# Color Informed Consent for the Extended Test

This Informed Consent reviews the benefits, risks and limitations of undergoing genetic testing as selected on your order form or in your account settings ("Test(s)", as described in further detail below) provided through Color Genomics, Inc. and its contractors ("Color"). It also explains how your information and sample will be used in connection with the Test and for other treatment, payment, and certain healthcare operations purposes as permitted by applicable law or regulation. Throughout this Informed Consent, "you", "your", "me", "my", and "I" refer to the person whose information and sample is being provided for this Test. If you are a parent or guardian requesting a Test for a minor, "you" will refer to "your child", as contextually appropriate. 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 healthcare provider about the Test.

The Color Hereditary Cancer Test aims to detect clinically relevant variants within 30 genes analyzed, subject to the Limitations of the Test section below. 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 Hereditary Heart Health Test aims to detect clinically relevant variants within 30 genes analyzed, subject to the Limitations of the Test section below. All genes in this test have been associated with an increased lifetime risk for heart attacks, strokes, and sudden cardiac death, although these risks may differ depending on the particular gene. This Test may be ordered for minors, provided that the minor's parent or legal guardian provides consent for this Test.

The Color Medication Response Genetic Test aims to detect clinically relevant variations (genotypes, alleles, or diplotypes) within 14 genes that may impact how you process and respond to certain medications, subject to the Limitations of the Test section below. The clinical relevance of all included genes has been informed by published evidence. The specific list of reportable variations will be available in the methods and limitations section of your report. Color may, at its sole discretion, update the list of reportable variations, as the clinical science develops. If re-analysis occurs based on this, or if re-analysis reveals significant changes to reported results, then results may be updated. Please visit www.color.com/product/color-genes for the most up to date list of included variations.

Additionally, Color may generate sequence data up to and including the entire genome. This data may be used by Color as described in this Informed Consent. It may also be used for Color Discovery or other Color services and products, if you opt into these features in the future. The data outside of the ordered test may not be validated for other clinical, medical, or diagnostic uses.

## 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 Color's website (www.color.com).

## WHAT WE COLLECT AND HOW IT IS USED

If you request a Test, you will be asked to provide your Personal and Family Health Information (PFHI). By way of example, PFHI may include the following information:

- Information about you and your biological family, such as ancestry, age, and biological sex; and/or
- Information about your history of certain health conditions, your family history of those conditions, your medication history, and any known genetic mutations in you or your family members.

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. If you are providing personal information about your relatives, you also represent and warrant that you have obtained permission from such relatives to disclose such information to Color.

An authorized provider will review the information you submit when you request a Test, and if they determine that the Test is appropriate for you, they will order the Test for you.

You will also be asked to provide a saliva or blood sample in accordance with Color's collection procedures. Your sample and PFHI will be transferred to Color's laboratory in California, USA, for processing. DNA will be extracted from the submitted sample and sequenced. Sequence data includes information about genes and regions relevant to the ordered Test, as well as other regions up to and including the entire genome. Because saliva samples frequently include DNA from other sources (e.g., bacteria, food), Color may also sequence and collect information about this DNA if present. All sequence data may be used only for regulatory compliance or to the extent needed for business management and general administrative activities (e.g. responding to inquiries or complaints as part of customer service activities) as permitted by applicable law or regulation, and de-identified for:

- internal quality assurance (e.g. monitoring operational metrics for irregularities);
- internal validation studies (e.g. validating changes to our bioinformatics pipeline);
- publications authored solely by Color, disclosing only aggregated information (e.g. research to estimate the prevalence of inherited cancer risk in certain populations);
- improvement of all current product areas offered by Color (e.g. the development of new or improved laboratory techniques); and
- business intelligence (e.g. ensuring we have sufficient genetic counselor coverage).

Analysis and reporting on genes and regions beyond those relevant to the ordered Test will not occur unless you consent to future products or services (e.g. Color Discovery). If you opt into third party research, research and development for future Color product areas, and Color's research database, additional analysis of your de-identified data may occur.

