Color Informed Consent for the Hereditary Cancer Test

This Informed Consent reviews the benefits, risks and limitations of undergoing genetic testing provided through Color Genomics, Inc. and its contractors ("Color") to assess your risk for certain types of hereditary disorders, as indicated on your order form ("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 counselor or your ordering or referring provider about the Test.

The Color Hereditary Cancer Test aims to detect all clinically relevant variants within 30 genes analyzed. All genes in this test have been implicated in cancer predisposition and are associated with an increased lifetime cancer risk, although these risks may differ, depending on the particular gene.

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. Color continues to add to the capabilities of its testing menu. For the most up to date information about Color's genetic testing options, please ask your provider or visit the Color website (www.color.com).

SAMPLE COLLECTION AND TESTING

An authorized provider will review your information, and upon their determination that the Test is appropriate for you, they 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 you and your ordering provider for review. We recommend that you further consult with a genetic counselor or your provider about your results.

BENEFITS OF THE TEST

Your results may show you have an inherited pathogenic or likely pathogenic genetic variant (mutation) in certain regions of your DNA that increase your risk for certain types of hereditary disorders. Knowing that you have a mutation in one or more of the genes analyzed may help you and your provider make more informed healthcare decisions to prevent or detect health disorders 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 hereditary disorders other than the one for which you are testing, or for disorders 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. If you live outside of the US, 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 mutations within a specified reportable range of selected genes known to be associated with an increased risk for certain types of inherited disorders. However, no currently available test can detect every mutation associated with an increased risk for inherited disorders, and no test can analyze all genetic causes for all disorders, as not all causes are known.

Analysis of results is based on currently available information in the medical literature and scientific databases, as well as laboratory informatics and algorithms that may be subject to change. New information may replace or add to the information that was used to analyze your results. Based on this new information and/or modifications to our laboratory informatics and algorithms, 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. Color will attempt to notify you of any material amendments or modifications. 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 a hereditary disorder. Color will provide further detail about such VUSs if: (a) you or your provider elects to receive such information; (b) additional research enables us to reclassify a variant; or (c) we determine at our reasonable discretion that you should be made aware of this information. You should discuss the results of the Test and the presence of VUS's (if any), as well as any changes to your Test report, with your provider or a genetic counselor.

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 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 disorder was identified. This result does not necessarily mean that you have that hereditary disorder or that you will develop the disorder in your lifetime. If you receive a positive result, you should consult with your provider or a genetic counselor to discuss the Test results.

Testing negative for a mutation means that no mutations associated with an increased risk for the disorders that were selected on your order form were identified. However, this does not eliminate your risk of developing a disorder. 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 disorders 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 provider, and that you should not make medical decisions without consulting a provider. Color does not provide medical services, diagnosis, treatment, or advice.

PRIVACY AND DATA SECURITY

Your privacy is Color's priority. 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 emailing support@color.com. Color complies with

PRIVACY AND DATA SECURITY *(Continued)*

the applicable requirements of the Health Insurance Portability and Accountability Act of 1996 (as amended) regarding Personally Identifiable Information (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 you transmit to Color or store on the Color website, and you do so at your own risk. 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 willful misconduct on the part of Color. In the event of a data breach, we intend to comply with all federal and state reporting requirements. If you are domiciled outside of the US, you should consult with your physician because genetic testing may be subject to specific regulatory constraints, or be prohibited, in certain countries. 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 your country of residence. You further agree that by providing your sample, you are not violating any export ban or other legal restriction in your country.

