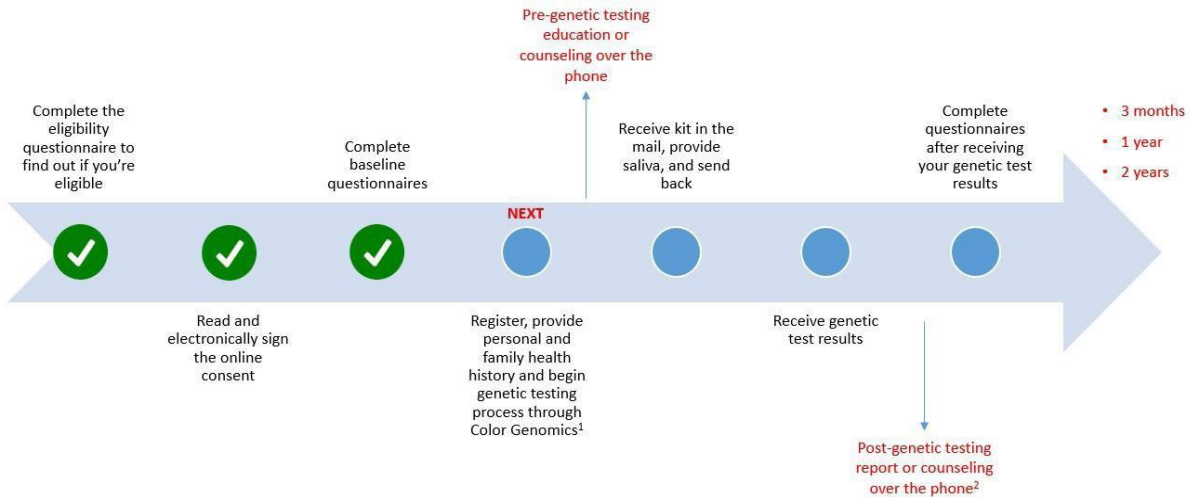
[Hyperlink to Baseline Questionnaires]

If the link above does not work, try copying the link below into your web browser.

[URL to REDCap]

This link is unique to you and should not be forwarded to others.

3. ***MAGENTA STUDY: You're Almost Ready To Begin The Genetic Testing Process (E-mail that participants receive <u>after</u> completing baseline questionnaire)***



[1] Color Genomics owns and operates a CLIA licensed and CAP-accredited laboratory in California, U.S.A. that will be performing the genetic testing.
[2]All participants with a positive test result will receive genetic counseling over the phone

Dear [MAGENTA participant],

Thank you for completing your baseline MAGENTA study questionnaires.

You will receive another e-mail from the MAGENTA study team in a few days with information on how to order your genetic testing kit.

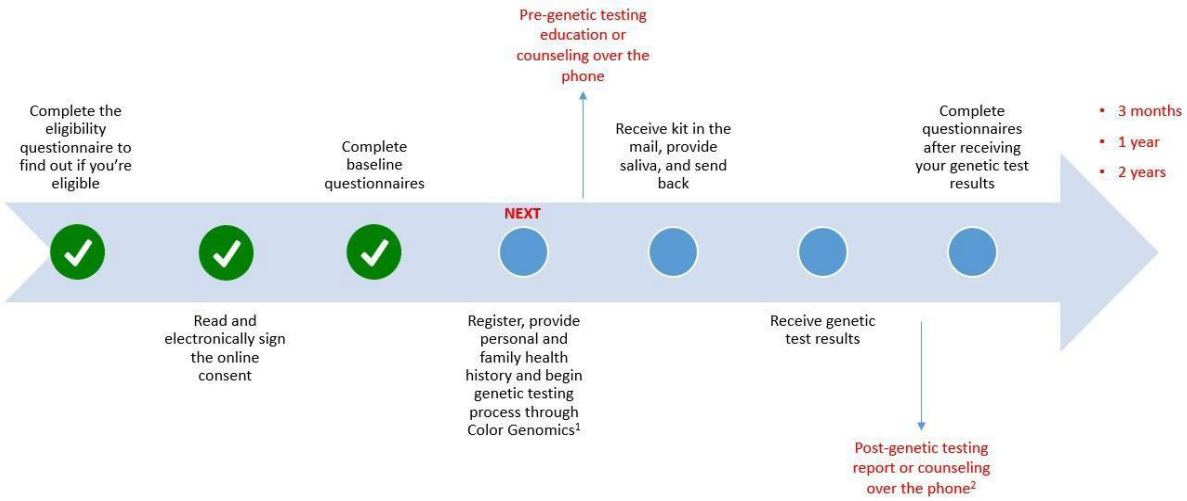
Questions? Please contact the MAGENTA study team by e-mail at magenta@mdanderson.org or by phone at 713-745-7877.

Sincerely,

The MAGENTA Team

4. *MAGENTA STUDY: You're ready to begin the genetic testing process*

Dear [MAGENTA participant],



[1] Color Genomics owns and operates a CLIA licensed and CAP-accredited laboratory in California, U.S.A. that will be performing the genetic testing.
[2]All participants with a positive test result will receive genetic counseling over the phone

You are ready to begin your genetic testing process through Color Genomics.

MAGENTA is partnering with Color Genomics to provide genetic testing for breast and ovarian cancer risk. The next step in the study is to create a Color account and request your saliva collection kit to be mailed to your home. We encourage you to research your family's health history, as this information will be needed. Specifically, you will be asked about:

- The ages of your children, parents, siblings, grandparents, aunts, and uncles.
- The history of cancer for any of these people - what types and at what age.

Estimates are fine, but this may be easier if you do a bit of research first. If you are adopted or don't have access to this information for another reason, you will still be able to request a saliva collection kit.

Note: Due to state regulations, it is important that you provide your sample **in the same state** that your saliva kit is shipped to.

Click on the link below to order your genetic testing kit.

Sincerely,

MAGENTA Team

You may open the survey in your web browser by clicking the link below:

[Hyperlink to Color Genomics]

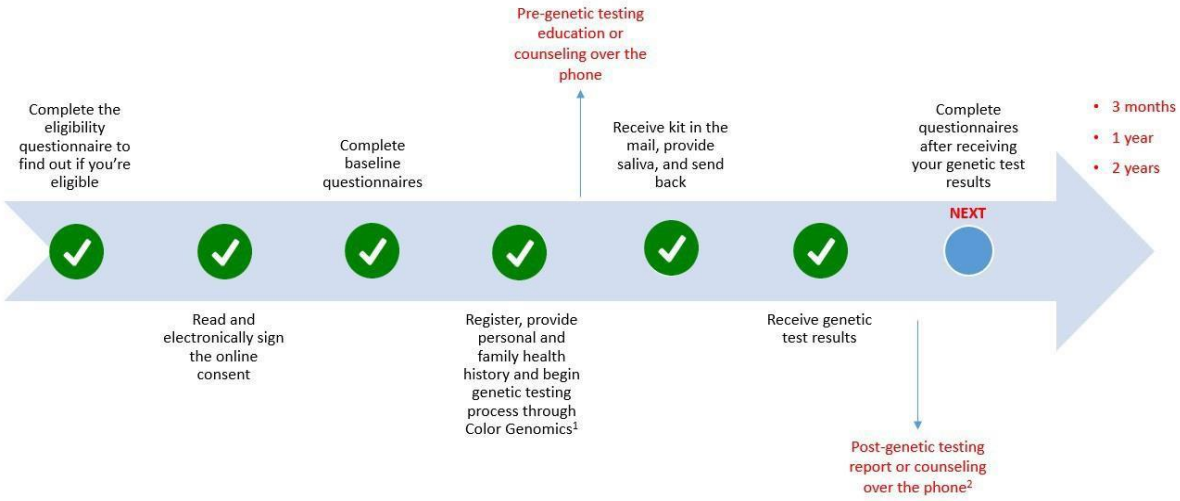
If the link above does not work, try copying the link below into your web browser.

[URL to REDCap]

This link is unique to you and should not be forwarded to others.

Click here to be taken to the Color Website

5. ***MAGENTA STUDY: Complete Your 3-Month Questionnaires (E-mail that participants receive to complete 3-month questionnaire after results disclosure)***



[1] Color Genomics owns and operates a CLIA licensed and CAP-accredited laboratory in California, U.S.A. that will be performing the genetic testing.
[2] All participants with a positive test result will receive genetic counseling over the phone

Dear [MAGENTA participant],

Thank you for your continued participation in the MAGENTA study.

The link below will take you to a 3-month questionnaire we would like you to complete. Your answers will help us evaluate the effectiveness of providing genetic testing and support to high-risk women using this method. It should take you about 20 minutes to complete.

You may receive e-mail reminders like this one if you have not completed them.

To log into the 3-month questionnaires, use the username and password you created. If you have problems logging in, please contact us at magenta@mdanderson.org.

Sincerely,

The MAGENTA Team

You may open the survey in your web browser by clicking the link below:

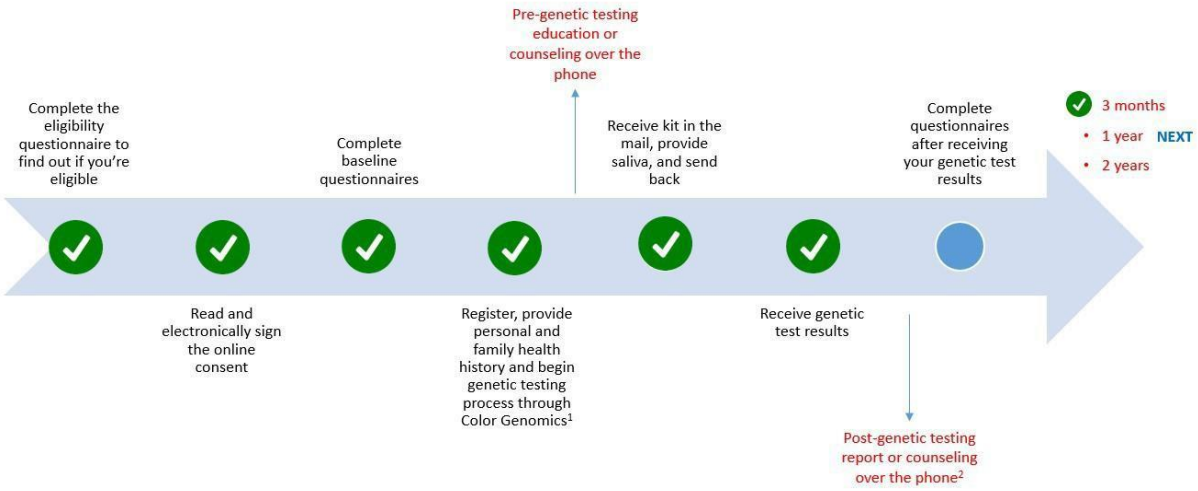
If the link above does not work, try copying the link below into your web browser.

[URL to REDCap]

This link is unique to you and should not be forwarded to others.

[Hyperlink to 3-month questionnaire]

6. ***MAGENTA STUDY: Complete Your 1-Year Questionnaires (E-mail that participants receive to complete 1-year questionnaire after results disclosure)***



[1] Color Genomics owns and operates a CLIA licensed and CAP-accredited laboratory in California, U.S.A. that will be performing the genetic testing.
[2]All participants with a positive test result will receive genetic counseling over the phone

Dear [MAGENTA participant],

Thank you for your continued participation in the MAGENTA study.

The link below will take you to a 1-year questionnaire we would like you to complete. Your answers will help us evaluate the effectiveness of providing genetic testing and support to high-risk women using this method. It should take you about 20 minutes to complete.

You may receive e-mail reminders like this one if you have not completed them.

To log into the 1-year questionnaires, use the username and password you created. If you have problems logging in, please contact us at magenta@mdanderson.org.

Sincerely,

The MAGENTA Team

You may open the survey in your web browser by clicking the link below:

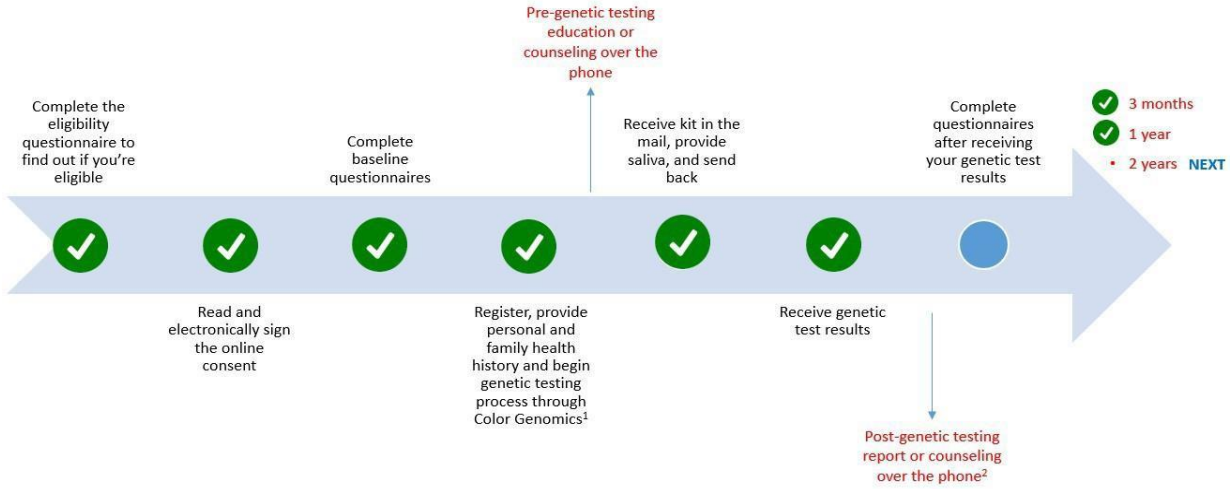
If the link above does not work, try copying the link below into your web browser.

[URL to REDCap]

This link is unique to you and should not be forwarded to others.

[Hyperlink to 3-month questionnaire]

7. ***MAGENTA STUDY: Complete Your 2-Year Questionnaires (E-mail that participants receive to complete 1-year questionnaire after results disclosure)***



[1] **Color Genomics owns and operates a CLIA licensed and CAP-accredited laboratory in California, U.S.A. that will be performing the genetic testing.**
[2]**All participants with a positive test result will receive genetic counseling over the phone**

Dear [MAGENTA participant],

Thank you for your continued participation in the MAGENTA study.

The link below will take you to a 2-year questionnaire we would like you to complete. Your answers will help us evaluate the effectiveness of providing genetic testing and support to high-risk women using this method. It should take you about 20 minutes to complete.

You may receive e-mail reminders like this one if you have not completed them.

To log into the 2-year questionnaires, use the username and password you created. If you have problems logging in, please contact us at magenta@mdanderson.org.

Sincerely,

The MAGENTA Team

You may open the survey in your web browser by clicking the link below:

If the link above does not work, try copying the link below into your web browser.

[URL to REDCap]

This link is unique to you and should not be forwarded to others.

[Hyperlink to 2-Year questionnaire

8. ***MAGENTA STUDY: We will contact you in 3 months to complete your next set of questionnaires (E-mail that participants receive after they complete genetic testing process with Color Genomics)***

Dear [MAGENTA participant],

Our most recent records indicate that you have completed the genetic testing process through Color Genomics. We appreciate your support and continued participation.

We will contact you in approximately **3 months** to complete the next set of questionnaires. Your answers will help us evaluate the effectiveness of providing genetic testing and support to high-risk women using this method. It should take you about 20 minutes to complete them.

In the meantime, please contact us with your questions.

If you think anyone may be interested in participating in our study, please ask them to visit us at https://magenta.mdanderson.org.

Sincerely,

The MAGENTA Team
E-mail: magenta@mdanderson.org Phone:
713-745-7877

9. ***MAGENTA STUDY: We will contact you in 9 months to complete your next set of questionnaires (E-mail that participants receive after they complete their 3-months questionnaire)***

Dear [MAGENTA participant],

Thank you for completing the 3-month questionnaires. We appreciate your support and continued participation.

We will contact you in approximately **9 months** to complete the next set of questionnaires. Your answers will help us evaluate the effectiveness of providing genetic testing and support to high-risk women using this method. It should take you about 20 minutes to complete them.

In the meantime, please contact us with your questions.

If you think anyone may be interested in participating in our study, please ask them to visit us at https://magenta.mdanderson.org.

Sincerely,

The MAGENTA Team
E-mail: magenta@mdanderson.org
Phone: 713-745-7877

10. ***MAGENTA STUDY: We will contact you in 12 months to complete your last set of questionnaires (E-mail that participants receive after they complete their 12-months questionnaire)***

Dear [MAGENTA participant],

Thank you for completing the 12-month questionnaires. We appreciate your support and continued participation.

We will contact you in approximately **1 year** to complete your last set of questionnaires. Your answers will help us evaluate the effectiveness of providing genetic testing and support to high-risk women using this method. It should take you about 20 minutes to complete them.

In the meantime, please contact us with your questions.

If you think anyone may be interested in participating in our study, please ask them to visit us at https://magenta.mdanderson.org.

Sincerely,

The MAGENTA Team
E-mail: magenta@mdanderson.org
Phone: 713-745-7877

11. ***MAGENTA STUDY: Your Participation in the study has concluded (E-mail that participants receive after they complete their 24-months questionnaire)***

Dear [MAGENTA participant],

Thank you for completing your last set of questionnaires, and more importantly, for your continued support and continued participation on this study.

If you think anyone may be interested in participating in our study, please ask them to visit us at https://magenta.mdanderson.org.

Sincerely,

The MAGENTA Team
E-mail: magenta@mdanderson.org Phone:
713-745-7877

MAGENTA Participant Media Features

Description of MAGENTA Participant Media Features

The goal of media features is to provide a platform for **MAGENTA** participants to share information about their experiences participating in the study, and using these to build interest in and direct potential participants to the study homepage.

Media features may include online publications/blog posts, or interviews through radio, television, or other mainstream media.

Contacting participants

Participants will be contacted initially by email through a REDCap survey (see page 13) to gauge interest in sharing their experience participating in the study through media features.

Those who agree to share their experience will be contacted by the personnel responsible for preparing the content

Media Feature Template

- Feature Opening: Brief description of the **MAGENTA** study. This may include:
    - General description of study goals:
        - The MAGENTA study aims to improve availability of genetic testing for hereditary cancer syndromes to at-risk individuals through the use of an online genetic testing service. Our hope is that making genetic testing accessible, without requiring them to travel to their healthcare provider, will save more lives by preventing cancer in women found to be at an increased risk of getting it.
    - Eligibility criteria*
        - Women 30 years or older, able to speak/read English, have a personal or family history of breast cancer or family history of ovarian cancer, never have had genetic testing/counseling, willing to undergo genetic testing (at no cost) and share results with a healthcare provider have at least ovary
        - *Other eligibility must be met
    - Description of benefits to participant:
        - MAGENTA: Eligible participants will receive genetic testing at no cost.
- Main Content: Participants will be prompted to share their experience participating in the **MAGENTA** study (this will not be scripted)
- Closing: Audience informed that the **MAGENTA** study is currently recruiting participants, and will be referred to the MD Anderson **MAGENTA** homepage (https://magenta.mdanderson.org) to learn more about the study and find out if they are eligible to participate.

12. **E-mail to invite participants to share their study experience**

Dear <name of participant>,

Thank you for your continued participation in the MAGENTA study.

We are contacting you at this time to offer you the opportunity to share your experience as a participant of this study, and help us raise awareness about the study to a wide audience. This may involve being interviewed and featured on a blog post or speaking on a radio or television program.

Please complete the survey at the bottom of this message to inform us of your interest.

If you agree to be part of this effort, you will be contacted by study personnel and/or Stand Up to Cancer (the study sponsor/supporter) with further instructions. If you have any questions about Stand Up to Cancer's role in this study, please contact the MD Anderson study team at magenta@mdanderson.org or 713-745-7877.

If you decline, your participation in the study will not be affected in any way.

We appreciate your commitment to the study.

Sincerely,

Team MAGENTA

13. **REDCap survey to invite participants to share their study experience**

Dear <name of participant>,

We would like to gauge your interest in being publicly featured by this study's sponsor, Stand up to Cancer. This may involve being interviewed and featured on a blog post or speaking on a radio or television program.

Please indicate your response below.

- I agree to be contacted to share my experience in the MAGENTA study.
    - If selected:

      Thank you for helping us. You will be contacted by the personnel responsible for coordinating these interviews with further instructions.
- I decline to be contacted to share my experience in the MAGENTA study
    - Thank you for completing our survey.

Appendix D

THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

About the MAGENTA Study

The Study of Genetic Testing from Your Living Room.

The MAGENTA study aims to improve availability of genetic testing for hereditary cancer syndromes to at-risk individuals through the use of an online genetic testing service. Our hope is that making genetic testing accessible, without requiring them to travel to their healthcare provider, will save more lives by preventing cancer in women found to be at an increased risk of getting it.

magenta
making genetic testing accessible

Complete the eligibility questionnaire to find out if you are eligible for our study

GET STARTED ›

Data from the MAGENTA study will be collected and managed using REDCap (Research Electronic Data Capture), a secure, HIPAA compliant, web-based application with controlled access designed to support data captured from research studies.

Eligible Participants

The MAGENTA study will focus on women who:

- Are 30 years of age or older
- Are able to read and speak English
- Have a valid mailing address in the U.S.

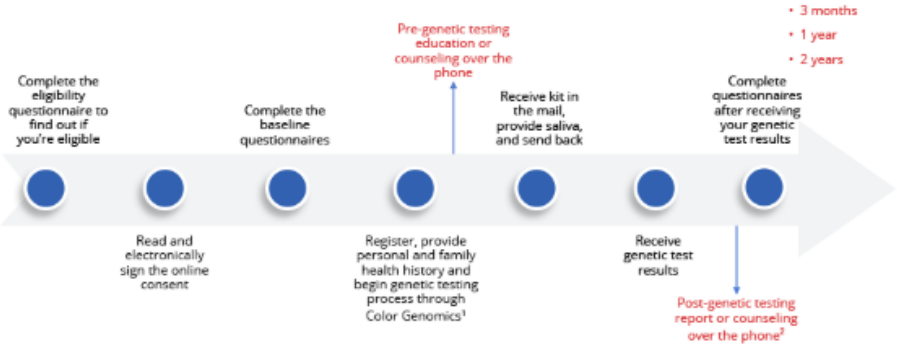
Participation in this trial will not require any travel, but will require access to the internet and phone.

Study Requirements

Participants who qualify for this study will fill out personal and family health history information, undergo genetic testing (saliva sample) for 19 genes associated with inherited cancer risk *, and complete a series of online questionnaires regarding their experience. Some individuals in this study will undergo genetic counseling over the phone; others not. For more information on study requirements, please review the MAGENTA Study Timeline below.

* The 19-gene panel includes: *ATM, BARD1, BRCA1, BRCA2, BRIP1, CDH1, CHEK2, EPCAM, MSH2, MSH6, MLH1, NBN, PALB2, PMS2, PTEN, RAD51C, RAD51D, TP53,* and *STK11*.

Study Timeline



1. Color Genomics owns and operates a CLIA licensed and CAP-accredited laboratory in California, U.S.A. that will be performing the genetic testing.
2. All participants with a positive test result will receive genetic counseling over the phone.

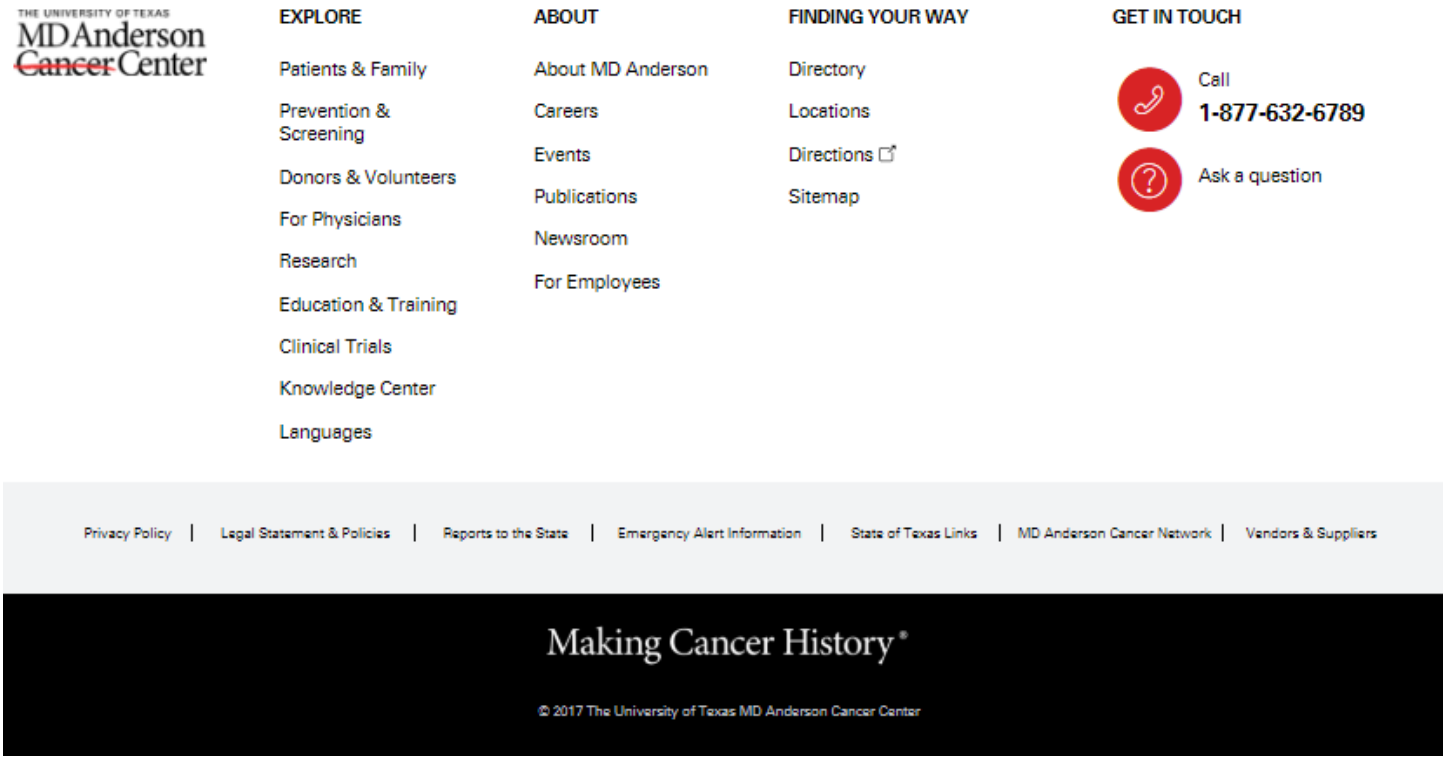
A Collaborative Research Effort

The MAGENTA study is supported by the Stand Up To Cancer-Ovarian Cancer Research Fund Alliance-National Ovarian Cancer Coalition Dream Team.

- Have a personal or family history of breast cancer OR a family history of ovarian cancer (no personal history of ovarian cancer allowed)
- Have at least one ovary
- Have never had genetic testing or counseling for cancer risk in the past
- Are willing to undergo genetic testing (at no cost) and share their results with their healthcare provider
- Are willing to complete a series of questionnaires for up to two years

Questions about the Study?

Email: magenta@mdanderson.org
Phone #: (713) 745-7877
Availability: Mon - Fri, 8am - 5pm CST



Should enrollment cease, the "Get Started" button will be taken off the site and the following message will be displayed in place of the "Complete the Eligibility Questionnaire…" statement:

[*We are not currently enrolling further participants. Please check again later.]*

Appendix E

Objective: Recruit participants to the MAGENTA Clinical Trial & lay the foundation of the study (MAGENTA: Making Genetic Testing Accessible)

Proposed Length: 2:00 (approx. 297 word script)

Frame	VO	On-Screen Text
1	Have you ever wondered if you might be at risk for ovarian cancer? What if there is a way that we can help?	
2	Studies show that 15% of ovarian cancer cases are due to DNA changes, called genetic mutations.	
3	Genetic testing can help people detect these changes that put them at increased risk for cancer. We are evaluating a new way to tell you about your risk and handing you the key to your own cancer prevention.	
4	We are Team MAGENTA, a nationwide coalition of scientists and advocacy groups intent on combating ovarian cancer using new methods of making genetic testing and education available to more women.	MAGENTA: MA-king GEN-etic Testing Accessible
5	We're developing a completely personal approach to determining ovarian cancer risk for women anywhere in the U.S. At no cost to you. Here's how it works.	
6	First, you'll fill out a confidential online questionnaire to determine your eligibility for the study based on personal and family health history. If you are eligible, you will be asked to review and sign the informed consent. Then, you will fill out a baseline questionnaire and set up a profile with the testing platform. In about a week, you'll receive a spit kit in the mail, provide some saliva and mail it back to us for DNA (genetic) analysis. As soon as your results are in, we'll send you an e-mail with instructions on how you can retrieve them via our web portal, in the privacy of your own home. Upon receiving your results, you're not alone. Some of you will talk to a genetic counselor at no cost to you via the telephone and other will receive educational support online.	

	You can call us if you have questions or concerns anywhere in the process, such as how many genetic mutations are there? Or, what happens if I receive a positive result? We will also ask you to fill out questionnaires over two years to assess your feelings about this approach to genetic testing and counseling. If you find out you have a mutation, your healthcare provider can help you create a personalized plan for early prevention and detection.	
7	Learning you're at risk is the beginning of a well-informed prevention plan. Start the questionnaire today.	This study is supported by Stand Up To Cancer, Ovarian Cancer Research Fund Alliance and the National Ovarian Cancer Coalition. (Subscript type)

Appendix F

MAGENTA Eligibility Questionnaire

MAGENTA Eligibility Questionnaire

Questionnaire Statement

The overall goal of this research study is to test the effects of online genetic education alone versus online genetic education with telephone genetic counseling in order to compare the two methods and the stress a person feels about their risk of cancer.

You are being asked to complete this questionnaire to determine your eligibility for this study.

If eligible, you will be asked to:

- Provide your name, email address, and date of birth
- Create a username and password to log into the study system to sign the study's consent form, review study information and answer study questionnaires

Authorization Statement

I have read the description of the MAGENTA (Making Genetic Testing Accessible) study, and I have decided to provide information that will help determine if I am eligible to participate in the research project described here. I understand that my answers will not guarantee my participation in this study, and that I may refuse to answer any (or all) of the questions at this or any other time. I understand that there is a possibility that I might be contacted in the future about this, but that I am free to refuse any further participation if I wish.

The Stand Up to Cancer research team at The University of Texas MD Anderson Cancer Center (MD Anderson) will collect and use my responses in this eligibility questionnaire in their research. My responses may be shared with study monitors who check the accuracy of the information, and individuals who put all the study information together in report form. I will not be identified in the publication of the results. By answering the questions, I am providing authorization for the research team to use and share my information. If I do not want to authorize the use and disclosure of my information, I may choose not to answer these questions. There is no expiration date for the use of this information as stated in this authorization.

I may withdraw my authorization at any time, in writing, for any reason as long as that information can be connected to me. For information on the Notice of Privacy Practices, please call 713-792-2933.

- ○ I agree to fill out the eligibility questionnaire.
- ○ I do not agree to fill out the eligibility questionnaire.

(The below is displayed if potential participants DO NOT AGREE to complete the eligibility questionnaire)

Thank you for your consideration of the MAGENTA Study.

(The below is displayed if participants AGREE to complete the Eligibility Questionnaire)

How did you hear about this study?

- ☐ from my healthcare provider (e.g., physician, nurse practitioner, or physician's assistant)
- ☐ from a friend
- ☐ from a family member
- ☐ from a patient advocacy organization
- ☐ in a magazine
- ☐ on television
- ☐ on the radio
- ☐ on the internet
- ☐ social media
- ☐ other

(Please select all that apply.)

(The questions below will populate IF any of the above appropriate boxes are selected)

Which advocacy organization?

- NOCC
- MOCA
- OCRFA
- FORCE
- Bright Pink
- TEAL
- Sisterhood of Ovarian Cancer Survivors
- Other

What magazine? _____

What television program? _____

What radio program? _____

What website? _____

What social media source?

☐ Facebook ☐ Twitter
☐ Other
(Select all that apply.)

What other social media source? _____
(If "Other", please specify.)

What advocacy organization?

What is your state of residence?

Alabama

Alaska

Arizona

Arkansas

California

Colorado

Connecticut

Delaware

Florida

Georgia

Hawaii

Idaho

Illinois

Indiana

Iowa

Kansas

Kentucky

Louisiana

Maine

Maryland

Massachusetts

Michigan

Minnesota

Mississippi

Missouri

Montana

Nebraska

Nevada

New Hampshire

New Jersey
New Mexico
New York
North Carolina
North Dakota
Ohio
Oklahoma
Oregon
Pennsylvania
Rhode Island
South Carolina
South Dakota
Tennessee
Texas
Utah
Vermont
Virginia
Washington
West Virginia
Wisconsin
Wyoming

What is your zip code?

(Please enter your 5 digit zip code.)