Upon successful completion of the Test, you hereby request that your Test results, PFHI, and other information you provide about yourself to Color be made available to you and your ordering provider. Results and information may be formatted, organized, and transferred in various electronic formats, as requested by your provider. If your ordering provider is part of a clinic or health system, your results and information may also be made available or distributed throughout such clinic or health system (including for example, through an electronic medical records system), as part of that clinic or health system's treatment, payment, and healthcare operations. Further, Color may provide your clinic or health system with other data it has collected or sequenced, and related analyses, for your clinic or health system's use for treatment, billing, healthcare operations, data analytics, research or other purposes for which they have agreed to comply with applicable laws. You can consult with your provider, clinic, or health system about their disclosure and use of such information.

## BENEFITS OF THE TEST

Your results may show you have an increased risk of developing certain types of hereditary disorders. Knowing this may help you and your provider make more informed healthcare decisions to prevent or detect hereditary disorders at an earlier and potentially more treatable stage. Your results may also show that the genes we analyzed and reported on may impact how you process or respond to certain medications. Knowing this information may help your provider make more informed prescribing or dosing decisions. Because relatives share some genetic features, your results may also be informative to your biological relatives.

## RISKS OF THE TEST

The Test is a genetic 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 (GINA) prohibits discrimination on the basis of genetic information with respect to health insurance and employment. However, certain exceptions apply, and we encourage you to review GINA and related laws and regulations. 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

Depending on the Test you have selected, such Test is intended to detect variants within a specified reportable range of selected genes known to be associated with an increased risk for certain types of inherited disorders; and/or such Test is intended to detect gene alleles and variants (within a specified reportable range) known to impact your ability to process and respond to medications. However, this test may not detect every variant associated with disease risk, or every variant or allele that may impact how a person processes or responds to medications.

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. This may result in a change in your risk assessment; the reclassification of a variant; a change or update to a previously reported pharmacogenomic allele; or a reclassification of a reported diplotype. 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 may 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 VUSs (if any), as well as any changes to your Test report, with your provider or a genetic counselor. In order for us to provide you with updates regarding your test results (including the reclassification of VUSs), your Color account must remain active with your up-to-date contact information.

If you have selected the Medication Response Genetic Test, it is intended to establish if any of the analyzed alleles are present. This test does not detect all possible variations in the analyzed genes. A "normal metabolizer" result does not guarantee that the gene functions normally, only that there is no conclusive evidence suggesting that any of the tested non-normal alleles were present. The activity of the tested genes is just one of the factors that influence your ability to process and respond to certain medications. Other factors include: the influence of other genes, your health history, environmental factors, and other medications you may be taking. Different genes and factors may interact in ways that are not completely understood.

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 that genetic variation was reported which is not in fact present. A false negative result means the Test failed to identify a genetic variation that is in fact present and within the reportable range.

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, kidney, liver or heart transplants, transfusions, or hematologic malignancies, these conditions may limit the accuracy or relevance 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 (including your medication history), and you expressly waive any claims against Color with respect thereto.

## POTENTIAL RESULTS

For genes related to disease risk, a positive result means that Color identified a genetic variant that may increase your risk for a certain type of disorder, and a negative result means that no variants that are known to increase risk were found. The Test is not a diagnostic test. Positive results do not necessarily mean that you have that hereditary disorder or that you will develop the disorder in your lifetime. Negative results do not eliminate your risk of developing a disorder, and do not guarantee that you will be healthy or will never develop any of the disorders that Color tests for.

For genes having pharmacogenomic relevance, your results may reveal that you may process or respond to certain medications more or less effectively than average. Genetics is only one of the factors influencing medication effectiveness. Your physician can consider this information along with other factors like the influence of other genes, your health history, environmental factors, and other medications. Always consult with a provider before stopping or making any other medication changes. Changing medications on your own could be harmful to your health.

