Informed Consent for Genetic Testing

Informed Consent

This Informed Consent reviews the benefits, risks and limitations of genetic testing provided through Dynacare ("Dynacare"), and Color Genomics, Inc. and its contractors ("Color" and "our") to assess your risk for certain types of hereditary cancer, as indicated on your order form for the Color Test ("Test"). It also explains how your information and sample will be used after performance of the Test. In order for us to process your sample and provide you and your healthcare provider with your results, you must confirm by signing below or otherwise acknowledging that you have read, understood, and agree to this Informed Consent. You are not required to have the Test. Prior to signing this Informed Consent, you may wish to speak with a genetic counsellor or your ordering or referring healthcare provider for further guidance about the Test.

Dynacare Services

Dynacare or its designate will collect a biological specimen from you and Dynacare will send your sample to Color's laboratory located at 863A Mitten Road, Suite 100F Burlingame, CA, USA, for testing. Dynacare will also collect the personal health information that is required to perform the Test, and Dynacare will transmit this personal health information to Color through the secure Color website. Upon completion of the Test, Dynacare will obtain your result and transmit it to the healthcare provider who prescribed your test. Dynacare Customer Care is available to assist you and your healthcare provider with any questions regarding the Test. Dynacare also offers you and your healthcare provider access to our team of genetic counsellors to answer any questions you may have about your results or for pre-test genetic counselling.

By submitting your sample to Dynacare, you consent to your sample and personal health information being sent to the United States where the collection, use, and disclosure of your sample and personal health information will be subject to US laws/regulations. Clients who are domiciled outside of the United States in certain jurisdictions may have the option of requesting that their personal information be deleted at any time from Color's databases, subject to the applicable laws and regulations of such jurisdiction. Please note that deletion of this information prior to completion of the Test will result in a cancellation of the Test, and no results will be provided to you or your healthcare provider. Although Color can delete your personal information from its active databases, some or all of your personal information will remain archived in back-ups for compliance with legal, regulatory, and other requirements. Information that has already been de-identified, anonymized, and/or aggregated may not be retrievable or traced back for destruction, deletion, or amendment. If you choose to have your personal information deleted from Color's active databases, please contact support@color.com.

The Color Test and the Color Laboratory

Color operates a clinical testing laboratory that is accredited by the College of American Pathologists and meets the certification requirements for high complexity testing established under the Clinical Laboratory Improvement Amendments. Based on available data, Color's testing has >99% accuracy for targeted regions. Color will sequence your sample to identify inherited genetic variants (mutations) in selected genes that may increase your risk for certain types of hereditary cancer. By agreeing to this Informed Consent, you acknowledge that you have also reviewed and agree to Color's Terms of Service and Privacy Policy. Color continues to add to the capabilities of its testing menu. For the most up to date information about Color's genetic testing options or to view Color's Terms of Service and Privacy Policy, please ask your healthcare provider or visit the Color website (www.color.com).

Testing Procedure; Sample and Data Collection

An authorized healthcare provider will review your information, and upon his or her determination that the Test is appropriate for you, he or she will order the Test for you. You will also be asked to provide a sample in accordance with Color's collection procedures, and to provide your Personal and Family Health Information (PFHI). Your sample and PFHI will then be transferred to Color's laboratory in California, USA, for analysis. In order for the Test to perform as intended, you must provide accurate and correct information. If another person is submitting your PFHI or related information on your behalf, by signing this Informed Consent, you represent and warrant that such person is authorized to provide such information, and that all such information is accurate and correct. Upon successful completion of the Test, you hereby request that a report be made available to your ordering healthcare provider for review. We recommend that you further consult with a genetic counsellor or your healthcare provider about your results. By signing this consent, you also acknowledge and agree that Dynacare and Color may de-identify the genetic information that Color obtains from its analysis and aggregate this genetic information with de-identified genetic information from other patients. De-identification means that Personally Identifiable Information (PII) associated with your genetic information will be removed prior to submission for public research. The de-identified genetic information may be submitted by Color to public databases to advance medical research.

Benefits of the Test

Your results may show you have mutations in certain regions of your DNA that increase your risk for certain types of hereditary cancer. Knowing that you have a mutation in one or more of the genes analyzed may help you and your healthcare provider make more informed healthcare decisions to prevent or detect cancer conditions at an earlier and potentially more treatable stage. Additionally, your results may be informative to biological relatives.