USE OF INFORMATION AND SAMPLES

- All samples from New York clients will be destroyed within 60 days after Color's receipt of the sample (or upon completion of the Test), unless you elect one of the options set forth below.
- We store your genetic sequencing and related data as required by applicable regulations, and we may use this data to conduct subsequent testing or analysis in the event that (a) you consent to any new product or service offering; or (b) our review of medical literature and/or advances in technology indicate that such analysis is useful or necessary to confirm results provided. Such subsequent testing or analysis may also require an updated physician order.
- If your employer has provided or paid for (in whole or in part) the Test, you acknowledge and agree that your de-identified results and PFHI may be anonymized and aggregated and returned to your employer or its designated plan administrator as a data analytics resource.
- Upon completion of the Test, you are requesting that your results be made available to you and your provider as specified in your account or order 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 Color may communicate with you about your collection kit, order, results, account details, and other Test logistics and procedures.
- Data and Sample Use for Public Variant Databases, Regulatory Compliance, Internal Quality Control, Laboratory Validation Studies, Research and Development, and Education: By signing this consent, you acknowledge and agree that Color may de-identify the genetic information obtained from its analysis and aggregate this genetic information with de-identified genetic information from other clients. De-identification means that PII associated with your genetic information will be removed. The de-identified genetic variants may be submitted by Color to public variant databases like ClinVar to advance medical research. You also agree that your sample (if you have chosen to store it), genetic information, PFHI, PII, and results may be de-identified, stored and used by Color for regulatory compliance purposes; internal quality control; validation studies; research and development; and to provide you with educational health information applicable to your condition. Color may also author publications using such de-identified information, either on its own or in collaboration with academic or commercial third parties (which publications may include, for example, blinded pedigree diagrams or de-identified family history).
- **Participation in Third Party Research and Inclusion in Color's Research Database (Optional):** You have the option of consenting to the use of your de-identified sample (if you have chosen to store it), genetic information, PFHI, PII, and results in Color's research with third party collaborators, and inclusion of such information in Color's research database.
    - Such third parties may include government, academic, or commercial third parties. Color may engage in research with such third parties to develop new tests and inventions, or to validate and improve existing technologies or processes. You acknowledge and understand that Color may receive financial compensation to conduct such research, which may include providing your de-identified data to such third parties.
    - Color's research database supports research in 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 involves the possible risk that your information might become known to individuals outside of 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, and will 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 Color's research database by updating your account settings or by notifying the provider who ordered your Test. However, if you have consented in the past and later change your settings to opt out, Color cannot exclude your de-identified sample (if you have chosen to store it), genetic information, PFHI, PII, and results from research already performed with your prior permission. Color will cease to share your information going forward and will remove your information from the database.
- **Sample Storage (Optional):** You have the option to store your sample and DNA at Color's expense for future use or testing. If you do not choose this option, 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 this option, and Color becomes unable to store your sample and/or DNA, Color will inform you in advance that your sample and/or DNA will be destroyed in accordance with Color's standard operating procedures. If you later ask us to destroy your sample and DNA, Color will destroy any remaining portion that has been stored and not yet used pursuant to this opt-in selection, in accordance with applicable federal and state regulations.
- If any new tests, technologies, processes, or inventions are made as a result of the research activities described above (whether made by Color or by a third party), you agree that you will not receive any compensation, nor will you have any right, title, and/or interest in or to such new or improved tests, technologies, processes, or inventions.
- Color may contact you to solicit feedback (including through optional surveys, interviews, or testimonials), and describe new tests and services developed by Color and its collaborators that may be of interest to you. You can opt out of this communication at any time.

CONSENT

I confirm 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 testing, 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.
- This Test is not intended to diagnose whether I have or will get a certain disorder in the future. It is intended to tell me about my hereditary risk related to certain types of disorders as indicated above.
- I should not make any medical decisions based on these results without speaking to my healthcare provider first.
- Genetic counseling services are available to me through Color at no additional charge.
- My de-identified sample (if I have chosen to store it), genetic information, PFHI, PII, and results may be retained and/or used in public variant databases; regulatory compliance; internal quality control; laboratory validation studies; research and development; and educational purposes. All samples from

CONSENT *(Continued)*

New York clients will be destroyed within 60 days after Color's receipt of the sample (or upon completion of the Test), unless I opt in to storing my sample.

- 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.
- I agree to the Color Terms of Service and Privacy Policy, which are available at color.com, or upon request.

☐ ***Optional*: I consent to the use of my data for third party research and to the inclusion of my data in Color's research database.**

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

Patient signature	Date
Patient name	

For patients domiciled outside the US: 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 our active 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 we can delete your personal information from our 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 our active databases, please contact us at support@color.com.