Are you able to read, speak, and understand English? Yes No

Do you have a valid United States mailing address for receipt of a saliva kit? Yes No

(On the previous 2 questions, the participant has to respond adequately for the items below to be displayed)

PERSONAL HISTORY

Are you a woman? ◯Yes ◯ No

(On the previous question, the participant has to select "Yes" for the item below to be displayed)

Have you ever had genetic testing or counseling regarding your cancer risk? Yes No

(On the previous question, the participant has to select "No" for the item below to be displayed)

Have you ever received a bone marrow transplant? Yes No

(On the previous question, the participant has to select "No" for the item below to be displayed)

Have you had a blood transfusion within the last seven (7) days? Yes No

(On the previous question, the participant has to select "No" for the item below to be displayed)

Do you have an active hematologic malignancy? Yes No
(cancer that begins in blood-forming tissue, such as leukemia or lymphoma)

(On the previous question, the participant has to select "No" for the item below to be displayed)

Are you 30 years of age or older? ◯ Yes ◯ No

(On the previous question, the participant has to select "Yes" for the item below to be displayed)

Do you have a healthcare provider that we can share your results with?

◯ Yes ◯ No

(Healthcare provider includes a physician, nurse practitioner, or physician's assistant.)

(On the previous question, the participant has to select "Yes" for the item below to be displayed)

◯ ◯

Do you have at least one ovary? Yes No

(On the previous question, the participant has to select "Yes" for the item below to be displayed)

◯ ◯

Have you been diagnosed with ovarian cancer? Yes No

(On the previous question, the participant has to select "No" for the item below to be displayed)

Have you been diagnosed with breast cancer? ◯ Yes ◯ No

(If the participant selects Yes, the following 2 questions will be displayed)

How old were you when you were diagnosed with breast cancer?

◯ 45 or younger ◯ 46 - 60
◯ I Don't Know

W ere you diagnosed with Triple Negative breast cancer? ◯ Yes ◯ No ◯ I Don't Know

(Triple-negative breast cancer is negative for estrogen receptors (ER-), progesterone receptors (PR-), and HER2 receptors (HER2-))

◯ Yes ◯ No ◯ I Don't Know

Do you have a blood relative with a known mutation in any of the following genes? *BRCA1, BRCA2, BRIP1, PALB2, RAD51C, RAD51D, BARD1, MSH2, MSH6, MLH1,* and *PMS2*

(On the previous question, the participant has to select "No" for the item below to be displayed)

FAMILY HISTORY OF OVARIAN CANCER (Family member is one that is a blood relative)

Do you have a blood relative diagnosed with ovarian cancer?

◯ Yes ◯ No ◯ I Don't Know

(On the previous question, the participant has to select "No" or "I don't know" for the item below to be displayed)

FAMILY HISTORY OF BREAST CANCER (Family member is one that is a blood relative)

Do you have a male blood relative diagnosed with breast cancer? ○ Yes ○ No ○ I Don't Know

(On the previous question, the participant has to select "No" or "I don't know" for the item below to be displayed)

Do you have <u>at least two (2) blood relatives</u> diagnosed with breast cancer on your <u>MOTHER'S SIDE OF THE FAMILY</u>? *(Such as: your mother, sister, daughter, aunt, grandmother or cousin)* ○ Yes ○ No ○ I Don't Know

(On the previous question, the participant has to select "Yes" for the item below to be displayed)

Was <u>at least one of these relatives</u> diagnosed with breast cancer <u>AT THE AGE OF 50 OR YOUNGER</u>? ○ Yes ○ No ○ I Don't Know

(On the previous question, the participant has to select "No" or "I don't know" for the item below to be displayed)

Do you have <u>at least two (2) blood relatives</u> diagnosed with breast cancer on your <u>FATHER'S SIDE OF THE FAMILY</u>? *(Such as: your sister, daughter, aunt, grandmother or cousin)* ○ Yes ○ No ○ I Don't Know

(On the previous question, the participant has to select "Yes" for the item below to be displayed)

Was at least one of those relatives diagnosed with breast cancer at the age of 50 or younger? Yes No I Don't Know

(The following is displayed if they are ELIGIBLE for the study)

Based on your answers to the questions above, you are ELIGIBLE to participate in the MAGENTA study. Please complete the information below if you would like to participate.

My responses to the questions above are correct to the best of my knowledge True False

(The below is displayed if participants select TRUE)

Name

_____

(First Name then Last Name)

Email address where you would like to receive study questionnaires and other information.

_____

Please check the box to the right after you have entered your e-mail address ***(Check Displayed)***

The email address you entered is [email address]
If this email address is not correct, please correct it above.

If this email address is correct, please check the box below.

☐ Email address is correct.

(If participants select "e-mail address is correct", the items below will be displayed)

Create a username and password that you will use to access future study questionnaires.

Please keep this information in your records in case you forget them later.

Username _____
Password _____
Date of
Birth

Once you have answered all the questions above, please click the SUBMIT button below.

(SUBMIT)

Arm A: Participant receives email from MAGENTA with URL & code

color

color

Welcome to Color. Before you get started…

As part of the MAGENTA study, please watch a video with important information about the benefits and limitations of genetic testing, as well as the results you might receive.

Read the content shown in this video.

☐ I have watched the video to the right.

Get Started

color

Sign In

Create a Color account to get started

This account will be used for activating your kit and returning your results.

First name | Last name

Email address

Create a password | Confirm password

I agree to the Color Terms of Service and Privacy Policy.

Create Account

Color Genomics

CLIA #05D2081492 - CAP #8975161

Mission Team Careers Privacy Press Contact

color

JENNY WALKER

You are receiving complimentary testing, courtesy of the MAGENTA study.

Ship to

Step 1 of 5

Color is currently only available in the US. We are not yet able to ship kits to New York.

Delivery address

Your kit will be delivered via USPS priority mail in 5-8 days.

Jenny Walker

Street address, P.O. box, company name, c/o

Apartment, suite, unit, building, floor, etc.

ZIP code

Phone number

Continue

color

JENNY WALKER

You are receiving complimentary testing, courtesy of the MAGENTA study.

Share results

Step 2 of 5

All participants of the MAGENTA Study are required to have a physician that their results will be shared with when they are complete.

Personal physician

Provider's first name

Provider's last name

Practice or hospital name

City

State

Study code

XTARSM

Continue

You are receiving complimentary testing, courtesy of the MAGENTA study.

Provide your health history

Step 3 of 5

Your responses are confidential and will be used to generate your overall breast and ovarian cancer risk. Please answer to the best of your knowledge, and estimate when you need to.

General information

What is your ancestry? (check all that apply)

- [ ] African
- [ ] Asian ...
- [ ] Caucasian
- [ ] Hispanic
- [ ] Native American
- [ ] Unknown
- [ ] Other

Are you of Ashkenazi Jewish descent?

- ○ Yes ○ No ○ I'm not sure

Why are you having genetic testing done?

- [ ] Learn if my family history of cancer is hereditary
- [ ] Learn if my personal history of cancer is hereditary
- [ ] Learn if I carry a mutation known to run in my family
- [ ] I'm curious to know more about my genetics

Personal history

How old were you when you had your first period?

Estimates are okay

Have you ever given birth to a child?

- ○ Yes ○ No

Have you had cancer before?

- ○ Yes ○ No

Have you had a mastectomy?

- ○ Yes ○ No

Have you had an oophorectomy?

- ○ Yes ○ No

Have you had a breast biopsy?

- ○ Yes ○ No

Have you had a genetic test for hereditary cancer risk?

- ○ Yes ○ No

Have you ever had a bone marrow transplant or blood transfusion?

- ○ Yes ○ No

Family tree

Age estimates are okay.

Are you adopted or do you have no health information about one, or both sides of your biological family members?

- ○ Yes ○ No

Do you have any siblings?

- ○ Yes ○ No ○ I'm not sure

Does your mother have any siblings?

- ○ Yes ○ No ○ I'm not sure

Does your father have any siblings?

- ○ Yes ○ No ○ I'm not sure

How old are your parents and grandparents? Estimates are okay.

Mother's age: Years Now

Fathers's age: Years Now

Maternal grandmother's age: Years Now

Maternal grandfather's age: Years Now

Paternal grandmother's age: Years Now

Paternal grandfather's age: Years Now

Continue

Finish providing history later

You are receiving complimentary testing, courtesy of the MAGENTA study.

Provide your family's health history

Step 4 of 5

Your responses are confidential and will be used to generate your overall breast and ovarian cancer risk. Please answer to the best of your knowledge, and estimate when you need to.

Children

Have any of your children had cancer?

- [ ] Daughter (age 6)
- [ ] Son (age 4)

Parents and siblings

Have any of your parents had cancer?

- [ ] Mother (age 70)
- [ ] Father (age 70)

Mother's side

Has anyone on your mother's side had cancer?

- [ ] Maternal grandmother (age 95, dec.)
- [ ] Maternal grandfather (age 75, dec.)

Father's side

Has anyone on your father's side had cancer?

- [ ] Paternal grandmother (age 75, dec.)
- [ ] Paternal grandfather (age 75, dec.)

Entire family

Has anyone had a genetic test for hereditary cancer risk?

○ No ○ Yes ○ I'm not sure

Is there anything else related to your personal or family history that you would like to share?

○ No ○ Yes ○ I'm not sure

Done

Finish providing history later

You are receiving complimentary testing, courtesy of the MAGENTA study.

Review

Step 5 of 5

Make sure the information below is correct.

Ship to

Jenny Walker
345 Spear St.
San Francisco, CA 94105
415-555-1212

EDIT

Share results with

Dr. Peggy Newcomer
One Medical
San Francisco, CA

EDIT

Personal health history

Provided

EDIT

Family health history

Provided

EDIT

Order Kit

Your Color kit will arrive in about a week.

We will email you at **jenny@getcolor.com** when it ships. We currently project that your results will be ready about 6-8 weeks after we receive your returned kit.

Your purchase number is **1234323423**.

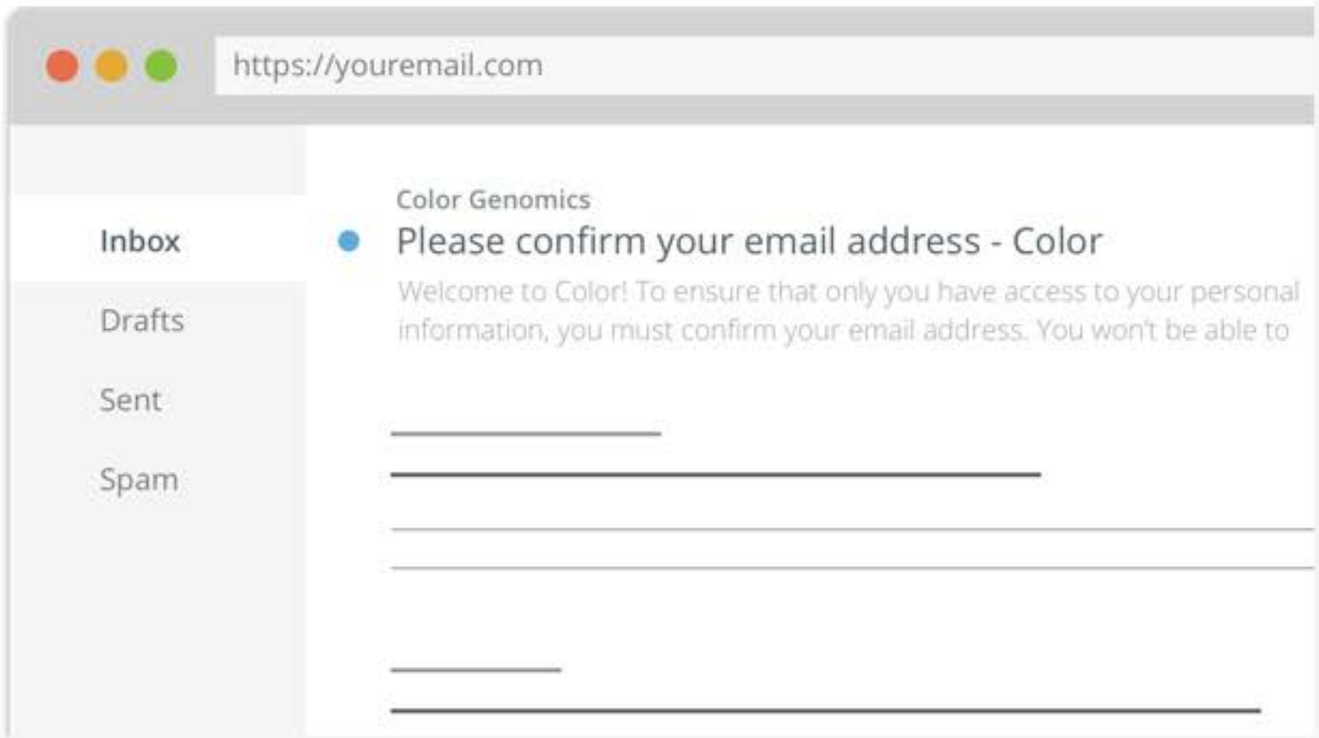
Next: Verify your email address

Check your email to verify your address.

To protect your privacy, we need to verify your email address before you can provide your health history.

An email was sent to **jenny@gmail.com** titled "Please confirm your email address - Color." If you don't see the email within 5 minutes, check your Spam folder.

I can't find the email - please resend it.



color

Please confirm this is your email address.

Hi Jenny,

Welcome to Color! To ensure that only you have access to your personal information, you must confirm your email address. You won't be able to access your account until you complete this step.

Thank you,
The Color Team
support@getcolor.com

Confirm Email Address

Color Genomics, Inc.
1801 Murchison Dr.. Ste. 128, Burlingame, CA 94010
support@getcolor.com

color

Purchase #: 123454354345

We're getting your kit ready.

We will email you when your kit ships, along with tracking information. If anything looks incorrect, email us at support@getcolor.com.

A copy of your results will be shared with the MAGENTA study and Dr. Peggy Newcomer at One Medical in San Francisco, CA when they are ready.

Ship to

Jenny Walker
345 Spear St.
San Francisco, CA 94105
(415) 555-1212

The MAGENTA Study

Color is partnering with the MAGENTA Study to provide genetic testing to enrollees. More content explaining study.

If you have questions, please contact your Study Coordinator at <email address> or <phone>.

Common questions

- What do I do if my kit was sent to the wrong address?
- When will my kit arrive?
- How will I provide a sample?

More questions? Browse Support or Contact us.

Color Genomics, Inc.
1801 Murchison Dr.. Ste. 128, Burlingame, CA 94010
support@getcolor.com

Color ships kit to participant

color

color

Purchase #: 123454354345

Your Color kit is on the way.

Your kit was shipped on Nov. 19th using USPS (tracking #234232524324342). It should arrive in 5-8 days.

Track Package

Info may not be available for 24 hours.

Shipped to

Jenny Walker
345 Spear St.
San Francisco, CA 94105
(415) 555-1212

Common questions

- What do I do if my kit was sent to the wrong address?
- When will my kit arrive?
- Can I give my Color kit to someone else?

More questions? Browse Support or Contact us.

Color Genomics, Inc.
1801 Murchison Dr.. Ste. 128, Burlingame, CA 94010
support@getcolor.com

Participant receives kit
and goes online to
activate it

color

color

Sign in to activate your kit

Email address

Password

Forgot your password?

Sign In

I need to create a Color account.

Color Genomics

CLIA #05D2081492 - CAP #8975161

Mission Team Careers Privacy Press Contact

Welcome to kit activation. Before you get started...

Watch a video with important information about the benefits and limitations of genetic testing, as well as the results you might receive.

IN SUMMARY

Results will not tell you whether or not you will get cancer; they indicate your hereditary chance of developing cancer in the future. Test results should be discussed with a Color genetic counselor as well as your healthcare provider.

Most people receive a negative result.

This means no mutations known to be associated with an increased risk for breast or ovarian cancer were found in the genes we analyzed.

A small percentage of people receive a positive result.

This means a mutation that increases risk for breast or ovarian cancer (or both) was identified.

This information can be used to potentially improve your health.

It is important you share your results with your healthcare provider to develop a personalized screening and prevention plan. This is important because detecting cancer at its earliest stage improves the likelihood of a favorable outcome.

It's normal to find variants of uncertain significance.

It is common to see changes in genes that require further research to determine if they are associated with an increased risk for developing cancer. To date, most have been found to be harmless.

Increased risk for other cancers may be found.

Mutations that impact breast and ovarian cancer risk may also increase the risk of developing other cancers.

Share your results with your relatives.

Your results may be useful to your relatives who may also wish to discuss genetic testing with their own providers.

☐ I understood the important information above.

Get Started

REFERENCES

1. Eggington JM, Bowles KR, Moyes K, et al. A comprehensive laboratory-based program for classification of variants of uncertain significance in hereditary cancer genes. *Clin Genet*. September 2014; 86(3):229-37.

2. Easton DF, Deffenbaugh AM, Pruss D et al. A systematic genetic assessment of 1,433 sequence variants of unknown clinical significance in the BRCA1 and BRCA2 breast cancer-predisposition genes. *Am J Hum Genet*. November 2007; 81(5):873-83.

3. Akbari MR, Zhang S, Fan I, et al. Clinical impact of unclassified variants of the BRCA1 and BRCA2 genes. *J Med Genet*. October 2011; 48(11): 783-6.

color

JENNY WALKER

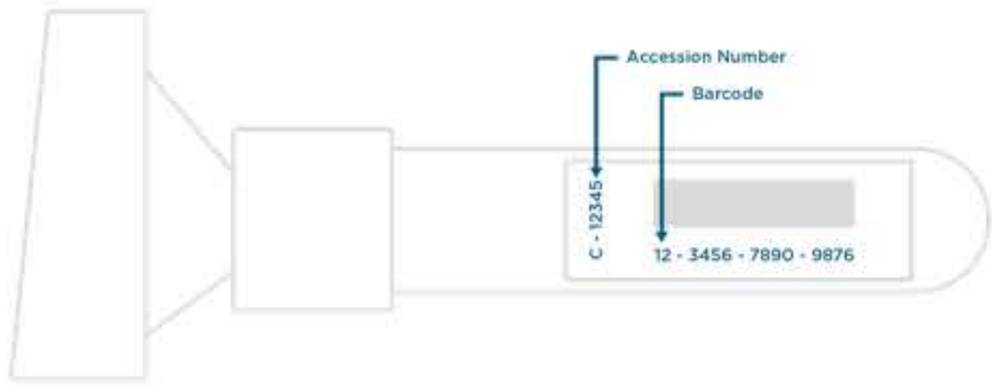
ACTIVATE > PERSONAL HISTORY > FAMILY HISTORY > COMPLETE

Activate your kit

The information below is required to ensure the quality of your results.

Information from your saliva tube

Having trouble? Get help.



Enter your tube's accession number

Enter your tube's barcode

About you

Your birthday and sex are required by the lab for sequencing.

Date of birth: MM / DD / YYYY

Sex

Phone number

Options

- [x] I consent to the use of my samples and data in third party research.
- [x] I consent to storing my samples and DNA with Color for future use or testing.

Consent

- [ ] I have read and agree to the Color Informed Consent. I specifically acknowledge and consent to the following:
  - I am the individual providing the sample and I am at least 18 years of age.
  - This test is not intended to diagnose whether I have or will get a certain disease in the future. It is intended to tell me about my hereditary risk related to certain diseases or other genetic conditions.
  - I should not make any medical decisions based on these results without speaking to my healthcare provider and discussing how these results may contribute to a personalized screening and prevention plan.
  - This test may not perform as intended or provide accurate results if I have not provided accurate personal information, or if I have certain rare biological conditions (e.g., mosaicism) or have had certain bone marrow transplants, transfusions, or hematologic malignancies (e.g., blood related diseases such as leukemia or lymphoma).
  - Genetic counseling services are available to me through Color at no additional charge.
  - The genes that Color analyzes are selected based on their known relationship with the diseases or genetic traits reported, but they may also indicate an increased risk for other health conditions for which Color may provide results that are not yet comprehensive for these other health conditions.
  - My anonymized sample, genetic information, and results may be used for internal quality control, laboratory validation studies, and research and development.
  - Color will contribute de-identified information about my genetic variants to public databases like NCBI's ClinVar, where de-identified genetic information is accessible to researchers to better understand the connection between genetics and disease.
  - My sample and all my related personal information will be transferred to Color's laboratory in the United States for analysis, use, processing, and storage and will be subject to the laws and regulations of the United States.
  - I agree to the Color Terms of Service and Privacy Policy.

Continue

Provide your health history

Your responses are confidential and will be used to generate your overall breast and ovarian cancer risk. Please answer to the best of your knowledge, and estimate when you need to.

General information

What is your ancestry? (check all that apply)

- [ ] African
- [ ] Asian ...
- [ ] Caucasian
- [ ] Hispanic
- [ ] Native American
- [ ] Unknown
- [ ] Other

Are you of Ashkenazi Jewish descent?

○ Yes ○ No ○ I'm not sure

Why are you having genetic testing done?

- [ ] Learn if my family history of cancer is hereditary
- [ ] Learn if my personal history of cancer is hereditary
- [ ] Learn if I carry a mutation known to run in my family
- [ ] I'm curious to know more about my genetics

Personal history

How old were you when you had your first period?

Estimates are okay

Have you ever given birth to a child?

○ Yes ○ No

Have you had cancer before?

○ Yes ○ No

Have you had a mastectomy?

○ Yes ○ No

Have you had an oophorectomy?

○ Yes ○ No

Have you had a breast biopsy?

○ Yes ○ No

Have you had a genetic test for hereditary cancer risk?

○ Yes ○ No

Have you ever had a bone marrow transplant or blood transfusion?

○ Yes ○ No

Family tree

Age estimates are okay.

Are you adopted or do you have no health information about one, or both sides of your biological family members?

○ Yes ○ No

Do you have any siblings?

○ Yes ○ No ○ I'm not sure

Does your mother have any siblings?

○ Yes ○ No ○ I'm not sure

Does your father have any siblings?

○ Yes ○ No ○ I'm not sure

How old are your parents and grandparents? Estimates are okay.

Mother's age: Years Now

Fathers's age: Years Now

Maternal grandmother's age: Years Now

Maternal grandfather's age: Years Now

Paternal grandmother's age: Years Now

Paternal grandfather's age: Years Now

Continue

Finish providing history later

Provide your family's health history

Your responses are confidential and will be used to generate your overall breast and ovarian cancer risk. Please answer to the best of your knowledge, and estimate when you need to.

Children

Have any of your children had cancer?

- [ ] Daughter (age 6)
- [ ] Son (age 4)

Parents and siblings

Have any of your parents had cancer?

- [ ] Mother (age 70)
- [ ] Father (age 70)

Mother's side

Has anyone on your mother's side had cancer?

- [ ] Maternal grandmother (age 95, dec.)
- [ ] Maternal grandfather (age 75, dec.)

Father's side

Has anyone on your father's side had cancer?

- [ ] Paternal grandmother (age 75, dec.)
- [ ] Paternal grandfather (age 75, dec.)

Entire family

Has anyone had a genetic test for hereditary cancer risk?

- ○ No ○ Yes ○ I'm not sure

Is there anything else related to your personal or family history that you would like to share?

- ○ No ○ Yes ○ I'm not sure

Done

Finish providing history later

Your Color kit is activated.

After you've provided a saliva sample, put the tube in the bag, seal it in the provided box, and drop it in any USPS mailbox.

Dr. Liz Swisher has already ordered this test for you, so analysis will begin as soon as we receive your kit.

▶ Learn how to provide a saliva sample.

color

Barcode: 123 45345353 354345

Your Color kit is activated. Now just return it.

Place your tube into the provided plastic bag, seal the bag, then place it back into the cardboard box it came in.

Postage has already been paid, so you can just drop it in any USPS mail box.

What happens next?

- We'll email you when we receive your sample. First, it is inspected to ensure that you have activated it and provided enough saliva for sequencing.
- Next, DNA from the saliva sample is extracted and sequenced, with several quality control checks at each point.
- After sequencing is complete, we review any variants found in 19 genes thought to have an especially strong impact on breast and ovarian cancer risk. The health history you provided is combined with your genetic test results in this step to create a personalized cancer risk assessment.
- All results are then reviewed by a physician before being released to you.
- A consultation with a genetic counselor is available to discuss your results if you have any questions.

Watch a quick video to prepare for your results.

Common questions

- How do I provide a sample?
- How is my health history used?
- How can I track the status of my sample?

More questions? Browse Support or Contact us.

Color Genomics, Inc.
1801 Murchison Dr.. Ste. 128, Burlingame, CA 94010
support@getcolor.com

Color receives sample
back at the lab

color

color

Barcode: 123 45345353 354345

We are beginning testing on your saliva sample.

After we verify that your sample meets our quality standards, we'll extract and sequence your DNA.

What happens next?

- First, we do a quality check on the sample you submitted.
- Next, DNA from the saliva sample is extracted and sequenced, with several quality control checks at each point.
- After sequencing is complete, we review any variants found in 19 genes thought to have an especially strong impact on breast and ovarian cancer risk. The health history you provided is combined with your genetic test results in this step to create a personalized cancer risk assessment.
- All results are then reviewed by a physician before being released to you.
- A consultation with a genetic counselor is available to discuss your results if you have any questions.

Watch a quick video to prepare for your results.

Common questions

- When will my results be ready?
- How should I prepare for my results?

More questions? Browse Support or Contact us.

Color Genomics, Inc.
1801 Murchison Dr.. Ste. 128, Burlingame, CA 94010
support@getcolor.com

Participant experience upon negative results release (standard)

color

color

Jenny, your Color results are ready.

Hello Jenny,

We've completed our analysis of your sample and health history, and your results are ready. If you'd like to review your results with a genetic counselor, schedule an appointment from within your results.

View Results

At your request, we've also sent a copy of your results to your healthcare provider Dr. Peggy Necomer at One Medical in San Francisco, CA.

Thank you,
Nadine Rayes, MS, LCGC
Board-certified Genetic Counselor

Color Genomics, Inc.
1801 Murchison Dr.. Ste. 128, Burlingame, CA 94010
support@getcolor.com

Your results are ready.

If you'd like to review them with a board-certified MAGENTA genetic counselor, you can schedule an appointment from within your results.

View Your Results

Your results are ready. Before you get started...

Watch a quick video covering important information about the benefits and limitations of genetic testing, as well as the results you might receive.

REMEMBER

We ask everyone, **regardless of their results**, to remember the important information below:

Some people without mutations still get cancer.

Environmental and lifestyle factors and family history without a known genetic link account for the majority of breast and ovarian cancers.

Some people with mutations never get cancer.

Mutations increase risk, but they do not mean that you have cancer or that you will definitely develop cancer in your lifetime.

This information can be used to potentially improve your health.

It is important you share your results with your healthcare provider to develop a personalized screening and prevention plan. MAGENTA's genetic counselors are here to answer any of your questions.

☐ I have read and understand this information. I am in a private, comfortable place and wish to view my results.

View Results

No mutations were identified.

This means no pathogenic or likely pathogenic genetic variants associated with an increased risk of breast or ovarian cancer were identified in any of the 19 genes tested.

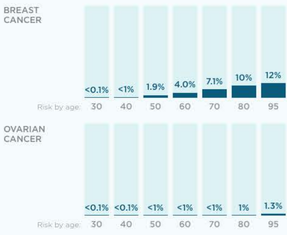
While this can be reassuring, it does not eliminate your risk of developing breast or ovarian cancers. Environmental and lifestyle factors, along with family history without a known genetic link, account for the majority of these cancers. Your healthcare provider can help determine how your screening plan might be influenced by your history and other factors.

Genes that were tested:
ATM, BARD1, BRCA1, BRCA2, BRIP1, CDH1, CHEK2, EPCAM, MLH1, MSH2, MSH6, NBN, PALB2, PMS2, PTEN, RAD51C, RAD51D, STK11, TP53

Learn more about your results and how to act on them below.

Average risk by age among US women

Your actual risk may be different based on other genetic and non-genetic factors.



Average risk among US women[1]

NEXT STEPS DETAILS HISTORY FAMILY QUESTIONS Schedule Appointment

KNOW YOUR SCREENING GUIDELINES

Below is a summary of screening guidelines established by experts at the National Comprehensive Cancer Network (NCCN). These guidelines are for women who have the same breast and ovarian cancer risk as the average US woman. Your healthcare provider may use these guidelines to help create a customized screening plan for you.

Breast cancer[2,3]

- **Starting at age 25:** Breast awareness - Women should be familiar with their breasts and promptly report changes to their healthcare provider. Performing regular breast self exams may help increase breast self awareness, especially when checked at the end of the menstrual cycle.
- **Between ages 25-39**: Clinical breast exam every 1-3 years.
- **Starting at age 40**: Clinical breast exam and mammogram every year.

Ovarian cancer[4]

- Currently, there are no standard screening guidelines for ovarian cancer. Please discuss any family history of ovarian cancer with your healthcare provider.

SHARE YOUR RESULTS

Share your results with your healthcare provider.

Color recommends you share your results with your healthcare provider. Sharing your results allows your provider to guide you to appropriate resources and discuss tailored options for cancer screening and prevention.

Provider's first name | Provider's last name

Practice or hospital name

City | State

Fax Results to Provider

We will email you when the results have been sent.

Your relatives may benefit from learning their genetic status.

Consider sharing your results with relatives who may also benefit from genetic testing. A few key points to remember:

- Your negative result significantly lowers the chance that you have an inherited mutation associated with breast or ovarian cancer.
- It is still possible for your relatives to have a mutation that you did not inherit. They may benefit from their own genetic testing, especially those who have had cancer.
- If any of your relatives has a mutation, there is a 50% chance that their siblings and children also have the same mutation.
- A father and mother are equally likely to pass on a mutation. Sons and daughters are equally likely to inherit a mutation if one of their parents has it.
- If you learn that a relative of yours has a mutation, contact a Color genetic counselor to learn how that information may impact your risk assessment and interpretation of results.

Email Relatives View a sample letter

SPEAK WITH A SPECIALIST

Speak with a MAGENTA genetic counselor.

MAGENTA's genetic counselors are board-certified healthcare professionals who can help you understand your results and answer your questions. You can schedule a genetic counseling session by clicking the button below. Learn how genetic counseling works.

Schedule Counseling Appointment

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Participant experience upon positive results release (standard)

color

color

Schedule an appointment to review your results.

Hello Jenny,

I'm Nadine Rayes, a genetic counselor with the MAGENTA study. We've completed analysis of your sample and health history, and your results are ready. Schedule a time to review your results with me, or another genetic counselor. MAGENTA's genetic counselors are board-certified healthcare professionals who can help you understand your results and answer your questions.

Schedule Counseling Appointment

At your request, a copy of your results will be sent to your healthcare provider Dr. Peggy Necomer at One Medical in San Francisco, CA after you've reviewed them.

Thank you,
Nadine Rayes, MS, LCGC
Board-certified Genetic Counselor

Color Genomics, Inc.
1801 Murchison Dr.. Ste. 128, Burlingame, CA 94010
support@getcolor.com

Your results are ready. Review them with a genetic counselor.

MAGENTA's genetic counselors are board-certified healthcare professionals who will help you understand your results and answer your questions. Learn how genetic counseling works.

Choose Appointment | Your Info | Confirmation

Set your time zone to continue:

(GMT-7:00) Pacific Time

Set time zone

(GMT-7:00) Pacific Time change

Your results are ready. Before you get started...

Watch a quick video covering important information about the benefits and limitations of genetic testing, as well as the results you might receive.

REMEMBER

We ask everyone, **regardless of their results**, to remember the important information below:

Some people without mutations still get cancer.

Environmental and lifestyle factors and family history without a known genetic link account for the majority of breast and ovarian cancers.

Some people with mutations never get cancer.

Mutations increase risk, but they do not mean that you have cancer or that you will definitely develop cancer in your lifetime.

This information can be used to potentially improve your health.

It is important you share your results with your healthcare provider to develop a personalized screening and prevention plan. MAGENTA's genetic counselors are here to answer any of your questions.

☐ I have read and understand this information. I am in a private, comfortable place and wish to view my results.

View Results

A pathogenic mutation was identified in the BRCA1 gene.