You should consult with your provider, a genetic counselor, or a pharmacist to ensure you understand your Test results and how they may inform your personalized healthcare plan going forward. 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 important to Color. 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 the applicable requirements of the US Health Insurance Portability and Accountability Act of 1996 (as amended) and, as applicable, the EU General Data Protection Regulation (GDPR). Color implements certain physical, managerial, and technical safeguards that are designed to protect the integrity and security of your protected information. 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 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 applicable 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 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 YOUR INFORMATION AND SAMPLES AFTER THE TEST IS COMPLETE

- 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, Test results, and analysis of this information 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.

## USE OF YOUR INFORMATION AND SAMPLES AFTER THE TEST IS COMPLETE *(continued)*

- We store your genetic sequencing and related data as required by applicable laws and 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 changes 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.
- Unless you elect the optional sample storage set forth below, Color will retain the sample (saliva, blood, and/or extracted DNA) only for the maximum duration permitted under applicable law or regulation ("Retention Period"), after which point it will be destroyed. Samples from New York clients will be destroyed within 60 days after Color's receipt of the sample (or upon completion of all Tests), unless you opt into the sample storage option set forth below. Until such time that your sample is destroyed, Color may (a) store or use it for regulatory compliance purposes; and (b) de-identify your sample and process and analyze it for internal quality assurance, internal validation studies, and internal research and development for all current product areas that Color offers.
- 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/or aggregated and returned to your employer or its designee (e.g., plan administrator or pharmacy benefits manager) as a data analytics resource.
- If your ordering provider is part of a clinic or health system, Color may provide such clinic or health system with your results and information, other sequencing data, PFHI, and related analyses, for your clinic or health system's use for treatment, payment, healthcare operations, data analytics, research or other purposes for which your clinic or health system has agreed to comply with applicable laws. Color or your clinic or health system may request you provide a HIPAA Authorization for certain disclosures or uses.
- Data and Sample Use for Public Variant Databases, Regulatory Compliance, Internal Quality Assurance, Internal Validation Studies, Improvement of all Current Product Areas, Business Intelligence, and Publications Authored Solely by Color:
    - By signing this consent, you acknowledge and agree that Color may de-identify the sequenced genetic information and aggregate this genetic information with de-identified genetic information from other clients. De-identification means that personal identifiers 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 genetic information, PFHI, personal data, and results may be stored and used by Color for regulatory compliance purposes.
    - Your genetic information, PFHI, personal data, and results may also be de-identified, stored and used for internal quality assurance; internal validation studies; improvement of all current product areas that Color offers; business intelligence; and in publications authored solely by Color, disclosing only aggregated information (which publications may include, for example, de-identified family history).
- If you request Color to deactivate your account, your account will be deactivated pursuant to Section 4 of the Terms of Service. This means the following:
    - Your login and account access will be terminated.
    - Color will not provide you with any of the Services going forward (including, without limitation, any Results that have not yet been reported, or any updates or changes to your Results).
    - If your sample had been stored, it will be destroyed.
    - If you had previously opted into third-party research, you will be opted out.
    - If you previously opted into Color Data, your information will not be made available in future publications of Color Data.
    - Your data will be deleted except for that data for which retention is required to enable Color to comply with law, rule, regulation, or applicable accreditation standards.
    - Your de-identified and genetic sequencing data shall be retained and usable by Color as set forth in this Informed Consent.

