Color Informed Consent for Genetic Testing

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 Health, Inc. (f/k/a Color Genomics, Inc.) and its affiliates (collectively, "Color"). It also explains how your information and sample will be used in connection with the Test, and for other 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. 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 Genetic Tests

Color offers genetic Tests, which are intended to detect clinically relevant variants (genotypes, alleles, or diplotypes) within certain analyzed genes associated with pharmacogenomics or with an increased risk of certain adult-onset of hereditary disorders. These genetic Tests are subject to the Test Limitations section below.

The clinical relevance of the included genes in each of the above Tests has been informed by published scientific studies. The specific list of reportable variants will be available in the methods and limitations section of your report. Color may, at its sole discretion, update the list of reportable variants, 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. For the most up-to-date information about Color's Tests including information about the specific genes and variants tested, please visit the Color website (www.color.com/learn/color-genes). Color continues to add to the capabilities of its testing menu.

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 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.

What We Collect

If you request a Test, you will be asked to provide your Personal and Family Health Information (PFHI), which 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 other 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 PFHI or other related 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 either to a Color laboratory or by us to a third-party laboratory in the United States 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.

How We Share Your Sequence Data, Test Results, PFHI, and Other Related Information

You agree that your sequence data, Test results, PFHI, and other related information you provide about yourself to Color will be made available to you and your ordering provider as specified in your account or order form. You also agree that Color may communicate with you about your collection kit, order, results, account details, and other Test logistics and procedures. Results and information may be formatted, organized, and transferred in various electronic formats, as requested by your ordering 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.

How We Share Your Sequence Data, Test Results, PFHI, and Other Related Information

You agree that your sequence data, Test results, PFHI, and other related information you provide about yourself to Color will be made available to you and your ordering provider as specified in your account or order form. You also agree that Color may communicate with you about your collection kit, order, results, account details, and other Test logistics and procedures. Results and information may be formatted, organized, and transferred in various electronic formats, as requested by your ordering 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.

If you are participating in research study(ies) and have provided separate research informed consent(s) and/or U.S. Health Insurance Portability and Accountability Act (HIPAA) Authorization for your sequence data (up to and including sequence data covering the entire genome), Test results, PFHI, and other related information to be shared with and used by the researcher(s), Color may share your information as set forth in such separate research informed consent(s). In the event of a conflict between any terms in this Informed Consent and your research informed consent(s), the terms of your research informed consent(s) shall control with respect to the disclosure and use of your information and your participation in such research study(ies).

Your Test 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 disease, 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 disease or that you will develop the disease in your lifetime. Negative test results do not eliminate your risk of developing a disease, and do not guarantee that you will be healthy or will never develop any of the diseases 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 practice medicine, and does not provide any form of medical care or medical advice. provide medical services, diagnosis, treatment, or advice. Color may connect you with clinicians at Color Medical, and/or unaffiliated clinicians, laboratories, and other professionals, all of whom may have their own applicable terms of services, informed consent, and other policies. Color does not control or interfere with the practice of medicine by clinicians, each of whom is solely responsible for the medical care, treatment, and diagnosis he or she provides to you.

Test Benefits

Your results may show you have an increased risk for developing certain types of hereditary diseases. Knowing this may help you and your provider make more informed healthcare decisions to prevent or detect hereditary diseases 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.

Test Risks

The Test is a genetic test that may cause you to discover sensitive or unexpected information about your health or disease risks, including risk for hereditary diseases other than the one for which you are testing, or for diseases that currently have no treatment. You may also discover sensitive or unexpected information about family relationships or potential health or disease risks in close biological family members. The U.S. 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 U.S. 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 United States, 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.

Test Limitations

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 diseases; 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; 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.

For genes related to disease risk, 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 disease. Color may provide further detail about such VUS 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 (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 VUS), your Color account must remain active with your up-to-date contact information.

For genes having pharmacogenomic relevance, Color identifies the presence of any of the analyzed alleles. This Test does not detect all possible variants 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 may 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 with Tests, but as with all such tests, there is a chance of a false positive or a false negative result. A false positive result means a genetic variant was reported which is not in fact present. A false negative result means the Test failed to identify a genetic variant 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.

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, may be found in Color’s Terms of Service (www.color.com/policies/tos), HIPAA Notice of Privacy Practices (www.color.com/policies/notice-of-privacy-practices), and Privacy Notice (www.color.com/policies/privacy), which may also be made available to you upon request by emailing support@color.com. Color complies with the applicable federal and state laws, including but not limited to HIPAA. For patients living outside of the United States, please also refer to our Privacy Notice.

Color implements certain physical, managerial, and technical safeguards that are designed to protect the integrity and security of your protected information. Color however, cannot ensure or warrant the security of any information you provide to Color. You agree that Color is not liable for the release of your information. In the event of a data security incident, Color may attempt to notify you electronically by posting a notice on Color’s website, by mail, or by sending an email. If you are domiciled outside of the US, you should consult with your local physician as genetic testing may be subject to specific regulatory constraints, or be prohibited, in certain countries.