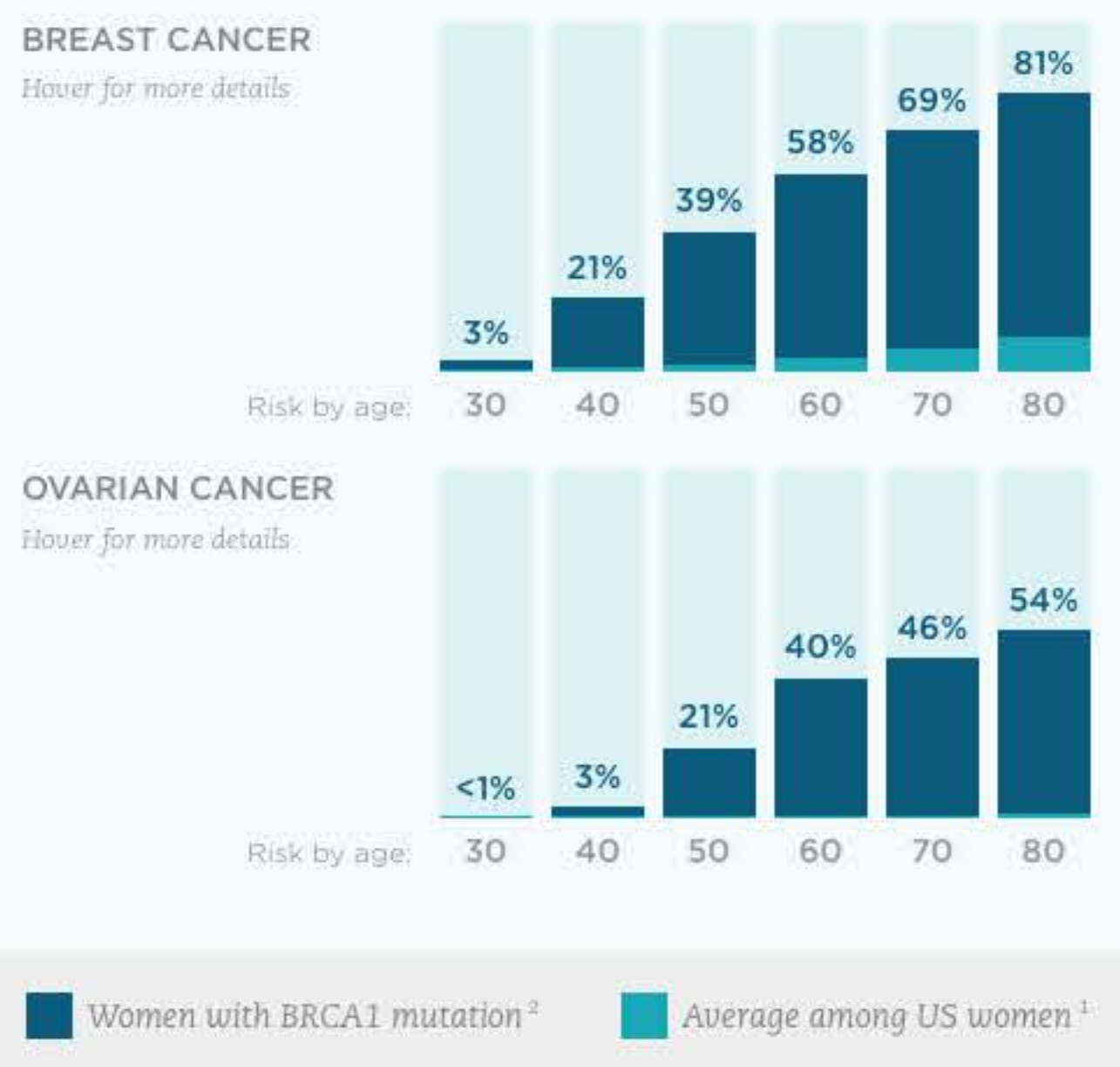
Testing positive for a pathogenic mutation in the BRCA1 gene means your chances of developing breast and ovarian cancer are greater than that of the average US woman. This result does **not** mean that you have a diagnosis of cancer or that you will definitely develop cancer in your lifetime. Learn more below.

Schedule an appointment with one of our board-certified genetic counselors at no additional cost to discuss your results.

Schedule Counseling Appointment

Risk by age with a BRCA1 mutation

Risk among US women with a *BRCA1* mutation to develop specific cancers by different ages in their lives.



Increased risk for other cancers.

In addition to increasing a woman's risk for breast and ovarian cancer, mutations in the BRCA1 gene are known to increase the risk of developing pancreatic cancer.

Please note that while having a BRCA1 gene mutation increases risk for pancreatic cancer, the Color test is not currently designed to detect mutations in other genes that may also increase risk for this cancer. Your actual risk may be different based on other genetic and non-genetic factors. We encourage you to discuss your results with one of our board-certified genetic counselors at no additional cost.

CANCER TYPE	WITH BRCA1 MUTATION [3]	AVG. US WOMAN [1]
Pancreatic	Elevated (3-5%)	<1%

The risk of developing cancer by age 80.

NEXT STEPS DETAILS HISTORY FAMILY QUESTIONS Schedule Counseling

KNOW YOUR SCREENING GUIDELINES

Below is a summary of screening guidelines established by experts at the National Comprehensive Cancer Network (NCCN).[4] They are specific to women who have a mutation in the BRCA1 gene. Your healthcare provider may use these guidelines to help create a customized screening plan for you.

Breast and ovarian cancer [5]

- **Starting at age 18**: Breast awareness - Women should be familiar with their breasts and promptly report changes to their healthcare provider. Performing regular breast self exams may help increase breast awareness, especially when checked at the end of the menstrual cycle.
- **Starting at age 25**: Breast exam by your provider every 6-12 months.
- **Between ages 25-29 or individualized based on family history**: Breast MRI screening (preferred) every year or mammogram if MRI is unavailable.
- **Between ages 30-75**: Mammogram and breast MRI screening every year. Your provider may wish to alternate between these two screenings every 6 months.
- **Between ages 35-40, or after you are finished having children**: NCCN recommends a risk-reducing salpingo-oophorectomy (the surgical removal of the ovaries and fallopian tubes) to lower the risk of developing breast and ovarian cancer. Ideally, this should involve a discussion with a gynecologic oncologist.
- **After age 75**: Your provider may discuss an individualized management plan with you.
- Your provider may discuss the option of having a risk-reducing bilateral mastectomy (the surgical removal of both breasts).
- Your provider may discuss the use of medications that might reduce the risk of developing breast or ovarian cancer.
- While there may be circumstances where ovarian cancer screening with transvaginal ultrasound and a blood test for a protein called CA-125 are helpful, these techniques have not been shown to be effective in detecting early ovarian cancer.

Pancreatic cancer [5]

- Currently, there are no pancreatic cancer screening guidelines from the NCCN specific to *BRCA1* mutation carriers. Please discuss your risk of pancreatic cancer with your healthcare provider.

SHARE YOUR RESULTS

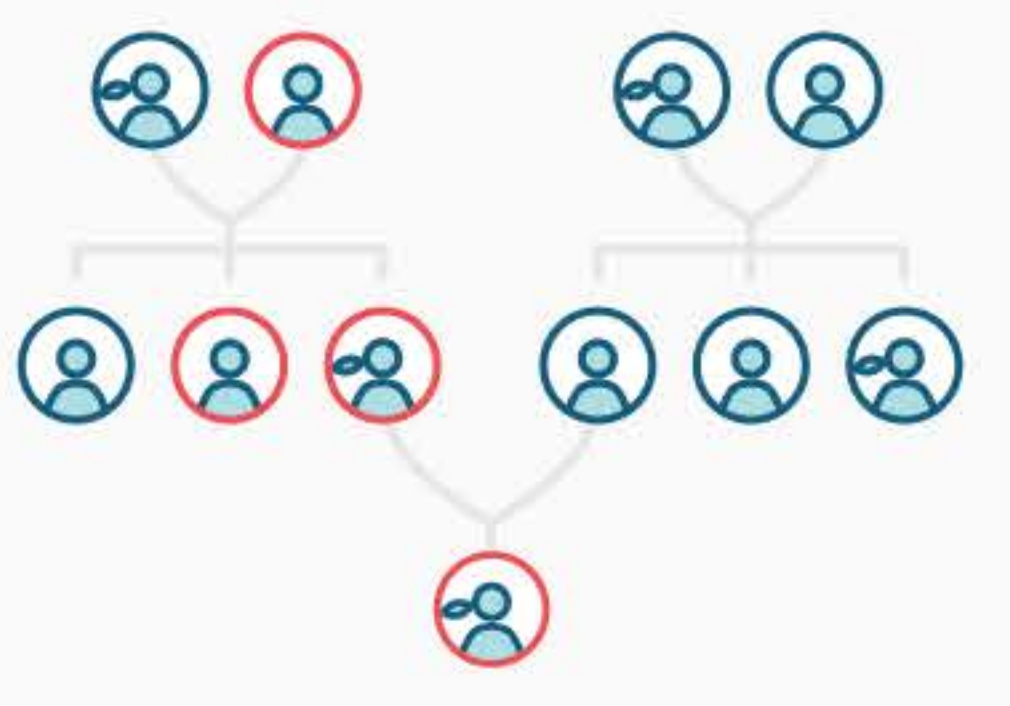
Discuss your results with your healthcare provider.

It is important to schedule an appointment with your healthcare provider to discuss your results and plan next steps.

Provider's first name
Provider's last name
Practice or hospital name
City
State

Fax Results to Provider

We will email you when the results have been sent.



Your relatives may also have this BRCA1 mutation.

Consider sharing your results with relatives because:

- This mutation was most likely inherited from either your mother or your father. This would mean that one of your parents has the same mutation, and that your relatives on that side of the family may also have the same mutation. Fathers are just as likely to pass on a mutation as mothers.
- Each of your siblings has a 50% chance of having inherited this mutation. Brothers are just as likely to inherit it as sisters.
- Each of your children has a 50% chance of inheriting the same mutation. Men are just as likely as women to pass the mutation on to their children, and daughters and sons are equally likely to inherit it. Please keep in mind that children are not recommended to be tested for this mutation as it does not impact health or affect medical management in childhood.
- If genetic testing indicates that a relative does not have the mutation (tests negative), that relative's children are not at risk to inherit this mutation. These mutations do not skip generations.

Email Relatives
View a sample letter

SPEAK WITH A SPECIALIST

Speak with a MAGENTA genetic counselor.

MAGENTA's genetic counselors are board-certified healthcare professionals who can help you understand your results and answer your questions. You can schedule a genetic counseling session by clicking the button below. Learn how genetic counseling works.

Schedule Counseling Appointment

CONNECT WITH OTHERS

FORCE

Committed to providing resources and support to individuals at high-risk of getting breast and ovarian cancer due to their family history and genetic status.

Visit www.facingourrisk.org

Bright Pink

Focused on the prevention and early detection of breast and ovarian cancer in young women, while providing support for high-risk individuals.

Visit www.brightpink.org

Susan G. Komen

Dedicated to reducing deaths from breast cancer by funding breast cancer research, ensuring access to care through community programs worldwide and supporting public health policies that help people facing breast cancer.

Visit www.komen.org

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4. Integrated with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). © 2015 National Comprehensive Cancer Network, Inc. All rights reserved. The NCCN Guidelines® and illustrations herein may not be reproduced in any form for any purpose without the express written permission of the NCCN. To view the most recent and complete version of the NCCN Guidelines, go online to NCCN.org.
5. National Comprehensive Cancer Network. Genetic/Familial High-Risk Assessment: Breast and Ovarian. NCCN Guidelines Version 1.2015. Available at www.nccn.org. Published March 2015.
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Appendix I

Arm B: Participant receives email from MAGENTA with URL & code

color

color

Welcome to Color. Before you get started…

As part of the MAGENTA study, please watch a video with important information about the benefits and limitations of genetic testing, as well as the results you might receive.

Read the content shown in this video.

☐ I have watched the video to the right.

Get Started

color

Sign In

Create a Color account to get started

This account will be used for activating your kit and returning your results.

First name | Last name

Email address

Create a password | Confirm password

I agree to the Color Terms of Service and Privacy Policy.

Create Account

Color Genomics

CLIA #05D2081492 - CAP #8975161

Mission Team Careers Privacy Press Contact

color

JENNY WALKER

You are receiving complimentary testing, courtesy of the MAGENTA study.

Ship to

Step 1 of 5

Color is currently only available in the US. We are not yet able to ship kits to New York.

Delivery address

Your kit will be delivered via USPS priority mail in 5-8 days.

Jenny Walker

Street address, P.O. box, company name, c/o

Apartment, suite, unit, building, floor, etc.

ZIP code

Phone number

Continue

color

JENNY WALKER

You are receiving complimentary testing, courtesy of the MAGENTA study.

Share results

Step 2 of 5

All participants of the MAGENTA Study are required to have a physician that their results will be shared with when they are complete.

Personal physician

Provider's first name

Provider's last name

Practice or hospital name

City

State

Study code

XTARSM

Continue

You are receiving complimentary testing, courtesy of the MAGENTA study.

Provide your health history

Step 3 of 5

Your responses are confidential and will be used to generate your overall breast and ovarian cancer risk. Please answer to the best of your knowledge, and estimate when you need to.

General information

What is your ancestry? (check all that apply)

- [ ] African
- [ ] Asian ...
- [ ] Caucasian
- [ ] Hispanic
- [ ] Native American
- [ ] Unknown
- [ ] Other

Are you of Ashkenazi Jewish descent?

- ○ Yes ○ No ○ I'm not sure

Why are you having genetic testing done?

- [ ] Learn if my family history of cancer is hereditary
- [ ] Learn if my personal history of cancer is hereditary
- [ ] Learn if I carry a mutation known to run in my family
- [ ] I'm curious to know more about my genetics

Personal history

How old were you when you had your first period?

Estimates are okay

Have you ever given birth to a child?

- ○ Yes ○ No

Have you had cancer before?

- ○ Yes ○ No

Have you had a mastectomy?

- ○ Yes ○ No

Have you had an oophorectomy?

- ○ Yes ○ No

Have you had a breast biopsy?

- ○ Yes ○ No

Have you had a genetic test for hereditary cancer risk?

- ○ Yes ○ No

Have you ever had a bone marrow transplant or blood transfusion?

- ○ Yes ○ No

Family tree

Age estimates are okay.

Are you adopted or do you have no health information about one, or both sides of your biological family members?

- ○ Yes ○ No

Do you have any siblings?

- ○ Yes ○ No ○ I'm not sure

Does your mother have any siblings?

- ○ Yes ○ No ○ I'm not sure

Does your father have any siblings?

- ○ Yes ○ No ○ I'm not sure

How old are your parents and grandparents? Estimates are okay.

Mother's age: Years Now

Fathers's age: Years Now

Maternal grandmother's age: Years Now

Maternal grandfather's age: Years Now

Paternal grandmother's age: Years Now

Paternal grandfather's age: Years Now

Continue

Finish providing history later

You are receiving complimentary testing, courtesy of the MAGENTA study.

Provide your family's health history

Step 4 of 5

Your responses are confidential and will be used to generate your overall breast and ovarian cancer risk. Please answer to the best of your knowledge, and estimate when you need to.

Children

Have any of your children had cancer?

- [ ] Daughter (age 6)
- [ ] Son (age 4)

Parents and siblings

Have any of your parents had cancer?

- [ ] Mother (age 70)
- [ ] Father (age 70)

Mother's side

Has anyone on your mother's side had cancer?

- [ ] Maternal grandmother (age 95, dec.)
- [ ] Maternal grandfather (age 75, dec.)

Father's side

Has anyone on your father's side had cancer?

- [ ] Paternal grandmother (age 75, dec.)
- [ ] Paternal grandfather (age 75, dec.)

Entire family

Has anyone had a genetic test for hereditary cancer risk?

○ No ○ Yes ○ I'm not sure

Is there anything else related to your personal or family history that you would like to share?

○ No ○ Yes ○ I'm not sure

Done

Finish providing history later

You are receiving complimentary testing, courtesy of the MAGENTA study.

Review

Step 5 of 5

Make sure the information below is correct.

Ship to

Jenny Walker
345 Spear St.
San Francisco, CA 94105
415-555-1212

EDIT

Share results with

Dr. Peggy Newcomer
One Medical
San Francisco, CA

EDIT

Personal health history

Provided

EDIT

Family health history

Provided

EDIT

Order Kit

Your Color kit will arrive in about a week.

We will email you at **jenny@getcolor.com** when it ships. We currently project that your results will be ready about 6-8 weeks after we receive your returned kit.

Your purchase number is **1234323423**.

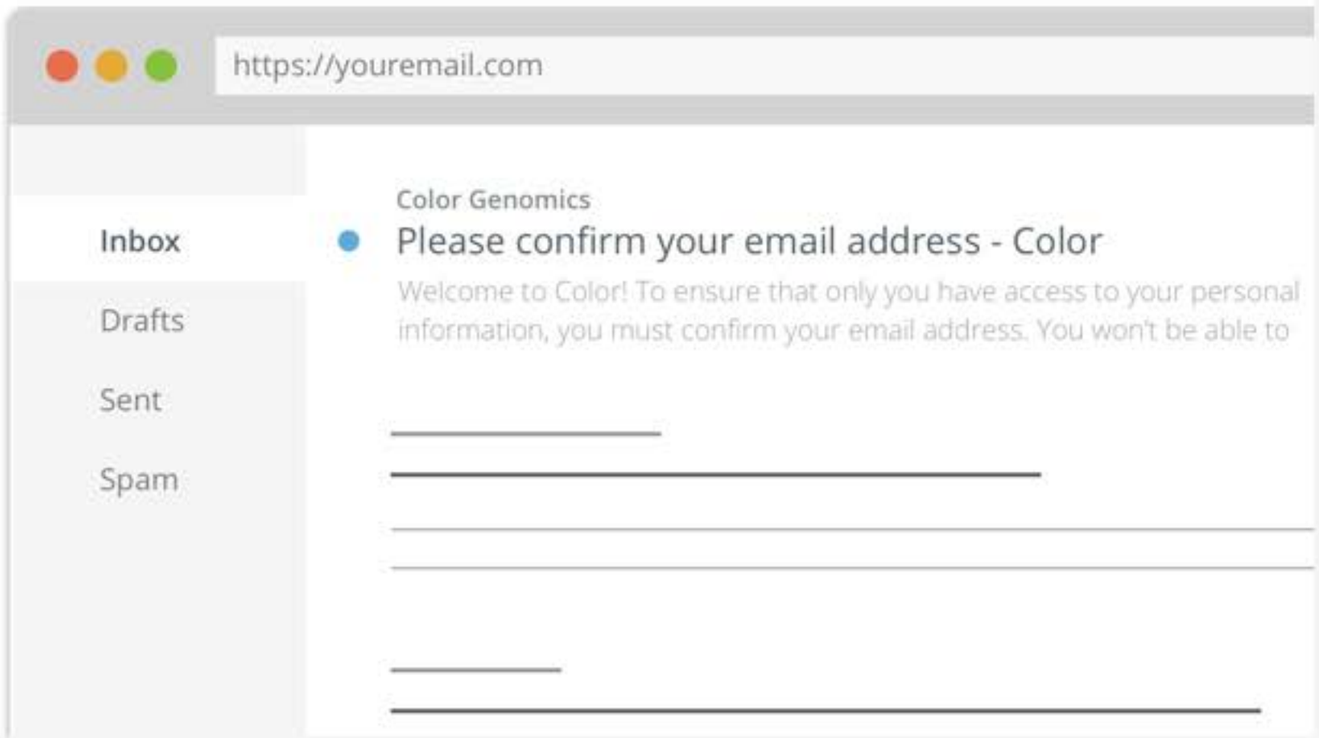
Next: Verify your email address

Check your email to verify your address.

To protect your privacy, we need to verify your email address before you can provide your health history.

An email was sent to **jenny@gmail.com** titled "Please confirm your email address - Color." If you don't see the email within 5 minutes, check your Spam folder.

I can't find the email - please resend it.



color

Please confirm this is your email address.

Hi Jenny,

Welcome to Color! To ensure that only you have access to your personal information, you must confirm your email address. You won't be able to access your account until you complete this step.

Thank you,
The Color Team
support@getcolor.com

Confirm Email Address

Color Genomics, Inc.
1801 Murchison Dr.. Ste. 128, Burlingame, CA 94010
support@getcolor.com

color

Purchase #: 123454354345

We're getting your kit ready.

We will email you when your kit ships, along with tracking information. If anything looks incorrect, email us at support@getcolor.com.

A copy of your results will be shared with the MAGENTA study and Dr. Peggy Newcomer at One Medical in San Francisco, CA when they are ready.

Ship to

Jenny Walker
345 Spear St.
San Francisco, CA 94105
(415) 555-1212

The MAGENTA Study

Color is partnering with the MAGENTA Study to provide genetic testing to enrollees. More content explaining study.

If you have questions, please contact your Study Coordinator at <email address> or <phone>.

Common questions

- What do I do if my kit was sent to the wrong address?
- When will my kit arrive?
- How will I provide a sample?

More questions? Browse Support or Contact us.

Color Genomics, Inc.
1801 Murchison Dr.. Ste. 128, Burlingame, CA 94010
support@getcolor.com

Color ships kit to participant

color

color

Purchase #: 123454354345

Your Color kit is on the way.

Your kit was shipped on Nov. 19th using USPS (tracking #234232524324342). It should arrive in 5-8 days.

Track Package

Info may not be available for 24 hours.

Shipped to

Jenny Walker
345 Spear St.
San Francisco, CA 94105
(415) 555-1212

Common questions

- What do I do if my kit was sent to the wrong address?
- When will my kit arrive?
- Can I give my Color kit to someone else?

More questions? Browse Support or Contact us.

Color Genomics, Inc.
1801 Murchison Dr.. Ste. 128, Burlingame, CA 94010
support@getcolor.com

Participant receives kit
and goes online to
activate it

color

color

Sign in to activate your kit

Email address

Password

Forgot your password?

Sign In

I need to create a Color account.

Color Genomics

CLIA #05D2081492 - CAP #8975161

Mission Team Careers Privacy Press Contact

Welcome to kit activation. Before you get started...

Watch a video with important information about the benefits and limitations of genetic testing, as well as the results you might receive.

IN SUMMARY

Results will not tell you whether or not you will get cancer; they indicate your hereditary chance of developing cancer in the future. Test results should be discussed with a Color genetic counselor as well as your healthcare provider.

Most people receive a negative result.

This means no mutations known to be associated with an increased risk for breast or ovarian cancer were found in the genes we analyzed.

A small percentage of people receive a positive result.

This means a mutation that increases risk for breast or ovarian cancer (or both) was identified.

This information can be used to potentially improve your health.

It is important you share your results with your healthcare provider to develop a personalized screening and prevention plan. This is important because detecting cancer at its earliest stage improves the likelihood of a favorable outcome.

It's normal to find variants of uncertain significance.

It is common to see changes in genes that require further research to determine if they are associated with an increased risk for developing cancer. To date, most have been found to be harmless.

Increased risk for other cancers may be found.

Mutations that impact breast and ovarian cancer risk may also increase the risk of developing other cancers.

Share your results with your relatives.

Your results may be useful to your relatives who may also wish to discuss genetic testing with their own providers.

☐ I understood the important information above.

Get Started

REFERENCES

1. Eggington JM, Bowles KR, Moyes K, et al. A comprehensive laboratory-based program for classification of variants of uncertain significance in hereditary cancer genes. *Clin Genet*. September 2014; 86(3):229-37.

2. Easton DF, Deffenbaugh AM, Pruss D et al. A systematic genetic assessment of 1,433 sequence variants of unknown clinical significance in the BRCA1 and BRCA2 breast cancer-predisposition genes. *Am J Hum Genet*. November 2007; 81(5):873-83.

3. Akbari MR, Zhang S, Fan I, et al. Clinical impact of unclassified variants of the BRCA1 and BRCA2 genes. *J Med Genet*. October 2011; 48(11): 783-6.

color

JENNY WALKER

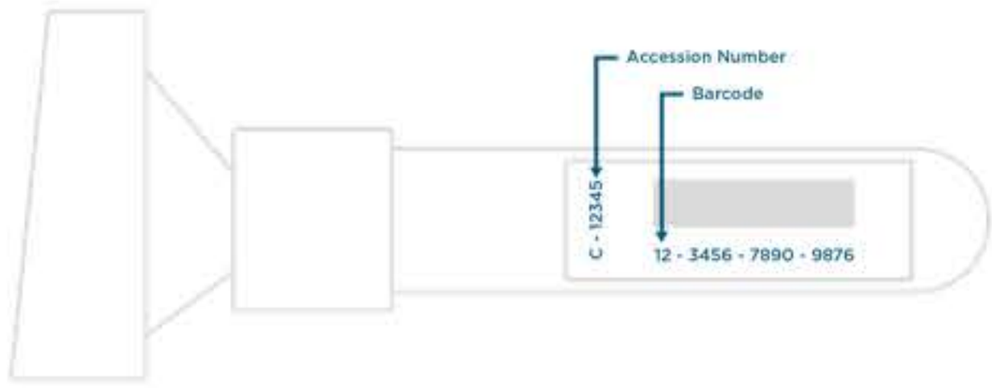
ACTIVATE > PERSONAL HISTORY > FAMILY HISTORY > COMPLETE

Activate your kit

The information below is required to ensure the quality of your results.

Information from your saliva tube

Having trouble? Get help.



Enter your tube's accession number

Enter your tube's barcode

About you

Your birthday and sex are required by the lab for sequencing.

Date of birth: MM / DD / YYYY

Sex

Phone number

Options

- [x] I consent to the use of my samples and data in third party research.
- [x] I consent to storing my samples and DNA with Color for future use or testing.

Consent

- [ ] I have read and agree to the Color Informed Consent. I specifically acknowledge and consent to the following:
  - I am the individual providing the sample and I am at least 18 years of age.
  - This test is not intended to diagnose whether I have or will get a certain disease in the future. It is intended to tell me about my hereditary risk related to certain diseases or other genetic conditions.
  - I should not make any medical decisions based on these results without speaking to my healthcare provider and discussing how these results may contribute to a personalized screening and prevention plan.
  - This test may not perform as intended or provide accurate results if I have not provided accurate personal information, or if I have certain rare biological conditions (e.g., mosaicism) or have had certain bone marrow transplants, transfusions, or hematologic malignancies (e.g., blood related diseases such as leukemia or lymphoma).
  - Genetic counseling services are available to me through Color at no additional charge.
  - The genes that Color analyzes are selected based on their known relationship with the diseases or genetic traits reported, but they may also indicate an increased risk for other health conditions for which Color may provide results that are not yet comprehensive for these other health conditions.
  - My anonymized sample, genetic information, and results may be used for internal quality control, laboratory validation studies, and research and development.
  - Color will contribute de-identified information about my genetic variants to public databases like NCBI's ClinVar, where de-identified genetic information is accessible to researchers to better understand the connection between genetics and disease.
  - My sample and all my related personal information will be transferred to Color's laboratory in the United States for analysis, use, processing, and storage and will be subject to the laws and regulations of the United States.
  - I agree to the Color Terms of Service and Privacy Policy.

Continue

Provide your health history

Your responses are confidential and will be used to generate your overall breast and ovarian cancer risk. Please answer to the best of your knowledge, and estimate when you need to.

General information

What is your ancestry? (check all that apply)

- [ ] African
- [ ] Asian ...
- [ ] Caucasian
- [ ] Hispanic
- [ ] Native American
- [ ] Unknown
- [ ] Other

Are you of Ashkenazi Jewish descent?

○ Yes ○ No ○ I'm not sure

Why are you having genetic testing done?

- [ ] Learn if my family history of cancer is hereditary
- [ ] Learn if my personal history of cancer is hereditary
- [ ] Learn if I carry a mutation known to run in my family
- [ ] I'm curious to know more about my genetics

Personal history

How old were you when you had your first period?

Estimates are okay

Have you ever given birth to a child?

○ Yes ○ No

Have you had cancer before?

○ Yes ○ No

Have you had a mastectomy?

○ Yes ○ No

Have you had an oophorectomy?

○ Yes ○ No

Have you had a breast biopsy?

○ Yes ○ No

Have you had a genetic test for hereditary cancer risk?

○ Yes ○ No

Have you ever had a bone marrow transplant or blood transfusion?

○ Yes ○ No

Family tree

Age estimates are okay.

Are you adopted or do you have no health information about one, or both sides of your biological family members?

○ Yes ○ No

Do you have any siblings?

○ Yes ○ No ○ I'm not sure

Does your mother have any siblings?

○ Yes ○ No ○ I'm not sure

Does your father have any siblings?

○ Yes ○ No ○ I'm not sure

How old are your parents and grandparents? Estimates are okay.

Mother's age: Years Now

Fathers's age: Years Now

Maternal grandmother's age: Years Now

Maternal grandfather's age: Years Now

Paternal grandmother's age: Years Now

Paternal grandfather's age: Years Now

Continue

Finish providing history later

Provide your family's health history

Your responses are confidential and will be used to generate your overall breast and ovarian cancer risk. Please answer to the best of your knowledge, and estimate when you need to.

Children

Have any of your children had cancer?

- [ ] Daughter (age 6)
- [ ] Son (age 4)

Parents and siblings

Have any of your parents had cancer?

- [ ] Mother (age 70)
- [ ] Father (age 70)

Mother's side

Has anyone on your mother's side had cancer?

- [ ] Maternal grandmother (age 95, dec.)
- [ ] Maternal grandfather (age 75, dec.)

Father's side

Has anyone on your father's side had cancer?

- [ ] Paternal grandmother (age 75, dec.)
- [ ] Paternal grandfather (age 75, dec.)

Entire family

Has anyone had a genetic test for hereditary cancer risk?

- ○ No ○ Yes ○ I'm not sure

Is there anything else related to your personal or family history that you would like to share?

- ○ No ○ Yes ○ I'm not sure

Done

Finish providing history later

Your Color kit is activated.

After you've provided a saliva sample, put the tube in the bag, seal it in the provided box, and drop it in any USPS mailbox.

Dr. Liz Swisher has already ordered this test for you, so analysis will begin as soon as we receive your kit.

▶ Learn how to provide a saliva sample.

color

Barcode: 123 45345353 354345

Your Color kit is activated. Now just return it.

Place your tube into the provided plastic bag, seal the bag, then place it back into the cardboard box it came in.

Postage has already been paid, so you can just drop it in any USPS mail box.

What happens next?

- We'll email you when we receive your sample. First, it is inspected to ensure that you have activated it and provided enough saliva for sequencing.
- Next, DNA from the saliva sample is extracted and sequenced, with several quality control checks at each point.
- After sequencing is complete, we review any variants found in 19 genes thought to have an especially strong impact on breast and ovarian cancer risk. The health history you provided is combined with your genetic test results in this step to create a personalized cancer risk assessment.
- All results are then reviewed by a physician before being released to you.
- A consultation with a genetic counselor is available to discuss your results if you have any questions.

Watch a quick video to prepare for your results.

Common questions

- How do I provide a sample?
- How is my health history used?
- How can I track the status of my sample?

More questions? Browse Support or Contact us.

Color Genomics, Inc.
1801 Murchison Dr.. Ste. 128, Burlingame, CA 94010
support@getcolor.com

Color receives sample
back at the lab

color

color

Barcode: 123 45345353 354345

We are beginning testing on your saliva sample.

After we verify that your sample meets our quality standards, we'll extract and sequence your DNA.

What happens next?

- First, we do a quality check on the sample you submitted.
- Next, DNA from the saliva sample is extracted and sequenced, with several quality control checks at each point.
- After sequencing is complete, we review any variants found in 19 genes thought to have an especially strong impact on breast and ovarian cancer risk. The health history you provided is combined with your genetic test results in this step to create a personalized cancer risk assessment.
- All results are then reviewed by a physician before being released to you.
- A consultation with a genetic counselor is available to discuss your results if you have any questions.

Watch a quick video to prepare for your results.

Common questions

- When will my results be ready?
- How should I prepare for my results?

More questions? Browse Support or Contact us.

Color Genomics, Inc.
1801 Murchison Dr.. Ste. 128, Burlingame, CA 94010
support@getcolor.com

Participant experience upon any results release (study)

color

color

Schedule an appointment to review your results.

Hello Jenny,

I'm Nadine Rayes, a genetic counselor with the MAGENTA study. We've completed analysis of your sample and health history, and your results are ready. Schedule a time to review your results with me, or another genetic counselor. MAGENTA's genetic counselors are board-certified healthcare professionals who can help you understand your results and answer your questions.

Schedule Counseling Appointment

At your request, a copy of your results will be sent to your healthcare provider Dr. Peggy Necomer at One Medical in San Francisco, CA after you've reviewed them.

Thank you,
Nadine Rayes, MS, LCGC
Board-certified Genetic Counselor

Color Genomics, Inc.
1801 Murchison Dr.. Ste. 128, Burlingame, CA 94010
support@getcolor.com

Your results are ready. Review them with a genetic counselor.

MAGENTA's genetic counselors are board-certified healthcare professionals who will help you understand your results and answer your questions. Learn how genetic counseling works.

Choose Appointment | Your Info | Confirmation

Set your time zone to continue:

(GMT-7:00) Pacific Time

Set time zone

(GMT-7:00) Pacific Time change

Your results are ready. Before you get started...

Watch a quick video covering important information about the benefits and limitations of genetic testing, as well as the results you might receive.

REMEMBER

We ask everyone, **regardless of their results**, to remember the important information below:

Some people without mutations still get cancer.

Environmental and lifestyle factors and family history without a known genetic link account for the majority of breast and ovarian cancers.

Some people with mutations never get cancer.

Mutations increase risk, but they do not mean that you have cancer or that you will definitely develop cancer in your lifetime.

This information can be used to potentially improve your health.

It is important you share your results with your healthcare provider to develop a personalized screening and prevention plan. MAGENTA's genetic counselors are here to answer any of your questions.

☐ I have read and understand this information. I am in a private, comfortable place and wish to view my results.

View Results

No mutations were identified.