Risks of the Test

The Test is a genetic screening test that may cause you to discover sensitive information about your health or disease risks, including risk for diseases other than the one for which you are testing, or for diseases that currently have no treatment. The US Genetic Information Nondiscrimination Act of 2008 prohibits discrimination on the basis of genetic information with respect to health insurance and employment. However, there are currently no US federal laws that prohibit discrimination in life insurance, disability insurance or long-term care insurance, which may be governed by state law. Depending on your country of residence, there may be significant differences in the laws and regulations governing the use and disclosure of genetic information, or there may not yet be any laws or regulations governing the use or disclosure of genetic information.

Limitations of the Test

The Test is intended to detect inherited genetic variations (mutations) on selected genes known to be associated with an increased risk for certain types of cancer. However, no currently available test can detect every mutation associated with an increased risk for cancer, and no test can analyze all genetic causes for cancer, as not all causes are known. Analysis of results is based on currently available information in the medical literature and scientific databases. New information may replace or add to the information that was used to analyze your results. Based on this new information, you understand and agree that Color may, at its sole discretion, amend or modify your Test report, which may result in a change in your risk assessment or the reclassification of a variant. You hereby irrevocably waive any and all claims against Color for any amendment or modification of the Test report in accordance with Color's standard operating procedures. As part of the Test, Color may also identify the presence of Variants of Uncertain Significance (VUS), which are genetic variants that require further research to determine if they are associated with an increased risk for disease. Color will provide further detail about these VUS's if: (a) you or your healthcare provider actively elects to receive such information; (b) additional research enables us to reclassify a variant; or (c) we determine at our reasonable discretion that you or your provider should be made aware of this information. You should discuss the results of the Test and the presence of VUS's (if any) with your healthcare provider or a genetic counsellor.

Color implements several safeguards to avoid technical errors, but as with all medical tests, there is a chance of a false positive or a false negative result. A false positive result means a genetic mutation was detected, which is not in fact present. A false negative result means the Test failed to identify a genetic mutation that is in fact present. Other sources of error, while rare, include sample mix-up, poor sample quality or contamination, inherent DNA sequence properties, and technical errors in the laboratory. In addition, if you have certain rare biological conditions or have had certain bone marrow transplants, transfusions, or hematologic malignancies, these conditions may limit the accuracy of the results or prevent the Test from being completed. Color expressly disclaims any liability for the inaccuracy of Test results resulting from such conditions or the failure to provide accurate, correct or complete PFHI, and you expressly waive any claims against Color with respect thereto.

Potential Results

Testing positive for a mutation means a genetic variant that increases your risk for a certain type of cancer condition was identified. This result does not necessarily mean that you have that disease or that you will develop the disease in your lifetime. If you receive a positive result, you should consult with your healthcare provider or a genetic counsellor to discuss the Test results. Testing negative for a mutation means that no mutations associated with an increased risk for the diseases that were selected on your order form were identified. However, this does not eliminate your risk of developing a disease. The Test is not a diagnostic test. It is important to note that results indicating that no mutation was found do not guarantee that you will be healthy or will never develop any of the diseases that Color tests for. By signing this Informed Consent, you understand and agree that your results must be considered in the context of broader medical management by a healthcare provider, and that you should not make medical decisions without consulting a healthcare provider. Color does not provide medical services, diagnosis, treatment, or advice.

Privacy and Data Security

Your privacy is Dynacare and Color's priority. Details on Dynacare's policies and procedures governing patient privacy and health information, including patient rights regarding such information, can be found at dynacare.ca/privacy-policy. Details about Color's policies governing patient privacy and health information, including patient rights regarding such information, can be found at www.color.com/privacy, or will be made available to you upon request by e-mailing support@color.com. Color complies with the applicable requirements of the Health Insurance Portability and Accountability Act of 1996 (as amended) regarding PII. Color implements certain physical, managerial, and technical safeguards that are designed to protect the integrity and security of your PII. Color cannot, however, guarantee the security of any information Dynacare transmits to Color or stores on the Color website. You agree that Color is not liable for the unauthorized release of your PII, results or medical information, unless such release was the result of gross negligence or wilful misconduct on the part of Color. In the event of a data breach, we intend to comply with all federal and state reporting requirements. By agreeing to this Informed Consent, you agree that the laws and regulations of the US regarding data privacy and collection, use, processing, and storage of patient information shall govern Color's performance of the Test and handling of your sample and information, even if they may differ from those of Canada. You further agree that by providing your sample, you are not violating any export ban or other legal restriction in Canada.

Use of Information and Samples

Upon completion of the Test, you are requesting that your results be made available to your healthcare provider as specified in your requisition form. By agreeing to this Informed Consent, you also agree that your genetic information, PFHI, PII, and results can be shared with your ordering provider, and with any healthcare provider that you or your ordering provider designates. You also agree that Dynacare and Color may communicate with you about your order, account details, and Test logistics.