How We Store and Use Your Information and Sample for Other Purposes

Storage and Use of Your Information

We store and use your sequence data, Test results, PFHI, and other related information for regulatory compliance purposes. By signing this Informed Consent, you acknowledge and agree that Color may use your PFHI to determine eligibility for research, including but limited to medical, clinical, and public health research, and/or to contact you to seek your consent to use or share your sequence data, Test results, PFHI, and other related information for research. Please note that Color will never use your PFHI or other personal information to conduct research without your consent as detailed below.

You acknowledge and agree that Color may also store and use this information 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, scientific databases, 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.

You acknowledge and agree that Color may use your sequence data, Test results, PFHI, and other related information to create de-identified and/or aggregated information. As detailed below, such de-identified and/or aggregated information may be stored and used 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:

- 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);
- internal research by Color such as 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).

You acknowledge and agree that Color may de-identify the sequenced genetic information and aggregate your de-identified 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.

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, you acknowledge and agree that 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, your clinic, or health system may request you provide a HIPAA Authorization for certain disclosures or uses.

Storage and Use of Your Sample

Color will retain the sample (saliva, blood, and/or extracted DNA) as permitted under applicable law or regulation ("Retention Period"), after which point it will be destroyed unless you opt in to the optional sample storage set forth below. 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 in to the optional sample storage 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.

Optional Uses of Your Information and Sample

Analysis and reporting on genes and regions beyond those relevant to the ordered Test will not occur unless you opt in to the use of your de-identified sequence data, Test results, PFHI, other related information, and sample (if you have chosen to store it). You may choose to opt-in to any or all of the below uses of your de-identified sequence data, Test results, PFHI, other related information, and sample:

- **Research conducted by third-parties.** Color may engage in research with third parties such as the government, academic institutions, and commercial entities in order 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 and sample to such third parties.
- **Research and development of additional Color products and services.** Color may further analyze your de-identified sample or information as part of its research and development of additional genomic product areas. This will support our development of new genomic 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 third-parties such as academics or commercial entities (which publications may include, for example, blinded pedigree diagrams).
- **Color's research database (i.e., Color Data) supports research in genetics.** Color may place your de-identified sequence data, Test results, PFHI, and other related information on Color Data for an indefinite period of time in order to make it available and downloadable to researchers and the general public. Genetic information in Color Data 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 may opt out at any time 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 exclude your de-identified sequence data, Test results, PFHI, other related information, and sample (if you have chosen to store it) 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.

You also have the option of giving Color permission to store any of your samples such as saliva, blood, or any other DNA sample that remains after testing has been completed. If you select this option, Color may store your sample at its discretion and may use your sample for development of additional Color's products or services, or for third-party research (if you've opted in). You may opt out at any time by updating your account settings, notifying Color at support@color.com, 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 laws and regulations.

Deactivating Your Account

If you request Color to deactivate your account, your account will be deactivated pursuant to Color's Terms of Service (www.color.com/policies/tos). It may take Color up to 30 days from the date on which Color begins processing your request to deactivate your account. This means you agree any and all of the following may occur:

- Your login and account access will be terminated.
- Your sample(s) and PFHI will no longer be shared for research (if you opted into such research or sample storage).
- If your sample has been stored, it will be destroyed in compliance with legal and regulatory requirements.
- If you had previously opted into third-party research, you may be opted out.
- If you previously opted into Color Data, your information will not be made available in future publications of Color Data.
- Some or all of your information from your deactivated account will remain in Color's inactive database for compliance with legal and regulatory requirements. Your information 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 information that has already been de-identified, anonymized, aggregated, published and/or shared as set forth in Color's Privacy Notice prior to an account deactivation request may not be retrievable or traced back for destruction, deletion or amendment.
- Your de-identified, anonymized, and aggregated and genetic sequencing data shall be retained and usable by Color as set forth in this Informed Consent.
- 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).

Please refer to Color's Terms of Services (www.color.com/policies/tos) and Privacy Notice (www.color.com/policies/privacy) for more information regarding deactivating your account.

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. Any 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 diseases 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 may also sequence additional genes and regions, up to and including the entire genome, and any other DNA present in the submitted sample. My sequence data (up to and including sequence data covering the entire genome), Test results, PFHI, and other related information 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 sequence data, Test results, PFHI, other related information, and sample (if I have chosen to store it) may also be stored and used for internal quality assurance; internal validation studies; internal research by Color such as 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 in.

Consent (continued)

- 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.
- If my employer has provided or paid for (in whole or in part) the Test, I consent to Color providing my de-identified and/or aggregated results to my employer or its designee (e.g., plan administrator or pharmacy benefits manager) as a data analytics resource.
- My sample and all my related personal information will be transferred either to a Color laboratory or by us to a third-party laboratory in the United States for analysis, use, processing, and storage, and will be subject to applicable laws, rules, and regulations.
- All saliva and blood samples (including those received from New York patients) 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.
- I acknowledge that I have received and had an opportunity to review Color's Terms of Service, Privacy Policy, and HIPAA Notice of Privacy Practices.

☐ ***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
Print name	