This means no pathogenic or likely pathogenic genetic variants associated with an increased risk of breast or ovarian cancer were identified in any of the 19 genes tested.

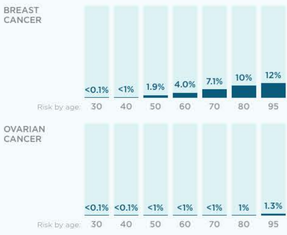
While this can be reassuring, it does not eliminate your risk of developing breast or ovarian cancers. Environmental and lifestyle factors, along with family history without a known genetic link, account for the majority of these cancers. Your healthcare provider can help determine how your screening plan might be influenced by your history and other factors.

Genes that were tested:
ATM, BARD1, BRCA1, BRCA2, BRIP1, CDH1, CHEK2, EPCAM, MLH1, MSH2, MSH6, NBN, PALB2, PMS2, PTEN, RAD51C, RAD51D, STK11, TP53

Learn more about your results and how to act on them below.

Average risk by age among US women

Your actual risk may be different based on other genetic and non-genetic factors.



Average risk among US women[1]

NEXT STEPS DETAILS HISTORY FAMILY QUESTIONS Schedule Appointment

KNOW YOUR SCREENING GUIDELINES

Below is a summary of screening guidelines established by experts at the National Comprehensive Cancer Network (NCCN). These guidelines are for women who have the same breast and ovarian cancer risk as the average US woman. Your healthcare provider may use these guidelines to help create a customized screening plan for you.

Breast cancer[2,3]

- **Starting at age 25:** Breast awareness - Women should be familiar with their breasts and promptly report changes to their healthcare provider. Performing regular breast self exams may help increase breast self awareness, especially when checked at the end of the menstrual cycle.
- **Between ages 25-39**: Clinical breast exam every 1-3 years.
- **Starting at age 40**: Clinical breast exam and mammogram every year.

Ovarian cancer[4]

- Currently, there are no standard screening guidelines for ovarian cancer. Please discuss any family history of ovarian cancer with your healthcare provider.

SHARE YOUR RESULTS

Share your results with your healthcare provider.

Color recommends you share your results with your healthcare provider. Sharing your results allows your provider to guide you to appropriate resources and discuss tailored options for cancer screening and prevention.

Provider's first name | Provider's last name

Practice or hospital name

City | State

Fax Results to Provider

We will email you when the results have been sent.

Your relatives may benefit from learning their genetic status.

Consider sharing your results with relatives who may also benefit from genetic testing. A few key points to remember:

- Your negative result significantly lowers the chance that you have an inherited mutation associated with breast or ovarian cancer.
- It is still possible for your relatives to have a mutation that you did not inherit. They may benefit from their own genetic testing, especially those who have had cancer.
- If any of your relatives has a mutation, there is a 50% chance that their siblings and children also have the same mutation.
- A father and mother are equally likely to pass on a mutation. Sons and daughters are equally likely to inherit a mutation if one of their parents has it.
- If you learn that a relative of yours has a mutation, contact a Color genetic counselor to learn how that information may impact your risk assessment and interpretation of results.

Email Relatives View a sample letter

SPEAK WITH A SPECIALIST

Speak with a MAGENTA genetic counselor.

MAGENTA's genetic counselors are board-certified healthcare professionals who can help you understand your results and answer your questions. You can schedule a genetic counseling session by clicking the button below. Learn how genetic counseling works.

Schedule Counseling Appointment

REFERENCES

1. Surveillance, Epidemiology, and End Results (SEER) Program, National Cancer Institute. 2010-2012. DevCan software (http://surveillance.cancer.gov/devcan) V 6.7.0, Accessed June 2015.

2. American Cancer Society Guidelines for the Early Detection of Cancer. American Cancer Society. http://www.cancer.org/healthy/findcancerearly/cancerscreeningguidelines/american-cancer-society-guidelines-for-the-early-detection-of-cancer. Updated October 2014. Accessed May 2015.

3. National Comprehensive Cancer Network. Breast Cancer Screening and Diagnosis. NCCN Guidelines Version 1.2014. Available at www.nccn.org. Published March 2014.

4. Ovarian, Fallopian Tube, and Primary Peritoneal Cancer Screening. National Cancer Institute. http://www.cancer.gov/cancertopics/pdq/screening/ovarian/Patient/page3. Updated March 2015. Accessed May 2015.

5. Eggington JM, Bowles KR, Moyes K, et al. A comprehensive laboratory-based program for classification of variants of uncertain significance in hereditary cancer genes. *Clinical Genetics*. September 2014; 86(3):229-37.

6. Easton DF, Deffenbaugh AM, Pruss D et al. A systematic genetic assessment of 1,433 sequence variants of unknown clinical significance in the BRCA1 and BRCA2 breast cancer-predisposition genes. *The American Journal of Human Genetics*. November 2007; 81(5):873-83.

7. Akbari MR, Zhang S, Fan I, et al. Clinical impact of unclassified variants of the BRCA1 and BRCA2 genes. *Journal of Medical Genetics*. October 2011; 48(11):783-6.

8. National Comprehensive Cancer Network. Genetic/Familial High-Risk Assessment: Breast and Ovarian. NCCN Guidelines Version 1.2015. Available at www.nccn.org. Published March 2015.

9. Ban KA and Godellas CV. Epidemiology of breast cancer. *Surgical Oncology Clinics of North America*. July 2014; 23(3):409-22.

10. Kelsey, JL, Gammon MD, John EM. Reproductive factors and breast cancer. *Epidemiologic Reviews*. 1993; 15(1):36-47.

11. Henderson TO, Amsterdam A, Bhatia S, et al. Systematic review: surveillance for breast cancer in women treated with chest radiation for childhood, adolescent, or young adult cancer. *Annals of Internal Medicine*. April 2010; 152(7):444-55.

A pathogenic mutation was identified in the BRCA1 gene.

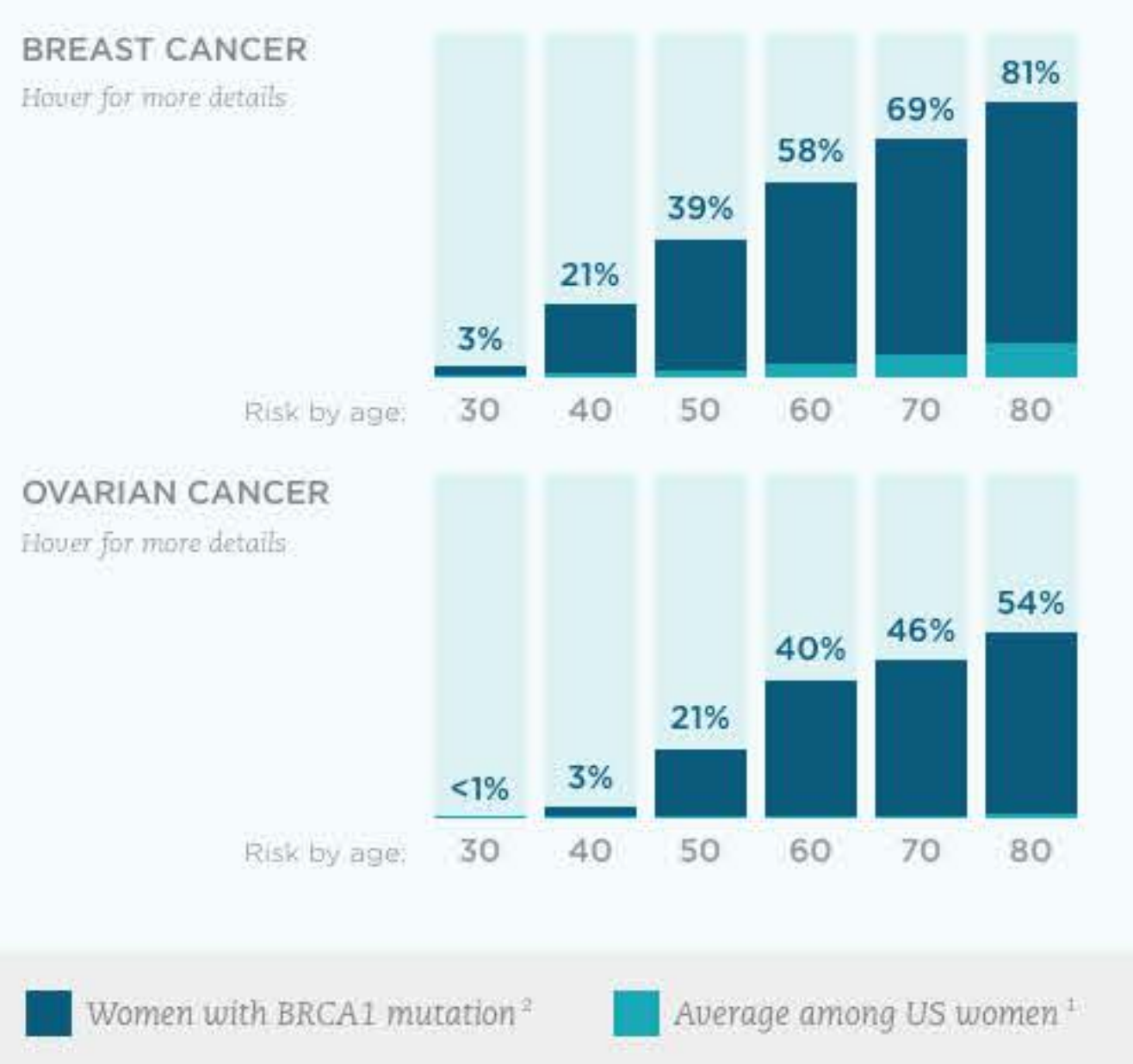
Testing positive for a pathogenic mutation in the BRCA1 gene means your chances of developing breast and ovarian cancer are greater than that of the average US woman. This result does **not** mean that you have a diagnosis of cancer or that you will definitely develop cancer in your lifetime. Learn more below.

Schedule an appointment with one of our board-certified genetic counselors at no additional cost to discuss your results.

Schedule Counseling Appointment

Risk by age with a BRCA1 mutation

Risk among US women with a *BRCA1* mutation to develop specific cancers by different ages in their lives.



Increased risk for other cancers.

In addition to increasing a woman's risk for breast and ovarian cancer, mutations in the BRCA1 gene are known to increase the risk of developing pancreatic cancer.

Please note that while having a BRCA1 gene mutation increases risk for pancreatic cancer, the Color test is not currently designed to detect mutations in other genes that may also increase risk for this cancer. Your actual risk may be different based on other genetic and non-genetic factors. We encourage you to discuss your results with one of our board-certified genetic counselors at no additional cost.

CANCER TYPE	WITH BRCA1 MUTATION [3]	AVG. US WOMAN [1]
Pancreatic	Elevated (3-5%)	<1%

The risk of developing cancer by age 80.

NEXT STEPS | DETAILS | HISTORY | FAMILY | QUESTIONS | Schedule Counseling

KNOW YOUR SCREENING GUIDELINES

Below is a summary of screening guidelines established by experts at the National Comprehensive Cancer Network (NCCN).[4] They are specific to women who have a mutation in the BRCA1 gene. Your healthcare provider may use these guidelines to help create a customized screening plan for you.

Breast and ovarian cancer [5]

- **Starting at age 18**: Breast awareness - Women should be familiar with their breasts and promptly report changes to their healthcare provider. Performing regular breast self exams may help increase breast awareness, especially when checked at the end of the menstrual cycle.
- **Starting at age 25**: Breast exam by your provider every 6-12 months.
- **Between ages 25-29 or individualized based on family history**: Breast MRI screening (preferred) every year or mammogram if MRI is unavailable.
- **Between ages 30-75**: Mammogram and breast MRI screening every year. Your provider may wish to alternate between these two screenings every 6 months.
- **Between ages 35-40, or after you are finished having children**: NCCN recommends a risk-reducing salpingo-oophorectomy (the surgical removal of the ovaries and fallopian tubes) to lower the risk of developing breast and ovarian cancer. Ideally, this should involve a discussion with a gynecologic oncologist.
- **After age 75**: Your provider may discuss an individualized management plan with you.
- Your provider may discuss the option of having a risk-reducing bilateral mastectomy (the surgical removal of both breasts).
- Your provider may discuss the use of medications that might reduce the risk of developing breast or ovarian cancer.
- While there may be circumstances where ovarian cancer screening with transvaginal ultrasound and a blood test for a protein called CA-125 are helpful, these techniques have not been shown to be effective in detecting early ovarian cancer.

Pancreatic cancer [5]

- Currently, there are no pancreatic cancer screening guidelines from the NCCN specific to *BRCA1* mutation carriers. Please discuss your risk of pancreatic cancer with your healthcare provider.

SHARE YOUR RESULTS

Discuss your results with your healthcare provider.

It is important to schedule an appointment with your healthcare provider to discuss your results and plan next steps.

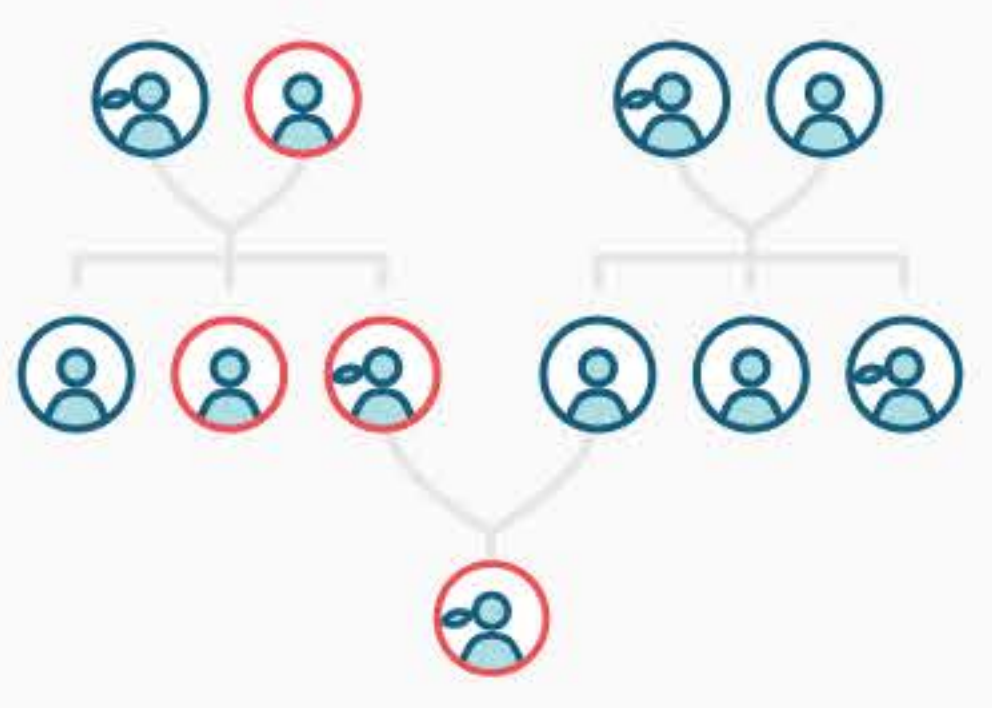
Provider's first name | Provider's last name

Practice or hospital name

City | State

Fax Results to Provider

We will email you when the results have been sent.



Your relatives may also have this BRCA1 mutation.

Consider sharing your results with relatives because:

- This mutation was most likely inherited from either your mother or your father. This would mean that one of your parents has the same mutation, and that your relatives on that side of the family may also have the same mutation. Fathers are just as likely to pass on a mutation as mothers.
- Each of your siblings has a 50% chance of having inherited this mutation. Brothers are just as likely to inherit it as sisters.
- Each of your children has a 50% chance of inheriting the same mutation. Men are just as likely as women to pass the mutation on to their children, and daughters and sons are equally likely to inherit it. Please keep in mind that children are not recommended to be tested for this mutation as it does not impact health or affect medical management in childhood.
- If genetic testing indicates that a relative does not have the mutation (tests negative), that relative's children are not at risk to inherit this mutation. These mutations do not skip generations.

Email Relatives | View a sample letter

SPEAK WITH A SPECIALIST

Speak with a MAGENTA genetic counselor.

MAGENTA's genetic counselors are board-certified healthcare professionals who can help you understand your results and answer your questions. You can schedule a genetic counseling session by clicking the button below. Learn how genetic counseling works.

Schedule Counseling Appointment

CONNECT WITH OTHERS

FORCE

Committed to providing resources and support to individuals at high-risk of getting breast and ovarian cancer due to their family history and genetic status.

Visit www.facingourrisk.org ›

Bright Pink

Focused on the prevention and early detection of breast and ovarian cancer in young women, while providing support for high-risk individuals.

Visit www.brightpink.org ›

Susan G. Komen

Dedicated to reducing deaths from breast cancer by funding breast cancer research, ensuring access to care through community programs worldwide and supporting public health policies that help people facing breast cancer.

Visit www.komen.org ›

REFERENCES

1. Surveillance, Epidemiology, and End Results (SEER) Program, National Cancer Institute. DevCan software (http://surveillance.cancer.gov/devcan) V 6.7.0. Accessed June 2015.

2. King MC, Marks JH, Mandell JB, New York Breast Cancer Study Group. Breast and Ovarian Cancer Risks Due to Inherited Mutations in BRCA1 and BRCA2. *Science*. October 2003; 302(5645):643-6.

3. Mocci E, Milne RL, Mendez-Villamil EY, et al. Risk of pancreatic cancer in breast cancer families from the breast cancer family registry. *Cancer Epidemiology Biomarkers Prevention*. May 2013; 22(5)803-11.

4. Integrated with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). © 2015 National Comprehensive Cancer Network, Inc. All rights reserved. The NCCN Guidelines® and illustrations herein may not be reproduced in any form for any purpose without the express written permission of the NCCN. To view the most recent and complete version of the NCCN Guidelines, go online to NCCN.org.

5. National Comprehensive Cancer Network. Genetic/Familial High-Risk Assessment: Breast and Ovarian. NCCN Guidelines Version 1.2015. Available at www.nccn.org. Published March 2015.

6. Liede A, Karlan BY, Narod SA. Cancer risks for male carriers of germline mutations in BRCA1 or BRCA2: a review of the literature. *Journal of Clinical Oncology*. February 2004; 22(4):735-42.

7. Leongamornlert D, Mahmud N, Tymrakiewicz M, et al. Germline BRCA1 mutations increase prostate cancer risk. *British Journal of Cancer*. May 2012; 106(10):1697-701.

8. Tai YC, Domchek S, Parmigiani G, Chen S. Breast cancer risk among male BRCA1 and BRCA2 mutation carriers. *Journal of the National Cancer Institute*. December 2007; 99(23):1811-4.

Appendix J

Arm C: Participant receives email from MAGENTA with URL & code

color

color

Welcome to Color. Before you get started…

As part of the MAGENTA study, please watch a video with important information about the benefits and limitations of genetic testing, as well as the results you might receive.

Read the content shown in this video.

☐ I have watched the video to the right.

Get Started

color

Sign In

Create a Color account to get started

This account will be used for activating your kit and returning your results.

First name | Last name

Email address

Create a password | Confirm password

I agree to the Color Terms of Service and Privacy Policy.

Create Account

Color Genomics

CLIA #05D2081492 - CAP #8975161

Mission Team Careers Privacy Press Contact

color

JENNY WALKER

You are receiving complimentary testing, courtesy of the MAGENTA study.

Ship to

Step 1 of 5

Color is currently only available in the US. We are not yet able to ship kits to New York.

Delivery address

Your kit will be delivered via USPS priority mail in 5-8 days.

Jenny Walker

Street address, P.O. box, company name, c/o

Apartment, suite, unit, building, floor, etc.

ZIP code

Phone number

Continue

color

JENNY WALKER

You are receiving complimentary testing, courtesy of the MAGENTA study.

Share results

Step 2 of 5

All participants of the MAGENTA Study are required to have a physician that their results will be shared with when they are complete.

Personal physician

Provider's first name

Provider's last name

Practice or hospital name

City

State

Study code

XTARSM

Continue

You are receiving complimentary testing, courtesy of the MAGENTA study.

Provide your health history

Step 3 of 5

Your responses are confidential and will be used to generate your overall breast and ovarian cancer risk. Please answer to the best of your knowledge, and estimate when you need to.

General information

What is your ancestry? (check all that apply)

- [ ] African
- [ ] Asian ...
- [ ] Caucasian
- [ ] Hispanic
- [ ] Native American
- [ ] Unknown
- [ ] Other

Are you of Ashkenazi Jewish descent?

- ○ Yes ○ No ○ I'm not sure

Why are you having genetic testing done?

- [ ] Learn if my family history of cancer is hereditary
- [ ] Learn if my personal history of cancer is hereditary
- [ ] Learn if I carry a mutation known to run in my family
- [ ] I'm curious to know more about my genetics

Personal history

How old were you when you had your first period?

Estimates are okay

Have you ever given birth to a child?

- ○ Yes ○ No

Have you had cancer before?

- ○ Yes ○ No

Have you had a mastectomy?

- ○ Yes ○ No

Have you had an oophorectomy?

- ○ Yes ○ No

Have you had a breast biopsy?

- ○ Yes ○ No

Have you had a genetic test for hereditary cancer risk?

- ○ Yes ○ No

Have you ever had a bone marrow transplant or blood transfusion?

- ○ Yes ○ No

Family tree

Age estimates are okay.

Are you adopted or do you have no health information about one, or both sides of your biological family members?

- ○ Yes ○ No

Do you have any siblings?

- ○ Yes ○ No ○ I'm not sure

Does your mother have any siblings?

- ○ Yes ○ No ○ I'm not sure

Does your father have any siblings?

- ○ Yes ○ No ○ I'm not sure

How old are your parents and grandparents? Estimates are okay.

Mother's age: Years Now

Fathers's age: Years Now

Maternal grandmother's age: Years Now

Maternal grandfather's age: Years Now

Paternal grandmother's age: Years Now

Paternal grandfather's age: Years Now

Continue

Finish providing history later

You are receiving complimentary testing, courtesy of the MAGENTA study.

Provide your family's health history

Step 4 of 5

Your responses are confidential and will be used to generate your overall breast and ovarian cancer risk. Please answer to the best of your knowledge, and estimate when you need to.

Children

Have any of your children had cancer?

- [ ] Daughter (age 6)
- [ ] Son (age 4)

Parents and siblings

Have any of your parents had cancer?

- [ ] Mother (age 70)
- [ ] Father (age 70)

Mother's side

Has anyone on your mother's side had cancer?

- [ ] Maternal grandmother (age 95, dec.)
- [ ] Maternal grandfather (age 75, dec.)

Father's side

Has anyone on your father's side had cancer?

- [ ] Paternal grandmother (age 75, dec.)
- [ ] Paternal grandfather (age 75, dec.)

Entire family

Has anyone had a genetic test for hereditary cancer risk?

○ No ○ Yes ○ I'm not sure

Is there anything else related to your personal or family history that you would like to share?

○ No ○ Yes ○ I'm not sure

Done

Finish providing history later

You are receiving complimentary testing, courtesy of the MAGENTA study.

Review

Step 5 of 5

Make sure the information below is correct.

Ship to

Jenny Walker
345 Spear St.
San Francisco, CA 94105
415-555-1212

EDIT

Share results with

Dr. Peggy Newcomer
One Medical
San Francisco, CA

EDIT

Personal health history

Provided

EDIT

Family health history

Provided

EDIT

Order Kit

Last step: Schedule a genetic counseling session.

After your genetic counseling session with the MAGENTA Study has been completed, we will ship your Color saliva collection kit.

Your purchase number is **1234323423**.

Schedule Appointment

color RESULTS LEARN GIFT SUPPORT JENNY WALKER

Last step: Schedule a genetic
cou

After yo
MAGEN
ship you

Your pu

Sc

Schedule a genetic counseling appointment

Choose Appointment | Your Info | Confirmation

< **April 2016** >

S	M	T	W	Th	F	S
					1	2
3	**4**	**5**	**6**	**7**	**8**	9
10	**11**	**12**	**13**	**14**	**15**	16
17	**18**	**19**	**20**	**21**	**22**	23
24	**25**	**26**	**27**	**28**	29	30

color

Purchase #: 123454354345

Schedule a genetic counseling session.

After your genetic counseling session with the MAGENTA Study has been completed, we will ship your Color saliva collection kit.

Schedule Appointment

The MAGENTA Study

Color is partnering with the MAGENTA Study to provide genetic testing to enrollees. More content explaining study.

If you have questions, please contact your Study Coordinator at <email address> or <phone>.

Color Genomics, Inc.
1801 Murchison Dr.. Ste. 128, Burlingame, CA 94010
support@getcolor.com

color

Please confirm this is your email address.

Hi Jenny,

Welcome to Color! To ensure that only you have access to your personal information, you must confirm your email address. You won't be able to access your account until you complete this step.

Thank you,
The Color Team
support@getcolor.com

Confirm Email Address

Color Genomics, Inc.
1801 Murchison Dr.. Ste. 128, Burlingame, CA 94010
support@getcolor.com

MAGENTA lets Color
know to ship kit

color

Jenny Walker Female, DOB: 05/25/77

BACK TO ORDERS

Results

Log

Order Details

Health History

Log

Ship Kit

FEB 17, 2016

Order placed
Your order for Jenny Walker has been succesfully placed.

FEB 17, 2016

Patient requested kit
Your participant has used their research code XTARSM to request their Color kit.

Pre-test counseling
Pre-test counseling is needed for Jenny Walker.

Sample received at Color lab
Results take 6-8 weeks on average once the sample has been received at the lab.

Results released to provider
Results will be sent to you and Dr. Liz Swisher.

Results released to patient
Results will be sent to Jenny Walker.

Post-test counseling
Post-test counseling will be needed for Jenny Walker.

Viewed by patient
Status will be updated when patient first views their results.

CONTACT US

8am-5pm PT
(844) 362-6567
providers@getcolor.com

color

Purchase #: 123454354345

Your Color kit is on the way.

Your kit was shipped on Nov. 19th using USPS (tracking #234232524324342). It should arrive in 5-8 days.

Track Package

Info may not be available for 24 hours.

Shipped to

Jenny Walker
345 Spear St.
San Francisco, CA 94105
(415) 555-1212

Common questions

- What do I do if my kit was sent to the wrong address?
- When will my kit arrive?
- Can I give my Color kit to someone else?

More questions? Browse Support or Contact us.

Color Genomics, Inc.
1801 Murchison Dr.. Ste. 128, Burlingame, CA 94010
support@getcolor.com

Participant receives kit
and goes online to
activate it

color

color

Sign in to activate your kit

Email address

Password

Forgot your password?

Sign In

I need to create a Color account.

Color Genomics

CLIA #05D2081492 - CAP #8975161

Mission Team Careers Privacy Press Contact

Welcome to kit activation. Before you get started...

Watch a video with important information about the benefits and limitations of genetic testing, as well as the results you might receive.

IN SUMMARY

Results will not tell you whether or not you will get cancer; they indicate your hereditary chance of developing cancer in the future. Test results should be discussed with a Color genetic counselor as well as your healthcare provider.

Most people receive a negative result.

This means no mutations known to be associated with an increased risk for breast or ovarian cancer were found in the genes we analyzed.

A small percentage of people receive a positive result.

This means a mutation that increases risk for breast or ovarian cancer (or both) was identified.

This information can be used to potentially improve your health.

It is important you share your results with your healthcare provider to develop a personalized screening and prevention plan. This is important because detecting cancer at its earliest stage improves the likelihood of a favorable outcome.

It's normal to find variants of uncertain significance.

It is common to see changes in genes that require further research to determine if they are associated with an increased risk for developing cancer. To date, most have been found to be harmless.

Increased risk for other cancers may be found.

Mutations that impact breast and ovarian cancer risk may also increase the risk of developing other cancers.

Share your results with your relatives.

Your results may be useful to your relatives who may also wish to discuss genetic testing with their own providers.

☐ I understood the important information above.

Get Started

REFERENCES

1. Eggington JM, Bowles KR, Moyes K, et al. A comprehensive laboratory-based program for classification of variants of uncertain significance in hereditary cancer genes. *Clin Genet*. September 2014; 86(3):229-37.

2. Easton DF, Deffenbaugh AM, Pruss D et al. A systematic genetic assessment of 1,433 sequence variants of unknown clinical significance in the BRCA1 and BRCA2 breast cancer-predisposition genes. *Am J Hum Genet*. November 2007; 81(5):873-83.

3. Akbari MR, Zhang S, Fan I, et al. Clinical impact of unclassified variants of the BRCA1 and BRCA2 genes. *J Med Genet*. October 2011; 48(11): 783-6.

color

JENNY WALKER

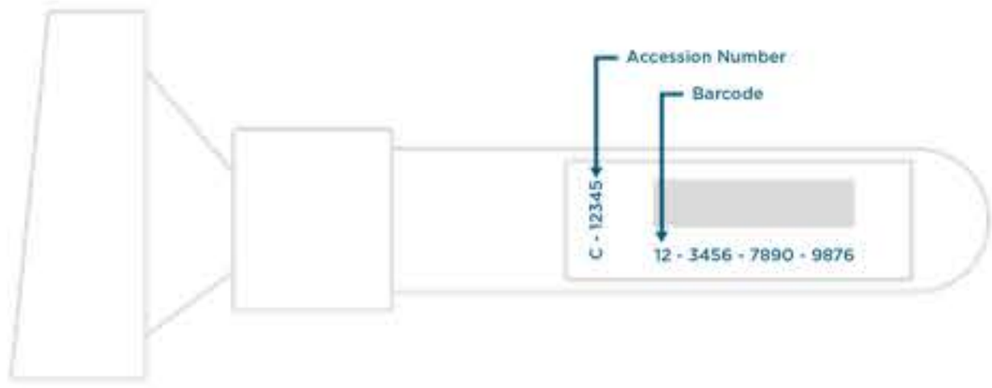
ACTIVATE > PERSONAL HISTORY > FAMILY HISTORY > COMPLETE

Activate your kit

The information below is required to ensure the quality of your results.

Information from your saliva tube

Having trouble? Get help.



Enter your tube's accession number

Enter your tube's barcode

About you

Your birthday and sex are required by the lab for sequencing.

Date of birth: MM / DD / YYYY

Sex

Phone number

Options

- [x] I consent to the use of my samples and data in third party research.
- [x] I consent to storing my samples and DNA with Color for future use or testing.

Consent

- [ ] I have read and agree to the Color Informed Consent. I specifically acknowledge and consent to the following:
  - I am the individual providing the sample and I am at least 18 years of age.
  - This test is not intended to diagnose whether I have or will get a certain disease in the future. It is intended to tell me about my hereditary risk related to certain diseases or other genetic conditions.
  - I should not make any medical decisions based on these results without speaking to my healthcare provider and discussing how these results may contribute to a personalized screening and prevention plan.
  - This test may not perform as intended or provide accurate results if I have not provided accurate personal information, or if I have certain rare biological conditions (e.g., mosaicism) or have had certain bone marrow transplants, transfusions, or hematologic malignancies (e.g., blood related diseases such as leukemia or lymphoma).
  - Genetic counseling services are available to me through Color at no additional charge.
  - The genes that Color analyzes are selected based on their known relationship with the diseases or genetic traits reported, but they may also indicate an increased risk for other health conditions for which Color may provide results that are not yet comprehensive for these other health conditions.
  - My anonymized sample, genetic information, and results may be used for internal quality control, laboratory validation studies, and research and development.
  - Color will contribute de-identified information about my genetic variants to public databases like NCBI's ClinVar, where de-identified genetic information is accessible to researchers to better understand the connection between genetics and disease.
  - My sample and all my related personal information will be transferred to Color's laboratory in the United States for analysis, use, processing, and storage and will be subject to the laws and regulations of the United States.
  - I agree to the Color Terms of Service and Privacy Policy.

Continue

Provide your health history

Your responses are confidential and will be used to generate your overall breast and ovarian cancer risk. Please answer to the best of your knowledge, and estimate when you need to.

General information

What is your ancestry? (check all that apply)

- [ ] African
- [ ] Asian ...
- [ ] Caucasian
- [ ] Hispanic
- [ ] Native American
- [ ] Unknown
- [ ] Other

Are you of Ashkenazi Jewish descent?

○ Yes ○ No ○ I'm not sure

Why are you having genetic testing done?

- [ ] Learn if my family history of cancer is hereditary
- [ ] Learn if my personal history of cancer is hereditary
- [ ] Learn if I carry a mutation known to run in my family
- [ ] I'm curious to know more about my genetics

Personal history

How old were you when you had your first period?

Estimates are okay

Have you ever given birth to a child?

○ Yes ○ No

Have you had cancer before?

○ Yes ○ No

Have you had a mastectomy?

○ Yes ○ No

Have you had an oophorectomy?

○ Yes ○ No

Have you had a breast biopsy?

○ Yes ○ No

Have you had a genetic test for hereditary cancer risk?

○ Yes ○ No

Have you ever had a bone marrow transplant or blood transfusion?

○ Yes ○ No

Family tree

Age estimates are okay.

Are you adopted or do you have no health information about one, or both sides of your biological family members?

○ Yes ○ No

Do you have any siblings?

○ Yes ○ No ○ I'm not sure

Does your mother have any siblings?