## OPTIONAL USE OF YOUR INFORMATION AND SAMPLES

- **Participation in Third Party Research; Research and Development for Future Product Areas; Publications using Non-Aggregate, De-identified Information; and Inclusion in Color's Research Database (referred to as "Participation in External Research and Future Products; Publications (Using Non-Aggregate Data); and Color Data") (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, personal data, and results in Color's research with third party collaborators; in research and development for future Color product areas; publications using non-aggregate, de-identified information; 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.
    - Research and development of future Color product areas: Color may further analyze your de-identified sample or data as part of its research and development of future product areas outside of cancer, heart, medication management, and Discovery. This will support our development of new product areas that may be of interest to you.
    - Publications: Color may author publications using non-aggregated, 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).
    - Color's research database supports research in genetics. If you consent, Color may de-identify your demographic, PFHI, and genetic information in order to aggregate it with other participants' data and make it accessible, searchable, and downloadable from the database by researchers and the general public, for an indefinite period of time. Genetic information in the database may include variants beyond those relevant to the product or service you consented to, but they will be de-identified. 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 change your Participation in External Research and Future Products; Publications (Using Non-Aggregate Data); and Color Data setting by updating your account or by notifying Color at support@color.com. However, if you have consented in the past and later change your settings to opt out, Color cannot retract your de-identified sample (if you have chosen to store it), genetic information, PFHI, personal data, and/or results from research already performed, or from previous releases of Color's research database that have already been published.
    - 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.
- **Sample Storage (Optional):** You have the option of giving Color permission to store any of your saliva, blood or DNA sample that remains after testing has been completed. If you select this option, Color may store your sample at its discretion. A stored sample may be useful, for example, for future use in Color's products or services, or for third party research (if you've opted in). You can change this option at any time by updating your account settings or by notifying the provider who ordered your Test. If you later ask us to destroy your sample, 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.

## 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:

- The sample being provided is mine and I am at least 18 years of age, or if consenting for someone else, I have the legal authority to consent for such person whose sample is being provided. If the sample being provided is from someone under the age of 18, I represent that I am the parent or legal guardian of the person being tested.
- 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 and/or how my genetics may impact how my body processes certain medications.
- The reported results and information are intended solely for use by a provider and do not constitute medical advice by Color. I should not make any medical decisions or medication changes based on these results without speaking to my provider first. My provider remains ultimately responsible for all diagnosis and treatment decisions.
- My doctor and I can speak with Color's genetic counselors and clinical pharmacists at no additional charge.
- My sample will be sequenced for the genes and regions identified in the Test(s) selected. Color will also sequence additional genes and regions, up to and including the entire genome, and any other DNA present in the submitted sample. My genetic information, PFHI, personal data and results may be stored and used by Color only for regulatory compliance purposes or to the extent needed for business management and general administrative activities. My de-identified sample (if I have chosen to store it), genetic information, PFHI, personal data, and results may also be stored and used for internal quality assurance; internal validation studies; improvement of all current product areas that Color offers; business intelligence; and in publications authored solely by Color, disclosing only aggregated information. Additional analysis and reporting of genes and regions beyond those relevant to the ordered Test will not occur, unless I consent to future products or services (e.g. Color Discovery), or unless I opt into Participation in External Research and Future Products; Publications (Using Non-Aggregate Data); and Color Data.
- If my ordering provider is part of a clinic or health system, I consent to Color providing such clinic or health system with my results and information, other sequencing data, PFHI, and related analyses, for such clinic or health system's treatment, payment, healthcare operations, data analytics, research or other purposes for which my clinic or health system has agreed to comply with applicable laws. Color or my clinic or health system may request I provide a HIPAA Authorization for certain disclosures or uses.
- 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.
- All saliva and blood samples (including those received from New York clients) will be destroyed after the end of the applicable Retention Period; however, I understand I can provide Color with permission to store my saliva sample for a longer period of time.
- If a minor will be tested, I further acknowledge and understand that while genetic report information may be similar for adults and minors, the consequences of genetic testing of minors are relatively new and less understood. The National Society of Genetic Counselors recommends that the social, psychological and legal risks and benefits of early identification of genetic issues from the perspective of the minor and parent/guardian be carefully considered and include genetic counseling when discussing adult onset disorders.
- 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 and sample (if I have chosen to store it) for external research and future products, publications using non-aggregated data, and Color Data.**

☐ ***Optional*: I give Color permission to store, at its sole discretion, my sample beyond 60 days for future use or testing.**

| Patient name (please print) | Patient's date of birth |
|---|---|
| Patient signature | Date |

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.