Data and Sample Use in Internal Quality Control, Laboratory Validation Studies, Research and Development, and Education: By agreeing to this Informed Consent, you agree that your sample, genetic information, PFHI, PII, and results may be anonymized, stored and used by Dynacare and Color for internal quality control; validation studies; research and development; and to provide you with educational health information applicable to your condition.

Participation in Third Party Research and Inclusion in Color's Research Database (Optional): You have the option of consenting to the use of your anonymized sample, genetic information, PFHI, PII, and results in Dynacare and Color's research with third party collaborators, and inclusion of such information in Dynacare and Color's research database. Dynacare and Color may engage in research with third parties to develop new tests or validate and improve its technologies or processes. Color also operates a research database to support research on genetics. If you consent, Color will anonymize your information and make it accessible and searchable in the database by researchers and the general public, for an indefinite period of time. Participation in this database is voluntary and involves the possible risk that your information might become known to individuals outside of Dynacare and Color, or that you may be identifiable from information in the database. Color will attempt to protect your identity and preserve the confidentiality of your information by removing certain personal identifiers from information in the database. Color will also use commercially reasonable efforts to restrict any searches that identify you as a unique or rare carrier of any variants. You can opt out of such third party research and the database by notifying Dynacare. However, if you have agreed to share your information and sample in the past and later opt out of third party research and the database, Dynacare and Color cannot exclude your data or sample from research already performed with your prior permission, but will cease to share your data in third party research going forward and will remove your information from the database. Following receipt of such request, Color will also destroy any remaining portion of your sample that has been stored and not yet used for research pursuant to this opt-in selection, in accordance with applicable federal and state regulations (unless you have also opted in for sample storage, as set forth below).

Sample Storage (Optional): You have the option of consenting to storing your sample and DNA at Color's expense to allow you to have additional testing through Color in the future. If you do not choose to store your sample with Color, then Color may only retain your sample and DNA for the maximum duration permitted under applicable law or regulation ("Retention Period"). Your sample and any DNA derived from the sample will be destroyed after the Retention Period. If you do choose to store your sample with Color, and Color becomes unable to store such samples, Color will inform you in advance that your sample will be destroyed in accordance with Color's standard operating procedures. Dynacare and Color may also contact you to solicit feedback and describe new tests and services developed by Dynacare, Color or its collaborators that may be of interest to you. You can opt out of this communication at any time.

Consent

My signature below confirms that I have read or have had read to me, all of the information in this Informed Consent document, and I understand what it says. I have had the opportunity to ask any questions I may have about the Color Test and related issues, and all of my questions have been answered to my satisfaction. I freely and voluntarily consent to undergo this test, and I specifically acknowledge and consent to the following:

- I am the individual providing the sample and I am at least 18 years of age.
- It is possible that the quantity or quality of sample submitted may be inadequate for testing.
- 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 types of cancer. A negative test result does not necessarily rule out a genetic condition or my potential to develop cancer.
- I should not make any medical decisions based on these results without speaking to my healthcare provider first.
- This Test may not perform as intended or provide accurate results if I have not provided accurate and correct personal information, or if I have certain rare biological conditions or have had certain bone marrow transplants, transfusions, or hematologic malignancies.
- If multiple family members are being tested, non-paternity may be disclosed by these results.
- Genetic counselling services are available to me through Dynacare at no additional charge.
- The genes that Color analyzes are selected based on their known relationship with disease, but they may also indicate an increased risk for other health conditions for which Color may provide results that are not yet comprehensive or final. Results may be re-assessed over time as new information becomes available, and Dynacare and Color may re-issue my test report in the future.
- My anonymized sample, genetic information, and results may be used for internal quality control; laboratory validation studies; research and development; and educational purposes.
- Color may contribute de-identified information about my genetic variants to public databases.
- 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, rules, and regulations of the United States (with respect to Color) and Canada (with respect to Dynacare).
- Only you or the referring specialist designated on the Requisition Form will receive a written report of test results.
- I agree to the Dynacare Privacy Policies, which are available at dynacare.ca and Color Terms of Service and Privacy Policy, which are available at color.com, or upon request.

☐ Optional: I consent to the use of my samples and data beyond 60 days for third party research, and to the inclusion of my data in Dynacare and Color's research databases.

☐ Optional: I consent to storing my samples with Color beyond 60 days for future use or testing.

Patient signature	Date (YYYY/MM/DD)
Patient name	