○ Yes ○ No ○ I'm not sure

Does your father have any siblings?

○ Yes ○ No ○ I'm not sure

How old are your parents and grandparents? Estimates are okay.

Mother's age: Years Now

Fathers's age: Years Now

Maternal grandmother's age: Years Now

Maternal grandfather's age: Years Now

Paternal grandmother's age: Years Now

Paternal grandfather's age: Years Now

Continue

Finish providing history later

Provide your family's health history

Your responses are confidential and will be used to generate your overall breast and ovarian cancer risk. Please answer to the best of your knowledge, and estimate when you need to.

Children

Have any of your children had cancer?

- [ ] Daughter (age 6)
- [ ] Son (age 4)

Parents and siblings

Have any of your parents had cancer?

- [ ] Mother (age 70)
- [ ] Father (age 70)

Mother's side

Has anyone on your mother's side had cancer?

- [ ] Maternal grandmother (age 95, dec.)
- [ ] Maternal grandfather (age 75, dec.)

Father's side

Has anyone on your father's side had cancer?

- [ ] Paternal grandmother (age 75, dec.)
- [ ] Paternal grandfather (age 75, dec.)

Entire family

Has anyone had a genetic test for hereditary cancer risk?

- ○ No ○ Yes ○ I'm not sure

Is there anything else related to your personal or family history that you would like to share?

- ○ No ○ Yes ○ I'm not sure

Done

Finish providing history later

Your Color kit is activated.

After you've provided a saliva sample, put the tube in the bag, seal it in the provided box, and drop it in any USPS mailbox.

Dr. Liz Swisher has already ordered this test for you, so analysis will begin as soon as we receive your kit.

▶ Learn how to provide a saliva sample.

color

Barcode: 123 45345353 354345

Your Color kit is activated. Now just return it.

Place your tube into the provided plastic bag, seal the bag, then place it back into the cardboard box it came in.

Postage has already been paid, so you can just drop it in any USPS mail box.

What happens next?

- We'll email you when we receive your sample. First, it is inspected to ensure that you have activated it and provided enough saliva for sequencing.
- Next, DNA from the saliva sample is extracted and sequenced, with several quality control checks at each point.
- After sequencing is complete, we review any variants found in 19 genes thought to have an especially strong impact on breast and ovarian cancer risk. The health history you provided is combined with your genetic test results in this step to create a personalized cancer risk assessment.
- All results are then reviewed by a physician before being released to you.
- A consultation with a genetic counselor is available to discuss your results if you have any questions.

Watch a quick video to prepare for your results.

Common questions

- How do I provide a sample?
- How is my health history used?
- How can I track the status of my sample?

More questions? Browse Support or Contact us.

Color Genomics, Inc.
1801 Murchison Dr.. Ste. 128, Burlingame, CA 94010
support@getcolor.com

Color receives sample
back at the lab

color

color

Barcode: 123 45345353 354345

We are beginning testing on your saliva sample.

After we verify that your sample meets our quality standards, we'll extract and sequence your DNA.

What happens next?

- First, we do a quality check on the sample you submitted.
- Next, DNA from the saliva sample is extracted and sequenced, with several quality control checks at each point.
- After sequencing is complete, we review any variants found in 19 genes thought to have an especially strong impact on breast and ovarian cancer risk. The health history you provided is combined with your genetic test results in this step to create a personalized cancer risk assessment.
- All results are then reviewed by a physician before being released to you.
- A consultation with a genetic counselor is available to discuss your results if you have any questions.

Watch a quick video to prepare for your results.

Common questions

- When will my results be ready?
- How should I prepare for my results?

More questions? Browse Support or Contact us.

Color Genomics, Inc.
1801 Murchison Dr.. Ste. 128, Burlingame, CA 94010
support@getcolor.com

Participant experience upon any results release (study)

color

color

Schedule an appointment to review your results.

Hello Jenny,

I'm Nadine Rayes, a genetic counselor with the MAGENTA study. We've completed analysis of your sample and health history, and your results are ready. Schedule a time to review your results with me, or another genetic counselor. MAGENTA's genetic counselors are board-certified healthcare professionals who can help you understand your results and answer your questions.

Schedule Counseling Appointment

At your request, a copy of your results will be sent to your healthcare provider Dr. Peggy Necomer at One Medical in San Francisco, CA after you've reviewed them.

Thank you,
Nadine Rayes, MS, LCGC
Board-certified Genetic Counselor

Color Genomics, Inc.
1801 Murchison Dr.. Ste. 128, Burlingame, CA 94010
support@getcolor.com

Your results are ready. Review them with a genetic counselor.

MAGENTA's genetic counselors are board-certified healthcare professionals who will help you understand your results and answer your questions. Learn how genetic counseling works.

Choose Appointment | Your Info | Confirmation

Set your time zone to continue:

(GMT-7:00) Pacific Time

Set time zone

(GMT-7:00) Pacific Time change

Your results are ready. Before you get started...

Watch a quick video covering important information about the benefits and limitations of genetic testing, as well as the results you might receive.

REMEMBER

We ask everyone, **regardless of their results**, to remember the important information below:

Some people without mutations still get cancer.

Environmental and lifestyle factors and family history without a known genetic link account for the majority of breast and ovarian cancers.

Some people with mutations never get cancer.

Mutations increase risk, but they do not mean that you have cancer or that you will definitely develop cancer in your lifetime.

This information can be used to potentially improve your health.

It is important you share your results with your healthcare provider to develop a personalized screening and prevention plan. MAGENTA's genetic counselors are here to answer any of your questions.

☐ I have read and understand this information. I am in a private, comfortable place and wish to view my results.

View Results

No mutations were identified.

This means no pathogenic or likely pathogenic genetic variants associated with an increased risk of breast or ovarian cancer were identified in any of the 19 genes tested.

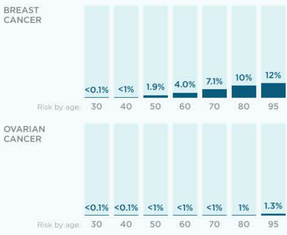
While this can be reassuring, it does not eliminate your risk of developing breast or ovarian cancers. Environmental and lifestyle factors, along with family history without a known genetic link, account for the majority of these cancers. Your healthcare provider can help determine how your screening plan might be influenced by your history and other factors.

Genes that were tested:
ATM, BARD1, BRCA1, BRCA2, BRIP1, CDH1, CHEK2, EPCAM, MLH1, MSH2, MSH6, NBN, PALB2, PMS2, PTEN, RAD51C, RAD51D, STK11, TP53

Learn more about your results and how to act on them below.

Average risk by age among US women

Your actual risk may be different based on other genetic and non-genetic factors.



Average risk among US women[1]

NEXT STEPS DETAILS HISTORY FAMILY QUESTIONS Schedule Appointment

KNOW YOUR SCREENING GUIDELINES

Below is a summary of screening guidelines established by experts at the National Comprehensive Cancer Network (NCCN). These guidelines are for women who have the same breast and ovarian cancer risk as the average US woman. Your healthcare provider may use these guidelines to help create a customized screening plan for you.

Breast cancer[2,3]

- **Starting at age 25:** Breast awareness - Women should be familiar with their breasts and promptly report changes to their healthcare provider. Performing regular breast self exams may help increase breast self awareness, especially when checked at the end of the menstrual cycle.
- **Between ages 25-39**: Clinical breast exam every 1-3 years.
- **Starting at age 40**: Clinical breast exam and mammogram every year.

Ovarian cancer[4]

- Currently, there are no standard screening guidelines for ovarian cancer. Please discuss any family history of ovarian cancer with your healthcare provider.

SHARE YOUR RESULTS

Share your results with your healthcare provider.

Color recommends you share your results with your healthcare provider. Sharing your results allows your provider to guide you to appropriate resources and discuss tailored options for cancer screening and prevention.

Provider's first name | Provider's last name

Practice or hospital name

City | State

Fax Results to Provider

We will email you when the results have been sent.

Your relatives may benefit from learning their genetic status.

Consider sharing your results with relatives who may also benefit from genetic testing. A few key points to remember:

- Your negative result significantly lowers the chance that you have an inherited mutation associated with breast or ovarian cancer.
- It is still possible for your relatives to have a mutation that you did not inherit. They may benefit from their own genetic testing, especially those who have had cancer.
- If any of your relatives has a mutation, there is a 50% chance that their siblings and children also have the same mutation.
- A father and mother are equally likely to pass on a mutation. Sons and daughters are equally likely to inherit a mutation if one of their parents has it.
- If you learn that a relative of yours has a mutation, contact a Color genetic counselor to learn how that information may impact your risk assessment and interpretation of results.

Email Relatives View a sample letter

SPEAK WITH A SPECIALIST

Speak with a MAGENTA genetic counselor.

MAGENTA's genetic counselors are board-certified healthcare professionals who can help you understand your results and answer your questions. You can schedule a genetic counseling session by clicking the button below. Learn how genetic counseling works.

Schedule Counseling Appointment

REFERENCES

1. Surveillance, Epidemiology, and End Results (SEER) Program, National Cancer Institute. 2010-2012. DevCan software (http://surveillance.cancer.gov/devcan) V 6.7.0, Accessed June 2015.

2. American Cancer Society Guidelines for the Early Detection of Cancer. American Cancer Society. http://www.cancer.org/healthy/findcancerearly/cancerscreeningguidelines/american-cancer-society-guidelines-for-the-early-detection-of-cancer. Updated October 2014. Accessed May 2015.

3. National Comprehensive Cancer Network. Breast Cancer Screening and Diagnosis. NCCN Guidelines Version 1.2014. Available at www.nccn.org. Published March 2014.

4. Ovarian, Fallopian Tube, and Primary Peritoneal Cancer Screening. National Cancer Institute. http://www.cancer.gov/cancertopics/pdq/screening/ovarian/Patient/page3. Updated March 2015. Accessed May 2015.

5. Eggington JM, Bowles KR, Moyes K, et al. A comprehensive laboratory-based program for classification of variants of uncertain significance in hereditary cancer genes. *Clinical Genetics*. September 2014; 86(3):229-37.

6. Easton DF, Deffenbaugh AM, Pruss D et al. A systematic genetic assessment of 1,433 sequence variants of unknown clinical significance in the BRCA1 and BRCA2 breast cancer-predisposition genes. *The American Journal of Human Genetics*. November 2007; 81(5):873-83.

7. Akbari MR, Zhang S, Fan I, et al. Clinical impact of unclassified variants of the BRCA1 and BRCA2 genes. *Journal of Medical Genetics*. October 2011; 48(11):783-6.

8. National Comprehensive Cancer Network. Genetic/Familial High-Risk Assessment: Breast and Ovarian. NCCN Guidelines Version 1.2015. Available at www.nccn.org. Published March 2015.

9. Ban KA and Godellas CV. Epidemiology of breast cancer. *Surgical Oncology Clinics of North America*. July 2014; 23(3):409-22.

10. Kelsey, JL, Gammon MD, John EM. Reproductive factors and breast cancer. *Epidemiologic Reviews*. 1993; 15(1):36-47.

11. Henderson TO, Amsterdam A, Bhatia S, et al. Systematic review: surveillance for breast cancer in women treated with chest radiation for childhood, adolescent, or young adult cancer. *Annals of Internal Medicine*. April 2010; 152(7):444-55.

A pathogenic mutation was identified in the BRCA1 gene.

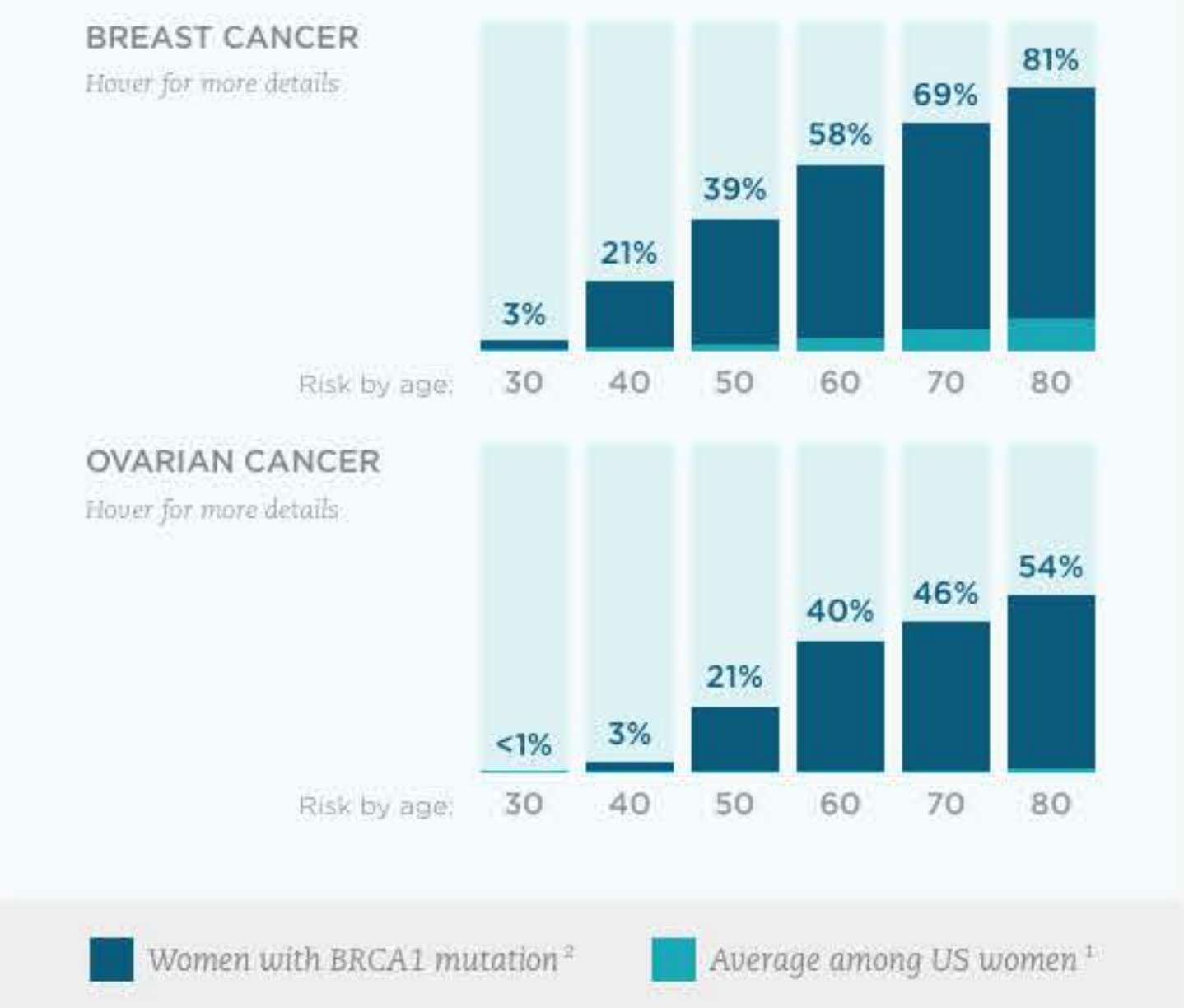
Testing positive for a pathogenic mutation in the BRCA1 gene means your chances of developing breast and ovarian cancer are greater than that of the average US woman. This result does **not** mean that you have a diagnosis of cancer or that you will definitely develop cancer in your lifetime. Learn more below.

Schedule an appointment with one of our board-certified genetic counselors at no additional cost to discuss your results.

Schedule Counseling Appointment

Risk by age with a BRCA1 mutation

Risk among US women with a *BRCA1* mutation to develop specific cancers by different ages in their lives.



Increased risk for other cancers.

In addition to increasing a woman's risk for breast and ovarian cancer, mutations in the BRCA1 gene are known to increase the risk of developing pancreatic cancer.

Please note that while having a BRCA1 gene mutation increases risk for pancreatic cancer, the Color test is not currently designed to detect mutations in other genes that may also increase risk for this cancer. Your actual risk may be different based on other genetic and non-genetic factors. We encourage you to discuss your results with one of our board-certified genetic counselors at no additional cost.

CANCER TYPE	WITH BRCA1 MUTATION [3]	AVG. US WOMAN [1]
Pancreatic	Elevated (3-5%)	<1%

The risk of developing cancer by age 80.

NEXT STEPS DETAILS HISTORY FAMILY QUESTIONS Schedule Counseling

KNOW YOUR SCREENING GUIDELINES

Below is a summary of screening guidelines established by experts at the National Comprehensive Cancer Network (NCCN).[4] They are specific to women who have a mutation in the BRCA1 gene. Your healthcare provider may use these guidelines to help create a customized screening plan for you.

Breast and ovarian cancer [5]

- **Starting at age 18**: Breast awareness - Women should be familiar with their breasts and promptly report changes to their healthcare provider. Performing regular breast self exams may help increase breast awareness, especially when checked at the end of the menstrual cycle.
- **Starting at age 25**: Breast exam by your provider every 6-12 months.
- **Between ages 25-29 or individualized based on family history**: Breast MRI screening (preferred) every year or mammogram if MRI is unavailable.
- **Between ages 30-75**: Mammogram and breast MRI screening every year. Your provider may wish to alternate between these two screenings every 6 months.
- **Between ages 35-40, or after you are finished having children**: NCCN recommends a risk-reducing salpingo-oophorectomy (the surgical removal of the ovaries and fallopian tubes) to lower the risk of developing breast and ovarian cancer. Ideally, this should involve a discussion with a gynecologic oncologist.
- **After age 75**: Your provider may discuss an individualized management plan with you.
- Your provider may discuss the option of having a risk-reducing bilateral mastectomy (the surgical removal of both breasts).
- Your provider may discuss the use of medications that might reduce the risk of developing breast or ovarian cancer.
- While there may be circumstances where ovarian cancer screening with transvaginal ultrasound and a blood test for a protein called CA-125 are helpful, these techniques have not been shown to be effective in detecting early ovarian cancer.

Pancreatic cancer [5]

- Currently, there are no pancreatic cancer screening guidelines from the NCCN specific to *BRCA1* mutation carriers. Please discuss your risk of pancreatic cancer with your healthcare provider.

SHARE YOUR RESULTS

Discuss your results with your healthcare provider.

It is important to schedule an appointment with your healthcare provider to discuss your results and plan next steps.

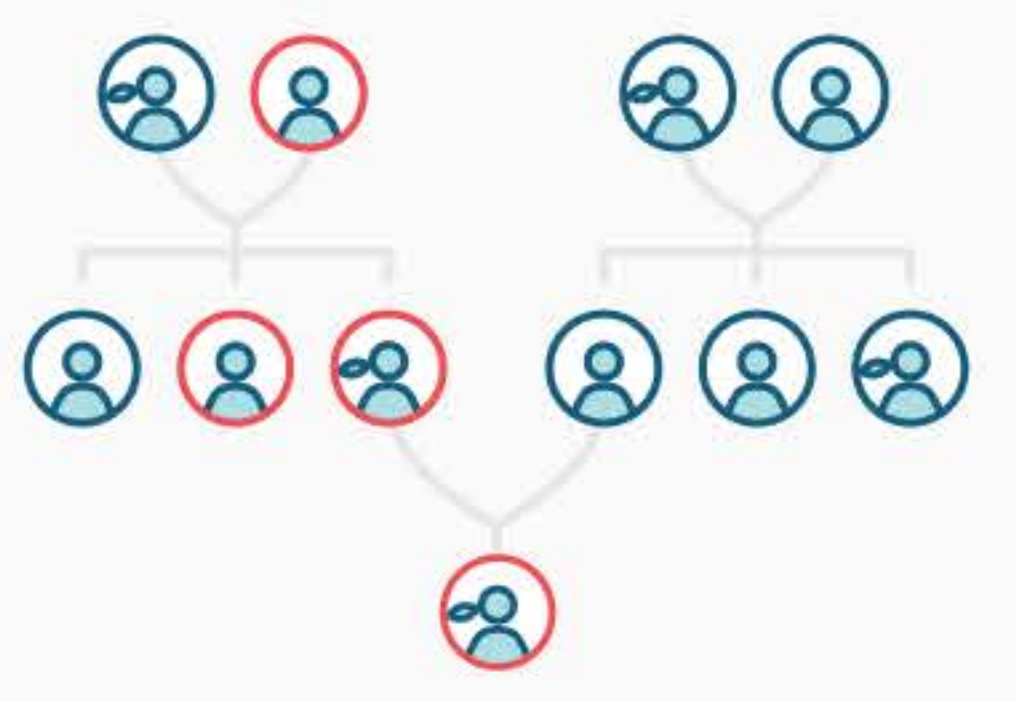
Provider's first name | Provider's last name

Practice or hospital name

City | State

Fax Results to Provider

We will email you when the results have been sent.



Your relatives may also have this BRCA1 mutation.

Consider sharing your results with relatives because:

- This mutation was most likely inherited from either your mother or your father. This would mean that one of your parents has the same mutation, and that your relatives on that side of the family may also have the same mutation. Fathers are just as likely to pass on a mutation as mothers.
- Each of your siblings has a 50% chance of having inherited this mutation. Brothers are just as likely to inherit it as sisters.
- Each of your children has a 50% chance of inheriting the same mutation. Men are just as likely as women to pass the mutation on to their children, and daughters and sons are equally likely to inherit it. Please keep in mind that children are not recommended to be tested for this mutation as it does not impact health or affect medical management in childhood.
- If genetic testing indicates that a relative does not have the mutation (tests negative), that relative's children are not at risk to inherit this mutation. These mutations do not skip generations.

Email Relatives   View a sample letter

SPEAK WITH A SPECIALIST

Speak with a MAGENTA genetic counselor.

MAGENTA's genetic counselors are board-certified healthcare professionals who can help you understand your results and answer your questions. You can schedule a genetic counseling session by clicking the button below. Learn how genetic counseling works.

Schedule Counseling Appointment

CONNECT WITH OTHERS

FORCE

Committed to providing resources and support to individuals at high-risk of getting breast and ovarian cancer due to their family history and genetic status.

Visit www.facingourrisk.org

Bright Pink

Focused on the prevention and early detection of breast and ovarian cancer in young women, while providing support for high-risk individuals.

Visit www.brightpink.org

Susan G. Komen

Dedicated to reducing deaths from breast cancer by funding breast cancer research, ensuring access to care through community programs worldwide and supporting public health policies that help people facing breast cancer.

Visit www.komen.org

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Appendix K

Arm D: Participant receives email from MAGENTA with URL & code

color

Welcome to Color. Before you get started…

As part of the MAGENTA study, please watch a video with important information about the benefits and limitations of genetic testing, as well as the results you might receive.

Read the content shown in this video.

☐ I have watched the video to the right.

Get Started

color

Sign In

Create a Color account to get started

This account will be used for activating your kit and returning your results.

First name | Last name

Email address

Create a password | Confirm password

I agree to the Color Terms of Service and Privacy Policy.

Create Account

Color Genomics

CLIA #05D2081492 - CAP #8975161

Mission Team Careers Privacy Press Contact

color

JENNY WALKER

You are receiving complimentary testing, courtesy of the MAGENTA study.

Ship to

Step 1 of 5

Color is currently only available in the US. We are not yet able to ship kits to New York.

Delivery address

Your kit will be delivered via USPS priority mail in 5-8 days.

Jenny Walker

Street address, P.O. box, company name, c/o

Apartment, suite, unit, building, floor, etc.

ZIP code

Phone number

Continue

color

JENNY WALKER

You are receiving complimentary testing, courtesy of the MAGENTA study.

Share results

Step 2 of 5

All participants of the MAGENTA Study are required to have a physician that their results will be shared with when they are complete.

Personal physician

Provider's first name

Provider's last name

Practice or hospital name

City

State

Study code

XTARSM

Continue

You are receiving complimentary testing, courtesy of the MAGENTA study.

Provide your health history

Step 3 of 5

Your responses are confidential and will be used to generate your overall breast and ovarian cancer risk. Please answer to the best of your knowledge, and estimate when you need to.

General information

What is your ancestry? (check all that apply)

- [ ] African
- [ ] Asian ...
- [ ] Caucasian
- [ ] Hispanic
- [ ] Native American
- [ ] Unknown
- [ ] Other

Are you of Ashkenazi Jewish descent?

- ○ Yes ○ No ○ I'm not sure

Why are you having genetic testing done?

- [ ] Learn if my family history of cancer is hereditary
- [ ] Learn if my personal history of cancer is hereditary
- [ ] Learn if I carry a mutation known to run in my family
- [ ] I'm curious to know more about my genetics

Personal history

How old were you when you had your first period?

Estimates are okay

Have you ever given birth to a child?

- ○ Yes ○ No

Have you had cancer before?

- ○ Yes ○ No

Have you had a mastectomy?

- ○ Yes ○ No

Have you had an oophorectomy?

- ○ Yes ○ No

Have you had a breast biopsy?

- ○ Yes ○ No

Have you had a genetic test for hereditary cancer risk?

- ○ Yes ○ No

Have you ever had a bone marrow transplant or blood transfusion?

- ○ Yes ○ No

Family tree

Age estimates are okay.

Are you adopted or do you have no health information about one, or both sides of your biological family members?

- ○ Yes ○ No

Do you have any siblings?

- ○ Yes ○ No ○ I'm not sure

Does your mother have any siblings?

- ○ Yes ○ No ○ I'm not sure

Does your father have any siblings?

- ○ Yes ○ No ○ I'm not sure

How old are your parents and grandparents? Estimates are okay.

Mother's age: Years Now

Fathers's age: Years Now

Maternal grandmother's age: Years Now

Maternal grandfather's age: Years Now

Paternal grandmother's age: Years Now

Paternal grandfather's age: Years Now

Continue

Finish providing history later

You are receiving complimentary testing, courtesy of the MAGENTA study.

Provide your family's health history

Step 4 of 5

Your responses are confidential and will be used to generate your overall breast and ovarian cancer risk. Please answer to the best of your knowledge, and estimate when you need to.

Children

Have any of your children had cancer?

- [ ] Daughter (age 6)
- [ ] Son (age 4)

Parents and siblings

Have any of your parents had cancer?

- [ ] Mother (age 70)
- [ ] Father (age 70)

Mother's side

Has anyone on your mother's side had cancer?

- [ ] Maternal grandmother (age 95, dec.)
- [ ] Maternal grandfather (age 75, dec.)

Father's side

Has anyone on your father's side had cancer?

- [ ] Paternal grandmother (age 75, dec.)
- [ ] Paternal grandfather (age 75, dec.)

Entire family

Has anyone had a genetic test for hereditary cancer risk?

○ No ○ Yes ○ I'm not sure

Is there anything else related to your personal or family history that you would like to share?

○ No ○ Yes ○ I'm not sure

Done

Finish providing history later

You are receiving complimentary testing, courtesy of the MAGENTA study.

Review

Step 5 of 5

Make sure the information below is correct.

Ship to

Jenny Walker
345 Spear St.
San Francisco, CA 94105
415-555-1212

EDIT

Share results with

Dr. Peggy Newcomer
One Medical
San Francisco, CA

EDIT

Personal health history

Provided

EDIT

Family health history

Provided

EDIT

Order Kit

Last step: Schedule a genetic counseling session.

After your genetic counseling session with the MAGENTA Study has been completed, we will ship your Color saliva collection kit.

Your purchase number is **1234323423**.

Schedule Appointment

color RESULTS LEARN GIFT SUPPORT JENNY WALKER

Last step: Schedule a genetic
cou

After yo
MAGEN
ship you

Your pu

Sc

Schedule a genetic counseling appointment

Choose Appointment | Your Info | Confirmation

< **April 2016** >

S	M	T	W	Th	F	S
					1	2
3	**4**	**5**	**6**	**7**	**8**	9
10	**11**	**12**	**13**	**14**	**15**	16
17	**18**	**19**	**20**	**21**	**22**	23
24	**25**	**26**	**27**	**28**	29	30

color

Purchase #: 123454354345

Schedule a genetic counseling session.

After your genetic counseling session with the MAGENTA Study has been completed, we will ship your Color saliva collection kit.

Schedule Appointment

The MAGENTA Study

Color is partnering with the MAGENTA Study to provide genetic testing to enrollees. More content explaining study.

If you have questions, please contact your Study Coordinator at <email address> or <phone>.

Color Genomics, Inc.
1801 Murchison Dr.. Ste. 128, Burlingame, CA 94010
support@getcolor.com

color

Please confirm this is your email address.

Hi Jenny,

Welcome to Color! To ensure that only you have access to your personal information, you must confirm your email address. You won't be able to access your account until you complete this step.

Thank you,
The Color Team
support@getcolor.com

Confirm Email Address

Color Genomics, Inc.
1801 Murchison Dr.. Ste. 128, Burlingame, CA 94010
support@getcolor.com

MAGENTA lets Color
know to ship kit

color

Jenny Walker Female, DOB: 05/25/77

BACK TO ORDERS

Results

Log

Order Details

Health History

Log

Ship Kit

FEB 17, 2016

Order placed
Your order for Jenny Walker has been succesfully placed.

FEB 17, 2016

Patient requested kit
Your participant has used their research code XTARSM to request their Color kit.

Pre-test counseling
Pre-test counseling is needed for Jenny Walker.

Sample received at Color lab
Results take 6-8 weeks on average once the sample has been received at the lab.

Results released to provider
Results will be sent to you and Dr. Liz Swisher.

Results released to patient
Results will be sent to Jenny Walker.

Post-test counseling
Post-test counseling will be needed for Jenny Walker.

Viewed by patient
Status will be updated when patient first views their results.

CONTACT US

8am-5pm PT
(844) 362-6567
providers@getcolor.com

color

Purchase #: 123454354345

Your Color kit is on the way.

Your kit was shipped on Nov. 19th using USPS (tracking #234232524324342). It should arrive in 5-8 days.

Track Package

Info may not be available for 24 hours.

Shipped to

Jenny Walker
345 Spear St.
San Francisco, CA 94105
(415) 555-1212

Common questions

- What do I do if my kit was sent to the wrong address?
- When will my kit arrive?
- Can I give my Color kit to someone else?

More questions? Browse Support or Contact us.

Color Genomics, Inc.
1801 Murchison Dr.. Ste. 128, Burlingame, CA 94010
support@getcolor.com

Participant receives kit
and goes online to
activate it

color

color

Sign in to activate your kit

Email address

Password

Forgot your password?

Sign In

I need to create a Color account.

Color Genomics

CLIA #05D2081492 - CAP #8975161

Mission Team Careers Privacy Press Contact

Welcome to kit activation. Before you get started...

Watch a video with important information about the benefits and limitations of genetic testing, as well as the results you might receive.

IN SUMMARY

Results will not tell you whether or not you will get cancer; they indicate your hereditary chance of developing cancer in the future. Test results should be discussed with a Color genetic counselor as well as your healthcare provider.

Most people receive a negative result.

This means no mutations known to be associated with an increased risk for breast or ovarian cancer were found in the genes we analyzed.

A small percentage of people receive a positive result.

This means a mutation that increases risk for breast or ovarian cancer (or both) was identified.

This information can be used to potentially improve your health.

It is important you share your results with your healthcare provider to develop a personalized screening and prevention plan. This is important because detecting cancer at its earliest stage improves the likelihood of a favorable outcome.

It's normal to find variants of uncertain significance.

It is common to see changes in genes that require further research to determine if they are associated with an increased risk for developing cancer. To date, most have been found to be harmless.

Increased risk for other cancers may be found.

Mutations that impact breast and ovarian cancer risk may also increase the risk of developing other cancers.

Share your results with your relatives.

Your results may be useful to your relatives who may also wish to discuss genetic testing with their own providers.

☐ I understood the important information above.

Get Started

REFERENCES

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2. Easton DF, Deffenbaugh AM, Pruss D et al. A systematic genetic assessment of 1,433 sequence variants of unknown clinical significance in the BRCA1 and BRCA2 breast cancer-predisposition genes. *Am J Hum Genet*. November 2007; 81(5):873-83.

3. Akbari MR, Zhang S, Fan I, et al. Clinical impact of unclassified variants of the BRCA1 and BRCA2 genes. *J Med Genet*. October 2011; 48(11): 783-6.

color

JENNY WALKER

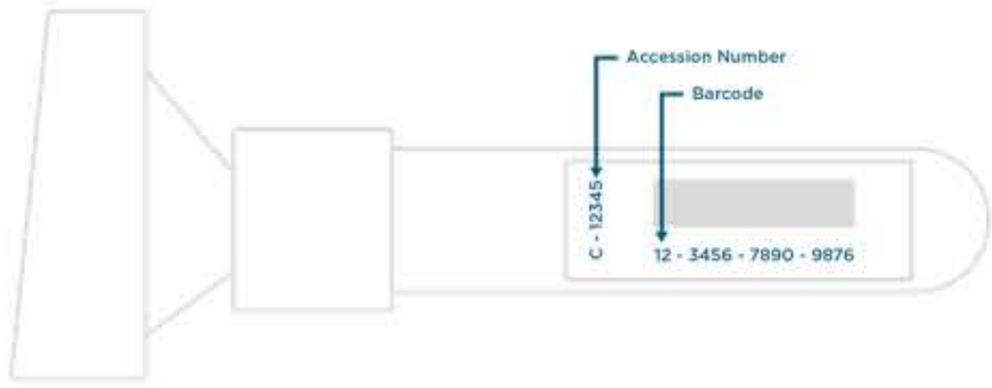
ACTIVATE > PERSONAL HISTORY > FAMILY HISTORY > COMPLETE

Activate your kit

The information below is required to ensure the quality of your results.

Information from your saliva tube

Having trouble? Get help.



Enter your tube's accession number

Enter your tube's barcode

About you

Your birthday and sex are required by the lab for sequencing.

Date of birth: MM / DD / YYYY

Sex

Phone number

Options

- [x] I consent to the use of my samples and data in third party research.
- [x] I consent to storing my samples and DNA with Color for future use or testing.

Consent

- [ ] I have read and agree to the Color Informed Consent. I specifically acknowledge and consent to the following:
  - I am the individual providing the sample and I am at least 18 years of age.
  - This test is not intended to diagnose whether I have or will get a certain disease in the future. It is intended to tell me about my hereditary risk related to certain diseases or other genetic conditions.
  - I should not make any medical decisions based on these results without speaking to my healthcare provider and discussing how these results may contribute to a personalized screening and prevention plan.
  - This test may not perform as intended or provide accurate results if I have not provided accurate personal information, or if I have certain rare biological conditions (e.g., mosaicism) or have had certain bone marrow transplants, transfusions, or hematologic malignancies (e.g., blood related diseases such as leukemia or lymphoma).
  - Genetic counseling services are available to me through Color at no additional charge.
  - The genes that Color analyzes are selected based on their known relationship with the diseases or genetic traits reported, but they may also indicate an increased risk for other health conditions for which Color may provide results that are not yet comprehensive for these other health conditions.
  - My anonymized sample, genetic information, and results may be used for internal quality control, laboratory validation studies, and research and development.
  - Color will contribute de-identified information about my genetic variants to public databases like NCBI's ClinVar, where de-identified genetic information is accessible to researchers to better understand the connection between genetics and disease.
  - My sample and all my related personal information will be transferred to Color's laboratory in the United States for analysis, use, processing, and storage and will be subject to the laws and regulations of the United States.
  - I agree to the Color Terms of Service and Privacy Policy.

Continue

Provide your health history

Your responses are confidential and will be used to generate your overall breast and ovarian cancer risk. Please answer to the best of your knowledge, and estimate when you need to.

General information

What is your ancestry? (check all that apply)

- [ ] African
- [ ] Asian ...
- [ ] Caucasian
- [ ] Hispanic
- [ ] Native American
- [ ] Unknown
- [ ] Other

Are you of Ashkenazi Jewish descent?

○ Yes ○ No ○ I'm not sure

Why are you having genetic testing done?

- [ ] Learn if my family history of cancer is hereditary
- [ ] Learn if my personal history of cancer is hereditary
- [ ] Learn if I carry a mutation known to run in my family
- [ ] I'm curious to know more about my genetics

Personal history

How old were you when you had your first period?

Estimates are okay

Have you ever given birth to a child?

○ Yes ○ No

Have you had cancer before?

○ Yes ○ No

Have you had a mastectomy?

○ Yes ○ No

Have you had an oophorectomy?

○ Yes ○ No

Have you had a breast biopsy?

○ Yes ○ No

Have you had a genetic test for hereditary cancer risk?

○ Yes ○ No

Have you ever had a bone marrow transplant or blood transfusion?

○ Yes ○ No

Family tree

Age estimates are okay.

Are you adopted or do you have no health information about one, or both sides of your biological family members?

○ Yes ○ No

Do you have any siblings?

○ Yes ○ No ○ I'm not sure

Does your mother have any siblings?

○ Yes ○ No ○ I'm not sure

Does your father have any siblings?

○ Yes ○ No ○ I'm not sure

How old are your parents and grandparents? Estimates are okay.

Mother's age: Years Now

Fathers's age: Years Now

Maternal grandmother's age: Years Now

Maternal grandfather's age: Years Now

Paternal grandmother's age: Years Now

Paternal grandfather's age: Years Now

Continue

Finish providing history later

Provide your family's health history

Your responses are confidential and will be used to generate your overall breast and ovarian cancer risk. Please answer to the best of your knowledge, and estimate when you need to.

Children

Have any of your children had cancer?

- [ ] Daughter (age 6)
- [ ] Son (age 4)

Parents and siblings

Have any of your parents had cancer?

- [ ] Mother (age 70)
- [ ] Father (age 70)

Mother's side

Has anyone on your mother's side had cancer?

- [ ] Maternal grandmother (age 95, dec.)
- [ ] Maternal grandfather (age 75, dec.)

Father's side

Has anyone on your father's side had cancer?

- [ ] Paternal grandmother (age 75, dec.)
- [ ] Paternal grandfather (age 75, dec.)

Entire family

Has anyone had a genetic test for hereditary cancer risk?

- ○ No ○ Yes ○ I'm not sure

Is there anything else related to your personal or family history that you would like to share?

- ○ No ○ Yes ○ I'm not sure

Done

Finish providing history later

Your Color kit is activated.

After you've provided a saliva sample, put the tube in the bag, seal it in the provided box, and drop it in any USPS mailbox.

Dr. Liz Swisher has already ordered this test for you, so analysis will begin as soon as we receive your kit.

▶ Learn how to provide a saliva sample.

color

Barcode: 123 45345353 354345

Your Color kit is activated. Now just return it.

Place your tube into the provided plastic bag, seal the bag, then place it back into the cardboard box it came in.

Postage has already been paid, so you can just drop it in any USPS mail box.

What happens next?

- We'll email you when we receive your sample. First, it is inspected to ensure that you have activated it and provided enough saliva for sequencing.
- Next, DNA from the saliva sample is extracted and sequenced, with several quality control checks at each point.
- After sequencing is complete, we review any variants found in 19 genes thought to have an especially strong impact on breast and ovarian cancer risk. The health history you provided is combined with your genetic test results in this step to create a personalized cancer risk assessment.
- All results are then reviewed by a physician before being released to you.
- A consultation with a genetic counselor is available to discuss your results if you have any questions.

Watch a quick video to prepare for your results.

Common questions

- How do I provide a sample?
- How is my health history used?
- How can I track the status of my sample?

More questions? Browse Support or Contact us.

Color Genomics, Inc.
1801 Murchison Dr.. Ste. 128, Burlingame, CA 94010
support@getcolor.com

Color receives sample
back at the lab

color

color

Barcode: 123 45345353 354345

We are beginning testing on your saliva sample.

After we verify that your sample meets our quality standards, we'll extract and sequence your DNA.

What happens next?

- First, we do a quality check on the sample you submitted.
- Next, DNA from the saliva sample is extracted and sequenced, with several quality control checks at each point.
- After sequencing is complete, we review any variants found in 19 genes thought to have an especially strong impact on breast and ovarian cancer risk. The health history you provided is combined with your genetic test results in this step to create a personalized cancer risk assessment.
- All results are then reviewed by a physician before being released to you.
- A consultation with a genetic counselor is available to discuss your results if you have any questions.

Watch a quick video to prepare for your results.

Common questions

- When will my results be ready?
- How should I prepare for my results?

More questions? Browse Support or Contact us.

Color Genomics, Inc.
1801 Murchison Dr.. Ste. 128, Burlingame, CA 94010
support@getcolor.com

Participant experience upon negative results release (standard)

color

color

Jenny, your Color results are ready.

Hello Jenny,

We've completed our analysis of your sample and health history, and your results are ready. If you'd like to review your results with a genetic counselor, schedule an appointment from within your results.

View Results

At your request, we've also sent a copy of your results to your healthcare provider Dr. Peggy Necomer at One Medical in San Francisco, CA.

Thank you,
Nadine Rayes, MS, LCGC
Board-certified Genetic Counselor

Color Genomics, Inc.
1801 Murchison Dr.. Ste. 128, Burlingame, CA 94010
support@getcolor.com

Your results are ready.

If you'd like to review them with a board-certified MAGENTA genetic counselor, you can schedule an appointment from within your results.

View Your Results

Your results are ready. Before you get started...

Watch a quick video covering important information about the benefits and limitations of genetic testing, as well as the results you might receive.

REMEMBER

We ask everyone, **regardless of their results**, to remember the important information below:

Some people without mutations still get cancer.

Environmental and lifestyle factors and family history without a known genetic link account for the majority of breast and ovarian cancers.

Some people with mutations never get cancer.

Mutations increase risk, but they do not mean that you have cancer or that you will definitely develop cancer in your lifetime.

This information can be used to potentially improve your health.

It is important you share your results with your healthcare provider to develop a personalized screening and prevention plan. MAGENTA's genetic counselors are here to answer any of your questions.

☐ I have read and understand this information. I am in a private, comfortable place and wish to view my results.

View Results

No mutations were identified.

This means no pathogenic or likely pathogenic genetic variants associated with an increased risk of breast or ovarian cancer were identified in any of the 19 genes tested.

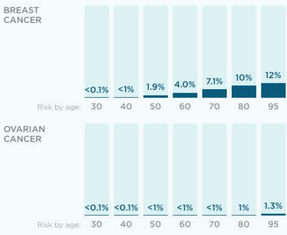
While this can be reassuring, it does not eliminate your risk of developing breast or ovarian cancers. Environmental and lifestyle factors, along with family history without a known genetic link, account for the majority of these cancers. Your healthcare provider can help determine how your screening plan might be influenced by your history and other factors.

Genes that were tested:
ATM, BARD1, BRCA1, BRCA2, BRIP1, CDH1, CHEK2, EPCAM, MLH1, MSH2, MSH6, NBN, PALB2, PMS2, PTEN, RAD51C, RAD51D, STK11, TP53

Learn more about your results and how to act on them below.

Average risk by age among US women

Your actual risk may be different based on other genetic and non-genetic factors.



Average risk among US women[1]

NEXT STEPS DETAILS HISTORY FAMILY QUESTIONS Schedule Appointment

KNOW YOUR SCREENING GUIDELINES

Below is a summary of screening guidelines established by experts at the National Comprehensive Cancer Network (NCCN). These guidelines are for women who have the same breast and ovarian cancer risk as the average US woman. Your healthcare provider may use these guidelines to help create a customized screening plan for you.

Breast cancer[2,3]

- **Starting at age 25:** Breast awareness - Women should be familiar with their breasts and promptly report changes to their healthcare provider. Performing regular breast self exams may help increase breast self awareness, especially when checked at the end of the menstrual cycle.
- **Between ages 25-39**: Clinical breast exam every 1-3 years.
- **Starting at age 40**: Clinical breast exam and mammogram every year.

Ovarian cancer[4]

- Currently, there are no standard screening guidelines for ovarian cancer. Please discuss any family history of ovarian cancer with your healthcare provider.

SHARE YOUR RESULTS

Share your results with your healthcare provider.

Color recommends you share your results with your healthcare provider. Sharing your results allows your provider to guide you to appropriate resources and discuss tailored options for cancer screening and prevention.

Provider's first name | Provider's last name

Practice or hospital name

City | State

Fax Results to Provider

We will email you when the results have been sent.

Your relatives may benefit from learning their genetic status.

Consider sharing your results with relatives who may also benefit from genetic testing. A few key points to remember:

- Your negative result significantly lowers the chance that you have an inherited mutation associated with breast or ovarian cancer.
- It is still possible for your relatives to have a mutation that you did not inherit. They may benefit from their own genetic testing, especially those who have had cancer.
- If any of your relatives has a mutation, there is a 50% chance that their siblings and children also have the same mutation.
- A father and mother are equally likely to pass on a mutation. Sons and daughters are equally likely to inherit a mutation if one of their parents has it.
- If you learn that a relative of yours has a mutation, contact a Color genetic counselor to learn how that information may impact your risk assessment and interpretation of results.

Email Relatives View a sample letter

SPEAK WITH A SPECIALIST

Speak with a MAGENTA genetic counselor.

MAGENTA's genetic counselors are board-certified healthcare professionals who can help you understand your results and answer your questions. You can schedule a genetic counseling session by clicking the button below. Learn how genetic counseling works.

Schedule Counseling Appointment

REFERENCES

1. Surveillance, Epidemiology, and End Results (SEER) Program, National Cancer Institute. 2010-2012. DevCan software (http://surveillance.cancer.gov/devcan) V 6.7.0, Accessed June 2015.

2. American Cancer Society Guidelines for the Early Detection of Cancer. American Cancer Society. http://www.cancer.org/healthy/findcancerearly/cancerscreeningguidelines/american-cancer-society-guidelines-for-the-early-detection-of-cancer. Updated October 2014. Accessed May 2015.

3. National Comprehensive Cancer Network. Breast Cancer Screening and Diagnosis. NCCN Guidelines Version 1.2014. Available at www.nccn.org. Published March 2014.

4. Ovarian, Fallopian Tube, and Primary Peritoneal Cancer Screening. National Cancer Institute. http://www.cancer.gov/cancertopics/pdq/screening/ovarian/Patient/page3. Updated March 2015. Accessed May 2015.

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6. Easton DF, Deffenbaugh AM, Pruss D et al. A systematic genetic assessment of 1,433 sequence variants of unknown clinical significance in the BRCA1 and BRCA2 breast cancer-predisposition genes. *The American Journal of Human Genetics*. November 2007; 81(5):873-83.

7. Akbari MR, Zhang S, Fan I, et al. Clinical impact of unclassified variants of the BRCA1 and BRCA2 genes. *Journal of Medical Genetics*. October 2011; 48(11):783-6.

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10. Kelsey, JL, Gammon MD, John EM. Reproductive factors and breast cancer. *Epidemiologic Reviews*. 1993; 15(1):36-47.

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Participant experience upon positive results release (standard)

color

color

Schedule an appointment to review your results.

Hello Jenny,

I'm Nadine Rayes, a genetic counselor with the MAGENTA study. We've completed analysis of your sample and health history, and your results are ready. Schedule a time to review your results with me, or another genetic counselor. MAGENTA's genetic counselors are board-certified healthcare professionals who can help you understand your results and answer your questions.

Schedule Counseling Appointment

At your request, a copy of your results will be sent to your healthcare provider Dr. Peggy Necomer at One Medical in San Francisco, CA after you've reviewed them.

Thank you,
Nadine Rayes, MS, LCGC
Board-certified Genetic Counselor

Color Genomics, Inc.
1801 Murchison Dr.. Ste. 128, Burlingame, CA 94010
support@getcolor.com

Your results are ready. Review them with a genetic counselor.

MAGENTA's genetic counselors are board-certified healthcare professionals who will help you understand your results and answer your questions. Learn how genetic counseling works.

Choose Appointment | Your Info | Confirmation

Set your time zone to continue:

(GMT-7:00) Pacific Time

Set time zone

(GMT-7:00) Pacific Time change

Your results are ready. Before you get started...

Watch a quick video covering important information about the benefits and limitations of genetic testing, as well as the results you might receive.

REMEMBER

We ask everyone, **regardless of their results**, to remember the important information below:

Some people without mutations still get cancer.

Environmental and lifestyle factors and family history without a known genetic link account for the majority of breast and ovarian cancers.

Some people with mutations never get cancer.

Mutations increase risk, but they do not mean that you have cancer or that you will definitely develop cancer in your lifetime.

This information can be used to potentially improve your health.

It is important you share your results with your healthcare provider to develop a personalized screening and prevention plan. MAGENTA's genetic counselors are here to answer any of your questions.

☐ I have read and understand this information. I am in a private, comfortable place and wish to view my results.

View Results

color RESULTS LEARN SUPPORT JENNY WALKER

A pathogenic mutation was identified in the BRCA1 gene.

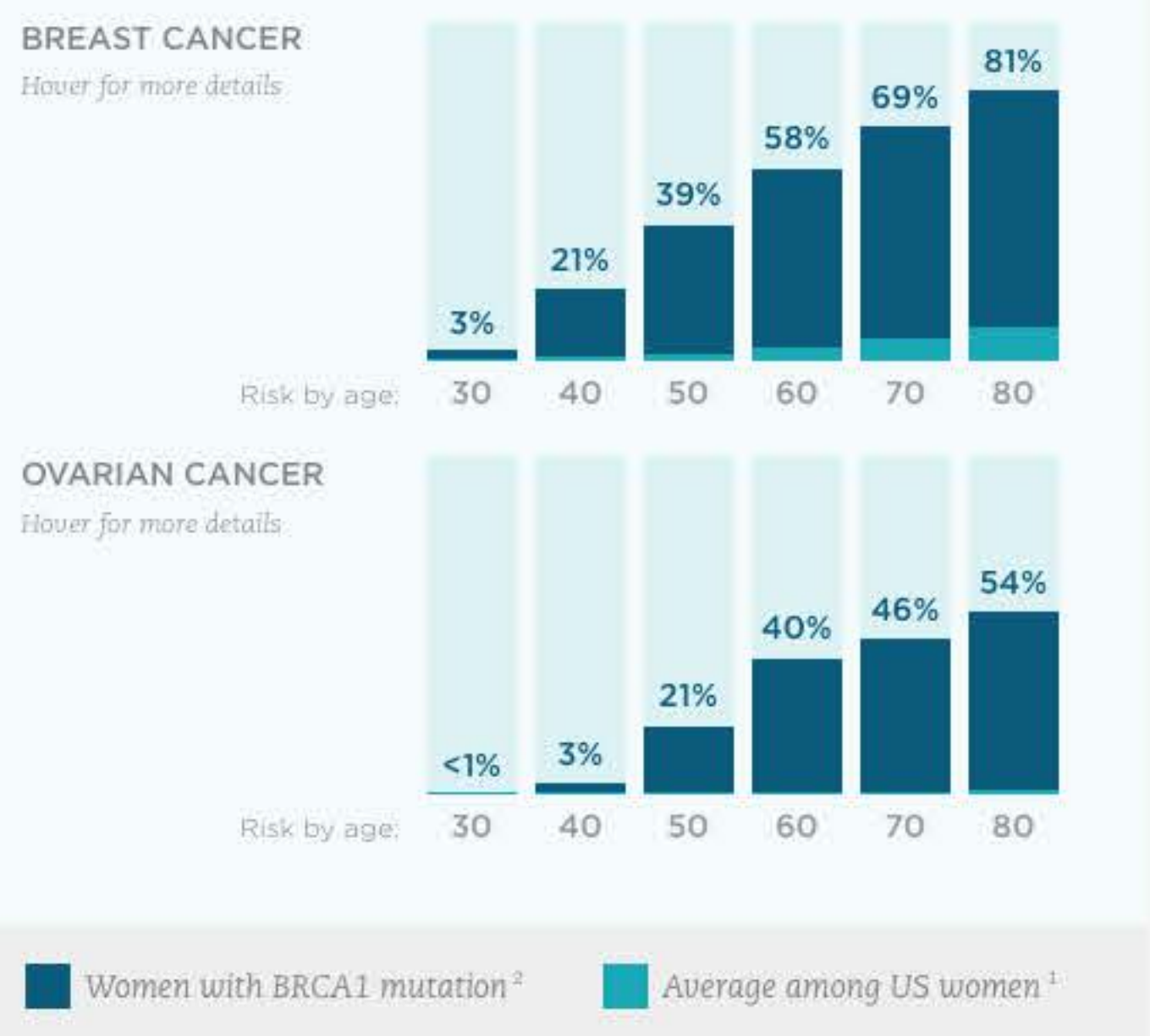
Testing positive for a pathogenic mutation in the BRCA1 gene means your chances of developing breast and ovarian cancer are greater than that of the average US woman. This result does **not** mean that you have a diagnosis of cancer or that you will definitely develop cancer in your lifetime. Learn more below.

Schedule an appointment with one of our board-certified genetic counselors at no additional cost to discuss your results.

Schedule Counseling Appointment

Risk by age with a BRCA1 mutation

Risk among US women with a *BRCA1* mutation to develop specific cancers by different ages in their lives.



Increased risk for other cancers.

In addition to increasing a woman's risk for breast and ovarian cancer, mutations in the BRCA1 gene are known to increase the risk of developing pancreatic cancer.

Please note that while having a BRCA1 gene mutation increases risk for pancreatic cancer, the Color test is not currently designed to detect mutations in other genes that may also increase risk for this cancer. Your actual risk may be different based on other genetic and non-genetic factors. We encourage you to discuss your results with one of our board-certified genetic counselors at no additional cost.

CANCER TYPE	WITH BRCA1 MUTATION [3]	AVG. US WOMAN [1]
Pancreatic	Elevated (3-5%)	<1%

The risk of developing cancer by age 80.

NEXT STEPS DETAILS HISTORY FAMILY QUESTIONS Schedule Counseling

KNOW YOUR SCREENING GUIDELINES

Below is a summary of screening guidelines established by experts at the National Comprehensive Cancer Network (NCCN).[4] They are specific to women who have a mutation in the BRCA1 gene. Your healthcare provider may use these guidelines to help create a customized screening plan for you.

Breast and ovarian cancer [5]

- **Starting at age 18**: Breast awareness - Women should be familiar with their breasts and promptly report changes to their healthcare provider. Performing regular breast self exams may help increase breast awareness, especially when checked at the end of the menstrual cycle.
- **Starting at age 25**: Breast exam by your provider every 6-12 months.
- **Between ages 25-29 or individualized based on family history**: Breast MRI screening (preferred) every year or mammogram if MRI is unavailable.
- **Between ages 30-75**: Mammogram and breast MRI screening every year. Your provider may wish to alternate between these two screenings every 6 months.
- **Between ages 35-40, or after you are finished having children**: NCCN recommends a risk-reducing salpingo-oophorectomy (the surgical removal of the ovaries and fallopian tubes) to lower the risk of developing breast and ovarian cancer. Ideally, this should involve a discussion with a gynecologic oncologist.
- **After age 75**: Your provider may discuss an individualized management plan with you.
- Your provider may discuss the option of having a risk-reducing bilateral mastectomy (the surgical removal of both breasts).
- Your provider may discuss the use of medications that might reduce the risk of developing breast or ovarian cancer.
- While there may be circumstances where ovarian cancer screening with transvaginal ultrasound and a blood test for a protein called CA-125 are helpful, these techniques have not been shown to be effective in detecting early ovarian cancer.

Pancreatic cancer [5]

- Currently, there are no pancreatic cancer screening guidelines from the NCCN specific to *BRCA1* mutation carriers. Please discuss your risk of pancreatic cancer with your healthcare provider.

SHARE YOUR RESULTS

Discuss your results with your healthcare provider.

It is important to schedule an appointment with your healthcare provider to discuss your results and plan next steps.

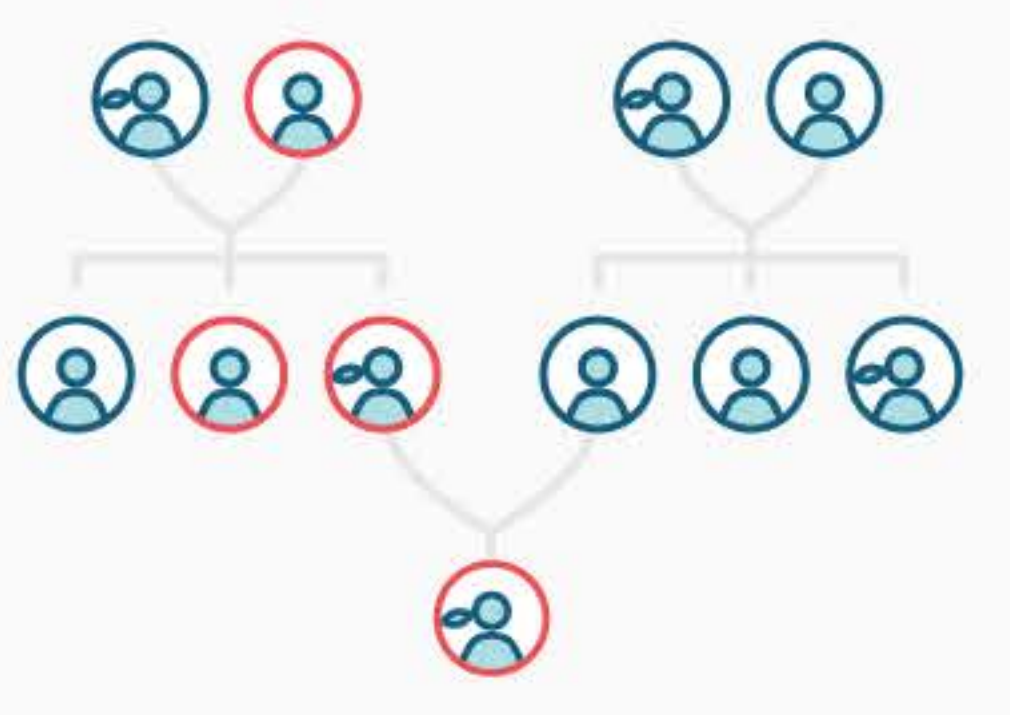
Provider's first name | Provider's last name

Practice or hospital name

City | State

Fax Results to Provider

We will email you when the results have been sent.



Your relatives may also have this BRCA1 mutation.

Consider sharing your results with relatives because:

- This mutation was most likely inherited from either your mother or your father. This would mean that one of your parents has the same mutation, and that your relatives on that side of the family may also have the same mutation. Fathers are just as likely to pass on a mutation as mothers.
- Each of your siblings has a 50% chance of having inherited this mutation. Brothers are just as likely to inherit it as sisters.
- Each of your children has a 50% chance of inheriting the same mutation. Men are just as likely as women to pass the mutation on to their children, and daughters and sons are equally likely to inherit it. Please keep in mind that children are not recommended to be tested for this mutation as it does not impact health or affect medical management in childhood.
- If genetic testing indicates that a relative does not have the mutation (tests negative), that relative's children are not at risk to inherit this mutation. These mutations do not skip generations.

Email Relatives View a sample letter

SPEAK WITH A SPECIALIST

Speak with a MAGENTA genetic counselor.

MAGENTA's genetic counselors are board-certified healthcare professionals who can help you understand your results and answer your questions. You can schedule a genetic counseling session by clicking the button below. Learn how genetic counseling works.

Schedule Counseling Appointment

CONNECT WITH OTHERS

FORCE

Committed to providing resources and support to individuals at high-risk of getting breast and ovarian cancer due to their family history and genetic status.

Visit www.facingourrisk.org ›

Bright Pink

Focused on the prevention and early detection of breast and ovarian cancer in young women, while providing support for high-risk individuals.

Visit www.brightpink.org ›

Susan G. Komen

Dedicated to reducing deaths from breast cancer by funding breast cancer research, ensuring access to care through community programs worldwide and supporting public health policies that help people facing breast cancer.

Visit www.komen.org ›

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Appendix L

Benefits & Limitations

Goal: Educate user on what they can and can't learn from genetic testing

Sample flow:

Welcome to Color. In this video, you'll learn useful information about genetic testing for breast and ovarian cancer, as well as the types of results it can provide.

Learning if you have an increased genetic risk for breast or ovarian cancer can make a difference

- **Breast and ovarian cancers are complex and have many causes**. Most cancers are sporadic and not due to one identifiable cause. But about 10-15% of breast and ovarian cancers are due to harmful genetic changes, called mutations, that are passed down through families[1][2][3][4]. Color's genetic risk analysis is designed to detect mutations in a comprehensive set of genes associated with breast and ovarian cancer.
- **Understanding if you have a genetic predisposition to cancer allows you and your healthcare provider to create a screening and prevention plan that is tailored to you.** This is important because detecting cancer at its earliest stage improves the likelihood of a favorable outcome.
- **Screening is useful for men as well.** Fathers have a 50% chance of passing a mutation onto each child, including daughters and sons. And while it is rare, men can develop male breast cancer and can be screened according to their risk.

Color believes it is important for you to understand what can and cannot be learned from genetic testing.

- **Genetic mutations can increase risks for certain cancers, but this does not mean cancer will definitely develop.** A positive result, or finding a mutation, is not a cancer diagnosis, and does not mean that you will ever develop cancer. For example, most women have a 12% chance in their lifetime of getting breast cancer and a 1-2% chance of getting ovarian cancer. A woman with a mutation in the BRCA1 gene can have up to an 81% chance of breast cancer and up to a 54% chance of ovarian cancer by age 80[5].

---

[1] Tung, N., et al. (2014). Frequency of mutations in individuals with breast cancer referred for BRCA1 and BRCA2 testing using next-generation sequencing with a 25-gene panel. *Cancer.* Sep 3. doi: 10.1002/cncr.29010.

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Appendix M

Participant:
Participant DOB:
Date of Consultation:
Genetic Counselor:

Dear Ms. ___,

Thank you for taking the time to speak with me by phone regarding the results of your genetic testing, performed by Color genomics as part of the MAGENTA research study. Our conversation and the information we discussed is summarized below.

Personal History

-

Family History

-

Genetic Testing Results

Topics Discussed

- **General genetics information**
  - Most of the time, cancers happen by chance and are considered sporadic. They are probably caused by some combination of genetics, environmental and lifestyle factors, and chance events. About 5-10% of cancer is believed to be caused by an inherited susceptibility.
  - We discussed that genes are pieces of DNA that provide instructions for making proteins. Proteins do much of the work inside our cells. They control how the cell works, grows, divides, and dies. Sometimes changes happen in genes that cause the protein they make not to work normally. This kind of gene change is called a mutation. Sometimes genetic testing is available and can look for mutations in these genes.
  - Some of our genes make proteins that help protect our bodies from cancer. If someone has a mutation in a gene that normally functions to protect against cancer, his or her risk for cancer may be higher than average.
  - Knowing if someone carries a mutation that increases their risk for cancer allows them to work with their healthcare providers to create a cancer prevention plan that may lower their risk of developing cancer or help to detect cancer earlier when it is most treatable.

- **NCCN Screening and risk-reduction options**

- **Sharing with providers**
  - We discussed sharing your testing results with your provider. Sharing your results allows your provider to guide you to appropriate resources and discuss tailored options for cancer screening and prevention.
    - You will work with your provider to determine the best screening and prevention plan for you.
    - In addition to your primary care provider, you indicated you would like to speak with a genetic counselor near you who specializes in hereditary

breast and ovarian cancer. Based on the city where you live, one option for genetic counseling is:

- ■

- **Sharing with family**
  - We discussed sharing your results with your relatives. With regards to family members, remember:

- **Genetic Counseling Notes**
  -

Resources

- We reviewed the following resources that you may find helpful:
  - FORCE:Committed to providing resources and support to individuals at high-risk of getting breast and ovarian cancer due to their family history and genetic status. Visit www.facingourrisk.org
  - Bright Pink: Focused on the prevention and early detection of breast and ovarian cancer in young women, while providing support for high-risk individuals. Visit www.brightpink.org

Next Steps

- You are going to schedule appointment with your primary provider, surgeon, and local genetic counselor to share results and discuss screening and risk reduction options.
- You are going to share your results with your family members.

Closing

It was a pleasure to speak with you and we hope this information was helpful. If you have any questions about your genetic counseling, we encourage you to contact us at 713-745-7877 or at magenta@mdanderson.org . We will speak again in one month to follow up on any additional questions that arise.

Sincerely,

_____

Genetic Counselor, MAGENTA Research Study

The level of increased cancer risk differs from gene to gene.

- **Even if your results show no mutations, you may still get cancer.** While inherited mutations explain some cases of cancer, the majority are sporadic and can't be explained by a single cause. Some non-genetic factors that can influence cancer risk include environment and lifestyle, as well as family history without a known genetic link.
- **No genetic test detects everything.** It is possible that some types of genetic changes, which increase the chance of cancer, will not be detected by genetic testing. This is why family history and lifestyle still play important roles in assessing your risk for cancer.

You should be prepared to receive positive or negative results.

- **Most people receive a negative result,** meaning no mutations associated with an increased risk for breast or ovarian cancer were found in the genes we analyzed. While this can be reassuring, particularly for those with no family history of cancer, it does not eliminate your risks. Environmental factors and family history without a known genetic link account for the majority of breast and ovarian cancers. It is therefore important to follow the screening and prevention plan recommended by your healthcare provider.
- **A small percentage of people receive a positive result,** meaning a mutation that increases risk for breast or ovarian cancer (or both) was identified. This result does not mean that you have cancer or that you will definitely develop cancer in your lifetime. But it is important that you share your results with your healthcare provider to create a personalized screening and prevention plan.
- **It's normal to have variants of uncertain significance.** We are all different at the genetic level. It is common to see changes in genes that require further research to determine if they are associated with an increased risk for developing cancer. Most are eventually found to be harmless[6][7], and when we have more information we will let you know. In this situation, you and your healthcare provider should rely on your personal and family history to formulate your screening and prevention plan.
- **Mutations that impact breast and ovarian cancer risk can also increase the risk of developing other cancers.** This means we may come across information about your genetic risk for other cancers, such as colon, uterine, and prostate cancers, among others, depending on the gene in which a mutation is found. If we believe your risk for these cancers are increased due to a mutation, we will let you know.
- **Your results could be useful to your relatives, regarding their own chances of developing cancer.** We encourage you to share your results, as testing may be useful for them as well. Keep in mind though that your results are unique to you. Even if you don’t have a mutation, your family members may.
- **A consultation with one of our board-certified genetic counselors is included at no extra charge if you have questions about your results.** You can also visit www.getcolor.com if you have questions about anything else.

---

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[7] Easton, DF., et al. (2007). A systematic genetic assessment of 1,433 sequence variants of unknown clinical significance in the BRCA1 and BRCA2 breast cancer-predisposition genes. *Am J Hum Genet.* 2007 Nov;81(5):873-83.

Appendix N

How to provide a sample
[Script]

Welcome to Color. In this video, you'll learn how to provide a saliva sample, activate your kit, and return it to Color.

- Each kit comes in a cardboard box, with instructions and a clear tray. Inside the clear tray is the saliva tube, more detailed instructions, a blue cap, and a plastic bag.
- **Hold onto the cardboard box, as you'll need it to return your sample to Color.**

Okay, let's get started by providing a sample.

- Wait 30 minutes if you have: eaten, drank, brushed your teeth, used mouthwash, smoked, or chewed gum. These activities can delay the return of your results as they might ruin your sample.
- Remove the tube from the clear tray.
- Don't remove the plastic film from the lid attached to the funnel. It contains stabilizing liquid that will mix with your saliva later when you close the lid.
- Spit into the funnel until the amount of saliva reaches the "fill to" line. This might take a few minutes. Thinking of candy or rubbing your cheeks can speed things up. Saliva bubbles don't count.
- Once you've reached the "fill to" line, hold the tube upright with one hand and close the funnel lid with the other hand by firmly pushing until you hear a loud click. Don't be surprised when the fluid from the lid is released into the tube. Make sure it is closed tightly.
- Next, take the small blue cap out of the clear tray. Holding the tube upright, unscrew the funnel to remove it completely. Then screw the small cap onto the tube tightly.
- Shake the tube for 5 seconds to mix the liquid from the funnel lid with your saliva. This will preserve your sample across a wide range of temperatures.

Now activate your kit online

- Visit www.getcolor.com/activate to link your sample to your Color account. It will only take a few minutes, but it is a very important step.
- You will need the barcode found on your saliva tube.
- It is absolutely necessary that you activate your kit, or we will not be able to analyze your sample.

You are one step away from complete! Now just send your sample back to Color.

- Place your tube into the provided plastic bag, seal the bag, then place it back in the cardboard box.
- **Just seal the box and drop it in any USPS mailbox. Your postage has already been paid.**
- Everything else can be thrown away, as long as you have activated your kit successfully.
- **You will receive an email when your sample has been received at the lab and another email when your results are ready.**

For more information, visit support.getcolor.com.

Thank you for using Color.

Appendix O

Impact of Events Scale (IES)

Please read each item, and then indicate how **frequently** those comments were true for you during the past 7 days with respect to your experience with cancer risk…

0 (not at all), 1 (rarely), 3 (sometimes), and 5 (often)

1. I thought about my cancer risk when I didn't mean to
2. I avoided letting myself get upset with I thought about it or was reminded of it
3. I tried to remove it from memory
4. I had trouble falling asleep or staying asleep because of pictures or thoughts about it that came into my mind
5. I had waves of strong feelings about it
6. I had dreams about it
7. I stayed away from reminders of it
8. I felt as if it hadn't happened or wasn't real
9. I tried not to talk about it
10. Pictures about it popped into my mind
11. Other things kept making me think about it
12. I was aware I still had a lot of feeling about it but I didn't deal with them
13. I tried not to think about it
14. Any reminder brought back feelings about it
15. My feelings about it were kind of numb

Confidential

Satisfaction With Decision (SWD)

Answer the following questions about your decision to have genetic testing. Please indicate to what extent each statement is true for you AT THIS TIME.

	strongly agree	disagree	neither agree nor disagree	agree	strongly agree
I am satisfied that I am adequately informed about the issues important to my decision.	○	○	○	○	○
The decision I made was the best decision possible for me personally.	○	○	○	○	○
I am satisfied that my decision was consistent with my personal values.	○	○	○	○	○
I expect to successfully carry out (or continue to carry out) the decision I made.	○	○	○	○	○
I am satisfied that this was my decision to make.	○	○	○	○	○
I am satisfied.	○	○	○	○	○

Appendix Q

The Multidimensional Impact of Cancer Risk Assessment (MICRA) Questionnaire

The questions below are about some specific responses you may have had after receiving your genetic test results. Please answer every question in Section 1, regardless of whether you were given a positive or negative test result. Please indicate whether you have experienced each statement never, rarely, sometimes, or often in the past week, by checking the corresponding box.

Section 1	Never 0	Rarely 1	Sometimes 3	Often 5
1. Feeling upset about my test result				
2. Feeling sad about my test result				
3. Feeling anxious or nervous about my test result				
4. Feeling guilty about my test result				
5. Feeling relieved about my test result				
6. Feeling happy about my test result				
7. Feeling a loss of control				
8. Having problems enjoying life because of my test result				
9. Worrying about my risk of getting cancer [or getting cancer again if you have ever been diagnosed with cancer]				
10. Being uncertain about what my test result means about my cancer risk				
11. Being uncertain about what my test result means for my child(ren) and/or family's cancer risk				
12. Having difficulty making decisions about cancer screening or prevention (e.g., having preventive surgery or getting medical tests done)				
13. Understanding clearly my choices for cancer prevention or early detection				
14. Feeling frustrated that there are no definite cancer prevention guidelines for me				
15. Thinking about my test results has affected my work or family life.				
16. Feeling concerned about how my test results will affect my insurance status				
17. Having difficulty talking about my test results with family members				
18. Feeling that my family has been supportive during the genetic counseling and testing process				
19. Feeling satisfied with family communication about my genetic test result				
20. Worrying that the genetic counseling and testing				

process has brought about conflict within my family				
21. Feeling regret about getting my test results				

Section 2. If you have children, regardless of your test result, please answer Questions 22 and 23. Otherwise, please go to Section 3

Section 2.	Never 0	Rarely 1	Sometimes 3	Often 5
22. Worrying about the possibility of my children getting cancer				
23. Feeling guilty about possibly passing on the disease risk to my child(ren)				

Section 3. If you currently have cancer, or have had it in the past, please answer Questions 24 and 25. Otherwise, please check this box ☐ You are finished with this questionnaire.

Section 3.	Never 0	Rarely 1	Sometimes 3	Often 5
24. Feeling that the genetic test result has made it harder to cope with my cancer				
25. Feeling that the genetic test result has made it easier to cope with my cancer				

Appendix R

Generalized Anxiety Disorder 7-item (GAD-7) scale

Over the last 2 weeks, how often have you been bothered by the following problems?	Not at all sure	Several days	Over half the days	Nearly every day
1. Feeling nervous, anxious, or on edge	0	1	2	3
2. Not being able to stop or control worrying	0	1	2	3
3. Worrying too much about different things	0	1	2	3
4. Trouble relaxing	0	1	2	3
5. Being so restless that it's hard to sit still	0	1	2	3
6. Becoming easily annoyed or irritable	0	1	2	3
7. Feeling afraid as if something awful might happen	0	1	2	3
Add the score for each column	+	+	+	
Total Score *(add your column scores)* =				

If you checked off any problems, how difficult have these made it for you to do your work, take care of things at home, or get along with other people?

Not difficult at all _____
Somewhat difficult _____
Very difficult _____
Extremely difficult _____

Source: Spitzer RL, Kroenke K, Williams JBW, Lowe B. A brief measure for assessing generalized anxiety disorder. *Arch Inern Med.* 2006;166:1092-1097.

Appendix S

Over the last 2 weeks, how often have you been bothered by any of the following problems?

	Notat all	Severaldays	More thanhalf the days	Nearlyevery day
Little interest or pleasure in doing things	○	○	○	○
Feeling down, depressed, or hopeless	○	○	○	○
Trouble falling or staying asleep, or sleeping too much	○	○	○	○
Feeling tired or having little energy	○	○	○	○
Poor appetite or overeating	○	○	○	○
Feeling bad about yourself - or that you are a failure or have let yourself or your family down	○	○	○	○
Trouble concentrating on things, such as reading the newspaper or watching television	○	○	○	○
Moving or speaking so slowly that other people could have noticed. Or the opposite - being so fidgety or restless that you have been moving around a lot more than usual	○	○	○	○

Appendix T

Confidential

Decision Regret Scale (DRS)

Think about the decision you made about having genetic testing. Please show how you feel about these statements by selecting the appropriate choice below.

	Strongly Agree	Agree	Neither Agree Nor Disagree	Disagree	Strongly Disagree
It was the right decision	○	○	○	○	○
I regret the choice that was made	○	○	○	○	○
I would go for the same choice if I had to do it over again	○	○	○	○	○
The choice did me a lot of harm	○	○	○	○	○
The decision was a wise one	○	○	○	○	○

Appendix U

Self-Administered

OMB ###-####

Administrative use only:

Local Identifier

Study ID: _____ **Navigator:** _____

Date: _____

THE VETERANS RAND 12-ITEM HEALTH SURVEY (VR-12)

The following questions ask for your views about your health—how you feel and how well you are able to do your usual activities. All kinds of people across the country are being asked these same questions. Their answers and yours will help to improve health care for everyone. There are no right or wrong answers; please choose the answer that best fits your life right now.

Answer each question by marking an 'X' next to the best response. For example:

What is your gender?

- ☐ Male
- ☒ Female

Q1. In general, would you say your health is:

- ❑ Excellent
- ❑ Very good
- ❑ Good
- ❑ Fair
- ❑ Poor

Q2. The following questions are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so, how much?

a. **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling or playing golf?

- ❑ Yes, limited a lot
- ❑ Yes, limited a little
- ❑ No, not limited at all

b. Climbing **several** flights of stairs?

- ❑ Yes, limited a lot
- ❑ Yes, limited a little
- ❑ No, not limited at all

Q3. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**?

a. Accomplished **less** than you would like.

- ❑ No, none of the time
- ❑ Yes, a little of the time
- ❑ Yes, some of the time
- ❑ Yes, most of the time
- ❑ Yes, all of the time

b. Were limited in the **kind** of work or other activities.

- ❑ No, none of the time
- ❑ Yes, a little of the time
- ❑ Yes, some of the time
- ❑ Yes, most of the time
- ❑ Yes, all of the time

Q4. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

a. **Accomplished less** than you would like.

- ❑ No, none of the time
- ❑ Yes, a little of the time
- ❑ Yes, some of the time
- ❑ Yes, most of the time
- ❑ Yes, all of the time

b. Didn't do work or other activities as **carefully** as usual.

- ❑ No, none of the time
- ❑ Yes, a little of the time
- ❑ Yes, some of the time
- ❑ Yes, most of the time
- ❑ Yes, all of the time

↳Continue to next page

Q5. During the past 4 weeks, how much did **pain** interfere with your normal work (including both work outside the home and housework)?

- ❑ Not at all
- ❑ A little bit
- ❑ Moderately
- ❑ Quite a bit
- ❑ Extremely

These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling.

Q6a. How much of the time during the past 4 weeks:

Have you felt calm and peaceful?

- ❑ All of the time
- ❑ Most of the time
- ❑ A good bit of the time
- ❑ Some of the time
- ❑ A little of the time
- ❑ None of the time

Q6b. How much of the time during the past 4 weeks:

Did you have a lot of energy?

- ❑ All of the time
- ❑ Most of the time
- ❑ A good bit of the time
- ❑ Some of the time
- ❑ A little of the time
- ❑ None of the time

Q6c. How much of the time during the past 4 weeks:

Have you felt downhearted and blue?

- ❑ All of the time
- ❑ Most of the time
- ❑ A good bit of the time
- ❑ Some of the time
- ❑ A little of the time
- ❑ None of the time

↳Continue to next page

Q7. During the past 4 weeks, how much of the time has your **physical health or emotional problems** interfered with your social activities (like visiting with friends, relatives, etc.)?

- ❑ All of the time
- ❑ Most of the time
- ❑ Some of the time
- ❑ A little of the time
- ❑ None of the time

Now, we'd like to ask you some questions about how your health may have changed.

Q8. Compared to one year ago, how would you rate your **physical health** in general now?

- ❑ Much better
- ❑ Slightly better
- ❑ About the same
- ❑ Slightly worse
- ❑ Much worse

Q9. Compared to one year ago, how would you rate your **emotional problems** (such as feeling anxious, depressed or irritable) **now?**

- ❑ Much better
- ❑ Slightly better
- ❑ About the same
- ❑ Slightly worse
- ❑ Much worse

Your answers are important!

Thank you for completing this questionnaire!

Appendix V

BRFSS Surveillance * MODIFIED

1. Have you ever had breast cancer before?

a. Yes

b. No

2. Have you had a bilateral mastectomy?

If no: proceed to next question (#3)

If yes: Was it for prevention, therapy, or both? (After this question, skip the next 4 questions, go to #7)

3. A mammogram is an x-ray of each breast to look for breast cancer. Have you ever had a mammogram?

a. Yes
b. No → If no, skip next question and proceed to #5
c. Don't know / Not sure

4. How long has it been since you had your last mammogram?

a. Within the past year (anytime less than 12 months ago)
b. Within the past 2 years (1 year but less than 2 years ago)
c. Within the past 3 years (2 years but less than 3 years ago)
d. Within the past 5 years (3 years but less than 5 years ago)
e. 5 or more years ago
f. Don't know/Not sure

5. A breast MRI (Magnetic Resonance Imaging) uses magnets and radio waves to produce detailed cross-sectional images of the inside of the breast. Have you ever had a breast MRI?

a. Yes
b. No → If no, skip next question and proceed to #7
c. Don't know / Not sure

6. How long has it been since you had your last breast MRI?

a. Within the past year (anytime less than 12 months ago)
b. Within the past 2 years (1 year but less than 2 years ago)
c. Within the past 3 years (2 years but less than 3 years ago)
d. Within the past 5 years (3 years but less than 5 years ago)
e. 5 or more years ago
f. Don't know/Not sure
g. I have never had a breast MRI before

7. A pelvic ultrasound uses sound waves to make a picture of the organs and structures in the lower belly (pelvis), such as the ovaries, fallopian tubes, uterus, cervix and vagina. How long has it been since your last pelvic ultrasound?

a. Within the past year (anytime less than 12 months ago)
b. Within the past 2 years (1 year but less than 2 years ago)
c. Within the past 3 years (2 years but less than 3 years ago)
d. Within the past 5 years (3 years but less than 5 years ago)
e. 5 or more years ago
f. Never had a pelvic ultrasound before
g. Don't know/Not sure

8. How long has it been since your last CA 125 blood test?

a. Within the past year (anytime less than 12 months ago)
b. Within the past 2 years (1 year but less than 2 years ago)
c. Within the past 3 years (2 years but less than 3 years ago)
d. Within the past 5 years (3 years but less than 5 years ago)
e. 5 or more years ago
f. Never had a CA 125 blood test before
g. Don't know/Not sure

9. Have you ever had any of the following gynecological surgeries before? Please choose all that apply:

☐ Tubal ligation (tubes tied)
☐ Hysterectomy (removal of uterus)
☐ Bilateral salpingo- oophorectomy (removal of both fallopian tubes and both ovaries)
☐ Unilateral salpingo- oophorectomy (removal of only 1 ovary and 1 fallopian tube)
☐ Salpingectomy (removal of fallopian tubes, preservation of ovaries)
☐ N/A (never had any of the above surgeries before)

10. Have you ever received any diagnoses for any of the following health conditions?

☐ Ovarian cancer

☐ Breast Cancer

☐ Other cancer _____

11. Are you currently using any hormonal birth control, including oral contraceptive pills or a vaginal ring (such as NuvaRing)?

☐ Yes

☐ No

Appendix W

General Knowledge about Hereditary Breast and Ovarian Cancer (HBOC)

	True	False	Don't Know
1. Breast cancer is always caused by hereditary factors.			
2. Ovarian cancer is always caused by hereditary factors.			
3. All women who carry a gene mutation associated with breast/ovarian cancer will develop breast/ovarian cancer at some point, during their lifetime.			
4. A woman who does not carry a gene mutation associated with breast/ovarian cancer, still can develop these diseases.			
5. There is more than one gene mutation that causes breast/ovarian cancer.			
6. A woman who carries a gene mutation associated with breast/ovarian cancer, can pass this gene mutation on to her children.			
7. If more than two individuals of the same family have breast/ovarian cancer then it always concerns a hereditary disease.			
8. A woman can inherit a gene mutation associated with breast/ovarian cancer from her father.			
9. Women diagnosed at an early stage, have a better chance of being cured.			

Claes E, Evers-Kiebooms G, Boogaerts A, Decruyenaere M, Denayer L, Legius E: **Communication with close and distant relatives in the context of genetic testing for hereditary breast and ovarian cancer in cancer patients.** *Am J Med Genet A* 2003, **116:**11–19.

Appendix X

MAGENTA (DEMOGRAPHICS)

1. All participants of the MAGENTA study are required to have a healthcare provider (such as a physician, physician assistant, nurse practitioner) that their genetic test results can be shared with. Please provide their information below:

    a. Personal Healthcare Provider

    - Provider's first name _____
    - Provider's last name _____
    - Doctor's Office or Hospital name _____
    - City _____
    - State _____
    - Phone Number _____

2. Please provide your phone number for the study team to contact you about important study information

    _____

3. Ethnic Background

    ☐ White, Not Hispanic or Latina

    ☐ Black, Not Hispanic or Latina

    ☐ American Indian (Native American, Aleutian, Eskimo)

    ☐ Asian

    ☐ Native Hawaiian or Pacific Islander

    ☐ Hispanic or Latina

    ☐ Other

    (Select all that apply)

4. What is the highest grade or year of school you completed?

    o Never attended school or only attended kindergarten

    o Grades 1 through 8 (Elementary)

    o Grades 9 through 11 (Some high school)

    o Grade 12 or GED (High school graduate)

    o College 1 year to 3 years (Some college or technical school)

- College 4 years or more (College graduate)
- Post college (Graduate school or professional school)

5. Which category best represents your total household income last calendar year, from all sources, before taxes?
   - Less than $10,000
   - $10,000 to $14,999
   - $15,000 to $19,999
   - $20,000 to $24,999
   - $25,000 to $34,999
   - $35,000 to $49,999
   - $50,000 to $74,999
   - $75,000 or more
   - I prefer not to answer.
6. How many people, including yourself, did this income support?

   _____
7. What is your employment status?
   - Employed by someone else
   - Self-employed
   - Out of work for 1 year or more
   - Out of work for less than 1 year
   - A homemaker
   - A student
   - Retired
   - Unable to work
8. What is your marital status?
   - Married
   - Divorced
   - Widowed
   - Separated

- Never married

9. Do you have any kind of health care coverage, including health insurance, prepaid plans such as HMOs, government plans such as Medicare, or Indian Health Service?
   - Yes
   - No
   - Don't Know/Not Sure
10. What is the primary source of your health care coverage (either for yourself or through someone else)?
   - ☐ A plan purchased through an employer or union
   - ☐ A plan purchased individually in the marketplace (<u>not</u> through an employer or union)
   - ☐ Medicare
   - ☐ Medicaid or other state program
   - ☐ TRICARE (formerly CHAMPUS), VA, or Military
   - ☐ Alaska Native, Indian Health Service, Tribal Health Services
   - ☐ Some other source _____

Appendix Z

MAGENTA EligibilityQuestionnaire

MAGENTA EligibilityQuestionnaire

Questionnaire Statement

The overall goal of this research study is to test the effects of online genetic education alone versus online genetic education with telephone genetic counseling in order to compare the two methods and the stress a person feels about their risk of cancer.

You are being asked to complete this questionnaire to determine your eligibility for this study.

If eligible, you will be asked to:

- Provide your name,email address, and date of birth
- Create a username and password to log into the study system to sign the study's consent form, review study information and answer study questionnaires.

Authorization Statement

I have read the description of the MAGENTA (Making Genetic Testing Accessible) study, and I have decided to provide information that will help determine if I am eligible to participate in the research project described here. I understand that my answers will not guarantee my participation in this study, and that I may refuse to answer any (or all) of the questions at this or any other time. I understand that there is a possibility that I might be contacted in the future about this, but that I am free to refuse any further participation if I wish.

The Stand Up to Cancer research team at The University of Texas MD Anderson Cancer Center (MD Anderson) will collect and use my responses in this eligibility questionnaire in their research. My responses may be shared with study monitors who check the accuracy of the information, and individuals who put all the study information together in report form. I will not be identified in the publication of the results. By answering the questions, I am providing authorization for the research team to use and share my information. If I do not want to authorize the use and disclosure of my information, I may choose not to answer these questions. There is no expiration date for the use of this information as stated in this authorization.

I may withdraw my authorization at any time, in writing, for any reason as long as that information can be connected to me. For information on the Notice of Privacy Practices, please call 713-792-2933.

- ○ I agree to fill out the eligibility questionnaire.
- ○ I do not agree to fill out the eligibility questionnaire.

(The below is displayed if potential participants DO NOT AGREE to complete the eligibility questionnaire)

Thank you for your consideration of the MAGENTA Study.

(The below is displayed if participants AGREE to complete the Eligibility Questionnaire)

How did you hear about this study?

- ☐ from my healthcare provider (e.g., physician, nurse practitioner, or physician's assistant)
- ☐ from a friend
- ☐ from a family member
- ☐ from a patient advocacy organization
- ☐ in a magazine
- ☐ on television
- ☐ on the radio
- ☐ on the internet
- ☐ social media
- ☐ other

(Please select all that apply.)

(The questions below will populate IF any of the above appropriate boxes are selected)

Which advocacy organization?

- NOCC
- MOCA
- OCRFA
- FORCE
- Bright Pink
- TEAL
- Sisterhood of Ovarian Cancer Survivors
- Other _____

What magazine? _____

What television program? _____

What radio program? _____

What website? _____

What social media source?

☐ Facebook ☐ Twitter
☐ Other
(Select all that apply.)

What other social media source? _____
(If "Other", please specify.)

What advocacy organization?

What is your state of residence?

Alabama
Alaska
Arizona
Arkansas
California
Colorado
Connecticut
Delaware
Florida
Georgia
Hawaii
Idaho
Illinois
Indiana
Iowa
Kansas
Kentucky
Louisiana
Maine
Maryland
Massachusetts
Michigan
Minnesota
Mississippi
Missouri
Montana
Nebraska
Nevada
New Hampshire
New Jersey
New Mexico
New York
North Carolina
North Dakota
Ohio
Oklahoma
Oregon
Penns ylvania
Rhode Island
South Carolina
South Dakota
Tennessee
Texas
Utah
Vermont
Virginia
Washington
West Virginia
Wisconsin
Wyoming

What is your zipcode?

_____

_____

(Please enter your 5 digit zip code.)

Are you able to read, speak, and understand English? Yes No

Do you have a valid United States mailing address for receipt of a saliva kit? Yes No

(On the previous 2 questions, the participant has to respond adequately for the items below to be displayed)

PERSONAL HISTORY

Are you a woman? ◯Yes ◯ No

(On the previous question, the participant has to select "Yes" for the item below to be displayed)

Have you ever had genetic testing or counseling regarding your cancer risk? Yes No

(On the previous question, the participant has to select "No" for the item below to be displayed)

Have you ever received a bone marrow transplant? Yes No

(On the previous question, the participant has to select "No" for the item below to be displayed)

Have you had a blood transfusion within the last seven (7) days? Yes No

(On the previous question, the participant has to select "No" for the item below to be displayed)

Do you have an active hematologic malignancy? Yes No
(cancer that begins in blood-forming tissue, such as leukemia or lymphoma)

(On the previous question, the participant has to select "No" for the item below to be displayed)

Are you 30 years of age or older? ◯ Yes ◯ No

(On the previous question, the participant has to select "Yes" for the item below to be displayed)

Do you have a healthcare provider that we can share your results with?

◯ Yes ◯ No

(Healthcare provider includes a physician, nurse practitioner, or physician's assistant.)

(On the previous question, the participant has to select "Yes" for the item below to be displayed)

◯ ◯

Do you have at least one ovary? ◯ Yes ◯ No

(On the previous question, the participant has to select "Yes" for the item below to be displayed)

Have you been diagnosed with ovarian cancer? Yes No

(On the previous question, the participant has to select "No" for the item below to be displayed)

Have you been diagnosed with breast cancer? ◯ Yes ◯ No

(If the participant selects Yes, the following 2 questions will be displayed)

How old were you when you were diagnosed with breast cancer? ◯ 45 or younger ◯ 46 - 60 ◯ I Don't Know

W ere you diagnosed with Triple Negative breast cancer? ◯ Yes ◯ No ◯ I Don't Know

(Triple-negative breast cancer is negative for estrogen receptors (ER-), progesterone receptors (PR-), and HER2 receptors (HER2-))

○ Yes ○ No ○ I Don't Know

Do you have a blood relative with a known mutation in any of the following genes? *BRCA1, BRCA2, BRIP1, PALB2, RAD51C, RAD51D, BARD1, MSH2, MSH6, MLH1,* and *PMS2*

(On the previous question, the participant has to select "No" for the item below to be displayed)

FAMILY HISTORY OF OVARI AN CANCER (Family member is one that is a blood relative)

Do you have a blood relative diagnosed with ovarian cancer?

○ Yes ○ No ○ I Don't Know

(On the previous question, the participant has to select "No" or "I don't know" for the item below to be displayed)

FAMILY HISTORY OF BREAST CANCER (Family member is one that is a blood relative)

Do you have a male blood relative diagnosed with breastcancer? ○ Yes ○ No ○ I Don't Know

(On the previous question, the participant has to select "No" or "I don't know" for the item below to be displayed)

Do you have at least two (2) blood relatives with breast cancer on your MOTHER'S SIDE OF THE FAMILY? ○ Yes ○ No ○ I Don't Know

(On the previous question, the participant has to select "Yes" for the item below to bedisplayed)

Was at least one of these relatives diagnosed with breast cancer AT THE AGE OF 50 OR YOUNGER? ○ Yes ○ No ○ I Don't Know

(On the previous question, the participant has to select "No" or "I don't know" for the item below to be displayed)

Do you have at least two blood relatives with breast cancer on your FATHER'S SIDE OF THE FAMILY? Yes No I Don't Know

(On the previous question, the participant has to select "Yes" for the item below to be displayed)

Was at least one of these relatives diagnosed AT THE AGE OF 50 OR YOUNGER? Yes No I Don't Know

(SUBMIT)

(The following is displayed if they ARE NOT ELIGIBLE for the study)

Based on your answers to the previous questions, you are not eligible to participate.

We are currently recruiting women who:

- **Are 30 years of age or older**
- **Are able to read and speak English**
- **Have a valid mailing address in the U.S.**
- **Have a personal or family history of breast cancer OR a family history of ovarian cancer (no personal history of ovarian cancer allowed)**
- **Have at least one ovary**
- **Have never had genetic testing or counseling for cancer risk in the past**
- **Have never had a bone marrow transplant or a blood transfusion within the last seven days**
- **Do not have an active hematologic malignancy**
- **Are willing to undergo genetic testing (at no cost) and share their results with their healthcare provider**

If you have concerns about your risk for hereditary cancer, please discuss these with your healthcare provider. For additional resources and information, visit FORCE (www.facingourrisk.org), a national non-profit organization devoted to hereditary breast and ovarian cancer.

(The following is displayed if they DO NOT HAVE A HEALTHCARE PROVIDER TO SHARE THEIR GENETIC RESULTS WITH)

You must have a healthcare provider that you are willing to share your results with in order to enroll in the study. If you get a healthcare provider (such as a physician, nurse practitioner, or physician assistant), you may return to this website to see if you are then eligible for this study.

MAGENTA
Making Genetic Testing Accessible

MAGENTA IS THE STUDY OF GENETIC TESTING FROM YOUR LIVING ROOM.

Thank you from team MAGENTA!

What MAGENTA is all about…

MAGENTA is testing this concept of "genetic testing from your living room". By providing genetic testing at no cost through an online genetic testing service, the MAGENTA study aims to improve availability of genetic testing for hereditary cancer syndromes to at-risk individuals. In a nutshell, MAGENTA aims to identify the best way to 1) make sure genetic testing is accessible to all women who have a family history and 2) identify the best way to deliver it.

"…you know, based on your family history, that you're at increased risk and by doing the genetic testing it helps to 'turn on the light'…It's powerful to know" -Dr. Karen Lu

As access improves, we hope to see outcomes follow, as more women learn about their risk of hereditary cancer. And with your participation, we are that much closer to seeing this goal realized!

Who's behind MAGENTA…

The MAGENTA study is a collaborative research effort, supported by the Stand Up To Cancer-Ovarian Cancer Research Fund Alliance-National Ovarian Cancer Coalition Dream Team. We're working alongside SU2C, OCRFA, NOCC, AACR, MOCA, and FORCE.

What's next?

By now, you have received genetic test results and completed your 3-mo follow up questionnaire. At the 12-mo mark, you will receive an email prompting you to complete some additional questionnaires. These help us learn more about your experience with MAGENTA.

Know someone who may be interested in learning more?

If you know someone who is interested in learning more about MAGENTA, please refer them to the MD Anderson MAGENTA homepage!

We want to hear from you!

As a participant in the MAGENTA study, we'd love to hear from you and learn more about your experience participating in the study. We're on the hunt for participants who are interested in sharing their story and get the word out about MAGENTA!

Have questions?

Email: magenta@mdanderson.org
Phone: (713) 745-7877
Availability: Mon - Fri, 8am - 5pm CST

magenta
making genetic testing accessible

MAGENTA
Making Genetic Testing Accessible

MAGENTA IS THE STUDY OF GENETIC TESTING FROM YOUR LIVING ROOM.

Thank you from team MAGENTA!

FAST FACTS ABOUT OVARIAN CANCER

1 in 75

women will get ovarian cancer in their lifetime

70%

Nearly 70% of women are diagnosed in advanced stages

5th leading cause of cancer-related deaths in women

19 genes

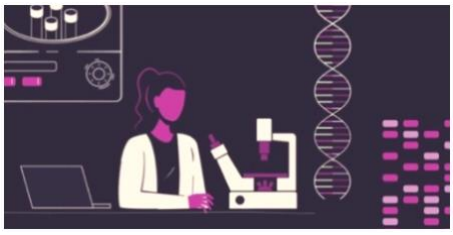
Genetic test results for 19 genes associated with inherited cancer may inform health decision making surrounding ovarian cancer prevention

Thanks for your support!

The MAGENTA study is a collaborative research effort, supported by the Stand Up To Cancer-Ovarian Cancer Research Fund Alliance-National Ovarian Cancer Coalition Dream Team. MAGENTA is testing this concept of "genetic testing from your living room," by providing genetic testing, at no cost through an online genetic testing service. In a nutshell, MAGENTA aims to identify the best way to 1) make sure genetic testing is accessible to all at-risk women, and 2) identify the best way to deliver it. With your participation, we are that much closer to seeing this goal realized!

What's next?

By now, you have received your genetic testing results and completed your 12-mo follow up questionnaires. You will receive another email at the 2-year mark, with information about the final series of questionnaires.



We want to hear from you!

As a participant in the MAGENTA study, we'd love to hear about your experience participating in the study. Please reach out if you would like to share your story or have any questions or concerns. And if you know someone who may be interested in participating, please refer them to the MD Anderson MAGENTA homepage to learn more!

Email: magenta@mdanderson.org
Phone: (713) 745-7877
Availability: Mon - Fri, 8am - 5pm CST

magenta
making genetic testing accessible

Appendix YYY

Attached are the materials that our colleague Stand Up To Cancer proposes to use to advertise the MAGENTA study. The SU2C staff, as well as other community organizations, will advertise in multiple social media outlets including Facebook and Twitter. Current research suggests that social media is an adaptable, cost-effective means of recruiting research participants (Gorman et al., 2014; Seltzer et al., 2014; Yuan et al., 2014). Researchers can capitalize on this environment, using imagery and content tailored to catch the attention of specific populations (Chiang et al., 2016; Rus & Cameron, 2016). Social media also allows researchers to leverage existing social networks through respondent driven sampling (Bhutta, 2012).
All social media messages will be posted from non-MD Anderson social media accounts. Each specific message was selected from among multiple qualitative and survey-based studies of women who were considering or undergoing genetic testing, using their own words and ideas. The photographs were provided via publically available images sources (e.g. Flickr or Facebook) or by community organizations from their multiple community events, and all have media releases for permission to use in marketing. The attached examples provide to Stand Up To Cancer (SU2C), our community partner, who will be coordinating the advertising campaign.

References

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Yuan, P., Bare, M. G., Johnson, M. O., & Saberi, P. (2014). Using online social media for recruitment of human immunodeficiency virus-positive participants: A cross-sectional survey. *Journal of Medical Internet Research*, *16*(5). https://doi.org/10.2196/jmir.3229

PART 1: ADVERTISING ON SOCIAL MEDIA

We will provide relevant organizations with the following tweet/Instagram/Facebook posts to use over their respective social media accounts. Each of these will be composed of an image, a, and message, and a hashtag. Participants will be directed to the MAGENTA website (https://magenta.mdanderson.org)

Component 1: Images



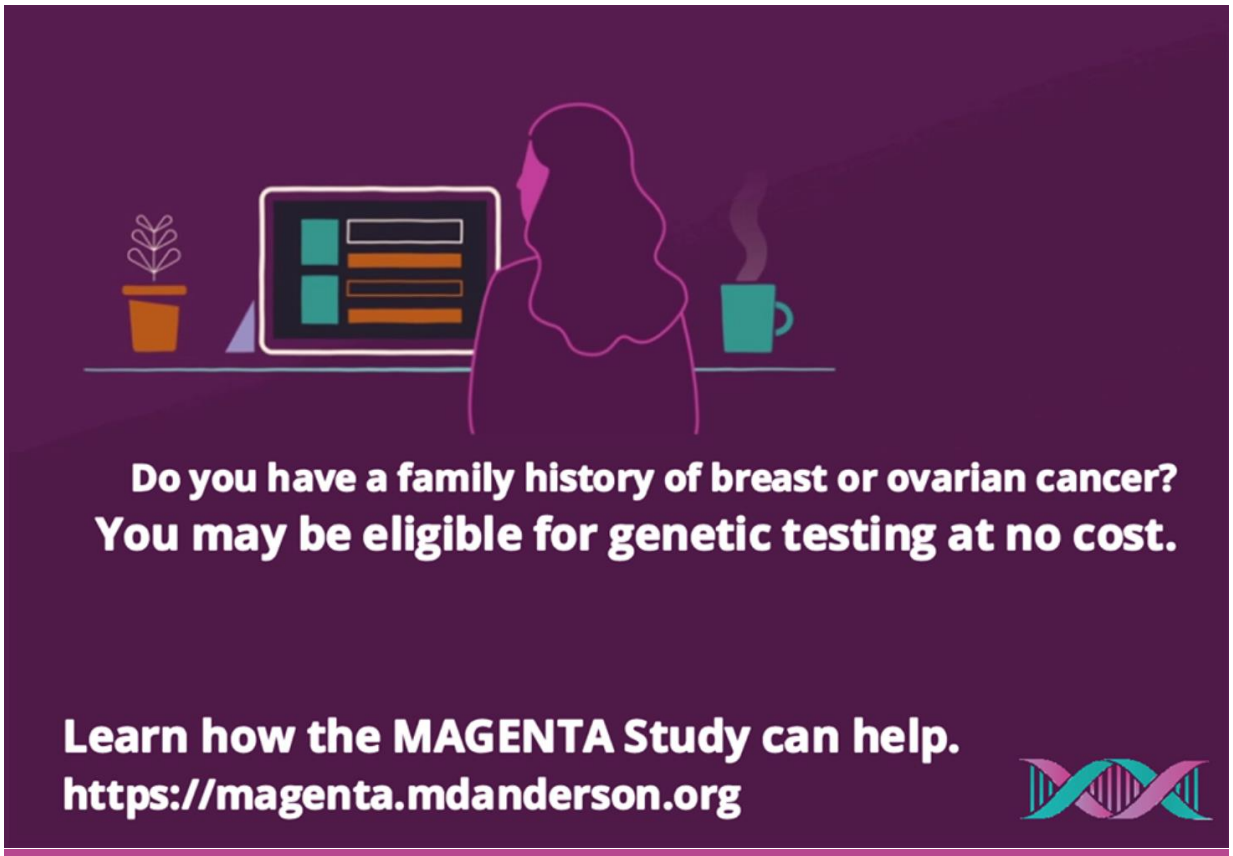









TEAM MAGENTA



I would rather have information and lead my life in a different way with that information.

You can learn your risk of ovarian cancer at no cost, with the MAGENTA Study

EVERY 23 MINUTES

a woman is diagnosed with ovarian cancer

Learn your risk with the MAGENTA Study

Only 15% of women with ovarian cancer are diagnosed in Stage 1

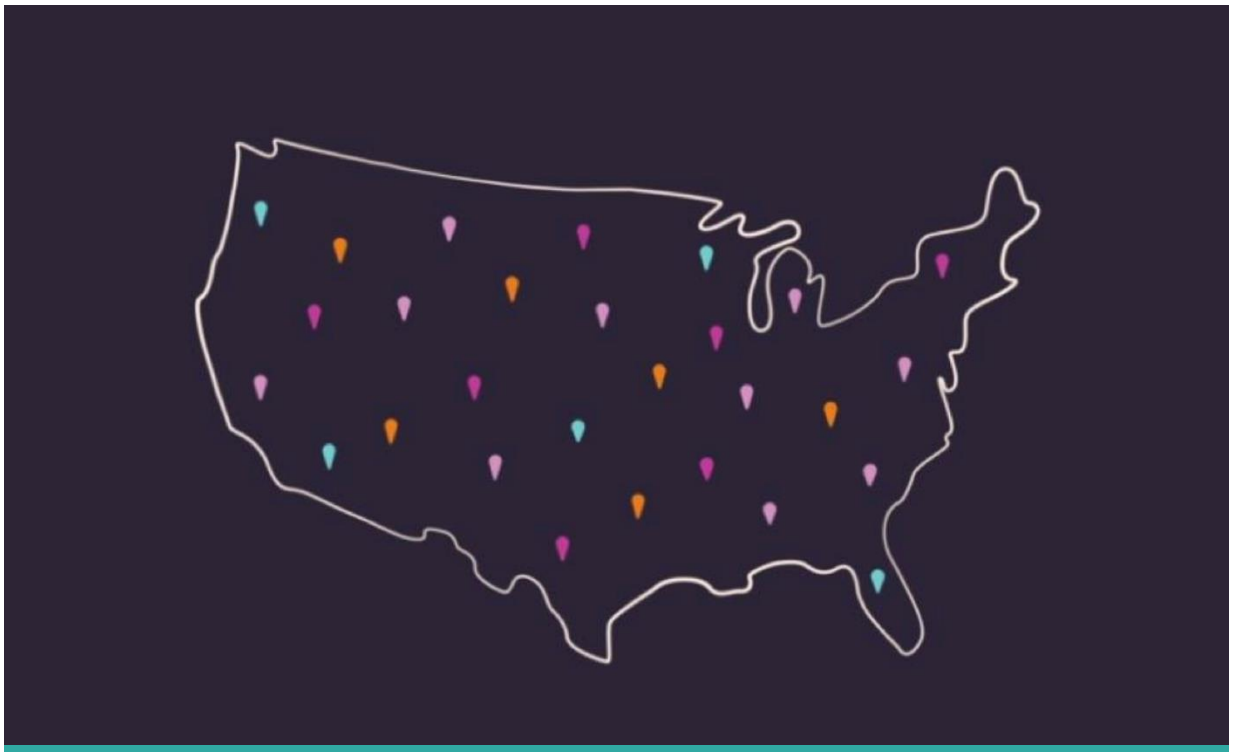
You can learn your risk of ovarian cancer with the MAGENTA Study

I want to do anything I can to help someone prevent ovarian cancer.

Learn your risk with the MAGENTA Study

Women with certain genetic mutations have a great risk of ovarian cancer

You can learn your risk of ovarian cancer with the MAGENTA Study



60% of women diagnosed with ovarian cancer are already Stage 3

Learn your risk with the MAGENTA Study

Every woman over the age of 30 should be given an opportunity to know their risk of ovarian cancer. The MAGENTA study provides that opportunity.

Learn your risk with the MAGENTA Study

Nearly 80% of cases of ovarian cancer are in late stages, when prognosis is poor.

Learn your risk with the MAGENTA Study

Pap smears do not detect ovarian cancer

Learn your risk of ovarian cancer, at no cost, with the MAGENTA Study

Worried about your risk of ovarian cancer?

You may be eligible for genetic testing, at no cost.

Learn more about the MAGENTA study

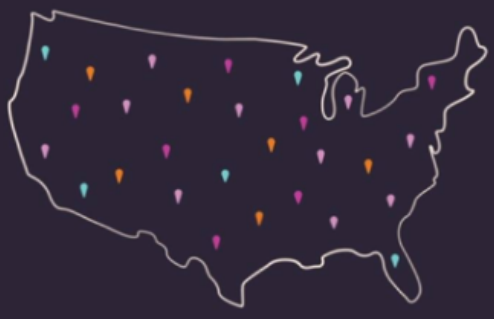
Our current screening for ovarian cancer is not good enough for women at normal risk. It is important to identify women at high inherited risk of ovarian cancer through genetic testing.

Learn more about the MAGENTA Study

1 in 75 women will get ovarian cancer
Genetic testing may reduce your risk

The MAGENTA study offers genetic testing for those who qualify, at no cost.

Our current screening for ovarian cancer is not good enough for women at normal risk. It is important to identify women at high inherited risk of ovarian cancer through genetic testing.



Learn more about the MAGENTA study.

Ovarian cancer is the

#1

deadliest gynecologic cancer

Learn your risk of ovarian cancer, at no cost, with the MAGENTA Study

Knowledge is power.
You can't fight what you don't know.
Genetic testing gives you choices.

Learn more about the MAGENTA Study

Ovarian cancer is the 5th cause of cancer-related death in women

Learn your risk with the MAGENTA Study

We women want to know. When we have the tools we need to empower us, we want to know.

Learn more about the MAGENTA Study

Women with a family history of breast and ovarian cancer are at an increased risk of developing ovarian cancer

You can learn your risk of ovarian cancer with the MAGENTA Study

MAGENTA is the study of genetic testing in your living room.

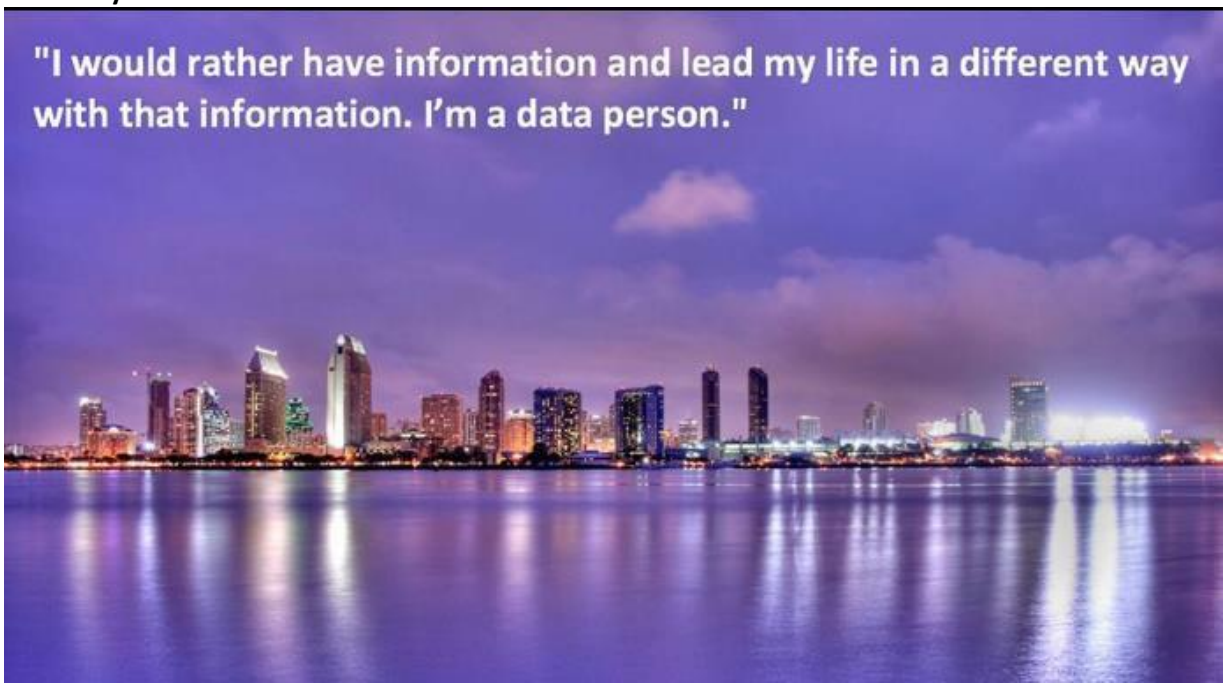
Learn more about the MAGENTA study

Women with a personal or family history of breast cancer have an increased risk for ovarian cancer

Learn your risk of ovarian cancer, at no cost, with the MAGENTA Study

Component 2: Participant Stories

Liz's Story

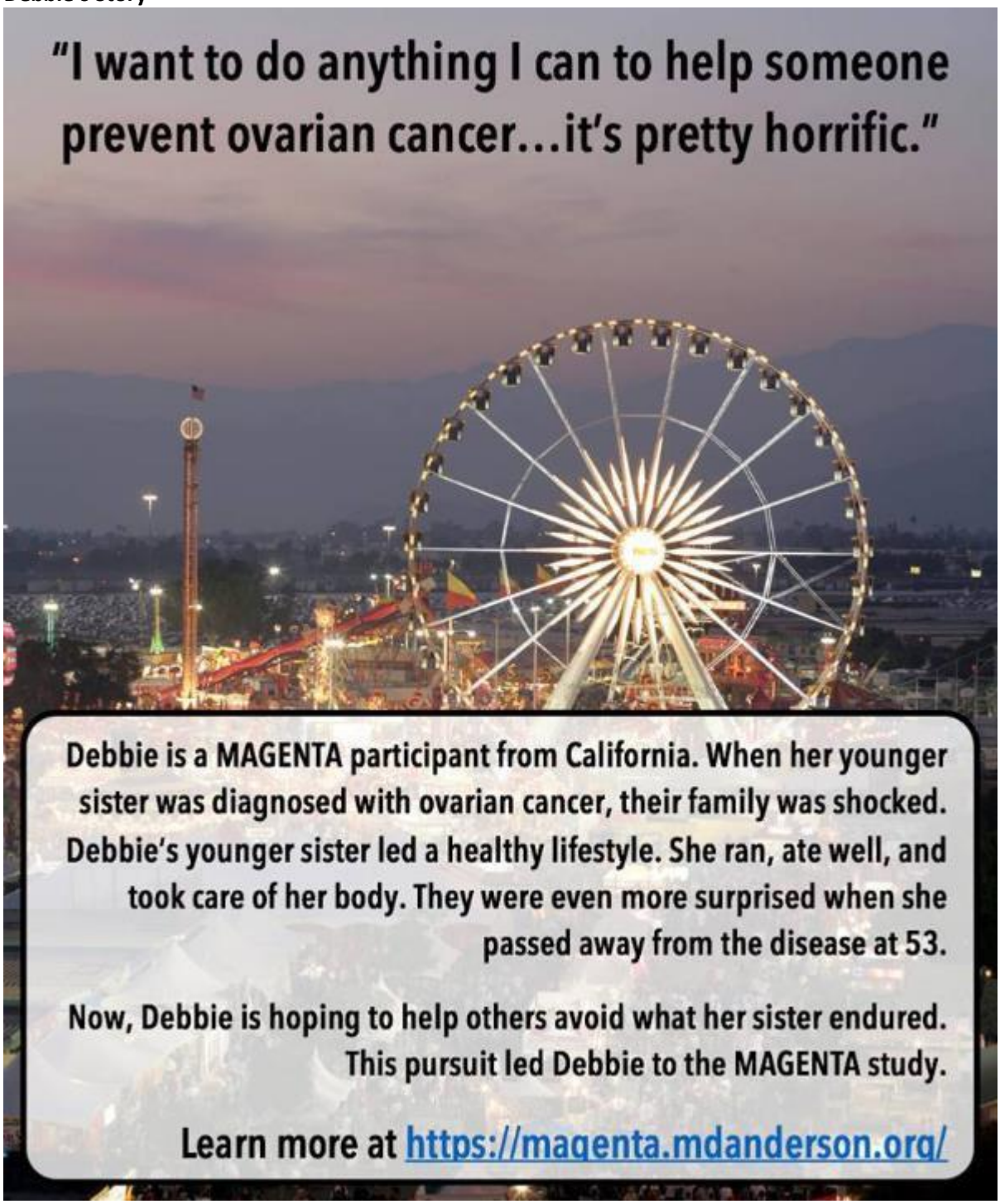


With an extensive family history of breast and ovarian cancer on her father's side and not a lot of information about her mother's family health history, Liz, a MAGENTA participant from California, was interested in learning more about her personal risk of ovarian cancer. To her, knowledge is power. She had already made up her mind that a positive result would bring about prophylactic, risk-reducing surgery. "If I could take those risks away, I would."

"I'm just happy we live in a time where we can get genetic testing if we want to. And hopefully, we can leverage that information, to make better decisions."

https://magenta.mdanderson.org/

Debbie's Story

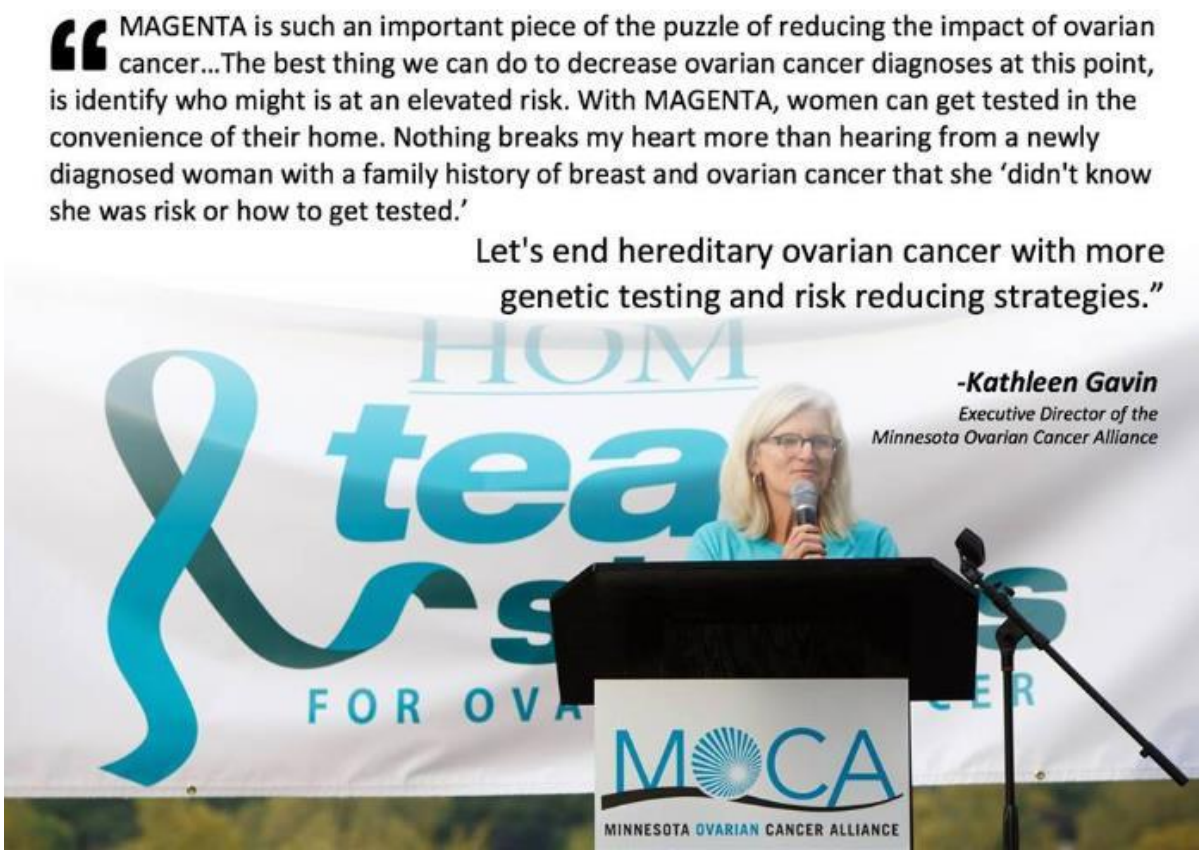


"I want to do anything I can to help someone prevent ovarian cancer." -Debbie, MAGENTA participant.

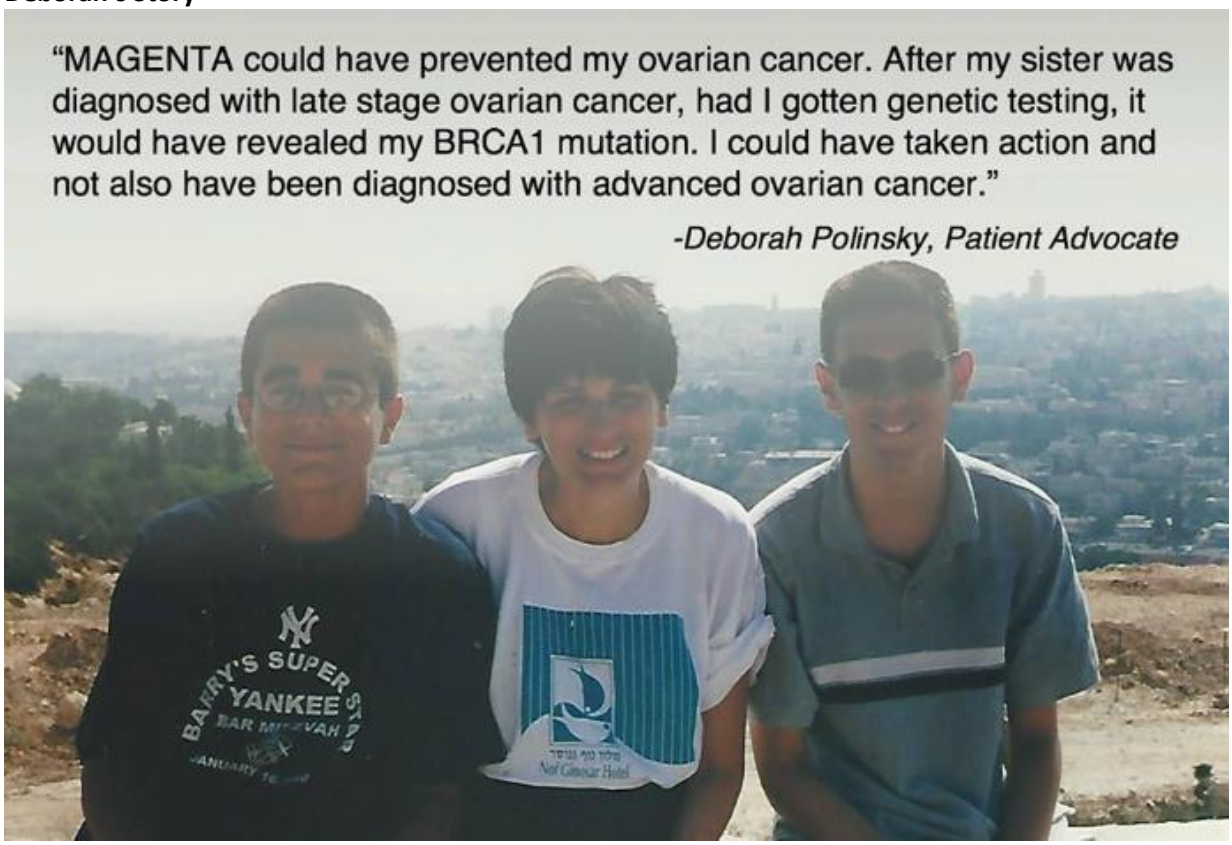
Learn more about the MAGENTA study at https://magenta.mdanderson.org/.

Jamie's Story

Kathleen's Story



Deborah's Story



Jolyn's Story

"With my family history of cancer, I was really worried that I was at high risk too. My gynecologist recommended genetic testing, but my insurance denied coverage. Thanks to MAGENTA, I was able to get genetic testing and learned that I do not carry a mutation associated with an increased risk for cancer."

– Jolyn, MAGENTA participant

Jolyn was initially reluctant to learn more about the MAGENTA study. She worried about emotional stress or concern over receiving information connected to cancer risk. After a while, she decided to go for it.

Jolyn said that the MAGENTA study helped her overcome what may be a major roadblock for many who may benefit from genetic testing. "The major road block would be, the insurance part. The MAGENTA study helped to overcome that barrier."

Since Jolyn enrolled in the MAGENTA study, she's made it a point to tell others in her community about the study. "We're a sisterhood of women, the purpose that we're seeking, to get people, women, empowered." To Jolyn, the MAGENTA study provides information that can empower women with information.

Jennifer's Story

With a family history of breast and ovarian cancer, Jennifer's attention perked when she heard about the MAGENTA study. In thinking about her experience participating in the study, Jennifer noted that it was "super easy, they send the kit right to your house. I didn't really feel stressed about the whole thing, because they do such a good job prepping you."

Jennifer adds that, "even if you don't have the gene, it's still important to be as healthy as you can…but a genetic test can push you to be a little bit healthier!"

Alicia's Story

After losing her mother to ovarian cancer and her grandmother to breast cancer, Alicia found herself diagnosed with stage 2 triple negative breast cancer at the age of 34. While completing her cancer treatment, her older sister was diagnosed with breast cancer, and several years later her middle sister was diagnosed as well and passed away from the disease.

With a personal and family history of breast and ovarian cancer, Alicia, and many members of her family, soon turned to genetic testing for answers. The information they received helped to inform preventative screening practices. Alicia said that the knowledge genetic testing supplied allows you to make different decisions, and to focus on prevention.

"Knowledge is power. You can't fight what you don't know."

"Genetic testing gives you choices. There are things you can do."

Component 3: Messages

1. Learn your risk of ovarian cancer with genetic testing at no cost. Enroll here: https://magenta.mdanderson.org/
2. Know your risk for ovarian cancer, get genetic testing at no cost. Enroll here: https://magenta.mdanderson.org/.
3. Know your risk of ovarian cancer—Do it for your family & yourself. Get genetic testing at no cost https://magenta.mdanderson.org/
4. Be a hero and learn your risk for ovarian cancer with genetic testing at no cost https://magenta.mdanderson.org/
5. Worried about your risk of ovarian cancer? Get informed with genetic testing at no cost. Learn more: https://magenta.mdanderson.org/
6. Learn how you can make a difference and contribute to the fight against ovarian cancer—without ever leaving home. https://magenta.mdanderson.org/
7. Protect your family by learning your risk of ovarian cancer. https://magenta.mdanderson.org/
8. You might be at risk for developing ovarian cancer. Learn more about your personal risk with genetic testing at no cost to you. https://magenta.mdanderson.org/
9. Join the team in the fight against ovarian cancer and receive genetic testing at no cost to you. https://magenta.mdanderson.org/
10. We're working together to protect your future. Lend a hand today by learning your risk of ovarian cancer, at no cost to you. Working together to make testing accessible. Learn how to receive genetic testing from the comfort of your home. https://magenta.mdanderson.org/
11. We're working together to tackle ovarian cancer. Now you can lend a hand by learning your risk with genetic testing. https://magenta.mdanderson.org/
12. Do you know someone battling ovarian cancer? Do you have a family member diagnosed with hereditary cancer? Are you worried about your risk? If you are a woman 30 years of age or older, you may be eligible to learn your risk of ovarian cancer with genetic testing, at no cost. Testing is completed from the privacy of your home, and will provide you with important information you may be able to use to protect your future. Take action today and find out if you're eligible for our study. https://magenta.mdanderson.org/
13. Are you worried about your risk of ovarian cancer? If you are a woman 30 years of age or older, you may be eligible to learn your risk of ovarian cancer with genetic testing, at no cost. Testing is completed from the privacy of your home, and will provide you with important information you may be able to use to protect your future. Take action today and find out if you're eligible for our study. https://magenta.mdanderson.org/
14. You're Wonder Woman—you do it all. But even Wonder Woman isn't immune to ovarian cancer. Do you know your risk? If you are a woman 30 years of age or older, you may be eligible to learn your risk of ovarian cancer with genetic testing, at no cost. Testing is completed from the privacy of your home, and will provide you with important information you may be able to use to protect your future. Take action today and find out if you're eligible for our study. https://magenta.mdanderson.org/
15. Do you know someone battling ovarian cancer? Are you worried about your risk? Want to do something about it? If you are a woman 30 years of age or older, you may be eligible to learn your risk of ovarian cancer with genetic testing, at no cost. Testing is completed from the privacy of your home, and will provide you with important

information you may be able to use to protect your future. Take action today and find out if you're eligible for our study. https://magenta.mdanderson.org/

16. The #MAGENTA study aims to use online genetic testing services to make #GeneticTesting for #HereditaryCancer syndromes more accessible to at-risk individuals—ushering in the era of genetic testing from your livingroom. #Awareness #CancerSucks #StandUpToCancer #Teal #OvarianCancer #SU2C #BRCA #OvarianCancerAwareness https://magenta.mdanderson.org/

Component 4: Hashtags

#Awareness
#SuperHero
#CancerSucks
#StandUpToCancer
#Teal
#OvarianCancer
#SU2C
#SuperMom
#BRCA
#StandUp2Cancer
#OvarianCancerAwareness
#TealTakeOver
#GeneticTesting
#TeamTeal
#HereditaryCancer
#WhyTeal
#TealIsABigDeal
#TealWarrior
#TurnItTeal

PART 2: BLOG POST ABOUT STUDY

The following blog post is for use in email newsletters, through online blogs, and other relevant press releases. Blue font indicates hyperlink placeholder. This document will be shared with organizations posting information about the study on behalf of MAGENTA.

MAGENTA: The study of genetic testing from your living room…

Ovarian cancer is the deadliest of the gynecological cancers, resulting in about 14,000 deaths and 22,000 new cases every year. With few symptoms typically present in early stages of the disease, early detection lags, and with it treatment and prognosis. Family history and other risk factors may raise important red flags, but now more physicians are turning to genetic testing for new answers.

Genetic testing has the potential to address the high morbidity and mortality rates associated with ovarian cancer through innovative prevention and treatment efforts. But with low genetic testing uptake among eligible individuals, it's clear that not enough women are taking advantage of genetic testing. This is where the **Making Genetic Testing Accessible (MAGENTA) study** comes into play.

MAGENTA is the study of genetic testing from your living room. This Stand Up To Cancer initiative seeks to improve the availability of genetic testing for hereditary cancer syndromes to at-risk individuals using an online genetic testing service. Through this platform, the MAGENTA study ensures that eligible individuals have access to genetic testing services, without needing to travel to their health care provider. The hope is that by increasing the availability of genetic testing for hereditary cancer syndromes, more lives will be saved by preventing cancer in individuals who have been found to be at an increased risk.

The MAGENTA study will focus on individuals with a family history of breast or ovarian cancer. Those who have had breast cancer may also qualify for this study. Participants who qualify for the study will fill out family history information, provide a saliva sample for genetic testing and complete a series of online questionnaires regarding their experience. Some individuals in this study will undergo genetic counseling by phone as part of their participation, others will not. Participation in this trial will not require any travel, but will require access to the internet and a phone.

To learn more about the MAGENTA study and find out if you are eligible, please visit http://MAGENTA.mdanderson.org.

PART 3: PRESS RELEASE

<Month> <year>
Contact: magenta@mdanderson.org, (713) 745-7877

Recruitment opens for ovarian cancer genetic testing study
Women with a family history of encouraged to participate

Summary

Making Genetic Testing Accessible (MAGENTA) study enrollment is now open! You may be eligible for genetic testing from the comfort of your own home. Visit the **MAGENTA website** to see if you are eligible for genetic testing and education.

Story

Genetic testing can address the high morbidity and mortality rates associated with ovarian cancer through innovative prevention and treatment. The Making Genetic Testing Accessible (MAGENTA) study will help more women take advantage of these benefits, ensuring they have access to genetic testing from the comfort of their own living rooms.

By using online genetic testing services, MAGENTA effectively democratizes genetic testing, with the goal of improving service availability for individuals at-risk for hereditary cancer.

"Genetic testing is no longer just for people who have the time and means to travel to their healthcare provider--it's a service for everyone," said Dr. Liz Swisher, one of the principal investigator of the Magenta Study. "The hope is that when more at risk individuals have access to these services, more lives will be saved by preventing cancer."

Eligibility and Study Requirements

The MAGENTA study will focus on women who:

- Are 30 years of age or older
- Are able to read and speak English
- Have a valid mailing address in the U.S.
- Have a personal or family history of breast cancer OR a family history of ovarian cancer (no personal history of ovarian cancer)
- Have at least one ovary
- Have never had genetic testing or counseling for cancer risk in the past

- Have access to a healthcare provider and are willing to share their results with that provider

Participants who qualify for the study will fill out family history information, provide a saliva sample for genetic testing (at no cost) and complete a series of online questionnaires regarding their experience.

To find out if you're eligible, please visit https://MAGENTA.mdanderson.org.

Background on ovarian cancer

Ovarian cancer is the deadliest of the gynecological cancers, resulting in about 14,000 deaths and 22,000 new cases every year. With few symptoms present in the early stages of the disease, early detection lags, and with it treatment and prognosis. Family history and other risk factors may raise important red flags, but now more physicians are turning their sights to genetic testing for an answer. While genetic testing holds promise, testing uptake lags. MAGENTA hopes to address low uptake by improving access to genetic testing.

Questions about the study?

The MAGENTA study is coordinated at MD Anderson Cancer Center and is supported by the Stand Up To Cancer Ovarian Cancer-National Ovarian Cancer Coalition Dream Team. For more information about this study, please contact us by e-mail or phone:

Email: magenta@mdanderson.org
Phone #: (713) 745-7877
Availability: Mon - Fri, 8am - 5pm CST (excluding holidays)

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